

Long-term impact of physical activity on the prevention of cognitive function decline: study protocol for an extended randomized controlled trial (PA Protect study)

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ABSTRACT

The PA Protect study investigated the impact of increased daily physical activity on preventing cognitive decline, and maintaining healthy biomarker levels in individuals with mild cognitive impairment. Participants

aged 50–70 years, selected based on their performance in the Montreal Cognitive Assessment test were enrolled in a double-blind randomized controlled trial and randomly assigned to either an active or passive group. The active group was instructed to achieve over 10,000 daily steps, while the passive group maintained usual activity levels. Preliminary findings revealed a positive influence of increased physical activity on cognitive function, with significant differences observed between the two groups in selected cognitive tests. Building on these results, this study extends the PA Protect trial for an additional three years. All participants will undergo cognitive assessments and biomarker analyses at the beginning and after the extended intervention period, providing further insights into long-term intervention effects.

Research project objectives

Previously, 198 subjects aged 50–70 years with mild cognitive impairment (MCI), assessed using the Montreal Cognitive Assessment (MoCA) test, were recruited to a double-blind randomized controlled trial (PA Protect). Participants were randomly allocated into two groups: active and passive. The active group was instructed, encouraged, and motivated to increase their physical activity (>10,000 steps/day), while the passive group was advised to maintain their usual activity levels. All subjects underwent cognitive assessments, neuroimaging, and biomarker tests before and after the one-year intervention. The previous study has created a unique opportunity to extend the period of the observation for additional three years. This study aims to assess the effect of prolonged, 4-year increases in daily physical activity on cognitive decline prevention in subjects with MCI. We will also evaluate the effect of physical activity on neurodegenerative parameters, anthropometric, and densitometric parameters, body composition, blood pressure, glucose and insulin homeostasis, lipid metabolism and inflammatory markers. Moreover, we will investigate the usefulness of mobile applications to improve compliance with the recommended physical activity.

The research hypotheses are as follows:

1. Increased physical activity does not affect cognitive function in subjects with MCI.
2. Increased physical activity does not affect neurodegenerative parameters in subjects with MCI.
3. Increased physical activity does not affect anthropometric parameters in subjects with MCI.
4. Increased physical activity does not affect body composition in subjects with MCI.
5. Increased physical activity does not affect densitometric parameters in subjects with MCI.
6. Increased physical activity does not affect glucose and insulin homeostasis in subjects with MCI.
7. Increased physical activity does not affect lipid metabolism in subjects with MCI.
8. Increased physical activity does not affect inflammatory markers in subjects with MCI.
9. Increased physical activity does not affect blood pressure in subjects with MCI.

Basic concept and research plan

Concept overview

As stated by the World Health Organization [1], the global population of elderly individuals is steadily growing. This trend is associated with an increasing occurrence of various conditions, among which MCI is frequently mentioned. MCI is a transitional stage between normal cognitive function and dementia, described as a subtle cognitive decline, while maintaining the ability to perform everyday tasks [2,3]. The worldwide prevalence of MCI among individuals aged 50 and older is estimated to be 19.7%, which makes it rapidly becoming one of the most common clinical manifestations affecting the elderly [4]. The likelihood of developing MCI rises with age, is lower among individuals with higher education levels, and occurs more frequently in men [5]. MCI increases the likelihood of progressing to dementia and Alzheimer's disease (AD) [6]. About 54% of MCI patients eventually develop AD [7]. The underlying pathological and molecular mechanisms in individuals with MCI are not yet clearly defined. Besides age, sex, and education level, numerous other risk factors can impact

the development of cognitive disorders. Physical activity level is among these factors. Physical exercise has been proven to effectively enhance cognitive performance in older adults, regardless of their initial cognitive abilities [8]. Multiple studies, including meta-analyses [9,10], have demonstrated that regular physical activity provides protective effects against cognitive decline by promoting mechanisms such as neurogenesis, angiogenesis, synaptic plasticity, increasing brain volume, and enhancing cognitive function. Zhao et al. [11] highlighted in their meta-analysis a significant positive impact of physical activity on cognition among sedentary elderly individuals, particularly those with cognitive impairment. The effect was more pronounced in studies with intervention periods exceeding 12 weeks and involving aerobic training. Conversely, Li et al. [12] examined the impact of various training types on cognitive function in older adults with MCI and observed that strength training improved executive function and attention, whereas endurance training showed no significant effect. Huang et al. [13] reported that resistance training is most likely the optimal exercise type for mitigating cognitive decline in individuals with cognitive dysfunction. For patients with MCI, multicomponent exercise appears to be the most effective in preserving overall cognitive abilities and improving executive function. A comprehensive meta-analysis performed by Smith et al. [14], encompassing 29 studies, revealed that slow walking and jogging led to modest yet significant improvements in attention, executive functions, and memory processes. Alosco et al. [15] demonstrated that among older adults with heart failure, a higher daily step count was associated with improved attention, executive functions, memory, and language skills. Oliveira et al. [16] observed that accelerometer-measured physical activity has a positive impact on cognition. However, a recent umbrella review of randomized controlled trials revealed only minor exercise-related benefits, which were significantly reduced when accounting for various moderators and became negligible after adjusting for publication bias [17]. Despite this, Dougherty et al. [18] found that older adults at high risk for AD who adhered to physical activity guidelines (150 minutes of moderate-to-vigorous activity per week) exhibited larger temporal lobe volumes compared to those

who did not. Regrettably, the current recommendations for physical activity levels are difficult for older adults to meet [19]. Moreover, current standards do not provide specific quantitative guidelines for physical activity levels that could help prevent cognitive impairment [20]. The aim of our study is to determine whether a prolonged 4-year intervention, focused on increasing physical activity levels using physical activity trackers integrated with a mobile application, significantly improves cognitive function and slows the progression of cognitive decline in 50–70 years old adults at risk, compared to a group with no intervention implemented. We hypothesize that a sufficiently prolonged intervention focused on increasing physical activity levels will demonstrate significant cognitive benefits, contributing to a slowdown in the progression of cognitive impairments. To support this process, we will incorporate the use of physical activity trackers integrated with a mobile application, enabling continuous activity monitoring. Ultimately, our intervention leverages advanced tracking tools to generate novel and objective insights into the relationship between physical activity and cognitive function over an extended duration. Extending the intervention period beyond typical short-term studies is crucial, as existing research suggests that cognitive benefits from physical activity become more pronounced with prolonged engagement. Many previous studies have been limited by short observation windows, potentially underestimating the long-term protective effects of sustained physical activity. By implementing a comprehensive 4-year-long intervention with continuous monitoring, we aim to capture more nuanced and meaningful changes in cognitive function that may not be detectable in shorter studies. We anticipate that this approach will not only validate the protective role of physical activity but also highlight effective strategies for implementing long-term interventions aimed at mitigating cognitive decline.

Study design

The study was designed as a prospective randomized controlled trial with parallel groups. Initially, the study was planned to last for one year; however, with the possibility of additional funding, a decision was made to extend the intervention period by an additional three years, enabling an

assessment of the intervention over a four-year timeframe. The first year of intervention was described in the previously published study protocol [21]. The study protocol was registered in the German Clinical Trials Register database (registration no. DRKS00020943, date of last update 23.10.2023) and was updated due to the prolongation of the study for the next three years. The study protocol has been prepared following the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines [22,23].

Ethical issues

The present study is conducted in accordance with the guidelines outlined in the Declaration of Helsinki. The study protocol was approved by the Bioethics Committee of Poznan University of Medical Sciences (refs. no. 813/23, date: 12.10.2023). Informed, written consent for further participation in the study and for data processing was obtained from all study participants, who agreed to continue the study. The previously published study protocol comprehensively described all aspects of participant data management, including data collection methods, personal data protection, participant rights, data storage duration, and potential protocol modifications [21]. At this stage, data will be collected online in the REDCap (Leavenworth, Omaha, NE) database. All questionnaires will be completed and entered into the online database during visits.

Study population

Previously, 198 subjects with MCI, aged 50–70 years old, were recruited to the study PA Protect. Inclusion and exclusion criteria were described in detail in the previous protocol from the first stage of the study [21].

At the beginning of the study, the participants were randomly assigned (1:1 allocation ratio) into two groups: active (Group A) and passive (Group P). The A group contained $n = 98$ participants and the P group contained $n = 100$ participants. Participants were evenly assigned to one of two groups, passive or active, as determined by the randomization code. The recruitment and randomization procedures were described in the original protocol from the first phase of the study [21].

The first phase of the study was successfully completed by 187 participants – 93 from the A group and 95 from the P group. All individuals

who completed the study will be invited by the research team to take part in its continuation. It was anticipated that approximately 130 participants (69.5%) would consent to continue their involvement in the extended phase of the study; however, ultimately only 115 individuals agreed to continue the study.

Intervention

Individuals who decided to continue their participation in the study will remain in the group to which they were originally assigned and will be asked to follow the recommendations provided at the beginning of the study. From group A, 53 participants decided to continue participation in the study, and from group P, 54 participants agreed to continue their involvement.

Consistent with the approach taken during the first phase of the study, throughout the further intervention, participants will be asked to keep their current diet and medication regimen unchanged. Any changes in medication or health status should be reported to the research team via phone or email. The main measurements (cognitive functions assessed by MoCA test, neurodegenerative markers, glucose and insulin metabolism, lipid metabolism, inflammatory markers, anthropometric parameters, body composition, densitometric parameters, and blood pressure) will be performed before the second year of intervention and after the intervention period, while physical activity via Garmin Vivosmart 5 tracker (Garmin Inc., Olathe, KS, USA) will be monitored continuously throughout the study. Participants will also complete an IPAQ, health status, medications, smoking habits, alcohol use, profession and education questionnaires at the beginning and at the end of the intervention period. At the end of the intervention, cognitive functions measured by the CANTAB test will be assessed as well. The scheduled survey plan (Gantt's chart), is presented in **Figure 1**.

Adherence to intervention

Adherence to the intervention will be monitored by the dietitians using daily step count data collected from Garmin devices. Vivosmart 5 trackers will be connected with the Garmin Connect app, dedicated to tracking physical activity with more advanced data (e.g. Body Battery, stress level, etc.) for review by participants, which include

Tasks	2023	2024				2025				2026				2027
	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1
Submission of an application to the Bioethics Committee	■													
Recruitment of study participants for prolonged duration of the study	■	■												
Intervention period			■	■	■	■	■	■	■	■	■			
Outcomes measurements		■										■	■	
Data analysis													■	■

Figure 1. Gantt's chart.

metrics such as daily step count, distance traveled, estimated energy expenditure, sedentary time, and minutes spent in low, moderate, and high-intensity activities, as well as sleep patterns. Daily step count data will be automatically synced to the participant's account and accessed by the research team through an application programming interface (API). The information collected from the Garmin device will provide an objective measure of adherence throughout the intervention period. Group P will have all notifications from the Garmin Connect app regarding increased physical activity turned off to avoid disrupting the representation of their current activity level. In Group A, a reminder will be enabled in the app settings to help participants meet the goal established at the beginning of the study. If the step requirements are still not met in this group, a phone call will be made to remind them about physical activity. To further enhance adherence, scheduled phone calls will be made to review compliance with physical activity recommendations. Participants will also have the option to request additional support calls if needed. If participants experience a medical problem or a situation that affects adherence to step count guidelines, the research team is informed and records all events. If a participant withdraws from the study, no further data will be collected from that individual.

Research methodology

Primary outcomes

Changes (Δ before – after) in cognitive function parameters and neurodegenerative markers will

serve as primary outcomes. Data collection will take place at the Department of Pediatric Gastroenterology and Metabolic Diseases, Poznan University of Medical Sciences.

Cognitive assessments: Cognitive function will be assessed using the MoCA test and the Cambridge Neuropsychological Test Automated Battery (CANTAB). Following tests: Motor Screening Task (MOT), Reaction Time (RTI), Paired Associates Learning (PAL), Spatial Working Memory (SWM), Pattern Recognition Memory (PRM), Delayed Matching to Sample (DMS), Rapid Visual Information Processing (RVP) will be used.

Blood collection: Blood samples (approximately 15 ml) will be obtained through standard venopuncture from the antecubital vein by licensed staff nurses or phlebologists. The blood collection will occur after a 12-hour fasting period. Blood will be collected by a commercial laboratory (Diagnostyka, Poznań, 77a Dąbrowskiego Street), which performs part of the lab tests.

Neurodegenerative markers: The neurodegenerative parameters to be evaluated are beta-amyloid 1–40 and 1–42, total tau protein, and brain-derived neurotrophic factor (BDNF). Blood samples will be collected by a commercial laboratory, while biochemical analyses will be carried out using ELISA kits in the Laboratory of the Department of Pediatric Gastroenterology and Metabolic Diseases at Poznan University of Medical Sciences: Amyloid-beta (1–40) ELISA, IBL; Amyloid-beta (1–42) ELISA, IBL, Human Tau proteins ELISA kit, Cusabio; Human Free BDNF Quantikine ELISA Kit, R&D Systems.

MoCA test and neurodegenerative markers will be evaluated after the first year of the intervention

and after the intervention period. CANTAB test will be assessed after the intervention period.

Secondary outcomes

Secondary outcomes will include changes in biochemical parameters (glucose, insulin and lipid metabolism, inflammatory markers), anthropometric measurements, body composition and densitometric parameters, blood pressure assessment.

Biochemical analysis: The study will evaluate a range of other biochemical parameters, including fasting glucose, insulin, total cholesterol (TC), low-density lipoprotein cholesterol (LDL-C), high-density lipoprotein cholesterol (HDL-C), triglycerides (TG) and inflammatory markers – high-sensitivity C-reactive protein (hs-CRP). All these parameters will be analyzed in a commercial laboratory.

Anthropometric measurements: Key anthropometric parameters, including height, weight, hip and waist circumferences, will be measured at the beginning and at the end of the extended intervention period. Body mass index (BMI) will be determined using the recorded height and weight data and waist-to-hip ratio (WHR) will be calculated using the measured hip and waist circumferences.

Body composition and densitometric parameters: Body composition (fat and free fat mass) and densitometric parameters (bone mineral density and content at the lumbar spine (L1-L4)) will be evaluated through dual-energy X-ray absorptiometry methods, utilizing the Hologic Discovery analyser (Bedford, Massachusetts, USA) before and after the extended intervention period.

Blood pressure: Blood pressure will be assessed before blood sample collection, adhering to the protocols established by the European Society of Hypertension (2021) [24]. Blood pressure will be measured on the arm at heart level and recorded as the average of three measurements for both systolic and diastolic pressure.

Assessment of dietary habits: Dietary habits and food group intake will be assessed during and after the extended intervention, using the Dietary Habits and Nutrition Beliefs Questionnaire (KOMPAN) [25], created by the Behavioural Conditions of Nutrition Team from the Committee of Human Nutrition Science of the Polish Academy of Sciences. The main objective of assessing par-

ticipants' dietary behaviors is to verify whether changes in dietary patterns are a variable affecting the obtained results in given individuals.

Physical activity: Physical activity will be measured objectively using the Garmin Vivosmart 5 tracker (Garmin Inc., Olathe, KS, USA) and subjectively through the Polish version of International Physical Activity Questionnaire (IPAQ) [26]. Previously, a Fitbit Inspire HR device (Fitbit Inc., San Francisco, CA, USA) was used; however, due to changes in Fitbit's privacy policy and the merger of Fitbit accounts with Google accounts, patient data management became challenging. Therefore, it was decided to choose another wristband model. Garmin Vivosmart 5 tracker is a wrist-mounted wireless device equipped with an accelerometer that monitors physical activity continuously throughout the day and can seamlessly synchronize with both smartphone applications and computers. Participants will be instructed to wear the Garmin device all day long, except showering, bathing or swimming, on their non-dominant wrist for the duration of three years. The Garmin Connect app will be installed on their smartphones, and individual anonymous Garmin Connect accounts will be created to facilitate data download. Participants will be reminded to regularly synchronize and charge their trackers. If a Garmin remains unsynchronized for a week, study staff will contact the participant to assist with synchronizing or provide technical support. Data on sedentary behavior, light, moderate, and vigorous activity, as well as steps taken, distance covered, and calories burned, will be collected.

Sociodemographic questionnaire: A sociodemographic questionnaire will be used to collect details about participants' backgrounds, including their place of residence, education level, family status, and financial situation. Furthermore, the questionnaire will inquire about lifestyle factors such as smoking habits and alcohol use.

Minimum sample size calculation: The minimum required sample size was determined using preliminary study (n = 152) findings and calculated with G*Power 3.1 software (University of Kiel, Kiel, Germany). Results were obtained from the MoCA and SWM tests. Preliminary outcomes are presented in **Table 1**. Based on the current trend, the study needed to include at least 94 participants to achieve statistical significance ($\alpha = 0.05$, $\beta = 0.2$).

Table 1. Preliminary (n = 152) outcomes of changes in cognitive test results (Δ) after one year of intervention.

	Active group (n = 76)	Passive group (n = 76)	p
	Median (Q1 – Q3)		
Δ MOCA [points]	1 (0 – 3)	0 (-2 – 2)	0.0197
Δ SWMBE468	-3 (-8 – 1)	0 (-5 – 6)	0.0312
Δ SWMBE6	-1 (-4 – 0)	0 (-2 – 2)	0.0061

Statistical analysis: The detailed statistical analysis methodology was comprehensively described in the previous project documentation [21]. Key analytical approaches will include descriptive statistics, normality testing, appropriate parametric or non-parametric tests based on data distribution, regression models, and multiple imputation methods for handling missing data. A two-tailed p-value of < 0.05 will be considered statistically significant.

Risk analysis: The following challenges were identified as potential factors influencing the study's feasibility:

Recruitment challenges (low risk): Participants from the PA Protect study will be invited to extend their involvement for an additional three years. Approximately 107 (54.04%) are willing to continue their participation.

Adherence to the intervention (moderate risk): Initial observations during the first year showed strong adherence among most participants. However, individuals with lower adherence levels have expressed limited interest in continuing the intervention for another year.

Drop-out rate (moderate risk): The longer duration of the intervention may lead to a slightly higher drop-out rate compared to studies with shorter time frames.

Collaboration with external partners (low risk): Biochemical analyses will be outsourced to a large, reliable commercial laboratory, reducing the risk of delays or complications. Alternative laboratories are available to provide similar services at comparable costs if needed.

Rising costs (moderate risk): Unstable market conditions and inflation could drive up the costs of materials and services, potentially affecting the project's financial feasibility.

Equipment availability (low risk): The Department of Pediatric Gastroenterology and Metabolic Diseases is fully equipped to perform all planned assessments, ensuring no equipment-related delays.

Data loss (low risk): Study data will be directly entered into the RedCap tool (Seattle, WA, USA), which provides secure and reliable data storage. The likelihood of data loss is minimal.

Measurable effects

Preliminary results from this study showed a promising effect of increasing physical activity on improving cognitive functions. Its prolongation may reveal differences between groups observed after the completion of the first phase of the study and offer valuable insights for optimizing and tailoring daily physical activity recommendations for individuals with MCI. We anticipate that the research will yield precise data on the intensity of physical activity needed to mitigate cognitive decline. The findings could also contribute to define desirable activity recommendations specifically designed to address this population's needs.

Expected results

This randomized controlled trial will involve an additional 3-year physical activity intervention targeting 115 individuals with MCI. Drawing on existing research and new data, the study aims to determine the optimal intensity and frequency of physical activity necessary to develop innovative guidelines for preventing cognitive decline in high-risk adults. Additionally, the study will explore the relationships between long-term physical activity, cognitive performance, and blood biomarkers. We hypothesize that specific thresholds of physical activity frequency and intensity can enhance overall cognitive function in at-risk individuals, and maintain biomarkers within normal ranges. The anticipated results will inform the creation of the first tailored physical activity guidelines focused on cognitive impair-

ment, designed to be both effective and practical for older adults. Walking, as an accessible and affordable form of exercise, offers the added benefit of reducing the risk of other chronic conditions such as diabetes, cardiovascular disease, obesity, and depression.

Study strengths and limitations

Strengths

The main strength of this study is its extended four-year intervention period, which represents one of the longest randomized controlled trials investigating the impact of increased physical activity on cognitive function in subjects with MCI. The study's design allows for comprehensive assessment of both cognitive and physiological outcomes through standardized tools and objective measurements. The use of wearable devices provides accurate, continuous monitoring of physical activity levels, while the mobile application offers a practical method for improving intervention adherence. The study benefits from the continuation of the previously established phase, allowing for longitudinal assessment of intervention effects. Additionally, the broad range of measured parameters, including neurodegenerative markers, metabolic parameters, and body composition, enables a thorough understanding of the multisystemic effects of increased physical activity in 50–70-year old subjects with MCI.

Limitations

Several limitations should be considered when interpreting the study results. The study population consists of individuals with MCI, which may limit the generalizability of the findings to populations with more severe cognitive impairments, such as dementia or Alzheimer's disease. Technical difficulties with smartphones or tracking devices may impact participants' ability to consistently follow physical activity recommendations and affect intervention adherence. The change in activity tracking devices from Fitbit to Garmin between study phases may affect data consistency, although both devices provide comparable basic metrics. Participants' awareness of their group allocation could potentially influence their behavior and the study outcomes.

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Contributors

Conceptualization, M.J., K.H.H. & J.W.; methodology, M.J. & J.W.; software, M.J. & J.K.N.; formal analysis, M.J.; investigation, A.M.A., M.J., K.K., A.M.B. & J.B.; resources, J.W.; writing—original draft preparation, A.M.A., M.J. & J.W.; writing—review and editing, K.K., A.M.B., J.B., A.D., J.G., E.M., J.K.N. & K.H.H.; visualization, A.M.A.; supervision, M.J. & J.W.; project administration, M.J.; funding acquisition, J.W. All authors have read and agreed to the published version of the manuscript.

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Conflict of interest statement

The authors declare no conflict of interest.

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