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Subjective self-assessment of physical activity is negatively affected by monitoring awareness in subjects with mild cognitive impairment: a crossover randomised controlled trial

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Abstract. – OBJECTIVE: Physical activity plays an important role in maintaining mental and physical health. This study assessed the effect of physical activity monitoring awareness on the physical activity level and subjective self-assessment of physical activity in middle-aged subjects with normal cognitive function (NCF) and mild cognitive impairment (MCI).

PATIENTS AND METHODS: Thirty-five subjects aged 50-65 years with NCF and MCI were randomised into two experimental groups, each taking part in two one-week intervention periods. Subjects in group A were not aware that their physical activity was monitored in the first week (phase I) and were aware of the monitoring in the second week (phase II), whereas it was the opposite order for group B. Physical activity was assessed using the ActiGraph GT9X accelerometer and International Physical Activity Questionnaire (IPAQ).

RESULTS: A total of 32 subjects (MCI: *n* = 12, NCF: *n* = 20) completed both intervention periods, with MCI subjects having significantly lower objectively assessed physical activity than NCF participants. Moreover, subjectively assessed physical activity in the MCI group was significantly higher when the participants were unaware of physical activity monitoring. A significant phase-group interaction was found in total (MET-min/d: *p* = 0.0072; min/d: *p* = 0.0194) and moderate (MET-min/d: *p* = 0.0015; min/d: *p* = 0.0020) physical activity as well as energy expenditure (*p* = 0.0366) assessed by the IPAQ and in the percentage of sedentary behaviour (*p* = 0.0330) and the average number of steps (*p* = 0.0342) assessed by ActiGraph.

CONCLUSIONS: The awareness of physical activity assessment might decrease the ability to subjectively assess physical activity in subjects with MCI.

Key Words:
Accelerometer, Physical activity, Self-monitoring, Cognition.

Introduction

Physical activity is defined as all bodily actions produced by skeletal muscle contraction that increase energy expenditure (EE) above basal levels[1]. Regular physical activity maintains mental and physical health and is associated with a decreased risk of several chronic diseases, such as metabolic syndrome, cardiovascular diseases, diabetes, some type of cancers, osteoporosis and Alzheimer's disease[2]. Increasing daily physical activity may help to maintain or reduce body weight, strengthen bones and muscles, improve overall function and reduce healthcare expenditure[3]. Physical activity is also positively associated with a decreased risk of all-cause mortality[2],

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while physical inactivity causes 9% of premature death[4] and is related to approximately 6-10% of the occurrence of major non-communicable diseases[5]. The current physical activity guidelines for adults recommend at least 150 minutes of moderate physical activity or 75 minutes of vigorous physical activity or an equivalent combination of moderate to vigorous physical activity per week[6]. Despite the known benefits, less than 5% of healthy adults aged 18-65 years meet these recommendations[7,8].

Mild cognitive impairment (MCI) is common in the elderly and characterised by the deterioration of cognitive functions, memory, and attention but does not affect the activities of daily living[9]. According to a recent review, physical activity is the most promising intervention for the prevention of dementia and cognitive decline and is beneficial for subjects' quality of life. There is no cure for MCI but preventive interventions such as increased physical activity can improve cognitive performance and delay or prevent progressive deficits[10]. Therefore, the adequate assessment of physical activity levels via validated and reliable methods is critical.

Physical activity can be assessed by subjective and objective methods. One of the most frequently used tools for subjective assessment of physical activity is the International Physical Activity Questionnaire (IPAQ), a standardised questionnaire designed to collect comparable and valid data on physical activity within and between countries[11]. The IPAQ measures physical activity in various domains of everyday life at work, at home or in free time, as well as in sports[12]. However, questionnaires can result in subjective overestimation or underestimation of physical activity. Objective physical activity can be evaluated via electronic trackers worn on the body to measure physical movements such as step counts, EE, physical activity of different durations, intensities and periods of inactivity[13-16]. It has been suggested that wearable technologies may increase physical activity due to the ability to monitor activity, which could soon impact entire societies as interest in and acceptability of these technologies increases[17,18]. Indeed, previous studies demonstrated that self-monitoring of physical activity was associated with improved awareness and increased physical activity in adolescents and adults[17-20]. The motivation to increase physical activity has also been demonstrated in subjects with chronic diseases[21]. Moreover, the impact of self-monitoring of physical activity on behaviour, goal achievement and adherence to the guidelines have been shown in several systematic reviews[21,22]. However, to our best knowledge, no randomised controlled trials have assessed the awareness of activity monitoring in middle-aged subjects with MCI.

Therefore, this study aimed to assess the effect of physical activity monitoring awareness on physical activity levels and subjective self-assessment of physical activity in middle-aged subjects with normal cognitive functions (NCF) and MCI.

Patients and Methods

Study Design

The study was designed as a crossover randomised controlled trial and conducted according to the Declaration of Helsinki and the standards of CONSORT[23]. The study protocol was approved by the Bioethical Committee of the Poznan University of Medical Sciences, Poland (refs. 453/19, 882/19, 1059/19, 1167/19, 481/20, 720/20 and 752/20) and registered retrospectively (29th October 2020) in the German Clinical Trials Register under the MOBILE II acronym and with the registration number DRKS00023446.

Study Population

Volunteers were recruited to the study between October and December 2019 through advertisements and posters, especially in general practitioner facilities. Recruitment was also conducted in Senior Clubs, Universities of the Third Age, and large companies in Poznań based on a vacancy announcement. After telephone contact, a physician screened potential subjects during an inclusion visit and performed the Montreal Cognitive Assessment (MoCA), Hamilton Depression Rating Scale (HAM-D) and medical examination. The subjects also received information about the study, its purpose, putative benefits, and possible risks. All subjects were informed that participation in this study was voluntary and that they could refuse to participate or withdraw from the trial at any time without giving reasons. All subjects signed an informed written consent form to participate in the study.

The eligibility criteria were:

- 50-65 years of age,
- NCF (MoCA score: 26-30 points) or MCI (MoCA score: 19-25 points),
- community-dwelling.

The exclusion criteria were as follows:

- diagnosed psychiatric disorders, Parkinson's

disease, Alzheimer's disease, dementia,
- depression[24] (the results of the HAM-D > 13 points),
- anaemia,
- diabetes for at least ten years,
- chronic renal and liver diseases,
- hypothyroidism with current misaligned thyroid-stimulating hormone levels,
- history of cancer within the past five years,
- history of stroke,
- any chronic diseases that might have limited training and testing of the cardiovascular and respiratory systems,
- current evidence or history in the past two years of seizures, head injury with loss of consciousness and/or immediate confusion after the injury,
- the use of cognitive boosting medications or psychotropic medications,
- substance abuse disorders (e.g., alcohol > 15 drinks per week),
- high level of subjectively evaluated physical activity before the study (at least 150 minutes of moderate physical activity or 75 minutes of vigorous physical activity or an equivalent combination of moderate to vigorous physical activity per week),
- blindness, deafness, language difficulties or any other disability which may prevent the subjects from participating or cooperating in the protocol.

Intervention

The study involved two one-week intervention periods (phases I and II). All eligible subjects (n = 35) were randomised (allocation ratio 1:1) to group A (starting with phase I) or group B (starting with phase II). During phase I, subjects wore a wrist physical activity tracker (ActiGraph GT9X Link) but were unaware that their physical activity was monitored in real-time, whereas during phase II, subjects wore an identical wrist physical activity tracker but were aware that their physical activity was continuously monitored. The tracker for phase I displayed information about date and time, while the numbers of steps and burned calories for each day were available during phase II. Subjects who started the first intervention with phase I in the second intervention period were assigned to phase II, and those who started the intervention with phase II in the first week were assigned to phase I in the second week, without a washout period. Subjects were instructed to maintain their dietary habits during the intervention periods.

Randomisation and Blinding

Blocked randomisation was performed via computer software (RRApp Robust Randomization App, the Icahn School of Medicine at Mount Sinai, New York, NY, USA)[25] by an independent researcher and a computer-generated randomisation list was generated. The subjects were stratified according to sex and MoCA results, with each subject assigned sequentially. The allocation sequence was concealed until participants were enrolled and assigned to the interventions. After randomisation, there was no blinding to study participants, health professionals and other research staff involved in the trial, only study team members who prepared the database and performed the statistical analysis were blinded.

Outcomes

The outcomes included objectively measured physical activity [total, light, moderate and vigorous activity, sedentary behaviour, the average number of steps per day, average kcals per day, metabolic equivalent (MET) rate] and subjectively measured physical activity (sedentary behaviour, moderate, vigorous and total physical activity). All measurements were conducted at the Poznan University of Medical Sciences during one visit before and/or after each intervention period (0, 1 and 2 weeks). Each visit was scheduled at the same time of day between 07:00 and 11:00 am.

At baseline, basic anthropometry parameters (body height and body weight) were measured and used to calculate body mass index (BMI), whereas body composition (fat mass and fat-free mass) was assessed using a plethysmography method with the application of the BOD POD analyser (Cosmed, Albano Laziale, RM, Italy)[26,27]. Subjects were tested barefoot, wearing minimum clothing and a swim cap. The BOD POD was calibrated before each test using a two-point calibration method with volumes of 0 and 50 l (manufacturer's calibration cylinder). Body volume was determined while subjects were placed in the BOD POD chamber. Thoracic gas volume (the average volume of air in the lungs and thorax during normal tidal breathing) was estimated based on the subject's height and age. Body density was calculated by dividing body weight by the volume of the human body. The percentage of body fat was calculated from the Siri formula[28]. Duplicate measurements were performed for each subject.

Physical activity was objectively measured by a triaxial accelerometer, ActiGraph GT9X Link (ActiGraph, Pensacola, FL, USA). The

participants were requested to wear the device on the non-dominating wrist at all times during the intervention periods, only removing the monitor during water-based activities. Adherence to the intervention was assessed by monitoring the ActiGraph wearing time. All subjects wore the device for at least 85% of the intervention period and were included in the analysis. The raw data from the devices were downloaded using the ActiLife software (version 6.13.4, ActiGraph, Pensacola, FL, USA). The Troiano algorithm was used for wear time validation[8], and the Freedson activity cut-point sets appropriate for adults were used to estimate the amount of time spent in sedentary behaviour, light, moderate, vigorous and very vigorous activity. The step counts, MET rates and EE were calculated from the Freedson adult algorithm[29].

Physical activity was also assessed subjectively by the long version of the IPAQ after each intervention period. The IPAQ measures physical activity (MET-minutes/week units) in various domains of everyday life at work, while travelling, doing housework or leisure activities and sports[12]. In the study, the IPAQ was used to measure total, moderate and vigorous physical activity, EE and sedentary behaviour. The collected data were divided by seven to obtain the physical activity results per day.

Cognitive functions were assessed using the MoCA questionnaire[30], which includes the following domains, executive function, visuospatial abilities, naming, short-term memory, attention, working memory, language, concentration, verbal abstraction and orientation. MoCA scores ranged between 0 and 30, with a score of 26-30 indicating NCF and 19-25 points suggesting MCI.

The prevalence of depression symptoms was estimated using the HAM-D scale[31], which predominantly assesses cognitive and vegetative symptoms, with relatively few items related to social, motor, anxiety and mood factors. The 17-item HAM-D was employed in the present study. Each item is scored from 0 to 2 or from 0 to 4, with total scores ranging from 0 to 52. The following cut-off points were used: ≥ 23 very severe depression, 18-22 severe depression, 14-18 moderate depression, 8-13 mild depression and < 7 not depressed[32].

The participants completed a socio-economic questionnaire at baseline, as well as answered questions about their lifestyle, including tobacco smoking habits and alcohol consumption. The medical history questionnaire was used to assess study participants' health status and verify if the respondents took any medications or dietary supplements.

Minimum Sample Size

The minimum sample size was calculated using G*Power 3.1.9.2 software (University of Kiel, Kiel, Germany). To obtain a power of 80% (α = 0.05, β = 0.2) with the difference of anticipated means equal to 25% and the expected value of standard deviation (SD) equal to 30% of the mean, at least 23 subjects should be included in the study. Assuming a maximum 20% drop-out rate, 29 subjects should be recruited. The minimum sample size was calculated based on a previous study by Barwais et al[33].

Statistical Analysis

Statistical analysis was performed using the STATISTICA 13.0 software (TIBCO Software Inc., Palo Alto, CA, USA), and the level of significance was set at $p < 0.05$. Data were presented as means, SD and 95% confidence interval (95% CI) as well as medians and interquartile range (Q1-Q3) or as frequencies and percentages. The normality of the data distribution was verified using the Shapiro-Wilk test. Contingency tables were used to assess relationships between categorical variables. At baseline, comparisons between two unpaired groups were determined using *t*-tests or the Mann-Whitney U test as appropriate. The results for the data without normal distribution were normalised and analysis of variance for repeated measures was performed to compare the physical activity results between the phases in the NCF and MCI groups. After the analysis, the results were converted back to the original. Moreover, a paired sample *t*-test was used to assess differences between phases I and II in the MCI and NCF groups, while an unpaired sample *t*-test was used to evaluate differences between groups in phases I and II.

Results

Participant Flow

The participant flow chart is presented in Figure 1. Out of 69 subjects assessed for eligibility, 34 were excluded, five of which did not meet the inclusion criteria (three of them presented a history of stroke and two subjects were older than 65 years), 17 subjects refused to participate, and 12 subjects were excluded for other reasons (all of them were not able to start the study within the next three weeks). All remaining subjects were

randomised to group A (n = 17) or group B (n = 18). Three subjects were lost to follow-up, one discontinued the study due to health reasons and two for personal reasons. The drop-out rates were comparable in both phases of the study (11.8% for group A and 5.6% for group B), leaving a total of 32 subjects (91.4%) included in the final analysis (MCI: n = 12, NCF: n = 20). The average wear time of the physical activity tracker was 97.3 ± 3.2% for phase I and 95.6 ± 8.4% for phase II. No significant side effects were reported.

Baseline Characteristics of the Study Population

The baseline characteristics of the study population are presented in Tables I-III. A total of 32 subjects (13 men and 19 women) completed the two intervention periods, with a mean age of 58 ± 5 years and a mean BMI of 27.36 ± 5.97 kg/m^2. Most subjects lived in a city, were married, professionally active, had higher education and were non-smokers but occasionally consumed alcohol. The mean MoCA results were 26 ± 3 points and 12 subjects had MCI, while 20 had NCF. The two groups were similar in all analysed parameters.

The Effect of Physical Activity Monitoring Awareness on Objectively Measured Physical Activity Levels

A comparison of objectively measured physical activity between study phases is provided in Table IV. No episode of vigorous activity was detected by the ActiGraph for any of the subjects, however, the average number of steps in both phases and groups was higher than the recommended 10,000 steps per day[34]. A statistically significant phase-group interaction in the percentage of sedentary behaviour (p = 0.0330) and the average number of steps (p = 0.0342) was found. In unpaired-samples t-tests, significant differences ($p < 0.05$) between MCI and NCF subjects were found for sedentary behavior (min/d and %), moderate activity (min/d and %), total physical activity (counts in Freedson bouts/min) and MET rate ($p < 0.05$) in both phases. Moreover, in paired-samples t-tests, the MCI group had a significantly lower number of steps when subjects were aware of physical activity monitoring. However, the NCF group did not show any statistically significant differences between phases.

Table I. Socio-economic characteristics of the study population.

	n (%)			
	Total (*n*=32)	**Group A (*n*=15)**	**Group B (*n*=17)**	***p****
Sex [% of women]	20 (62.5%)	10 (66.7%)	10 (58.8%)	0.6474
Place of residence				
City > 500.000 inhabitants	20 (62.5%)	10 (66.7%)	10 (58.8%)	0.6262
City 50.000-500.000 inhabitants	1 (3.2%)	0 (0.0%)	1 (5.9%)	
Town < 50.000 inhabitants	6 (18.8%)	2 (13.3%)	4 (23.5%)	
Village	5 (15.5%)	3 (20.0%)	2 (11.8%)	
Family status				
Single	7 (21.9%)	4 (26.7%)	3 (17.6%)	0.5518
Married	24 (75.0%)	11 (73.3%)	13 (76.5%)	
Informal relationship	1 (3.1%)	0 (0.0%)	1 (5.9%)	
Education				
Higher	23 (71.9%)	9 (60.0%)	14 (82.4%)	0.2906
Secondary	8 (25.0%)	5 (33.3%)	3 (17.6%)	
Primary	1 (3.1%)	1 (6.7%)	0 (0.0%)	
Social and professional status				
Active	21 (65.6%)	9 (60.0%)	12 (70.6%)	0.2976
Pensioner	9 (28.1%)	4 (26.7%)	5 (29.4%)	
Unemployed	2 (6.3%)	2 (13.3%)	0 (0.0%)	
Smoking [yes]	2 (6.3%)	2 (13.3%)	0 (0.0%)	0.1200
Alcohol consumption [yes]	17 (53.1%)	8 (53.3%)	9 (52.9%)	0.9823

*p for baseline differences between subjects randomised to group A or group B in the Chi-square test.

Table II. Anthropometric parameters and body composition at baseline of the study population.

	Total (n=32)		Group A (n=15)		Group B (n=17)		p^*
	Mean ± SD (95% CI)	Median (Q1 – Q3)	Mean ± SD (95% CI)	Median (Q1 – Q3)	Mean ± SD (95% CI)	Median (Q1 – Q3)	
Age [years]	58 ± 5 (56 – 60)	58 (53 – 63)	57 ± 5 (54 – 60)	56 (52 – 63)	58 ± 5 (56 – 61)	60 (53 – 63)	0.4629†
Weight [kg]	78.6 ± 18.9 (71.8 – 85.4)	79.5 (62.8 – 87.1)	73.2 ± 14.0 (65.4 – 80.9)	79.2 (61.1 – 83.9)	83.5 ± 21.5 (72.4 – 94.5)	79.8 (64.8 – 95.3)	0.1255†
BMI [kg/m^2]	27.36 ± 5.97 (25.21 – 29.51)	25.98 (23.36 – 29.87)	25.90 ± 4.21 (23.57 – 28.24)	25.87 (23.00 – 28.15)	28.65 ± 7.06 (25.02 – 32.28)	26.09 (23.72 – 32.08)	0.5209‡
Fat mass [%]	35.2 ± 11.4 (31.1 – 39.3)	34.0 (25.4 – 44.7)	33.1 ± 9.3 (27.9 – 38.2)	31.8 (24.4 – 38.1)	37.1 ± 12.9 (30.5 – 43.8)	35.0 (26.7 – 47.5)	0.3249†
Fat free mass [%]	64.8 ± 11.4 (60.7 – 68.9)	66.0 (55.4 – 74.7)	66.9 ± 9.3 (61.8 – 72.1)	68.2 (61.9 – 75.6)	62.9 ± 12.9 (56.2 – 69.5)	65.0 (52.5 – 73.3)	0.3249†
Fat mass [kg]	28.6 ± 13.9 (23.6 – 24.8)	24.8 (17.3 – 37.7)	24.6 ± 9.5 (19.3 – 29.8)	22.3 (16.8 – 32.2)	32.3 ± 16.3 (23.8 – 40.6)	27.9 (17.7 – 46.9)	0.1206†
Fat free mass [kg]	50.0 ± 11.6 (45.8 – 54.2)	47.6 (41.3 – 59.6)	48.6 ± 10.4 (42.9 – 54.4)	43.8 (40.4 – 61.8)	51.2 ± 12.7 (44.7 – 57.8)	50.0 (42.8 – 59.0)	0.5335†

BMI – body mass index; CI – confidence interval; Q1 – Q3 – interquartile range; SD – standard deviation. *p for baseline differences between subjects randomised to start with group A first or group B first. †Unpaired t-Student test. ‡Mann-Whitney U test.

The Effect of Physical Activity Monitoring Awareness on Subjectively Evaluated Physical Activity Levels

A comparison of subjectively evaluated physical activity between study phases is shown in Table V. Significant phase-group interactions were found in moderate and total physical activity expressed in MET-min/d (moderate physical activity: $p = 0.0015$, total physical activity: $p = 0.0072$) and min/d (moderate physical activity: $p = 0.0020$, total physical activity: $p = 0.0194$) as well as in EE ($p = 0.0094$). Moreover, MCI subjects had significantly higher subjectively assessed physical activity when they were not aware of physical activity monitoring. In this group, significant differences ($p < 0.05$) between phases in paired-samples t-tests were found for moderate activity (MET-min/d and min/d), total physical activity (MET-min/d) and EE (kcal/d). No differences between MCI and NCF subjects for all analysed parameters were observed in phases I and II.

The Comparison of Subjective and Objective Methods of Measuring Physical Activity

Table VI shows the differences between the subjective and objective assessments of physical activity between phases I and II in the MCI and the NCF groups. There was a statistically significant phase-group relationship in the differences between subjective and objective results for EE ($p = 0.0083$). Differences between the subjective and objective assessments of moderate activity significantly varied between groups in phases I and II ($p < 0.05$), while differences between the subjective and objective assessments of EE significantly differ between phases only in the MCI group ($p < 0.05$).

Discussion

Our study is the first crossover randomised controlled trial that compared the effect of physical activity monitoring awareness in middle-aged subjects with MCI or NCF, demonstrating that physical activity awareness negatively affects subjective self-assessment of physical activity in the MCI group.

The effectiveness of physical activity monitoring awareness to increase physical activity levels was previously shown in several[18,35-38], albeit not all[39,40] studies. A systematic review by Bravata et al[18] demonstrated that the use of pedometers increased physical activity by 2,500 steps per day in adults. Lynch et al[35] also observed a small yet significant positive effect in step count in a group using fitness trackers compared to control but a negative effect was noted in moderate to vigor-

ous physical activity for interventions compared to alternative methods. The meta-analysis of Brickwood et al[36] reported a significant increase in daily step count, moderate and vigorous physical activity as well as EE in those wearing activity trackers. Another systematic review showed that the use of wearable accelerometers improved physical activity levels[38], whereas Ellingson et al[37] demonstrated that activity trackers could have beneficial effects on physical activity behaviour. However, the results varied based on the subjects, with participants with low baseline physical activity increasing physical activity on their own, whereas subjects with higher initial physical activity were more successful at maintaining their activity levels with motivational interviewing or habit education. The positive effect of using a physical activity tracker was also reported in adolescents[17,40]. Jauho et al[17] found that a wrist-worn activity monitor providing feedback positively affected physical activity and sedentary behaviour in young men. Slootmaker et al[41] reported that girls aged 13-17 years using accelerometers providing feedback and having access to a web-based tailored physical activity advice spent significantly more time in moderate activity compared to the

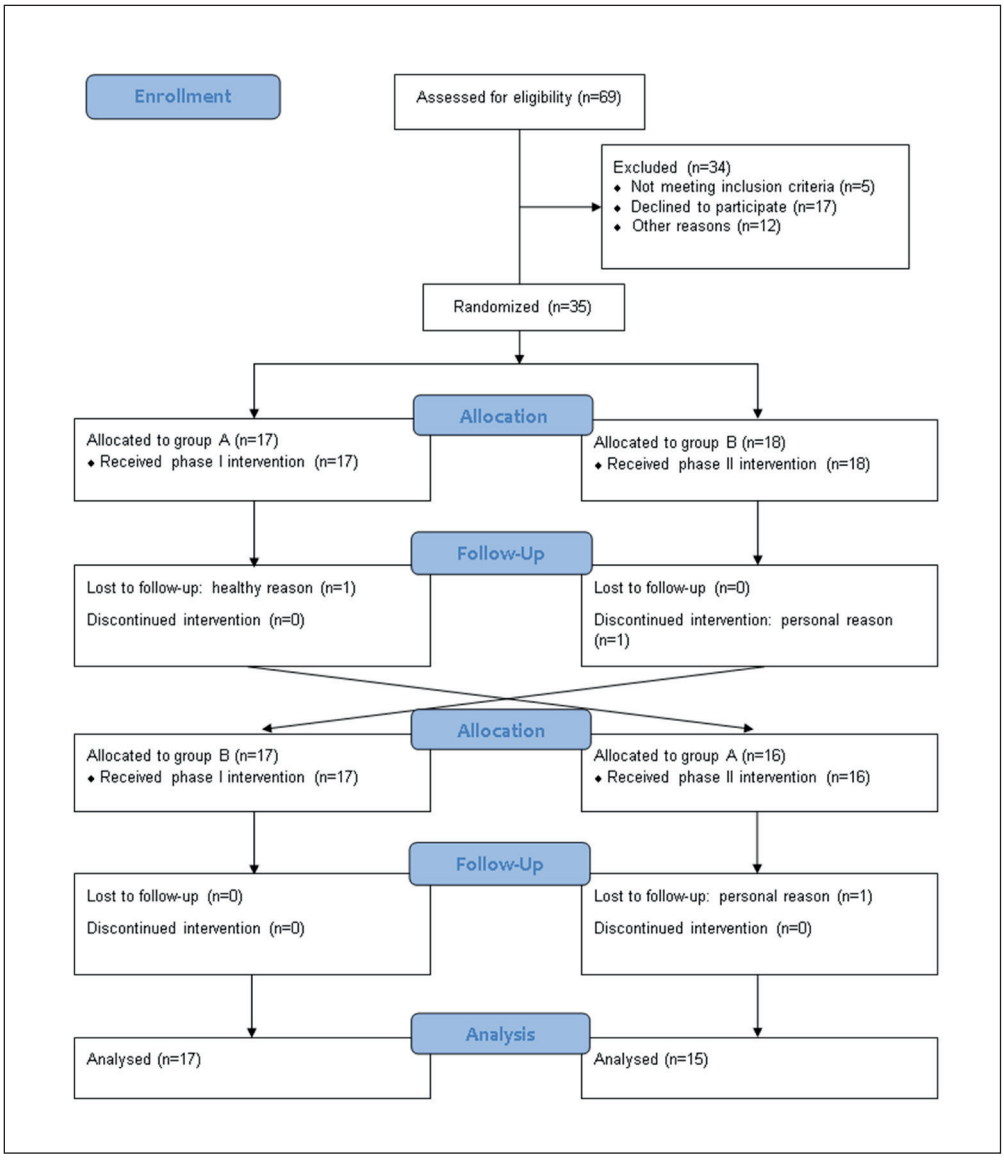

Figure 1. Participant flow through the study.

Table III. HAM-D scale and MoCA results of the study population.

	Total (*n*=32)		Group A (*n*=15)		Group B (*n*=17)		
	Mean ± SD (95% CI)	Median (Q1 – Q3)	Mean ± SD (95% CI)	Median (Q1 – Q3)	Mean ± SD (95% CI)	Median (Q1 – Q3)	*p**
HAM-D [points]	5 ± 3 (4 – 6)	5 (2 – 7)	4 ± 3 (3 – 6)	4 (2 – 6)	5 ± 3 (4 – 7)	5 (2 – 8)	0.3965†
MoCA [points]	26 ± 3 (25 – 27)	27 (24 – 29)	27 ± 3 (25 – 28)	27 (25 – 29)	26 ± 3 (24 – 27)	26 (24 – 29)	0.3024†
MoCA classification							
MCI *n* (%)	12 (37.5%)		4 (26.6%)		8 (47.1%)		0.2344‡
NCF	20 (62.5%)		11 (73.4%)		9 (52.9%)		

CI – confidence interval; HAM–D – Hamilton Depression Rating Scale; MCI – mild cognitive impairment; MoCA – Montreal Cognitive Assessment; NCF – normal cognitive function; Q1 – Q3 – interquartile range; SD – standard deviation. **p* for baseline differences between subjects randomised to start with group A first or group B first. †Unpaired *t*-Student test. ‡Chi-square test.

control group which received only an information brochure with brief general recommendations. Boys from the intervention group had significantly less sedentary time (difference between groups (β (95% CI)): -1801 (-3545 − -57) min/week; p = 0.04) at eight months follow-up compared to the control group. However, the effect of the intervention was assessed by self-reports. In contrast, in individuals suffering from peripheral artery disease, a home-based exercise intervention consisting of a wearable activity monitor and telephone coaching did not improve walking performance compared with usual care at nine-month follow-up[40]. Godino et al[39], in a parallel randomised controlled trial of 466 healthy adults aged 32-54 years, showed that feedback (simple, visual or contextualised) did not influence objectively measured physical activity, self-reported physical activity and intention to increase physical activity. The authors concluded that although feedback may increase awareness of behaviour, this is not sufficient to change behaviour alone. Several factors can explain the differences between our and previous findings. Firstly, it seems that physical activity trackers are especially effective among subjects with low physical activity at the baseline. Nuss et al[42] found that wearable fitness trackers proved effective among subjects who did not currently meet the physical activity guidelines but had little impact on other populations. Here, physical activity was evaluated subjectively before the study by the participants, so it is possible that the actual physical activity was higher than reported. Furthermore, the lack of differences in objectively measured physical activity between phases I and II in the total population could also be explained by an increase in physical activity caused by participation in the study. Although the ActiGraph registered no vigorous activity in any subjects, the mean number of steps and minutes spent in moderate activity per day as assessed by the ActiGraph in both intervention periods were in line with the recommendation. The differences between our findings and previous results may be partly explained by the different measurement methods. In the meta-analysis Cooper et al[38] reported that accelerometers, alone or in combination with other co-interventions increased physical activity in older adults, while pedometers did not. However, these findings were not confirmed by recent studies[43,44]. The meta-analysis of O'Driscoll et al[45] reported that devices with heart rate sensors often produced better estimates than devices without but this was not consistent across all activities. In a recent investigation of step detection and EE at different speeds by three accelerometers in a controlled environment, the mean absolute percentage error was different at different speeds, which is important when assessing the PA in obese subjects and the elderly. EE estimates of all three devices were inaccurate compared to indirect calorimetry[46]. Moreover, wrist-worn and arm-worn research-grade devices were more accurate than commercial devices for estimates of EE. However, commercial devices were statistically superior during sedentary

Table IV. Comparison of physical activity results measured by the ActiGraph between phase I and II in the MCI and the NCF groups.

	Phase I†				Phase II†						
	MCI (*n*=12)		NCF (*n*=20)		MCI (*n*=12)		NCF (*n*=20)				
	Mean ± SD (95% CI)	Median (Q1 – Q3)	Mean ± SD (95% CI)	Median (Q1 – Q3)	Mean ± SD (95% CI)	Median (Q1 – Q3)	Mean ± SD (95% CI)	Median (Q1 – Q3)	*P**	*P***	*P****
Sedentary behaviour [min/d] ‡,§	317 ± 87 (262 – 372)	304 (292 – 351)	258 ± 105 (209 – 307)	254 (190 – 287)	328 ± 99 (265 – 391)	336 (292 – 371)	238 ± 76 (203 – 274)	228 (187 – 293)	0.5944	**0.0201**	0.2419
Sedentary behaviour [%]‡,§	31.9 ± 7.5 (27.1 – 36.6)	32.6 (27.5 – 36.8)	25.7 ± 7.7 (22.1 – 29.3)	26.5 (19.4 – 30.0)	33.7 ± 8.9 (28.0 – 39.4)	33.6 (30.5 – 38.3)	24.8 ± 7.6 (21.2 – 28.3)	23.0 (19.7 – 30.6)	0.4793	**0.0112**	**0.0330**
Light activity [min/d]	537 ± 80 (487– 588)	520 (492 – 556)	537 ± 67 (505 – 568)	535 (495 – 590)	517 ± 98 (454 – 579)	534 (456 – 588)	531 ± 61 (503 – 560)	520 (487 – 578)	0.3038	0.7729	0.5379
Light activity [%]	54.3 ± 6.2 (50.4 – 58.3)	55.4 (50.9 – 56.8)	55.4 ± 4.4 (53.4 – 57.5)	56.7 (51.7 – 58.4)	53.0 ± 6.3 (49.0 – 57.0)	53.0 (51.3 – 56.7)	55.2 ± 5.4 (52.7 – 57.7)	56.0 (50.3 – 60.3)	0.1885	0.3942	0.3261
Moderate activity [min/d] ‡,§	137 ± 56 (101 – 172)	131 (95 – 177)	182 ± 61 (154 – 211)	166 (133 – 236)	129 ± 53 (95 – 163)	127 (80 – 166)	195 ± 79 (157 – 232)	184 (146 – 244)	0.6950	**0.0229**	0.1030
Moderate activity [%]‡,§	13.8 ± 5.4 (10.3 – 17.2)	12.6 (10.6 – 17.9)	18.9 ± 6.2 (16.0 – 21.8)	18.4 (14.4 – 23.5)	13.3 ± 5.6 (9.7 – 16.8)	12.5 (8.2 – 17.2)	20.0 ± 7.7 (16.4– 23.6)	19.6 (14.5 – 24.3)	0.5456	**0.0153**	0.1286
Total physical activity [counts in Freedson bouts/min] ‡,§	374 ± 239 (222 – 526)	275 (236 – 633)	574 ± 264 (451 – 698)	541 (393 – 749)	351 ± 260 (186 – 517)	329 (149 – 475)	609 ± 344 (448 – 770)	604 (408 – 823)	0.7004	**0.0206**	0.3328
Energy expenditure [kcal/d]	1322 ± 363 (1091 – 1553)	1332 (1097 – 1533)	1415 ± 459 (1200 – 1630)	1300 (1080 – 1640)	1247 ± 360 (1018 – 1475)	1177 (998 – 1467)	1431 ± 373 (1256 – 1605)	1314 (1153 – 1719)	0.5362	0.3048	0.1250
MET rate‡,§	1.59 ± 0.13 (1.51 – 1.67)	1.64 (1.501 – 1.68)	1.72 ± 0.17 (1.64 – 1.79)	1.70 (1.59 – 1.82)	1.57 ± 0.14 (1.49 – 1.66)	1.55 (1.457 – 1.69)	1.74 ± 0.18 (1.66 – 1.83)	1.72 (1.61 – 1.89)	0.8142	**0.0128**	0.1333
Steps [number//d] ¶	12867 ± 3119 (10885 – 14849)	12094 (10367 – 16305)	14004 ± 3300 (12459 – 15548)	13760 (11617 – 17015)	11755 ± 3083 (9796 – 13713)	10413 (9385 – 13688)	14264 ± 3775 (12497 – 16031)	13924 (10807 – 17788)	0.1053	0.1414	**0.0342**

CI – confidence interval; MCI – mild cognitive impairment; MET – metabolic equivalent of task; NCF – normal cognitive function; Q1 – Q3 – interquartile range; SD – standard deviation. †During phase I subjects were not aware, while during phase II subjects aware of physical activity monitoring. ‡Significant differences between groups in phase I ($p < 0.05$). §Significant differences between groups in phase II ($p < 0.05$). ¶Significant differences between phases in the MCI group ($p < 0.05$). *Phase. **Group (MCI vs. NCF). ***Phase x group.

Table V. Comparison of the physical activity results assessed by the IPAQ between phase I and II in the MCI and the NCF groups.

	Phase I†				Phase II†				p^{*}	p^{**}	p^{***}
	MCI (n=12)		NCF (n=20)		MCI (n=12)		NCF (n=20)				
	Mean ± SD (95% CI)	Median (Q1 – Q3)	Mean ± SD (95% CI)	Median (Q1 – Q3)	Mean ± SD (95% CI)	Median (Q1 – Q3)	Mean ± SD (95% CI)	Median (Q1 – Q3)			
Sedentary behaviour [min/d]	386 ± 120 (310 – 462)	369 (309 – 489)	444 ± 175 (362 – 525)	407 (349 – 485)	399 ± 152 (302 – 495)	411 (317 – 485)	410 ± 198 (317 – 502)	407 (300 – 499)	0.4613	0.5917	0.3241
Moderate activity [MET-min/d]‡	545 ± 481 (239 – 851)	317 (216 – 1024)	287 ± 325 (130 – 443)	180 (60 – 386)	255 ± 280 (77 – 433)	166 (48 – 347)	349 ± 330 (195 – 504)	193 (81 – 579)	0.1688	0.5763	**0.0015**
Moderate activity [min/d]‡	145 ± 126 (65 – 226)	86 (54 – 291)	84 ± 91 (41 – 127)	49 (15 – 134)	70 ± 73 (23 – 116)	47 (18 – 96)	98 ± 87 (57 – 139)	61 (24 – 186)	0.1367	0.5321	**0.0020**
Vigorous activity [MET-min/d]	86 ± 111 (15 – 156)	34 (0 – 137)	156 ± 203 (55 – 257)	86 (0 – 206)	80 ± 125 (-0 – 159)	6 (0 – 111)	154 ± 300 (14 – 295)	69 (0 – 137)	0.1937	0.3187	0.5284
Vigorous activity [min/d]	11 ± 14 (2 – 20)	4 (0 – 17)	18 ± 25 (6 – 31)	9 (0 – 26)	10 ± 16 (-0 – 20)	1 (0 – 14)	19 ± 38 (2 – 37)	9 (0 – 17)	0.3674	0.3433	0.8925
Total physical activity [MET-min/d]‡	838 ± 613 (448 – 1228)	614 (406 – 1177)	604 ± 472 (383 – 826)	484 (388 – 735)	456 ± 296 (268 – 644)	343 (219 – 730)	689 ± 524 (444 – 934)	535 (307 – 897)	**0.0334**	0.8106	**0.0072**
Total physical activity [min/d]	219 ± 178 (106 – 332)	150 (99 – 311)	160 ± 109 (108 – 211)	135 (86 – 206)	116 ± 80 (65 – 167)	89 (51 – 170)	173 ± 112 (121 – 226)	161 (67 – 241)	**0.0439**	0.6631	**0.0194**
Energy expenditure [kcal/d]‡	1068 ± 736 (600 – 1536)	877 (574 – 1372)	801 ± 871 (393 – 1208)	619 (471 – 795)	584 ± 342 (367 – 801)	487 (291 – 786)	891 ± 866 (486 – 1297)	650 (442 – 952)	**0.0366**	0.9203	**0.0094**

CI – confidence interval; IPAQ – International Physical Activity Questionnaire; MCI – mild cognitive impairment; NCF – normal cognitive function; Q1 – Q3 – interquartile range; SD – standard deviation. †During phase I subjects were not aware, while during phase II subjects aware of physical activity monitoring. ‡Significant differences between phases in the MCI group ($p < 0.05$). *Phase.**Group (MCI *vs*. NCF). ***Phase x group.

Table VI. Differences between subjective and objective results of physical activity between phase I and II in the MCI and the NCF groups.

	Phase I†				Phase II†				p^{*}	p^{**}	p^{***}
	MCI (n = 12)		NCF (n = 20)		MCI (n = 12)		NCF (n = 20)				
	Mean ± SD (95% CI)	Median (Q1 – Q3)	Mean ± SD (95% CI)	Median (Q1 – Q3)	Mean ± SD (95% CI)	Median (Q1 – Q3)	Mean ± SD (95% CI)	Median (Q1 – Q3)			
Sedentary behaviour [min/d]	69 ± 111 (-1 – 140)	73 (19 – 153)	186 ± 185 (99 – 272)	163 (91 – 298)	70 ± 190 (-50 – 191)	111 (1 – 199)	171 ± 201 (77 – 265)	182 (21 – 323)	0.6357	0.0904	0.8476
Moderate activity [min/d] ‡,§	8 ± 120 (-68 – 84)	-44 (-85 – 103)	-98 ± 88 (-140 – -57)	-105 (-153 – -68)	-60 ± 72 (-105 – -14)	-76 (-116 – -19)	-97 ± 76 (-132 – -61)	-87 (-144 – -70)	0.2521	**0.0113**	0.5414
Energy expenditure [kcal/d] ¶,#	-254 ± 796 (-760 – 252)	-449 (-772 – 278)	-614 ± 732 (-957 – -272)	-606 (-1041 – -370)	-663 ± 563 (-1020 – -305)	-755 (-1020 – -191)	-539 ± 773 (-901 – -178)	-658 (-994 – -189)	0.0954	0.6106	**0.0083**

CI – confidence interval; MCI – mild cognitive impairment; NCF – normal cognitive function; Q1 – Q3 – interquartile range; SD – standard deviation. †During phase I subjects were not aware, while during phase II subjects aware of physical activity monitoring. ‡Significant differences between groups in phase I ($p < 0.05$). §Significant differences between groups in phase II ($p < 0.05$). ¶The ActiGraph measures energy expenditure according to vigorous, moderate and light activity, and sedentary behaviour, while the IPAQ measures energy expenditure based on vigorous and moderate physical activity. #Significant differences between phases in the MCI group ($p < 0.05$). *Phase. **Group (MCI *vs*. NCF). ***Phase x group.

tasks. John et al[47] compared the ActiGraph with other devices, showing that they were accurate in detecting steps, whereas Shiroma et al[48] noted that the wrist-worn accelerometers consistently produced higher median activity counts as well as wider variability compared to hip-worn monitors. The differences between studies can be also explained by the time of the year when the studies were conducted, as the season has a significant impact on physical activity levels and dietary habits[49]. It is possible that personalised feedback about physical activity may produce the opposite effect to expected, hence, have harmful consequences. It is also possible that the subjects did not correctly interpret the feedback received from the device, thus incorrectly assessed their physical activity. Van der Wardt et al[50] showed a significant correlation between the results obtained by the IPAQ and the accelerometer, suggesting that the IPAQ is an appropriate tool for measuring physical activity in subjects aged 77 ± 6.9 years with dementia and MCI. This is in contrast to our findings which showed that awareness negatively affected subjective self-assessment of physical activity in subjects with MCI. This difference may also be explained by the fact that van der Wardt et al[50] recruited subjects with MCI and dementia using the Mini-Mental State Exam questionnaire and assessed physical activity using the Misfit Shine accelerometer. In our study, we included only subjects with MCI, assessed cognition using MoCA and evaluated physical activity by ActiGraph accelerometers. Moreover, in the study conducted by van der Wardt et al[50] the participants were older. Furthermore, the ActiGraph provided information about the number of steps and burned calories in phase II, while subjects were asked about time spent on moderate and vigorous activity as well as sedentary behaviour in the IPAQ. Therefore, it is possible that the information provided by the ActiGraph was not helpful to assess physical activity subjectively.

The main strengths of our study were the crossover randomised controlled design, as most previous studies were parallel trials[17,39,51]. The crossover study design offers more precise estimates of intervention effects compared to parallel studies due to the removal of biological and methodological variations. Importantly, the first period of a crossover trial can be viewed as independent and identical to a parallel trial[52]. Other strengths of the trial included the continuous measurement of physical activity and sedentary time during both intervention periods as well as providing feedback about physical activity to phase II. Most previous studies used either pedometers or fitness trackers to measure physical activity[51,53], while we used the ActiGraph GT9X Link, a validated three-axis accelerometer[54,55]. Compared to uniaxial sensors, three-axis accelerometers theoretically provide a more comprehensive assessment of body movements[56]. Our study population was well characterised and strict inclusion and exclusion criteria were applied, with both groups well matched at baseline. Possible limitations to the present study include a short-term intervention period, lack of washout periods and measured physical activity before the trial onset. Moreover, the subjects wore the tracker on a wrist and more accurate data may be obtained when the ActiGraph is worn on a hip[57]. Our study was conducted on middle-aged Caucasian subjects; hence, the results are not generalisable to other ethnic groups.

Conclusions

In the short-term period the awareness of assessment might reduce the ability to subjectively assess physical activity in the MCI group but not in the NCF group, hence, further long-term studies with larger sample sizes are needed to confirm these results.

Acknowledgments

The study protocol was registered retrospectively in the German Clinical Trials Register (acronym: MOBILE II, number: DRKS00023446, date: 29th October 2020).

Authors' Contributions

Aleksandra Makarewicz, Małgorzata Jamka, Jan Krzysztof Nowak, Dominque Gagnon, Karl-Heinz Herzig, Edyta Mądry and Jarosław Walkowiak made substantial contributions to conception and design. Jarosław Walkowiak developed the research methodology, provided resources, acquired funding, administered and supervised the project. Aleksandra Makarewicz, Małgorzata Jamka, Maria Wasiewicz-Gajdzis, Joanna Bajerska, Marta Kokot, Nina Kaczmarek and Wojciech Zawisza contributed to the data acquisition. The formal analysis was performed by Małgorzata Jamka and data curation by Aleksandra Makarewicz and Małgorzata Jamka. The first draft of the manuscript was written by Aleksandra Makarewicz, Małgorzata Jamka and Jarosław Walkowiak and the review and edition were done by Joanna Bajerska, Jan Krzysztof Nowak, Dominique Gagnon, Karl-Heinz Herzig and Edyta Mądry. All authors read and approved the final manuscript.

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Statement of Ethics
This study was conducted according to the guidelines laid down in the Declaration of Helsinki and the study protocol was approved by the Poznan University of Medical Sciences Bioethical Committee (refs. 453/19, 882/19, 1059/19, 1167/19, and 481/20, 720/20, 752/20).

Informed Consent
Informed consent was obtained from all individual participants included in the study.

Conflicts of Interest
Jan Krzysztof Nowak received personal fees from Norsa Pharma and grant support from Biocodex Microbiota Foundation. Jarosław Walkowiak received personal fees and non-financial support from Biocodex, BGP Products, Chiesi, Hipp, Humana, Mead Johnson Nutrition, Merck Sharp & Dohme, Nestle, Norsa Pharma, Nutricia, Roche, Sequoia Pharmaceuticals, and Vitis Pharma, as well as research grants, personal fees and non-financial support from Nutricia Research Foundation Poland, outside the submitted work. Other authors declare that they have no competing interests. The funders had no role in the design of the study; in the collection, analyses, or interpretation of data; in the writing of the manuscript, or in the decision to publish the results.

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