The effect of early active cycling on physical activity and cardiorespiratory fitness in stroke patients

Proefschrift voorgelegd tot het behalen van de graad van doctor in de Medische Wetenschappen aan de Universiteit Antwerpen en graad van doctor in de Revalidatiewetenschappen en Kinesitherapie aan de Katholieke Universiteit Leuven te verdedigen door

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Faculteit Geneeskunde en Gezondheidswetenschappen
Antwerpen 2017
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"Knowledge is power. Information is liberating.
Education is the premise of progress, in every society, in every family."
Kofi Annan

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List of abbreviations

AC	Active cycling
A-Cap	Aerobic capacity
ACG	Active cycling group
ADL	Activities of daily living
AT	Aerobic training
CG	Control group
Co-ACG	Active cycling group with coaching
CRF	Cardiorespiratory fitness
EE	Energy expenditure
FAC	Functional Ambulation Categories
HOM	home-living stroke patients
HOS	Stroke patients hospitalized in a rehabilitation center
HR	Heart rate
METs	Metabolic Equivalents
Nco-ACG	Active cycling group without coaching
PA	Physical activity
PASIPD	Physical Activity Scale for Individuals with Physical Disabilities
RCT	Randomized clinical trial
RMA-GF	Rivermead Motor Assessment gross function scale
SAM	Stepwatch Activity monitor
SWP2A	SenseWear Pro2 Accelerometer
THR	Heart rate training zones
VO_2	Oxygen consumption
VO_{2max}	Maximum rate of oxygen consumption
VO_{2peak}	Peak rate of oxygen consumption
Watt	Workload
$Watt_{peak}$	Last fulfilled increment in workload during the maximal graded exercise test
YDWP	Yamax Digi-Walker SW-200 pedometer

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General introduction

This doctoral thesis aims to identify assessment techniques evaluating physical activity and explores effects of an aerobic exercise program in subacute stroke patients. I would like to start with a general overview to introduce this population and their specific problems.

BACKGROUND

Stroke incidence and risk factors

The World Health Organization introduced the definition of stroke “as rapidly developing clinical signs of focal (or global) disturbance of cerebral function, lasting more than 24 hours or leading to death, with no apparent cause other than that of vascular origin”.[1] Recent data show that stroke events are either ischemic (85%) or hemorrhagic (15%), with significantly higher mortality noted in the latter.[2] An ischemic stroke is caused by an obstruction within a blood vessel supplying blood to the brain. The underlying condition for this obstruction is a blood thrombus forming by fatty deposits on the vessels walls in an artery leading to the brain or within one of the small vessels in brain tissue. A hemorrhagic stroke occurs when a weakened blood vessel ruptures and blood infiltrates into the surrounding brain. Because the blood accumulates and compresses the surrounding brain tissue, the damage caused can be greater than this caused by strokes due to an obstruction.

Recently, the American Heart Association described that 795 000 persons/year have a new or recurrent stroke (ischemic or hemorrhagic).[3] Approximately 610 000 of these are first stroke events and 185 000 are recurrent ones. In 2013, stroke caused 1 of every 20 deaths in the United States. On average, every 40 seconds, a person in the United States has a stroke, and someone dies of one approximately every 4 minutes. In Belgium, there are only a limited number of studies on the incidence and prevalence of stroke. One study, based on data from 178 general practitioner sentinel practices, estimated a yearly incidence of stroke of 185 per 100000 inhabitants in the period 1998-1999.[4] Another general practitioner network limited to the Flanders region in Belgium estimates an incidence of 2.18 per thousand yearly patient contacts in 2008.[5] Translation to an exact population based incidence rate is not available. The risk for recurrence is highest during the first five years following stroke and remains elevated for the next five years.[6] Throughout the years more attention has been given to prevention strategies with focus on risk factors as hypertension, cigarette smoking, physical activity, diet and abdominal obesity, excessive alcohol consumption, dyslipidemia, cardiac causes and psychosocial stress or depression, which are critical for improving cardiovascular health and reducing first and recurrent stroke.[7,8]

It is widely stated that stroke is the leading cause of long-term disability with persistent physical impairment reported by 50% to 65% of the patients and therefore require lifelong assistance with activities of daily living (ADL).[9,10] In addition, stroke patients often experience cognitive impairment, speech-language problems, depression and/or fatigue making it difficult for them to integrate into community living and predisposes them to an inactive lifestyle and increases the risk for a recurrent stroke.[11-14]

Definitions of physical activity, physical fitness and aerobic exercise

Throughout literature, concepts of 'physical activity', 'physical fitness' and 'aerobic exercise' are often confused and sometimes used interchangeably. However, these terms describe different aspects. For clarification the following definitions will be used in this thesis.

Physical activity (PA) is defined as any bodily movement produced by skeletal muscles that requires energy expenditure (EE), which can be measured in kilocalories. This includes muscular work required for walking, maintaining posture, ADL, occupational, leisure and sporting activities.[15]

In contrast with PA, which is related to the movements that people perform, physical fitness is a set of attributes that people have or achieve that relates to the ability to perform PA.[15] In literature, physical fitness is subdivided into health-related and skill-related fitness. Health-related physical fitness includes cardiorespiratory fitness (CRF), muscular endurance, muscular strength, body composition, and flexibility. Skill-related fitness concerns agility, balance, coordination, speed, power and reaction time.[15] Different tests can be used to determine the degree to which individuals have these attributes.

It is becoming evident that not only PA and health-related fitness have influences on one another, but are also being altered by other confounding factors, such as personal life-style, social and physical environment of an individual as shown in Figure 1.[16] Attention needs to be given on these factors when rehabilitation approaches want to increase either PA or health-related fitness or both.

Lastly, an exercise is a subset of physical activities that is planned, structured, and repetitive and has a final or an intermediate objective to achieve the improvement or maintenance of one or more components of physical fitness.[15] An exercise is called an aerobic exercise training (AT) as it induces fitness represented by the aerobic capacity (A-Cap). An AT can be given in different modalities and intensities. The major difference with anaerobic exercise training e.g. strength and high intensity training during a long period, is the accumulation of lactate.

Measuring physical activity and cardiorespiratory fitness

Accurately measuring daily PA and CRF remains a challenge in particular in stroke patients because of their hemiparetic gait disturbance with associated weakness, spasticity and slow gait speeds often combined with disturbed balance and cognitive deficits.[17]

Physical activity

To quantify PA in stroke patients, a variety of devices, questionnaires and diaries and observation methods have been used.[18-21] Pedometers and activity monitors are motion sensors, which provide an objective device to measure PA. Pedometers are inexpensive and easy to use in measuring steps. Activity monitors measure acceleration and have the strength to record continuously over several days under free-living conditions but on the downside sometimes tend to malfunction or the device loosening.[22] Also heart rate monitors are used with the advantage to easily reflect changes in the intensity of PA, but these can be influenced by environment, medication (e.g. beta-blockers), emotion and fitness level.[23,24] Furthermore, in a recent review in stroke patients 29 different devices were described, which make it difficult to pool data about PA in stroke studies.[18]

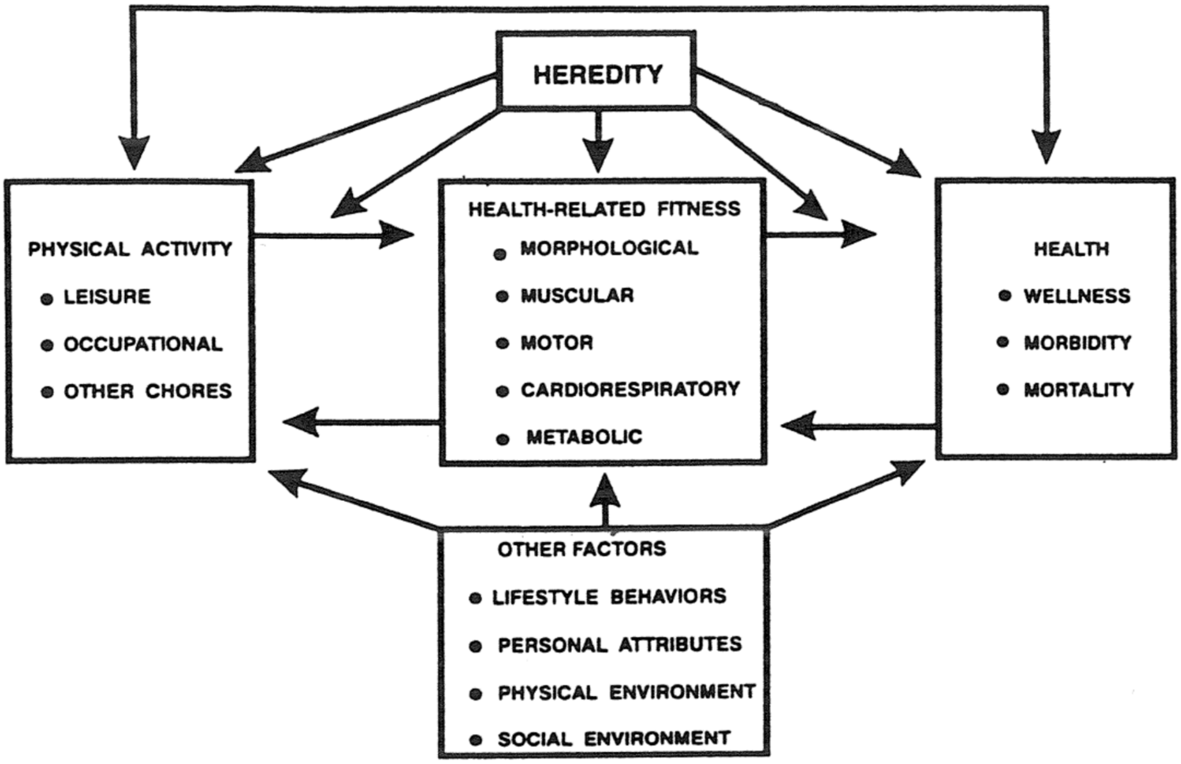

Figure 1: Scheme describing the relationship between physical activity and health-related fitness and many confounding factors. Note. From "Physical Activity, Fitness, and Health: The Model and Key Concepts" (p. 78) by C. Bouchard; R.J. Shephard, T. Stephens (Eds.), 1994, Champaign, IL: Human Kinetics.[16] Copyright 1994 by Human Kinetics. (Reprinted with permission)

Currently seven devices, in particular the Sensewear Pro 3[25,26], PAL 2[19], shoe-based sensor[27], Fitbit Ultra[28], Stepwatch Activity monitor (SAM)[28,29], wireless Triaxial accelerometer[30] and the Intelligent Device for Energy Expenditure and Activity[31] are proven to be valid in measuring activity intensity, frequency and duration in stroke patients. Devices, which measures the number of steps after stroke, tend to undercount when compared with visual observation, video analysis and another device, the SAM.[27,32,33] The Trictrac RT3[21], the SAM[29,34,35] and the Actical[36] are proven to be reliable devices in stroke patients.

Besides the many devices, also self-reported questionnaires[20,37] and activity diaries[38,39] are used in stroke research. These rely on recall and honest reporting and require patients to have cognitive and writing skills. Sometimes a combination of activity trackers and self-reported activity are used to quantify intensity, frequency and duration of PA in stroke populations.[18]

Also observational methods are often described, especially in inpatient settings. In a recent review, 25 studies used behavioral mapping and 4 worked with videotape observations to quantify PA.[18] These methods are laborious and time consuming. One of the major shortcomings of this method is that no activity intensity can be measured.[19]

Cardiorespiratory fitness

To determine the level of CRF, a measurement of the maximum rate of oxygen consumption (VO_{2max}) achieved during a maximal graded exercise test on a cycle ergometer or treadmill is considered to be the gold standard.[40]

Measuring VO_{2max} requires specific and expensive equipment and for executing the test and interpreting results specific skills are needed.[40] However, a maximal exercise test is not always executable in stroke patients due to stroke-related impairments, such as balance, strength and spasticity. Often in previous studies[41,42], an upright cycle ergometer or a treadmill test was used. However, the use of such modalities excludes a significant part of the stroke population, particularly those with postural and lower extremity dyscontrol, for whom testing is desired. Only a few studies examined CRF in these patients by using a weight-bearing treadmill test[43-45] or a recumbent cycle ergometer[46,47]. An ergometer has also the added benefit of the feet to be fixed to the pedals and thus participation of both legs is possible. Also an ergometer is preferred in patients, who cannot perform an active gait or a gait speed that is high enough to reach VO_{2max}.[48,49]

An alternative test to determine CRF, is the 6-minute walk test. This is an easy-to-administer submaximal exercise test, commonly used to determine walking endurance in individuals with decreased function. Although, this test has a good correlation with VO_{2max} in patients with moderate heart failure[50], only a low correlation was found in chronic stroke[51]. An explanation might be that the stroke-related impairments were better accommodated by cycle ergometer.

Physical activity and cardiorespiratory fitness are reduced after stroke

Despite the attention given to an active lifestyle, sedentary behavior continues to increase in many populations.[52,53] In general, PA levels in older adults tend to decline with age, with many classified as inactive, e.g. not executing any light/moderate or vigorous activity for at least 10 minutes per day.[54] Stroke patients seem to have little awareness of the risk of an inactive lifestyle and have little motivation to undertake regular PA.[55] Often these patients also lived an inactive life before they suffered a stroke.[55] In a recent meta-analysis of 16 stroke studies reporting step counts[56], a summary estimate of 4355.2 steps per day was given.[57] This is below what was advised in a healthy older population (6000 steps/day).[58]

Moreover, it is becoming evident that stroke patients live highly sedentarily, for example an average of 81% of the time per day patients lived in sedentary behavior, which remained so after one-year follow-up.[59] Increased sedentary behavior was observed in patients with higher stroke severity.[59] Sedentary time and low level of activity are concepts that are often used interchangeably. For instance, a person can be classified as inactive (e.g. do not meet the recommended guidelines for PA) but spend little time in seated postures, whereas another person can be physically active (e.g. walking for 30 minutes/day) and spend prolonged periods sitting at work. As such it is required to determine the length of time spent in sedentary behavior and the manner in which this time is accumulated.[60] Frequently interrupting sedentary episodes may have beneficial effects on metabolic health and hemostasis, emphasizing that both the extent and patterns of sedentary behavior are important for well-being.[61]

Previous studies have indicated that the level of CRF must be increased in order to function independently.[62] It is becoming evident that a VO_{2peak} of 20 mL kg-1 min-1 is needed for completely independent living for adults ranged between 65 to 97 years.[62] In particular, light ADL require 10.5 mL kg-1 min-1 and more strenuous demand 17.5 mL kg-1 min-1 in healthy persons.[63,64] However, in stroke populations values were found ranging from 11.4

± 3.7[65] to 17.3 ± 7.0[66] mL kg-1 min-1 after the insult. These low peak VO_2 values suggest that stroke patients often do not meet the minimum CRF level required for independent living and that basic ADL are, among others, also impaired by limited CRF as shown in Figure 2.[66,67,69] There is convincing evidence that a minor increase in VO_{2peak} could improve CRF, which could lead to higher levels of physical function and so enhance quality of life.[68]

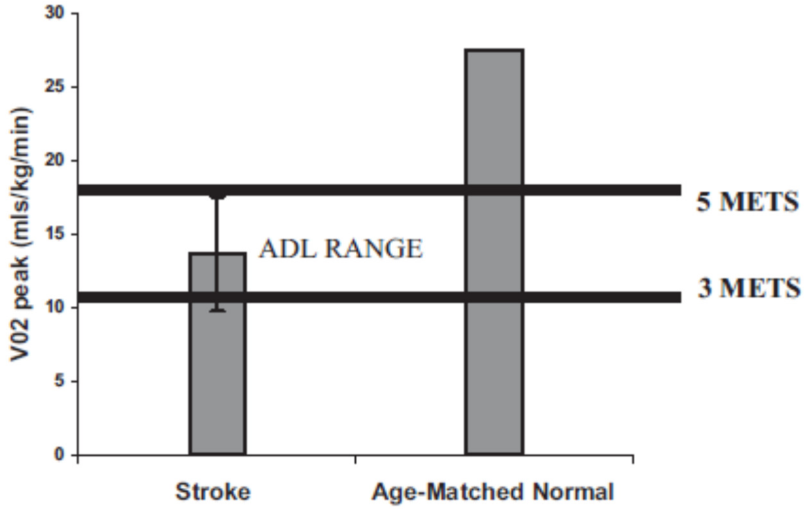

Figure 2: VO_2 levels (mean; standard deviation represented by error bars) of chronic stroke patients (n=131) relative to the energy requirements for activities of daily living. Note: From "Cardiovascular health and fitness after stroke" (p440) by Ivey FM, Macko RF, Ryan AS, Hafer-Macko CE, in Topics in Stroke Rehabilitation, 2005; 12(1):1-16.[69] Reproduced with permission from Topics in Stroke Rehabilitation.

Recommendations on physical activity and cardiorespiratory fitness

Most stroke patients do not recover spontaneously to the CRF level of age and gender-matched healthy persons.[67] Physical activity and exercise recommendations have been published in 2004 on how to improve CRF after stroke, more specifically different elements of intensity, duration, frequency, and mode were described.[70] The intensity should vary between 50% to 80% of the maximal heart rate (HR) or have an equal of 11 to 14 on the Borg[71] rating of perceived exertion scale. Session duration was set between 20 to 60 minute per session or divided in minimum multiple 10 min. sessions during the course of the day. Also, it was recommended to train 3 to 7 days in a week in such a way that large-muscle groups were trained (e.g. walking, treadmill, stationary cycle, combined arm-leg ergometer, arm ergometer, seated stepper).[70]

In healthy older persons it is recommended to perform 7000 and 10000 steps/day, of which at least 3000 steps should be taken at a step rate of ≥ 100 steps per minute to meet the recommendations of 30 minutes of moderate intensity.[58,70] However, this cadence may be unattainable for persons with disabilities.[58] Furthermore, it is recommended not to spend too much time in long, continuous periods of sedentary behavior as this is proven to be harmful for cardiovascular health.[72]

How to increase physical activity and cardiorespiratory fitness after stroke?

Throughout literature, researchers reported interventions to increase PA and CRF after stroke[41,42,73], often based on the Physical Activity and Exercise Recommendations[70]. As these guidelines were broadly formulated and included stroke patients had a wide range of motor impairments, described training programs showed differences. As a result, only a general conclusion can be given on how to increase PA and CRF.

Different training methods were described such as cycling exercises on a stationary bike (upright or recumbent), treadmill training (with or without weight-bearing), water exercises and combined programs (e.g. AT and strength exercises). Mostly cycling exercises were executed to increase CRF, in particular in acute to subacute phase, where patients are often unable to perform a safe and active gait training.[42] It was rarely investigated which training method is superior to improve PA and CRF in different phases of stroke recovery.[41,73] Also no consensus was found about the frequency (per week), the duration (per session) and intensity of exercise to increase PA and CRF after stroke. Mostly, the AT programs ranged from 2 to 3 weeks to 6 months, session durations ranged from 20 to 90 minutes, with most training lasting 30 to 60 minutes during 3 times/week.[41]

Notably, in cases in which stroke patients have attended organized AT classes, benefits are often lost at follow-up, suggesting these patients face barriers to undertaking self-directed PA.[74]

Effects of aerobic exercise training after stroke

Recent systematic reviews provide an overview of the effects of AT in different phases of stroke recovery.[41,42,73] In a few studies, AT have shown beneficial effects in VO_{2peak} (subacute[46,75-78] and chronic phase[79,80] of recovery), in peak workload ($Watt_{peak}$) (subacute[75] and chronic phase[79]) in walking distance (subacute[46,77,81-83] and chronic phase[79]) and gait speed in subacute phase[77,81,82]. In other studies, the results on walking speed[46] and balance[77,82,84] were conflicting. Other possible benefits were not sufficiently explored, such as the effects on quality of life, fatigue, depression, body composition and food intake.

Previous research often included minor impaired patients, tended to focus on short term effects of AT and offered no long-term participation in PA. Therefore, the current study was conducted to determine the short and long-term effects of AT combined with coaching early after stroke on AC, gait speed, leg strength and various secondary outcomes following stroke.

CONCLUSIONS FROM THE LITERATURE, QUESTIONS REMAINING AND AIMS OF THIS THESIS

In conclusion, the main goals of this thesis were to obtain more insight into the assessment of PA in stroke patients and to examine the short and long-term effects of an AT program.

This thesis is divided in 5 chapters:

- Part A consist of three scientific papers, in which the assessment of PA after stroke is explored. They are published in internationally peer-reviewed journals.
- In Part B two papers are presented, one published and one submitted, concerning the effects of an AT program in subacute stroke patients.

The rationales and aims of all 5 chapters are presented below. A schematic overview is given in Table 1.

PART A: Assessment of physical activity

Throughout the literature, a variety of objective devices are recommended to measure PA.

In stroke populations, hemiparetic gait disturbances with associated weakness and use of walking aids can cause unreliable recordings by PA measuring devices.[34,35] In this doctoral thesis, we searched for a simple (spring-levered) and inexpensive device to register the number of steps. We decided to use the Yamax Digi-walker SW-200 pedometer (YDWP), which is frequently used in healthy participants and has an acceptable reliability compared to other spring-levered pedometers[85]. The YDWP, as prescribed clipped on a belt, might work less accurate at slow walking speeds, because at low velocities the vertical accelerations of the hip are not sufficiently large to cause contact of the lever arm with the electrical contact.[86] We noticed that the ankle-worn SAM works more accurately, probably due to more vertical accelerations that can be measured at the unaffected-ankle.[35] We believe that the SAM is less clinical applicable in stroke patients compared to the YDWP, because it is an expensive device, needs programming, visible and no uniform attachment is possible in case of high orthopedic shoes. This brought up the idea to wear an YDWP at the unaffected knee. We expect to register more vertical accelerations at the knee at slow gait speeds compared to the hip. **Therefore, we hypothesize that a knee-worn YDWP is more valid and reliable then a hip-worn in stroke patients.**

Besides measuring the number of steps, we wanted to assess the intensity of PA in stroke patients. Also here, a variety of portable devices is described. In this doctoral thesis we decided to use an SenseWear Pro2 accelerometer (SWP2A), because this was already used and validated in different populations[87-89] except in stroke populations. It is positioned at the arm and so gait disturbances had less influence and also the devices were available at the University. It was unknown if the SWP2A was equally accurate when worn at the non-hemiplegic side instead of the right arm as prescribed by the developer's manual.

Therefore, we hypothesize that a SWP2A, worn on the non-paretic arm instead of the recommended right arm, is an accurate device to detect the intensity of PA. => *Research question Chapter 1: Which measurement technique is the most accurate to determine physical activity after stroke: a hip or knee Yamax Digi-walker SW-200 pedometer or a left or right arm-worn SenseWear Pro2 accelerometer?*

Other methods for determining individual PA patterns and suitable for clinical practice include self-report methods.[38,90] This is described as time efficient, easy to learn, inexpensive, reliable and reasonably valid and helps patients to become more aware of their PA, but with possible underestimation of activities of short duration, often to short recording periods are used and limited choice in activities is offered.[38,90,91]

In hospitalized stroke patients activities of short duration occur rarely, therapy is often scheduled in a 30-minute period and often these patients have writing difficulties. We need a self-report measure that combines the advantages of the earlier self-report methods, but with greater detail information about the type and intensity of activities and the position in which the activities are executed. Also we preferred using simple codes to minimize writing.

Hence, we hypothesize that a 3-day coded-activity diary, is easy to use and of low cost, and valid in reporting activity levels together with daily energy expenditure. => *Research question Chapter 2: How to determine the activity levels together with the daily energy expenditure in stroke patients at a low cost?*

In stroke research, different assessment tools are used for different stages of recovery, each with a specific outcome. To evaluate long-term PA behavior and detailed aspects of PA, the combination of the same tools should be used in each stage. Also limited information is found regarding the type of activities stroke patients execute and the time spent at different activity levels. Recently, this becomes more important as it is advised to reduce sedentary behavior and sitting and moderate activities needs to be varied.[72]

We assume that a detailed information about PA is obtained when using objective devices combined with a self-reported measure and when this is used in different phases of recovery. => *Research question Chapter 3: How physically active are hospitalized and home-living stroke patients?*

PART B: Effectiveness of an aerobic training program

Previous stroke studies have shown short-term beneficial effects of AT in particular increased A-Cap, gait endurance, gait speed and quality of life are described.[42,73] The effect on leg strength is not yet studied and the long-term effects are lacking. Little is known about the effects of AT in the early stages of stroke recovery.[73] However, most motor and functional recovery is expected in these stages.[92] Also, in the majority of studies severely impaired patients were excluded, because test or training material was not adapted.[73] In general, patients experience a lack of suitable devices to continue AT after ending a program, objective and verbal encouragement, knowledge of PA and support from family.[17] Recent studies examined the effect of supervised AT programs rather than implementing an approach to guide patients in adopting this as a part of a lifestyle change.[93]

Therefore, we hypothesize that a supervised AT program started in the subacute phase of recovery and combined with education, and followed by coaching might have a positive effect on aerobic capacity, leg strength and walking speed on the long-term. => *Research question Chapter 4: What are the effects of an aerobic training program on aerobic capacity, strength of the quadriceps muscle and gait speed in subacute stroke patients?*

Up till now, there is still need to search for an AT program that facilitates the carry-over effect of improved A-Cap to live more physically active and that is also feasible for moderate to severe motor impaired patients.[42,73] Throughout the different stages of recovery, a combination of objective and self-report PA measures should be used so detailed information can be obtained. In our thesis we used the combination that is used in the study described in Chapter 4 combined with 2 other self-report questionnaires (Baecke[94] and Physical Activity Scale for Individuals with Physical Disabilities[20]). We added these because we found that habitual work, sport and leisure activities were not sufficiently described by the other included PA measures. Both are short questionnaires that rely on retrospective information and honest reporting with a good reliability and validity compared to other questionnaires.[94-96]

We assume that the supervised AT program combined with education and followed by coaching facilitates stroke patients to life more physically active. => *Research question Chapter 5: What are the effects of an aerobic training program on physical activity in subacute stroke patients?*

The results of all 5 chapters will be discussed in a general discussion. Clinical implications, methodological considerations and recommendations for future studies will be formulated.

Table 1: Schematic overview of the chapters in the doctoral thesis.

Part	Chapter	Hypothesis	Research question	Design	Patients included	Sample description	Intervention	Outcome measures	Statistical Analysis
Part A: ASSESSSMENT of PA	1	A YDWP is more valid and reliable then a hip-worn in stroke patients. A SWP2A, worn on the non-paretic arm instead of the recommended right arm, is an accurate device to detect the intensity of PA.	Which measurement technique is the most accurate to determine physical activity after stroke: a left or right arm-worn SWP2A or a hip or knee YDWP?	Validity study Reliability study	<u>Stroke:</u> n=15 <u>Healthy:</u> n=15	<u>Stroke:</u> Age: 60.40years ±10.26 Intake: 6.20 years post stroke ±5.08 RMA-GF: 11 (0) <u>Healthy:</u> Age: 58.07years ±10.37	/	**YDWP**: steps **Handteller:** steps **SWP2A**: steps, EE, **Ergospiro device:** EE	Spearman correlation coefficient Intraclass correlation coefficient
	2	A 3-day coded-activity diary, is easy to use and of low cost, and valid in reporting activity levels together with daily EE in subacute stroke patients	How to determine the activity levels together with the daily EE in stroke patients at a low cost?	Observational study Validity study	n=16	Age: 68.31years ±10.95 Intake: 62.50days post stroke ±47.25 RMA-GF: 7 (5-11)	/	**SWP2A**: EE, activity levels **Diary**: EE, activity levels	Spearman correlation coëfficient
	3	A detailed information about PA is obtained when using objective devices combined with a self-reported measure and when this is used in different phases of recovery.	How physically active are hospitalized and home-living stroke patients?	Observational study	<u>HOS:</u> n=15 <u>HOM:</u> n=15	<u>HOS</u>: Age: 69.7years ±9.7 Intake: 69.1days post stroke ±40.5 RMA-GF: 7 (5-11) <u>HOM</u>: Age: 62.5years ±10.4 Intake: 2680.4days post stroke ±1878.3 RMA-GF: 11 (10-11)	/	**YDWP**: steps **SWP2A**: EE, **Diary**: EE, Total METs*min, activity levels	Two-way Repeated Measures Anova Mann-Whitney U test
Part B: EFFECTS of an AT PROGRAM	4	A supervised AT program started in the subacute phase of recovery and combined with education, and followed by coaching might have a positive effect on A-Cap, leg strength and walking speed on the long-term.	What are the effects of an AT program on A-Cap, strength of the quadriceps muscle and gait speed in subacute stroke patients?	Randomised Clinical Trial	<u>ACG:</u> n= 33	<u>ACG</u> Age: 66.7years ±8.8 Intake: 50.5days post stroke ±19.8 RMA-GF: 5 (3-10)	<u>ACG:</u> * 3 month Motomed cycling program with education session *After 3 month: <u>ACG + coaching</u>: 9 month coaching <u>ACG - coaching</u>: /	**Graded exercise test:** VO_{2peak}, HR_{peak}, $Watt_{peak}$, OUES, Borg **Dynamometer**: Leg strength **10m walk**: Gait speed	Mixed effects model
	5	A supervised AT program combined with education and followed by coaching facilitates stroke patients to life more physically active.	What are the effects of an AT program on PA in subacute stroke patients?		<u>CG:</u> n=26	<u>CG</u> Age: 63.8 y ±11.8 Intake: 48.5days post stroke ±19.2 RMA-GF: 5.5 (4-11)	<u>CG:</u> 3 month Kinetec passive mobilization, paretic hip/ knee	**YDWP**: steps **SWP2A**: EE **Diary**: Total METs*min, activity levels **Baecke:** sport/leisure scores **PASIPD**: Total METs*min wk	

A-Cap= aerobic capacity; ACG= Active cycling group; AT= aerobic training; CG= control group; EE= energy expenditure; HOM=Home-living patients; HOS= hospitalised patients; PA=Physical activity; PASIPD= Physical Activity Scale for Individuals with Physical Disabilities; RMA-GF= Rivermead Motor assessment gross function scale; SWP2A= SenseWear Pro2 accelerometer; YDWP = Yamax Digi-walker SW-200.

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Part A

The assessments of physical activity after stroke.

Chapter 1

Physical activity monitoring in stroke: SenseWear Pro 2 Activity Accelerometer versus Yamax Digi-walker SW-200 Pedometer.

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ABSTRACT

Purpose Determine validity and reliability of SWP2A and YDWP in stroke and healthy adults.

Method Fifteen stroke patients and 15 healthy participants wore SWP2A on upper arm and YDWP at hip/knee. Different activities were performed: treadmill walking, walking up/down a step, cycling and walking on an even surface. Steps and EE were measured and compared to steps counted manually and indirect calorimetry. Repeated measurements were compared to determine reliability of both devices.

Results Spearman correlation coefficients between knee-worn YDWP and counted steps while walking on an even surface was ≥0.89 in healthy and ≥0.95 in stroke. Treadmill walking revealed high Spearman correlation coefficients in healthy individuals ($r_s \geq 0.90$) and at 1.5 km/h in stroke ($r_s = 0.69$). During other activities YDWP often underestimated steps. SWP2A data revealed inconsistent results in EE and steps. Reliability tested by repeated measurements varied between 0.66 and 0.98 for YDWP and 0.61 and 0.97 for SWP2A.

Conclusion YDWP and SWP2A are both reliable. Only knee-worn YDWP is a valid device to measure steps except high intensity walking in stroke. YDWP systematically undercounts steps during other activities of short duration. This study could not demonstrate valid measurement of steps/EE in stroke using SWP2A.

Keywords Ambulatory monitoring, Energy expenditure, Step activity, Stroke.

INTRODUCTION

Promoting daily PA after stroke is found to be important and supported by clinical guidelines.[1-3] After an insult, many stroke patients are faced with residual neurologic deficits, which impair mobility and predispose them to sedentary life style, resulting in cardiovascular and metabolic deconditioning, muscle weakness, increased intramuscular fat and gait impairment.[4-7] As a result stroke patients suffer an increased risk for recurrent stroke and cardiac death.[8] Increasing daily PA is therefore a major goal in secondary stroke prevention. [9,10]

A variety of portable devices, including accelerometers and pedometers, have been used to determine PA.[11,12] These devices measure EE and/or ambulatory effort. Accelerometers tend to underestimate the activity level when the person is cycling, carrying goods or walking uphill. They also tend to detect more 'non-steps' (an artifact corresponding to inexistent activity) than pedometers, typically under travelling conditions, in which vibrations of the vehicle are registered as movement.[13] In stroke patients, hemiparetic gait disturbance with associated weakness, spasticity and abnormal central neural patterning of muscle activation caused unreliable recordings by similar devices.[14,15] In stroke there is still need for accurate devices to measure PA. The SWP2A is an example of an accelerometer-based activity monitor that is worn at the upper limb and might be therefore less susceptible to measurement errors in stroke. The SWP2A is a portable device that monitors various physiological parameters (heat flux, skin temperature, galvanic skin response at near-body temperature) and movement (bi-axial accelerometer). This portable multisensory armband has been used to measure PA in healthy participants[16], diabetes[16], cystic fibrosis[17] and chronic obstructive pulmonary disease patients[18,19]. The estimation of free-living EE has recently been validated in 50 participants (healthy and diabetic) compared to metabolic activity measured by doubly-labelled water.[16] In stroke patients, however, the validity and reliability has not yet been studied. It is also unknown whether the portable armband is equally accurate when worn at the hemiplegic side in stroke patients. Whereas the SW2PA is worn on the arm, hemiparetic gait disturbances might have no influence. This could improve the accuracy. The developer's manual requires the SW2PA to be worn on the right arm. Hence, there is a clear need to determine if the SW2PA is a clinically useful tool to monitor the intensity of PA in stroke patients.

A simple and inexpensive device which is frequently used to measure PA in healthy participants is a pedometer.[20,21] This device registers the number of steps, but even in healthy participants belt-worn conventional pedometers vary in accuracy under different walking speeds and test conditions. [22,23] The reliability of the YDWP was demonstrated as acceptable to use for research goals in comparison to other spring-levered pedometers.[11] The YDWP clipped on the belt might work less accurate at slow walking speeds, because at low velocity the accelerations at the hip are not sufficiently large to be registered.[21,23] When the YDWP was placed on the hip, the mechanism of the pedometer showed insufficient sensitivity in slow walking.[21] In a stroke population a device called StepWatch Step Activity Monitor, a microprocessor-linked step activity monitor, attached at the non-paretic ankle revealed to be a more reliable method in measuring steps in hemiparetic gait than a belt-worn pedometer.[14] However, a StepWatch Step Activity Monitor device is expensive and less clinically

useful because of its placement on the ankle. Stroke patients often wear high orthopedic shoes at both sides and therefore placement of the device is not standardized. Therefore it is relevant to investigate if in stroke patients a knee-worn spring-levered pedometer registers the number of steps better than a belt-worn pedometer.
In summary, there is still need to search for valid and reliable devices in determining PA after stroke. The aim of this study is to examine the validity and the reliability of the SWP2A and a knee-worn YDWP in measuring number of steps and EE. Both devices are compared with standardized methods (indirect calorimetry and manual counting) under controlled conditions in stroke patients and healthy participants.

METHODS

Participants

The sample size of 15 participants in each group was calculated prior to the study based on an expected Spearman correlation coefficient >0.80 as an acceptable correlation with a significance of $p<0.05$ and a power of 0.80. Recruitment of 15 stroke patients was conducted by telephone calls with physiotherapist working in private practices in the provinces of Antwerp and Flemish Brabant in Belgium. Patients provided informed consent during home visits. Healthy participants (N=15) were then individually age- and gender-matched to the patient group. Patients and healthy participants were included if they were under 80 years old and had sufficient cognitive abilities to understand the instructions. A diagnosis of stroke was warranted as defined by the World Health Organization[24], at least 3 months post stroke and a score >3 on the Functional Ambulation Categories (ability to walk with or without a walking aid or orthosis)[25]. Patients can also be included when motor function was unaffected; healthy participants may not have walking disabilities. Patients and healthy participants were excluded if they had medical problems that would preclude exercise testing as described by the American College of Cardiology Foundation/ American Heart Association[26].
So 19 stroke patients were screened, of whom 15 enrolled and completed the study. Reasons for exclusion included cardiovascular instability (n=1) and scheduled planned surgical intervention (n=1). Two others patients were excluded because of a low score on the Functional Ambulation Categories. Fifteen healthy participants were also included, age and gender matched to the patient group.
The protocol was reviewed and approved by the Medical Ethics Committee of the Antwerp University Hospital, Belgium (no. B30020084905). All participants provided written informed consent before the study.

Test procedure

For both groups of participants, the following measurements were taken or recorded at the home situation: age, gender, weight, height, hemiplegic side, handedness (using the Edinburgh Handedness Inventory[27]) and the level of mobility-related disability (using the Rivermead Motor Assessment of Gross Function, 0-13 scale, a high score equals minimal impairment[28]). After this baseline assessment, the experiment was performed in hospital so a test battery of activities under controlled conditions could be fulfilled. Activities to be performed were chosen to simulate functional activities: (1) treadmill walking (walking), (2) walking up and down a step (climbing stairs),

(3) cycling on ergometer (cycling), (4) walking on an even surface (free-living walking). Validity was examined by comparing the number of steps registered by YDWP/ SWP2A with the number of steps counted with a hand tally counter; EE was measured with SWP2A and compared to indirect calorimetry. To determine the reliability of both devices repeated measurements on treadmill and bike were compared for the number of steps and EE.

Number of steps measured

The YDWP (Yamasa Tokei Keiki co LTD, Japan) is a uni-axial spring-levered pedometer and measures the number of steps. In healthy participants, a pedometer was worn on the anterior side of the hip and the anterolateral side of the knee on the right side. In stroke patients, the pedometers were placed on the hip and knee of the non-hemiplegic side. The YDWP counts individual steps.

The SWP2A (Health Wear BodyMedia, Pittsburgh, PA, USA) was also used to determine the number of steps. The SWP2A was worn on both upper arms and positioned on the triceps muscle halfway between the acromion and the olecranon. The SWP2A is programmed with a computer interface taking into account the participants personal data (age, gender, height, weight, smoking habit and handedness) prior to testing. Using specific software (Bodymedia, Sense Wear 6.1) the data is converted into EE by a proprietary algorithm. The number of steps obtained by the YDWP and SWP2A were compared with the number of strides counted manually by two researchers using a manual tally counter. To allow comparison with the pedometer results, the number of counted strides was multiplied by 2. For later reference, each activity was video recorded with a digital camera so that the number of steps was monitored. This video footage was used when both researchers counted a different number of steps in order to achieve consensus.

Energy expenditure measured

The SWP2A was also used to assess EE by a proprietary algorithm. The data are stored per minute. The beginning and end of an activity is indicated by a digital time stamp, in order to facilitate data analysis.

Indirect calorimetry using O_2/CO_2 analysis (CardioVit CS-200 Ergo-Spiro, Schiller) was used as criterion standard to compare the results of EE values given by the SWP2A. Ergospirometry took place in all activities except while walking on a flat level surface, because the device was not portable.

Ergospirometry is a valid and reliable method for measuring oxygen consumption (VO_2) and CRF during walking, cycling and treadmill testing in stroke patients[29]. The participant's nose and mouth were covered by a mask, which was connected to a computerized measuring device. After each activity, a print was made. Only the inhaled VO_2 values were used and converted to EE per 10 second intervals as measured by breath-by-breath analyses. From these six values, an average was calculated, so the data per minute could be compared with the single outcome parameter per minute of the SWP2A.

Measurement protocol

The protocol consisted of a number of single, short-time activities which were carried out in the same sequence as described in Table 1, to examine validity of pedometer and accelerometer. To determine the reliability of both devices some activities on treadmill and bike are repeated. Participants were seated between activities until the HR descended to resting heart rate plus 20%, so the participants were recovered from previous activities.

Table 1: Activity protocol.

Activity	Duration (min)	Intensity
Lying down	3	/
Standing	3	/
Sitting	3	/
Treadmill	4	1.5 km/h*
		3 km/h*
		3 km/h + 5% slope
Step up and down	4	10 steps per min
		20 steps per min
Cycling	4	30 Watt*
		50 Watt*
		65 Watt
Walking	120 m	Normal walking speed
	(duration depending on walking speed)	Brisk walking speed

*= 2 repeated measurements.

First, measurements were taken with the participant lying down, standing and sitting, each activity lasting 3 min. Then the participant was invited to walk on the treadmill at speeds of 1.5 km/h (0.93mph), 3 km/h (1.86mph) and 3 km/h with a 5% slope. Walking at 1.5 km/h and 3 km/h was then repeated. Afterwards, the participants walked up and down a step to a rhythm indicated by a metronome: sequentially 10 and 20 beats/min. Afterwards they were asked to cycle at 30 Watt, 50 Watt and 65 Watt, each at 50 rpm. Cycling at 30 and 50 Watt was repeated. Every activity on the treadmill, step and cycle ergometer lasted for 4 min. Finally participants were asked to walk a self-selected walking speed on a flat level surface, once at normal and once at brisk walking speed. Participants were first instructed to walk on a flat level surface for a length of 120 m. The participants were told that the first speed should be typical of their normal everyday walking speed. The second time they were asked to walk as fast as possible, while remaining within safe limits. Counting the number of steps was executed during all activities except while cycling.

Statistical Analysis

All statistical analyses were performed using SPSS (version 20.0, SPSS Inc, Chicago, IL). Descriptive statistics of participant characteristics were calculated. Normality was verified with the Kolmogorov-Smirnoff test. Since the data were mostly not normally distributed non-parametric statistics were used to analyze the data. A Spearman correlation coefficient (r_s) was calculated to determine the level of association between the pedometer versus counted steps (steps) and accelerometer versus indirect calorimetry (EE). A Spearman correlation of 0.5-0.70 was considered a moderate correlation, 0.70-0.90 as a good too high correlation, >0.90 was considered as an excellent correlation.[30] Statistical significance was set at $p<0.05$. To visualize the level of agreement between the experimental device (YDWP, SWP2A) and the criterion standard (counted steps, indirect calorimetry) a Bland-Altman Plot was used.[31] In the Bland Altman Plot, the criterion standard measures were plotted against the difference between both measures to give an indication of agreement between the two methods of measurement. This also provides a 95% confidence interval based on the calculated standard deviation of the differences. To determine the test-retest reliability, two-way mixed intra-class correlation coefficients with single measures were calculated. An intra-class correlation coefficient between 0.40 and 0.59 was withheld as a fair correlation, 0.60 and 0.74 as a good correlation and ≥0.75 as excellent[32]

RESULTS

Participants

The demographic and clinical characteristics of included participants are presented in Table 2.
Fifteen patients with a mean age of 60.40 years (±10.26) and mean time since stroke 6.20 years (±05.08) participated. Fifteen healthy participants (mean age 58.07 years ±10.37) were included.

Table 2: Demographic and clinical characteristics of participants.

Characteristics	Stroke (n=15)	Healthy (n=15)
Age, mean(y) ±SD	60.40±10.26	58.07 ±10.37
Gender female, n (%)	6 (40.0)	10 (66.7)
Height, mean(m) ±SD	1.69±00.08	1.69±00.09
Weight, mean(kg) ±SD	82.40±09.62	84.33±19.62
BMI, mean (kg/m²) ±SD	28.87±03.49	29.39±06.39
Time since stroke, mean (y) ±SD	6.20± 05.08	
Stroke type		
Ischemic, n (%)	5 (33.3)	
Hemorrhagic, n (%)	6 (40.0)	
Both, n (%)	4 (26.7)	
Side of hemiparesis		
Left, n (%)	9 (60.0)	
Disability stroke		
RMA-GF, median (IQR)	11 (0.0)	
FAC, median (IQR)	4 (1.0)	
Mobility		
No use of walking aids in ADL, n (%)	7 (46.7)	15 (100.0)
Experience with walking on treadmill, n (%)	8 (53.3)	4 (26.7)
Handedness at moment of testing		
Right handed, n (%)	10 (66.7)	13 (86.7)
Left handed, n (%)	5 (33.3)	2 (13.3)
Pedometer worn right side, n(%)	9 (60)	15 (100)

BMI= Body Mass Index, RMA-GF= Rivermead Motor Assessment-Gross Function, IQR=interquartile range, FAC= Functional Ambulation Categories, ADL= Activity of daily living.

Table 3 shows the number of steps measured by YDWP, SWP2A and criterion standard while walking on a flat level surface at two different speeds in stroke and healthy adults. In stroke patients, only seven patients (50%) could walk without walking aids or orthosis, four patients (28.6%) needed a cane, one patient (7.1%) wore an ankle foot orthosis and two patients (14.3%) used a cane and ankle foot orthosis at two different walking speeds. One patient could not walk the entirely 120m distance, because of a knee prosthesis. In healthy adults, no walking, no walking aids or orthosis were used.

Table 3: Number of steps measured by Yamax Digi-Walker SW-200 Pedometer (YDWP), SenseWear Pro2 Armband (SWP2A) and criterion standard while walking on a flat level surface at two different speeds in stroke and healthy adults.

	Stroke *(n=14)*					Healthy *(n=15)*				
	Median	Min.	Max.	P25	P75	Median	Min.	Max.	P25	P75
Normal walking										
YDWP Hip	190	0	355	0	244	188	0	211	170	196
YDWP Knee	232	172	389	206	270	190	158	243	178	211
SWP2A right	127	0	297	45	178	124	70	202	81	146
SWP2A left	145	0	375	76	179	93	60	209	82	163
Manual counted	237	172	390	205	308	190	156	214	176	190
Brisk walking										
YDWP Hip	171	0	361	2	232	156	9	193	142	169
YDWP Knee	218	150	359	193	278	162	132	185	144	176
SWP2A right	177	0	368	84	153	98	40	187	56	141
SWP2A left	146	28	414	102	180	110	24	190	69	145
Manual counted	210	148	356	186	283	156	132	184	142	168

P25- P75= percentile 25 and 75, min= minimum, max= maximum.

Table 4: Spearman correlation coefficient for number of steps and energy expenditure in stroke and healthy participants while executing simulated functional activities.

Number of steps	Stroke					Healthy				
Activity	n	SWP2A right	SWP2A left	YDWP hip	YDWP knee	n	SWP2A right	SWP2A left	YDWP hip	YDWP Knee
YDTreadmill @ 1.5 km/h	12	0.51	0.40	0.38	0.69*	15	-0.08	-0.04	0.21	0.91**
Treadmill @ 3 km/h	7	-0.37	-0.52	-0.41	0.64	14	-0.13	-0.21	0.41	0.93**
Treadmill @ 3 km/h +5%	5	0.60	0.30	0.90*	0.30	14	0.09	0.29	0.21	0.97**
Step 10 beats/min	14	-0.30	0.08	-0.63*	-0.47	15	0.10	0.17	0.07	0.31
Step 20 beats/min	10	-0.63	-0.78	-0.30	-0.44	15	-0.23	-0.21	-0.50	-0.39
Normal walking 120m	14	-0.13	-0.23	0.33	0.95**	15	0.46	0.50	0.56*	0.89**
Brisk walking 120m	14	-0.04	0.46	0.46	0.98**	15	0.51	0.15	0.62*	0.99*

Energy expenditure	Stroke			Healthy		
Activity	n	SWP2A right	SWP2A left	n	SWP2A right	SWP2A left
Lying down	15	0.56*	0.49	15	0.77**	0.70**
Standing	15	0.79**	0.81**	15	0.66**	0.58**
Sitting	15	0.78**	0.85**	15	0.24	0.41
Treadmill @ 1.5 km/h	12	0.01	0.50	15	0.26	0.14
Treadmill @ 3 km/h	7	0.75	0.82*	14	0.67**	0.08
Treadmill @ 3 km/h +5%	5	0.50	0.70	14	0.84**	0.72**
Step 10 beats/min	14	0.59*	0.48	15	0.63*	0.49
Step 20 beats/min	10	0.29	0.71*	15	0.84**	0.58*
Cycling 30 Watt	13	0.71**	0.52	15	0.46	-0.29
Cycling 50 Watt	9	0.70*	0.33	14	0.63*	0.31
Cycling 65 Watt	7	0.54	0.00	13	0.40	0.01

n= number, SWP2A= Sense Wear Pro 2 Armband, YDWP= Yamax Digi-Walker SW-200 Pedometer, *= p<0.05, **= p<0.01.

Number of steps measured: validity

Table 4 summarizes the association (Spearman correlation coefficient) between the manually counted steps and the steps measured with the pedometer worn on the hip and knee and with both SWP2A (worn on left and right arm). When the intensity became more strenuous, less participants could fulfill the different activities. Each activity was separately analyzed. There were high to excellent correlations found between the pedometer worn on the knee and the manually counted number of steps ($r_s \geq 0.89$; $p<0.01$) in walking activities of the healthy participants. For the stroke group, significant moderate to excellent correlations were found for treadmill walking at 1.5 km/h ($r_s=0.69$) and walking on a flat level surface at two different speeds ($r_s>0.95$) between the pedometer worn on the knee and the gold standard. When the pedometer was worn on the hip, poor correlations were found in both groups. For the SWP2A no to little significant agreement was found when results were compared with the manually counted steps, both with the armband worn on the hemiplegic or the non-hemiplegic side.

In figure 1, the results are plotted to visualize steps measured with the pedometer worn on the knee and the manually counted steps in stroke and healthy participants. Results illustrate that the pedometer worn at the knee measures accurately at different intensities of walking in healthy participants and also in stroke patients at slow walking on a treadmill and at different intensities on a flat level surface. During walking on a treadmill, walking up and down a step and cycling, the pedometer is often undercounting the number of steps (results not shown).

Number of steps measured: reliability

Table 5 shows the test-retest reliability between the manually counted steps and the steps measured with the pedometer worn at the hip/knee and with left and right SWP2A. The test-retest reliability during treadmill walking at 1.5 km/h ranged from good to excellent (0.66≤ICCs≥0.98). The test-retest results found for walking on the treadmill at 3 km/h were categorized as excellent (0.79≤ICCs≥0.97).

Table 5: Intraclass correlation coefficient in stroke and healthy participants for the number of steps and energy expenditure calculated for the repeated measures.

		Stroke					Healthy				
	Activity	n	SWP2A right	SWP2A left	YDWP hip	YDWP knee	n	SWP2A right	SWP2A left	YDWP hip	YDWP knee
Steps	TM@1.5 km/h	12	0.98**	0.89**	0.88**	0.73**	15	0.96**	0.66**	0.79**	0.97**
	TM@3 km/h	7	0.93**	0.92**	0.96**	0.95**	14	0.79**	0.94**	0.97**	0.94**
EE	TM@1.5 km/h	12	0.85**	0.76**			15	0.85**	0.73**		
	TM@ 3 km/h	7	0.63	0.97**			14	0.61**	0.61**		
	Cycl. 30 Watt	13	0.90**	0.84**			15	0.52*	0.29		
	Cycl. 50 Watt	9	0.95**	0.98**			14	0.59*	0.96**		

TM= treadmill, Cycl= cycling, EE= energy expenditure, n= number (right= right hemi paretic), YDWP= Yamax Digi-Walker SW-200 Pedometer, SWP2A= Sense Wear Pro 2 Armband, *= p<0.05, **= p<0.01.

Energy expenditure measured: validity of SWP2A

Correlation coefficients between the ergospiro device and the SWP2A for measuring EE are presented in Table 4. In general, the results for the measurements taken in lying, sitting and standing show poor to fair correlations.

For the other activities varying results were found in both groups. Only a few participants could fulfill the more strenuous activities.

A Bland-Altman plot showed that there was both under- and overestimation in EE measured by the SWP2A compared to indirect calorimetry (see Figure 2 walking on treadmill at 1.5 km/h, not all data shown).

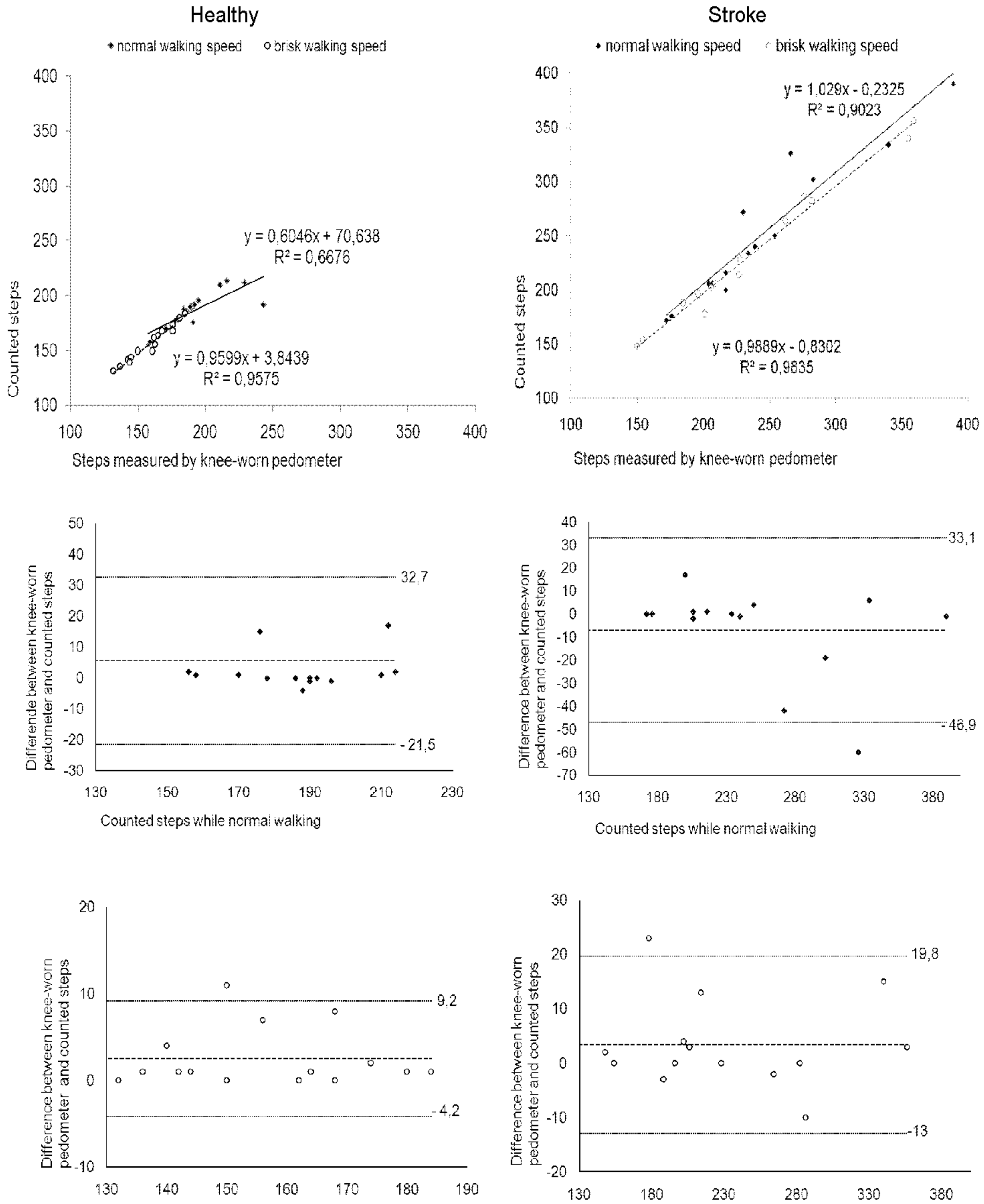

Figure 1: Agreement between the measured steps with the knee-worn pedometer and the counted steps in healthy participants and stroke patients while walking on ground level surface at two different walking speeds. The solid horizontal lines in Bland Altman plots represent the 95% limits of agreement corresponding to ± 2 standard deviations, the horizontal dotted lines represent the mean difference.

Energy expenditure measured: reliability of SWP2A

ICC's of parameters during the treadmill measurements ranged from good to excellent (0.61≤ICCs≥0.99), when not worn on the hemiparetic arm (Table 5). The ICC values found for cycling at 30 and 50 Watt were found to be excellent (ICCs≥0.84), except for the healthy participants at 30 Watt (ICCs=0.29-0.52) and 50 Watt (SWP2A right ICC=0.59).

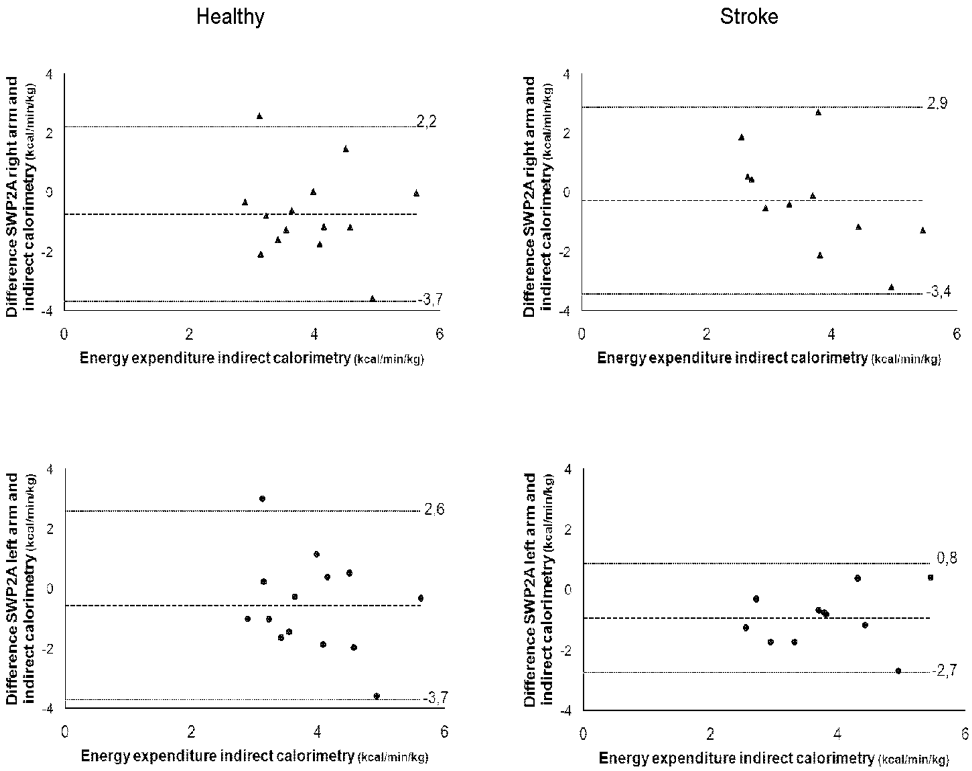

Figure 2: Agreement between the energy expenditure with the SWP2A left and right arm and the indirect calorimetry in healthy participants and stroke patients while walking on treadmill at 1.5km/h. Solid horizontal lines represent the 95% limits of agreement corresponding to ±2SD, horizontal dotted lines represent the mean difference.

DISCUSSION

Based-up on the test-retest reliability results of this study a knee-worn YDWP and SWP2A showed to be reliable devices to measure walking steps in stroke patients and healthy participants. The SWP2A was found to be a reliable instrument to measure EE in both groups.

This study also assessed the validity of the YDWP and the SWP2A. In general, no valid results were found for the SWP2A in measuring number of steps and EE in both groups. In stroke patients, the YDWP gave valid results when it was used in specific walking conditions: walking at normal and brisk intensity and at slow walking on the treadmill. Only in healthy participants the pedometer also showed to be valid at higher walking intensities. As has previously been reported, we also found that the YDWP was more valid when the walking speed increased in both groups.[23] An explanation might be that the YDWP is a spring-levered pedometer, which means that a vertical acceleration of the hip/knee is needed to cause contact of the lever arm with the electrical contact.[21]

This might explain why pedometers are less valid at slow walking speed. For the stroke patients we did not find better results when the walking intensity increased on the treadmill. Apparently many of the patients and healthy participants were not used to walk on a treadmill. They held onto the handrails and walked with a different gait pattern than customarily. A primary difference between treadmill walking and walking on a flat level surface is that participants walked on a treadmill more slowly, with shorter strides, and with more time spent in double support.[33] Also vision may impact on gait pattern. When walking on a treadmill participants do not receive the same optic flow as they do when walking over ground. This may alter their balance and stability or their perception of where they are on the treadmill or the speed at which they are ambulating.[34]

Walking at indoor level surface we noticed their usual gait pattern and also they were allowed to use their walking aid. People with short strides or shuffling gait have less vertical displacement of the area where the pedometer is attached than when walking similar distances using longer strides and smoother gait.[15] A pedometer does not account for asymmetries in gait. This might explain why our results were better in even surface conditions as compared to the treadmill. Here excellent correlation was found with the reference measurement at both walking intensities. Not only walking intensity is a determining factor in pedometer mechanism, also placement of the device is important.

We found higher correlations when the pedometer was worn on the knee, rather than on the hip. Also in previous reports a hip-worn pedometer showed limited validity in hemiparetic stroke patients at slow walking speeds.[14,35,36] An explanation given by the research group of Melanson is that accelerations at the hip in stroke patients are often insufficient in magnitude to cause contact of the lever arm with the electrical contact when a spring-levered pedometer is used.[21] At the hip a piezoelectric pedometer is recommended above a spring-levered pedometer at slower gait speeds.[21] A spring-levered pedometer attached to the knee has not yet been studied by other research groups. The unaffected ankle has been recently been described as a good location to measure ambulatory activity in stroke patients.[14] In the present study, the ankle was not preferred as a place to wear a pedometer, because stroke patients often wear high orthopedic shoes, hence uniform attachment of the pedometer could not be guaranteed. Well is know that a pedometer should have attachment to a firm elastic belt, which improves stability and reduces undercounting.[37] We used an elastic belt to attach the YDWP below the knee. This was well tolerated by our participants.

This study further assessed the validity of the SWP2A in measuring number of steps and EE. As previously reported in other studies, we also assessed that resting EE measured by the SW2PA correlated poorly to EE measured by indirect calorimetry in both groups.[38] The Bland Altman plots showed under- and overestimation of EE for participants executing simulated functional activities. The manufacturers prescribe the SWP2A to be worn on the right arm in healthy people. There could be a 10% difference in measuring steps and EE as described by the manufacturers. We could not replicate these differences as the accelerometer was both over- and undercounting at both arms. Also there could be a difference when the SWP2A was placed on the hemiparetic arm versus the unaffected side, because natural arm swing was reduced on the hemiparetic side and handrails were often hold. When arm swing was influenced gait disturbances were noted as is stated in previous studies. Patients and healthy participants took longer and less frequent strides when the arms were restrained through holding on to handles when walking on a treadmill at slow speeds.[39,40] Also the device might give better results when the measurements were based on more useful over a longer period of time registration to monitor daily EE.[41] Also the device might give better results when the measurements were based on free-living activities instead of simulated functional activities, allowing participants to demonstrate their used walking pattern associated with arm swing. The SWP2A may be more useful over a longer period of time registration to monitor daily EE.[41] Also the device might give better results when the measurements were based on free-living activities instead of simulated functional activities, allowing participants to demonstrate their used walking pattern associated with arm swing.

This study also warrants some critical reflections. A variety of simulated functional activities but of limited duration was chosen to make the protocol feasible for our patients. Simulated functional activities were included, so the measurements could be executed in a lab setting where indirect calorimetry using O_2/CO_2 analysis was possible. Also the protocol was designed to start with relatively easy activities whereas later on exercises became more intense.

A limitation of this study is the intensity of some of the functional activities. Not all participants could perform the more strenuous activities. Therefore generalization of results should be done with caution. Finally the protocol was only feasible for patients with light walking disabilities. In the future, it might be recommendable (1) to use YDWP and SWP2A in more free-living situations, (2) to include only patients with a hemiparesis or an asymmetrical gait, so more severe disabled patients can be included and (3) to use SWP2A for a period of at least 10 min.

CONCLUSION

A good test-retest reliability was found for the YDWP and the SWP2A in both groups. This study showed the YDWP to be a valid device in stroke patients, when the pedometer was worn on the non-hemiplegic knee during walking activities except high intensity walking in stroke. In healthy participants the knee-worn pedometer is valid during all walking activities. Still the pedometer systematically undercounts the number of steps during other short time functional activities. This study could not demonstrate valid measurement of number of steps and EE in stroke patients using the SWP2A. Further studies are needed to explore valid instruments to measure EE in stroke.

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Chapter 2

Is a coded physical activity diary valid for assessing physical activity level and energy expenditure in stroke patients?

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ABSTRACT

Objectives To determine the concurrent validity of a PA diary for measuring PA level and total EE in hospitalized stroke patients.

Method Sixteen stroke patients kept coded activity diaries and wore SWP2A multi-sensor activity monitors during daytime hours for one day. A researcher observed the patients and completed a diary. Data from the patients' diaries were compared with observed and measured data to determine total activity (METs*minutes), activity level and total EE.

Results Spearman correlations between the patients' and researchers' diaries revealed a high correlation for total METs*minutes (r_s=0.75, $p<0.01$) for sedentary (r_s=0.74, $p<0.01$) and moderate activities (r_s=0.71, $p<0.01$) and a very high correlation (r_s=0.92, $p<0.01$) for the total EE. Comparisons between the patients' diaries and activity monitor data revealed a low correlation ($r_s \leq 0.29$) for total METs*minutes and EE.

Conclusion Coded self-monitoring activity diaries appear feasible as a low-tech alternative to labor-intensive observational diaries for determining sedentary, moderate, and total physical activity and for quantifying EE in hospitalized stroke patients. Given the poor correlation with objective measurements of PA, however, further research is needed to validate its use against a gold-standard measure of PA intensity and EE.

Keywords Stroke, Rehabilitation, Physical activity, Energy expenditure, Activity diary, Activity monitor.

INTRODUCTION

The importance of PA promoting health has been well documented. Increased daily PA reduces cardiovascular risk for people with and without disabilities.[1,2] Stroke patients have reduced levels of PA due to the nature of their impairments. Several observational studies have described decreases in the activity patterns of sub-acute and chronic stroke patients.[2-4] There is considerable interest in exploring valid and reliable instruments for evaluating the level of daily PA and in identifying PA patterns to guide intervention strategies.

A variety of objective methods have been used to measure daily PA in stroke patients, including activity monitors[5-7] and pedometers[8-10]. Activity monitors based on accelerometry, measure acceleration, as expressed in EE and/or ambulatory movement. Advantages of activity monitors include their objectivity and the fact that they do not rely on cognitive/ memory skills. Activity monitoring also allows the possibility of testing a large sample, and recording continuously for long periods under free-living conditions.[7] Commonly reported major shortcomings include the loss of data due to noncompliance and the failure of activity monitors due to malfunctioning or loosening of the equipment.[6,11-13] In addition, hemiparetic gait disturbances and/or arm movements causes unreliable recordings in accelerometry systems.[9,10,14]

Pedometer are prescribed as a less expensive and simple alternative for taking objective measurements of PA in stroke patients.[8,15] Pedometers tend to undercount steps during slower gaits when the device is placed on the hip. In hemiparetic gait, speed accelerations at the hip were often of insufficient magnitude to be registered.[8] A knee-worn pedometer has recently been recommended for detecting all walking activities in stroke patients, with the exception of high intensity walking.[10] One explanation might be that, in hemiparetic gait, the knee joint shows more vertical acceleration, thus bringing the lever arm in contact with the electrical component of the device. Pedometers detect only the number of steps and provide no information about EE or the type and intensity of activities performed by patients.

Other methods for determining PA in stroke patients include observation[16], PA questionnaires[17-19] and activity diaries[20,21]. Observational methods require a researcher to observe a patient at set intervals over a specified period, in order to produce reliable data.[16,22] This method is time consuming and costly, and it is therefore less applicable in clinical settings. Activity questionnaires and diaries have the advantage of low cost and suitability for comparison between populations. Questionnaires are the most frequently used instruments in epidemiological studies for estimating PA and EE.[17-19] Although they save time, these questionnaires rely on retrospective information and honest reporting, and they do not allow for cognitive deficit. Questionnaires with greater detail are used for assessing the duration, frequency, and intensity of activity. Because of their complexity, however, they often result in lower compliance and lower validity.[23] Although questionnaires with less detail are easier to use, they are often less accurate, and they do not assess various dimensions of PA.[24] In stroke research, activity diaries are most commonly used as secondary outcome measurements, given the difficulty of recording activities due to patients impairments.[6] In healthy participants; a categorized three-day PA diary was used as an alternative method for assessing various dimensions of PA. Each day was divided into 96 15-minute intervals. The participants were asked to grade their activity into nine categories (cat.1= sleeping, cat.2= sitting, cat.3= standing, cat.4= walking inside, cat.5= walking outside, cat.6 9= low, moderate, high, and very high intensity activity, respectively).[25] Participants were asked to choose one dominant activity for each 15-minute period. This type of diary has been described as being time efficient, easy to learn, inexpensive, reliable, and reasonably valid.[20,26,27] One disadvantage of the three-day diary is that it underestimates activities of short duration, as it records only the major activity performed during each 15-minute period was recorded.[20] Researchers have noted that participants are unable to keep with the diary if periods of 5-10 minutes periods are used. Another difficulty involves the limited choice in activities. Researchers have concluded that the diary is an alternative method for evaluating individual physical patterns and that it is suitable for clinical practice in healthy participants.

For stroke patients, a tool is needed that combines the advantages of the three-day categorized-activity diary with greater detail information about the type and intensity of activities and the position in which the activities are executed, in order to provide accurate information with minimal effort, thus being useful in clinical settings. In stroke patients, activities of short duration occur rarely, if at all. The short time intervals recommended in the Bouchard study are therefore not preferable. Moreover, therapy in rehabilitation centers is often scheduled in 30-minutes blocks. Keeping the diary can help patients to become more aware of their physical activities, possibly strengthening their motivation to adopt a more active lifestyle. To this end, a simplified coded physical-activity diary was developed in which stroke patients choose the dominant activity in performed 30-minute time interval from a pre-defined list of activities, all linked to simple codes. This minimizes writing, making it possible for patients with writing problems to complete the diary. The time was adjusted to the pace of hospitalized stroke patients, who perform fewer activities within 30-minute time interval in a rehabilitation center.

To our knowledge, no study in stroke research has investigated the use of a coded self-monitoring activity diary to determine both total EE and intensity level of various activities, compared against criterion standards of observations and activity monitoring. In the present study the concurrent validity of an activity diary was evaluated in hospitalized stroke patients. We specifically compared self-monitoring diaries to observational diaries and activity-monitor outcomes.

METHODS

Ethics Statement

The protocol was reviewed and approved by the Medical Ethics Committee of the Antwerp University Hospital, Belgium (no. B30020084906). Patients received oral and written information about the design of the study; they provided written consent and agreed to the publication of the research data.

Participants

Stroke patients were recruited on a voluntary basis from an inpatient rehabilitation center in Belgium. Inclusion criteria were as follows: (1) a first-ever stroke as defined by the World Health Organization, (2) stroke less than six months ago, (3) ability to move independently with or without a walking aid and (4) understand and carry out simple instructions. Patients were excluded if they were not medically stable, as described by the American College of Cardiology Foundation/American Heart Association[28].

Design

On the first day demographic and clinical data were collected, including age, gender, duration and type of stroke, height, weight and the degree of loss of function (Rivermead Motor Assessment, Gross function[29]). The patients also had an introductory session with the equipment on this day. The SWP2A was placed on the non-hemiplegic arm and patients were told not to take off the monitor until the end of the study period. They also received instructions on completing the diary. The following day, all patients were asked to complete a daytime activity diary simultaneously, in addition to wearing an SWP2A.

After receiving instructions on completing the diary, each patient entered one activity diary independently, while another diary was completed by an observer, both between 8:00 AM and 8:00 PM. This timeframe was selected because patients were considered most active between these hours in rehabilitation centers. The patients were asked to list their main activities for each half hour. A researcher observed each patient once every 20 minutes, completing the observer activity diary independently. The following day, both diaries and the activity monitors were collected. Missing data in the patients' diaries were completed based on the recollections of the interviewer, independently of the observer. To test for concurrent validity, the patients' diaries were compared against two criterion measurements, the observers' diaries and the activity-monitor data.

Assessment

The coded activity diary was developed based on two existing activity diaries [24,30]. The simplified seven-day physical-activity diary has provided valid estimates of PA in working women[30] and non-obese free-living adults[24], thus allowing the assessment of total daily EE and PA level. As stroke patients often demonstrate writing impairment and concentration difficulties, codes were used to indicate activities. The newly developed activity diary consisted of bundled sheets of paper, each containing a table with four columns: 1) time, 2) activity 3) position and 4) intensity of the activity (Supplement A). For each activity, patients were asked to record one number reflecting the main activity of the past 30 minutes. The main activity was defined as the activity that had taken the most time within a 30-minute period. If two activities were performed for the same amount of time, participants were asked to report the most intense activity. The activity number was chosen from a list of 63 codes divided into six categories of activities: self-care, household tasks, work, therapy, leisure and home activities, and activities related to mobility and transport (Supplement B). Additional numbers could be added for activities that were not included in the list. To avoid mistakes in recall, patients were instructed to complete the diary each time at the end of the 30-minute period. They were also instructed to record the position (lying, sitting or standing) in which each activity was performed. Finally the perceived intensity of each activity was rated along a rating scale of 6-20.[31] Taking into account position and intensity, activities were converted in METs values, using the Compendium of Physical Activities Tracking Guide.[32] To calculate METs*minutes, Mets values were multiplied by 30 minutes. Mean METs values were subdivided into four levels, corresponding to sedentary

(≤1 METs), light (>1 - <3 METs), moderate (3-6 METs) and vigorous activity (>6 METs).[33,34] In order to obtain EE in kcal/30min, the following formula was used: [(METs-value X 3.5 X patient's weight)/200] X 30minutes.[35] These results were multiplied by 24 to calculate EE over 12 hours (kcal/12h).

According to the user's manual the SWP2A (HealthWear BodyMedia, Pittsburgh, PA, USA) should be worn on the right upper arm. For this study, however, it was worn on the non-hemiplegic upper arm positioned on the triceps muscle halfway between the acromion and the olecranon. The SWP2A was programmed using a computer interface, taking into account the participants' age, gender, height, weight, smoking habits and handedness prior to testing. This SWP2A contains two accelerometers, a galvanic skin response sensor, a heat flux sensor, a skin temperature sensor and a near-body ambient temperature sensor from which the data were stored minute by minute between 8:00 AM and 8:00 PM. Using a proprietary algorithm (Bodymedia, Sense Wear 6.1) the data were converted into Metabolic Equivalents minutes (METs*minutes) and EE It has been validated for measuring EE in 50 healthy and diabetic participants against double-labeled water[36] and in 23 participants during light-intensity stepping in a Whole Room Calorimeter[37].

Statistical Analysis

All data were analyzed using SPSS (version 20.0, SPSS Inc., Chicago). Descriptive statistics were calculated for patient characteristics. Normality was verified with the Kolmogorov-Smirnoff test. Because most of the data were not normally distributed, non-parametric statistics were used.

In order to study concurrent validity, a Spearman correlation coefficient (r_s) was calculated to evaluate the relationship between the patient's diary and the observer's diary and between the patient's diary and the SWP2A. Values less than 0.30 were taken to indicate poor correlations, with values between 0.30 and 0.50 indicating low correlations, between 0.50 and 0.70 moderate correlations, between 0.70 and 0.90 high correlations and greater than 0.90 very high correlations.[38] Statistical significance was set at $p<0.05$. To visualize

Table 1: Demographic and clinical characteristics of included patients.

Characteristics	Stroke=16
Age at stroke onset, mean (y)±SD	68.31±10.95
Gender female, n (%)	7(43.8)
Height, mean (m)±SD	1.69±00.17
Weight, mean (kg)±SD	67.83±12.39
BMI, mean (kg/m²)±SD	25.42±05.08
Time since stroke, median (d)(IQR)	62.50(47.25)
Stroke type	
Ischemic, n (%)	9(56.3)
Hemorrhagic, n (%)	7(43.8)
Side of hemiparesis, right, n (%)	10(62.5)
Disability stroke	
RMA-GF, median (IQR)	7(5-11)
FAC, median (IQR)	3(2-5)
Mobility	
No use of walking aids in ADL, n (%)	4(25)

d=days, SD= standard deviation, %= percentage, RMA-GF= Rivermead Motor Assessment Gross Function, FAC= Functional Ambulation Categories, n= number, IQR= Interquartile Range.

the level of agreement between the patient's self-monitoring diary and both criterion standards (observer's diary; SWP2A) the values of the criterion standard were plotted against the difference between the two methods, thus providing an indication of agreement. The median and percentiles 25 and 75 were calculated.

RESULTS

Descriptive statistics

The sample consisted of 16 patients with a mean age of 68 years (±11) and mean time since stroke of 78 days (± 53). Four patients used no walking aids. Table 1 provides a description of the characteristics of the patients. No data points were missing after recollection the diaries. When activities were missing, they were retrospectively added during the following day. Out of the 63 codes, the numbers which were frequently used were related to self-care (19.53%), therapy related activities (17.71%), resting in bed or in (wheel)chair (12.24%), watching television (9.38%), and talking (8.60%).

Table 2: METs*minutes and Energy Expenditure values measured by two activity diaries and an Activity monitor in 16 stroke patients.

METs*minutes	Median	Minimum	Maximum	P25	P75
Diary patient					
Sedentary	342.00	120.00	420.00	247.50	378.00
Light	457.50	270.00	960.00	367.50	502.50
Moderate	397.50	300.00	1125.00	390.00	570.00
Vigorous	/	/	/	/	/
Total	1227.00	1134.00	1740.00	1184.25	1437.00
Diary researcher					
Sedentary	379.50	150.00	474.00	284.25	419.25
Light	405.00	225.00	765.00	300.00	603.75
Moderate	405.00	180.00	705.00	390.00	480.00
Vigorous	/	/	/	/	/
Total	1176.00	1080.00	1515.00	1123.50	1299.75
Activity monitor					
Sedentary	293.52	116.96	538.31	209.24	437.95
Light	521.82	5.88	768.17	345.30	575.41
Moderate	70.96	0.00	326.43	27.09	216.62
Vigorous	/	/	/	/	/
Total	896.16	486.74	1246.07	839.57	1026.45
Energy Expenditure	**Median**	**Minimum**	**Maximum**	**P25**	**P75**
Diary patient	1604.93	977.55	1927.80	1361.59	1610.44
Diary researcher	1473.78	967.26	1875.83	1249.63	1749.23
Activity monitor	965.33	728.12	1450.70	867.49	1056.56

Metabolic Equivalents (METs)-values:

- Diary: METs- values per activity based on Compendium of Ainsworth[20] X 30 minutes, subdivided in sedentary activity (≤ 1 METs), light activity (>1-< 3 METs), moderate activity (3-6 METs), vigorous activity (>6 METs).
- Activity monitor: calculated by SenseWear Pro 2 armband.

Energy expenditure kilocalories (kcal/12h)-values:

- Diary: kcal/12h calculated by ((METs valuereported per activity X3.5 X patients weight)/ 200 X 30minutes)[23] X 24.
- Activity monitor: kcal/12h calculated by SenseWear Pro 2 armband.

Almost every activity number was mentioned in the diaries except brushing hair, performing handicraft, and driving a car. A few new codes (N=4) were listed, such as reading, smoking, resting in a (wheel)chair or in bed. Mostly activities were executed in sitting (84.1%) and standing position (9.9%). It concerned sedentary activities. Patients noted that help was required in 26.3% of all activities.

Table 2 provides summary of the results for METs*minutes and EE per 12 hours, as collected through the activity diaries of the patient and observer, as well as through activity monitoring. None of the patients performed vigorous activities.

Concurrent Validity

The correlation for METs*minutes in the diaries of the patients and the observers diaries was 0.75 (p<0.001), thus indicating a high correlation (Table 3). High correlations were also revealed for sedentary (r_s=0.74, p<0.01) and moderate (r_s=0.71, p<0.01) activity levels. A low and non-significant correlation was found for the activity category "light". When the patients' activity diaries were compared to the SWP2A, the correlation coefficients were not significant.

Table 3: Spearman Rank Correlations between Patient's diary versus Researcher's Diary and versus Activity monitor in 16 stroke patients for physical activity (METs*minutes) and energy expenditure.

METs*minutes	Diary patient-Diary researcher	Diary patient-Activity monitor
Sedentary	0.74(p=0.001)**	0.16 (p=0.567)
Light	0.37 (p=0.162)	0.11 (p=0.691)
Moderate	0.71 (p=0.002)**	0.22 (p=0.410)
Vigorous	/	/
Total	0.75 (p=0.001)**	0.15 (p=0.590)
Energy expenditure	Diary patient-Diary researcher	Diary patient-Activity monitor
Total	0.92 (p=0.000)**	0.29(p=0.276)

**= p<0.01.

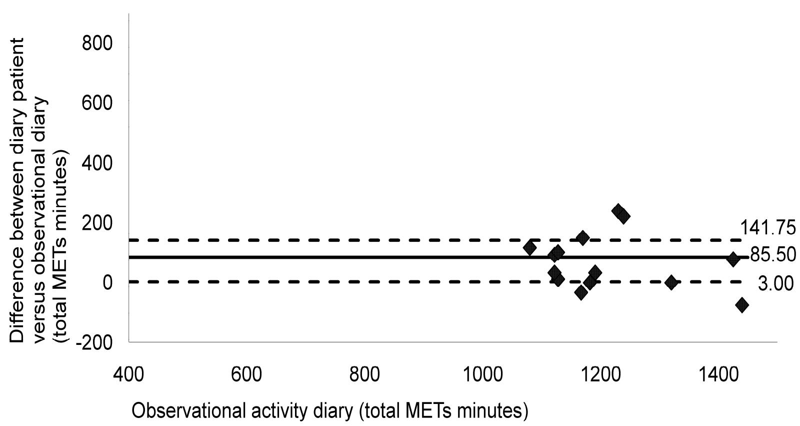

Figure 1: Comparing total Mets*minutes in 16 stroke patients: observational diary versus patient diary.
Legend: Total Mets*minutes of observer activity diary was compared with diary of stroke patients. Broken horizontal lines represent percentiles 25 and 75, bold solid lines represent the median value of difference. Data analysis showed a good level of agreement between both diaries, data points clustering around zero (Median=85.50; P25=3.00; P75=141.75). An underestimation of total METs*minutes for all patients is noted in comparison with the patient's diary. Visual inspection revealed no systematic bias.

Graphic analysis indicated a good level of agreement between both diaries (median value of the difference=85.50; P25=3.00; P75=141.75) (Figure 1). Data points were clustered around zero. Less agreement was found between the patients' diaries and the SWP2A (median value of the difference=352.24; P25=242.44; P75=601.46) (Figure 2). Lower total METs*minutes for all patients was observed in comparison with the patients' diaries. Visual inspection revealed no systematic bias.

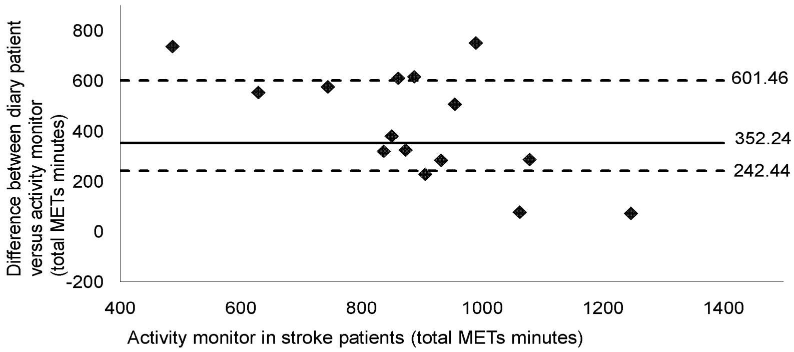

Figure 2: Comparing total Mets*minutes in 16 stroke patients: activity monitor versus patient diary.
Legend: Total Mets*minutes of activity monitor was compared with diary of stroke patients. Broken horizontal lines represent percentiles 25 and 75, bold solid lines represent the median value of difference. Data analysis showed no good level of agreement between patient diary and the activity monitor (Median=352.24; P25=242.44; P75=601.46). Visual inspection revealed no systematic bias.

Comparison of the data from the two diaries, revealed a very high correlation (r_s=0.92, p<0.01) for EE, as measured between 8:00 AM and 8:00 PM (Table 3). Comparison between the patients' diaries and the SWP2A revealed a poor correlation (r_s=0.29, p<0.01) with regard to EE. Graphic analysis of the data concerning total EE indicated good agreement between the two diaries (median value of the difference=91.90; P25=2.57; P75=194.51) (Figure 3). Most of the data were clustered around the zero point.
The SWP2A underestimated EE for all patients, in comparison to the diaries completed by the patient (median value of the difference=507.27; P25=301.05; P75=804.44) (Figure 4).

DISCUSSION

This study assessed the concurrent validity of a coded self-monitoring activity diary for measuring activity level and total EE in hospitalized stroke patients. The diary generated valid results in comparison to the diary kept simultaneously by an observer, as used to determine sedentary PA (<1METs), moderate PA (3-6 METs) and total PA over 12 daytime hours. A very high correlation between the two diaries was observed for total EE during daytime hours. Poor correlations were observed, however, when comparing the diary to the SWP2A for measuring activity level and EE.

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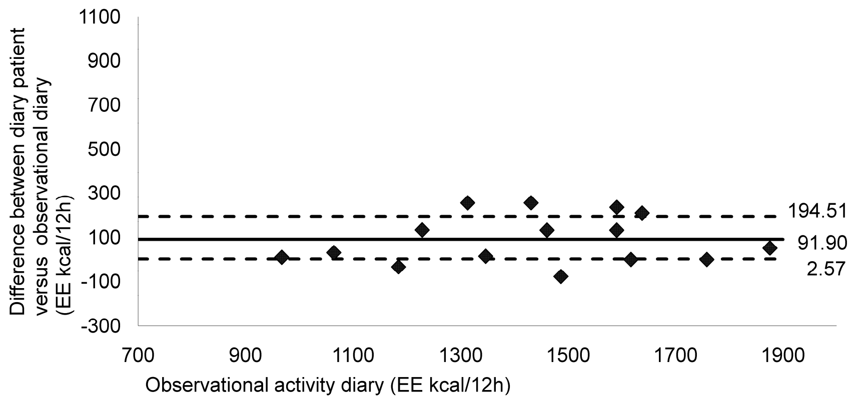

Figure 3: Comparing energy expenditure in 16 stroke patients: observational diary versus patient diary.
Legend: Energy expenditure (kcal/12h) of observer activity diary was compared with diary of stroke patients. Broken horizontal lines represent percentiles 25 and 75 value, bold solid lines represent the median value of difference. Data analysis showed good agreement between both diaries (Median=91.90; P25=2.57; P75=194.51). Most data are clustered around the zero point.

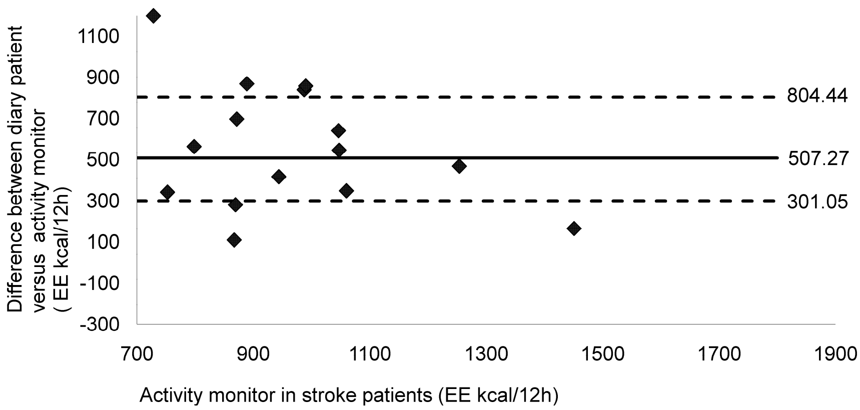

Figure 4: Comparing energy expenditure in 16 stroke patients: activity monitor versus patient diary.
Legend: Energy expenditure (kcal/12h) of observer activity diary was compared with diary of stroke patients. Broken horizontal lines represent percentiles 25 and 75 value, bold solid lines represent the median value of difference. The activity monitor is underestimating data for all patients in comparison to the diary filled in by the patient (Median=507.27; P25=301.05; P75=804.44).

A high correlation was found between the two diaries, when measuring *sedentary and moderate* physical activities during daytime hours, while a low correlation was found for light activities

One possible explanation is that activities in the levels of sedentary and moderate activities are more easily recalled than are light activities. Sedentary activities include activities in very low intensity (e.g., sleeping or sitting quietly), which are often longer in duration. Moderate activities are more intense (e.g., such as physical therapy or occupational therapy), and they are well reported in the daily schedules of rehabilitation centers. The lack of a good correlation between the two diaries with regard to *light* physical activities could be that these relatively brief activities (e.g. talking, grooming and reading) of limited duration which are often less planned and remembered than are activities of other levels. Another explanation might have to do with outliers. The scores entered by two patients differed excessively from those entered by the other patients and by the observers. When the Spearman correlation was recalculated excluding the data from these two patients, a moderate correlation for light activities was observed (r_s=0.63, $p<0.05$). The correlations for sedentary and moderate levels, however, remained slightly higher. Moderate activity is considered an important activity level in stroke rehabilitation, as it may be sufficient to produce a significant reduction in stroke risk.[2,39] With regard to total EE, comparison of the two diaries revealed a very high correlation. These results thus indicate that self-reported coded-activity diaries constitute a potentially valuable method for use in clinical settings, but that they should be explored further in relation to an objective "gold standard".

Comparisons of the patients' diaries to the SWP2A data revealed poor correlations. In general, the activity monitor reported lower values for 12-hour EE than did either diary. One explanation might be that the activity diary over-estimated the EE and the time in moderate activity as time intervals were long and only one activity was allowed to be reported every 30 minutes. This would suggest a need to shorten the time intervals in which activities are reported. The SWP2A has not been validated to measure EE against a "gold standard" method in stroke patients, who have inefficient gait patterns causing higher cost of energy for given activity. As such the SWP2A may have underestimated total EE and time in moderate PA. It would be advisable to develop patient-specific algorithms to accurately use the SWP2A in stroke patients.

This study is the first study to use a coded self-monitoring activity diary to assess PA in stroke patients. Because understanding the instructions of the diary requires a certain level of comprehension, patients with severe cognitive deficits were excluded. No inconvenience was reported. This study showed no missing data points, because all missing activities were collected by an interviewer through recollection, and the previously completed periods facilitated this. We estimate that less than 10% of the activities were missing in the diaries. Missing data often concerned periods during which patients performed sedentary and light physical activities (e.g., reading, resting, watching television) of long duration (<3 METs). Also evening activities were sometimes forgotten, which could be attributed to the fact that nursing care started at this time moment. In many cases, only one 30-minute period was completed. Patients started filling in the diaries when a new activity started. Considering the fact that the missing activities were filled in at the next day and the type of missing activities were easy to remember and low in percentage, we think that this diary is well applicable in stroke patients.

Completing the diary can be a tool for helping patients and family/caregivers reflect on the types of activity level, possibly leading to increases in the activity level. When evaluating the clinical relevance of the results of this study, it is important to note the lack of severe stroke patients in the research sample. Also in this study, no activities were categorized as vigorous by any of the three measurement tools. This is not surprising as aerobic exercises are seldom integrated as part of neuro-motor rehabilitation programs despite evidence supporting the importance.[3] Previous research strongly suggests that AT is necessary in stroke rehabilitation, however, and that it should be supplemented with strength-developing exercises for both lower limbs.[40-42]

Further research is required before the self-monitoring coded-activity diary can be implemented into clinical practice. Studies with objective criterion standards, (e.g., such as doubly labeled water or indirect calorimetry) and the development and examination of a digitized version are recommended. It might also be advisable to delete the fourth column of the diary, where the perceived intensity of an activity was marked on a rating scale of 6-20. This seemed difficult for patients to fill in. Also this could not be retrospectively added. Also it might be recommendable to shorten the time intervals in which activities are reported, to collect data for periods longer than one day, to ask patients about inconvenience filling in the diary, and provide an additional day to familiarize patients with the process of completing a diary.

CONCLUSION

Coded self-monitoring activity diaries appear feasible as a low-tech alternative to labor-intensive observational diaries for determining sedentary, moderate, and total PA and for quantifying EE in hospitalized stroke patients. Given the poor correlation with the objective measurement of PA, however, further research is needed to validate its use against a gold standard measure of PA intensity and EE (e.g., doubly labeled water or indirect calorimetry).

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SUPPLEMENTARY FILES

Supplement A: Activity diary.

Duration		Activity number	Position	How intense was the activity?
8h00	8h30		Lying, Sitting, Standing	6-7-8-9-10-11-12-13-14-15-16-17-18-19-20
8h30	9h00		Lying, Sitting, Standing	6-7-8-9-10-11-12-13-14-15-16-17-18-19-20
9h00	9h30		Lying, Sitting, Standing	6-7-8-9-10-11-12-13-14-15-16-17-18-19-20
9h30	10h00		Lying, Sitting, Standing	6-7-8-9-10-11-12-13-14-15-16-17-18-19-20
10h00	10h30		Lying, Sitting, Standing	6-7-8-9-10-11-12-13-14-15-16-17-18-19-20
10h30	11h00		Lying, Sitting, Standing	6-7-8-9-10-11-12-13-14-15-16-17-18-19-20
11h00	11h30		Lying, Sitting, Standing	6-7-8-9-10-11-12-13-14-15-16-17-18-19-20
11h30	12h00		Lying, Sitting, Standing	6-7-8-9-10-11-12-13-14-15-16-17-18-19-20
12h00	12h30		Lying, Sitting, Standing	6-7-8-9-10-11-12-13-14-15-16-17-18-19-20
12h30	13h00		Lying, Sitting, Standing	6-7-8-9-10-11-12-13-14-15-16-17-18-19-20
13h00	13h30		Lying, Sitting, Standing	6-7-8-9-10-11-12-13-14-15-16-17-18-19-20
13h30	14h00		Lying, Sitting, Standing	6-7-8-9-10-11-12-13-14-15-16-17-18-19-20
14h00	14h30		Lying, Sitting, Standing	6-7-8-9-10-11-12-13-14-15-16-17-18-19-20
14h30	15h00		Lying, Sitting, Standing	6-7-8-9-10-11-12-13-14-15-16-17-18-19-20
15h00	15h30		Lying, Sitting, Standing	6-7-8-9-10-11-12-13-14-15-16-17-18-19-20
15h30	16h00		Lying, Sitting, Standing	6-7-8-9-10-11-12-13-14-15-16-17-18-19-20
16h00	16h30		Lying, Sitting, Standing	6-7-8-9-10-11-12-13-14-15-16-17-18-19-20
16h30	17h00		Lying, Sitting, Standing	6-7-8-9-10-11-12-13-14-15-16-17-18-19-20
17h00	17h30		Lying, Sitting, Standing	6-7-8-9-10-11-12-13-14-15-16-17-18-19-20
17h30	18h00		Lying, Sitting, Standing	6-7-8-9-10-11-12-13-14-15-16-17-18-19-20
18h00	18h30		Lying, Sitting, Standing	6-7-8-9-10-11-12-13-14-15-16-17-18-19-20
18h30	19h00		Lying, Sitting, Standing	6-7-8-9-10-11-12-13-14-15-16-17-18-19-20
19h00	19h30		Lying, Sitting, Standing	6-7-8-9-10-11-12-13-14-15-16-17-18-19-20
19h30	20h00		Lying, Sitting, Standing	6-7-8-9-10-11-12-13-14-15-16-17-18-19-20

Supplement B: Scheme of codes that are used to fill in the activity diary.

Codes	Activities
Self-care	
1	Dressing/ undressing
2	Physical care (eg brushing teeth, shaving, washing at a sink, make-up, combing hair)
3	Bathing
4	Shower
5	Brushing hair
6	Toilet use
7	Eating
Household activities	
8	Making bed
9	Vacuuming
10	Cleaning
11	Food preparations, cooking
12	Covering table, clear table
13	Washing dishes or drying
14	Shopping
15	Putting away groceries
16	Doing laundry, folding or hanging clothes, putting clothes in washer or dryer, putting away clothes
17	Ironing
18	Watering plants
19	Getting wood
20	Walking in house
21	Playing with child(ren)
22	Playing with animals
23	Child care: dressing/bathing/ grooming/ feeding/ occasional lifting
Work and related activities	
24	Occupation
25	Volunteering
26	Regulating financial affairs
27	Repairing
28	Following a course
Therapy	
29	Physiotherapy in group
30	Individual physiotherapy
31	Occupational therapy in group
32	Individual occupational therapy
33	Speech therapy
34	Psychology
35	Nursing care
36	Doctor care
Leisure activities and home activities	
38	Playing music
39	Surfing on computer, Financial affairs on computer
40	Talking to persons directly or by phone
41	Playing board games, cards
42	Doing puzzles
43	Drawing
44	Writing
45	Performing handicraft (knitting,.........)
46	Watching television, listening to music
47	Sitting
48	Cinema and theater going, other trips
49	Sleeping
50	Mowing lawn
51	Weeding
52	Shoveling
53	Bicycling
54	Swimming
55	Conditioning exercises
56	Walking outside
57	Sexual activities
Mobility, transport related activities	
58	Driving a car
59	Travelling with someone / public transport
60	Walking short distances
61	Driving a wheelchair
62/63	Pushed in wheelchair/ Climbing stairs

Chapter 3

Physical activity in chronic home-living and sub-acute hospitalized stroke patients using objective and self-reported measures.

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ABSTRACT

Background Despite confirmed reduced PA after stroke in various stages of recovery, the type of activities stroke patients executed and the time spent at different activity levels have not been sufficiently verified with stroke-validated assessment tools.

Design Observational study

Objective To determine PA of subacute stroke patients hospitalized in a rehabilitation center (HOS) compared to chronic home-living stroke patients (HOM) using objective and self-reported measures during 2 weekdays and 1 weekend day.

Methods Fifteen HOS and 15 HOM patients wore a SWP2A (METs*minutes/ 24h) and a knee-worn pedometer YDWP (steps) and filled in a coded activity diary (kcal/ 24h; METs*minutes/ 24h) during three consecutive days.

Results In HOM significantly more steps ($steps_{total\ HOM}$= 18722.6 ±10063.6; $steps_{total\ HOS}$= 7097.8 ±5850.5) and higher energy expenditure levels ($EE_{total\ HOM}$= 7759.34 ±2243.04; $EE_{total\ HOS}$=5860.15 ±1412.78) were measured. In this group less moderate activity (≥3-6≤ METs) was performed on a weekday (p_{day1}=0.006; p_{day2}=0.027) and in total (p=0.037). Few therapy hours (physical, occupational and speech therapy and psychological support) were provided in HOM compared to HOS (p<0.001). Vigorous activities were only seen in HOM. In both groups few patients executed sport activities.

Conclusions In HOM significantly more steps were performed and higher energy expenditure values were measured. However, participation in moderate activities and time spent on therapy were less in HOM. Evaluating PA with quantitative measures is feasible in both chronic home-living and subacute hospitalized patients with stroke.

Keywords Stroke; Rehabilitation; Physical activity; Pedometer; Activity monitor; Activity diary.

INTRODUCTION

A lifestyle that includes regular PA reduces the risk of mortality and chronic disease.[1] For instance, an increase in activity of 1000 kcal/week or an increase in physical fitness of 1 Metabolic Equivalent (MET) was associated with a mortality reduction of 20%.[2] However, stroke patients experience difficulty to live a physically active lifestyle due to neuromusculoskeletal impairment, which results in muscle weakness, gait disturbance and cardiovascular deconditioning.[3,4] Previous research showed that PA immediately after stroke is reduced and remains below recommended health levels after six months[3] and after one year[4]. At least 150 minutes/week of moderate intensity PA spread over a minimum of 3 days/week are recommended after stroke.[5] Recent studies show that also sedentary behavior needs to be targeted and that sitting and moderate activities, e.g. walking, cycling, physical therapy, should be varied.[1]

It remains a challenge to measure daily PA in stroke patients as they often demonstrate disturbed walking patterns, slow gait speeds, cognitive deficits and influences of environmental factors such as little opportunity or incentive for PA.[3] There are several measuring devices available to monitor PA, evaluating energy expenditure or step counts, namely activity monitors and pedometers. A variety of accelerometers, placed at different positions on the body, has proved to be useful in monitoring PA of stroke patients at different phases of recovery.[6] These instruments do not rely on cognitive skills and are therefore useful for long periods in large patient groups.[6] Pedometers are a less expensive alternative to monitor PA objectively by means of step counts.[7] In particular, a pedometer attached at the anterolateral side of the non-hemiplegic knee has recently been recommended in stroke patients for measuring all but high-intensity walking activities .[8] Other methods for monitoring PA include observations[9], video recordings[9], self-reported questionnaires[10] and activity diaries[11]. Structured observations and video recordings offer detailed information about various dimensions of PA.[9] Both are applicable in hospitalized patients, but are time consuming and expensive. Questionnaires are useful in large sample groups.[10,12] However, they are based on retrospective information and therefore depend on cognitive skills. Finally, a coded self-monitoring activity diary was shown to be feasible in determining sedentary, moderate and total PA and in quantifying EE in stroke patients.[11]

Previous efforts have been made to determine the minimum number of days needed to obtain a reliable estimation of PA. Objective devices were found to require fewer days of monitoring to reliably record PA than subjective assessment tools.[13] In older individuals three to four days of monitoring was required to reliably assess PA, regardless of which instrument was used.[13]

Common to stroke research, different assessment tools are used for different stages of recovery. However, prerequisite to evaluating long-term PA behavior, the same tools should be used in each stage. In addition, limited information is found in the literature regarding the type of activities stroke patients execute and the time spent at different activity levels.

Therefore, the goal of this study was to determine PA in stroke patients at two different stages of recovery using the same assessment tools, hereby aiming to 1) examine the difference in PA during three consecutive days in home-living stroke patients and in subacute patients hospitalized in a rehabilitation center using a pedometer, an accelerometer and an activity diary and 2) evaluate the time both groups spent in different levels of PA based on self- report.

METHODS

Participants

During a period of three months 19 stroke patients hospitalized in an inpatient rehabilitation facility in the province of Limburg and 17 stroke patients treated in 11 private practices near the University Hospital of Antwerp in the province of Antwerp were screened. Inclusion criteria were (1) first-ever stroke as defined by the World Health Organization[14], (2) stroke more than one month and less than six months ago and being hospitalized in rehabilitation center or stroke more than six months ago and living at home, (3) able to move independently (with or without a walking-aid) and (4) understand and carry out simple instructions. Patients were excluded when not medically stable as described by the American College of Cardiology Foundation/ American Heart Association[15]. Two patients were excluded for not being medically stable and four for not being able to move independently. Therefore, a total of 30 stroke patients were included in this study: a subacute hospitalized group (HOS, n=15) and a chronic home-living group (HOM, n=15). They were verbally informed, received written information, and signed an informed consent form. The study was approved by the Medical Ethics Committee of the Antwerp University Hospital, Belgium (no. B30020084906).

Design

All demographic and clinical data, such as age, gender, time since onset and type of stroke, height, weight, use of walking aids, were collected out the medical file and by direct questioning. The degree of loss of gross motor function was assessed by the Rivermead Motor Assessment Gross function (RMA, GF)[16], in which 13 test items are ordered hierarchically. The items are scored dichotomously (0–1). Maximum score is 13, with a higher score reflecting better motor performance. Functional ambulation was determined by the Functional Ambulation Categories (FAC)[17], which distinguishes 6 levels of walking ability on the basis of the amount of physical support required. Concurrently, patients were instructed about the equipment, and an activity monitor and pedometer were placed on the patient’s arm and knee respectively. Patients were instructed to wear the activity monitor and pedometer during three consecutive days (Thursday - Saturday) and complete a daytime activity diary every half hour. At day five all material was recollected and missing data in patients’ diaries were completed based on recall by interviewing patients and care-givers.

Outcome measurements

Steps per day

The YDWP (Yamasa Tokei Keiki co LTD, Japan) is a uni-axial spring-levered pedometer and measures the number of steps. The pedometer was placed on the anterolateral side of the non-hemiplegic knee attached to a patella support strap (S300 Aptonia knee strap). Patients were instructed to wear the pedometer during day-hours.

Every evening the pedometer was removed and the numbers of steps noted. The following day, as soon patients started walking, they were advised to wear the pedometer. A knee-worn YDWP is proven to be a valid device to measure steps in stroke patients except during high intensity walking.[8]

Energy expenditure and PA level

The SWP2A (Health Wear BodyMedia, Pittsburgh, PA, USA) was worn on the non-hemiplegic upper arm positioned on the triceps muscle halfway between acromion and olecranon. Patients were asked to wear the SWP2A 24 hours/day. The SWP2A is a multi-sensor activity monitor and is programmed with a computer interface taking into account the participants' age, gender, height, weight, smoking habit and handedness prior to testing. Using a proprietary algorithm (Bodymedia, SenseWear 6.1) the data is used to compute the number of steps and the energy expenditure (EE). Data are stored per minute. The estimation of energy expenditure has been validated in 12 chronic stroke patients compared to a portable metabolic cart (ICC unaffected arm = 0.702).[18] Also during sedentary and light activity office behaviors the SWA strongly correlated with indirect calorimetry.[19]

A standardized coded activity diary previously developed to measure total energy expenditure and PA level in hospitalized stroke patients was used.[11] The diary consisted of bundled sheets of paper, each containing a table with four columns: 1) time, 2) activity 3) position and 4) intensity of the activity. Patients were asked to write down one code number reflecting the main activity carried out in the past 30 minutes. The main activity was defined as the activity that had taken the most time within the 30-minute period. The number was chosen out of a list of 63 codes divided into six categories of activities: self-care, household tasks, work, therapy, leisure and home activities, and activities related to mobility and transport. Additional numbers could be added, when an activity was not found in the list. For each 30 minute period the patient had to start a new row. To avoid mistakes in recall patients were instructed to fill in the diary at the end of the 30 min period. Using the Compendium of Physical Activities Tracking Guide and taking into account position and intensity, activities were converted to Metabolic Equivalent (MET) values.[20] METs values were multiplied by 30 minutes (METs*minutes). Total METs values were subdivided in four activity levels: sedentary (≤1 METs), light (>1-<3 METs), moderate (≥3-6≤ METs) and vigorous activity (>6 METs). Finally these levels were summed per group over 24 hours. In order to obtain energy expenditure in kcal/30 minutes, METs*minutes were recalculated by the following formula: [(METs value X 3.5 X patient's weight)/200] X 30 minutes.[21] These results were multiplied by 48 to calculate energy expenditure over 24 hours (kcal/24h). Such a coded activity diary has been found to be valid in determining total METs*minutes (r_s=0.75, p<0.01) for sedentary level (r_s=0.74, p<0.01) and moderate activity level (r_s=0.71, p<0.01) and to have a very high correlation (r_s=0.92, p<0.01) with total EE in stroke patients.[11]

Statistical Analysis

All statistical analyses were performed using SPSS version 22.0 (SPSS Inc., Chicago, USA) and R version 3.0.1 (R Core Team 2013). Normality was verified with the Kolmogorov-Smirnoff test. Descriptive statistics were calculated for patient characteristics. To assess differences in patient characteristics between HOS versus HOM, numerical data were analyzed using the independent samples t-test (age, weight, height, Body mass index and time since stroke) and ordinal data were compared with Mann-Whitney U test (Rivermead Motor Assessment, Functional Ambulation Categories). Other data concerning patient characteristics were analyzed using Chi-square test and if numbers were too small Fisher's exact test was used.

Two-way Repeated Measures Anova was used to determine differences between both groups in amount of PA in 3 days in normally distributed data (number of steps and energy expenditure by pedometer and activity monitor). In non-normally distributed data (type of activities and activity levels by diary), the equivalent non-parametric Mann-Whitney U test was used. When significant differences between groups were found, a post hoc analysis was used to determine on which day the difference was found (unpaired t-test in normally distributed data; Mann-Whitney U test in non-normally distributed data). Bonferroni correction was used to adjust for multiple testing. Box plots were used to visualize the differences between both groups. Significance level was set at $p<0.05$.

RESULTS

Participants

In HOS all patients had physical therapy on both weekdays (total hours day 1= 40.5, total hours day 2 =39.5) and no therapy was provided on weekend days. In HOM, only a few hours of physical therapy were provided during the weekdays (total hours day 1= 5, total hours day 2= 4.5 hours) and therapy was similarly lacking on weekend days.

Table 1: Demographic and Clinical Characteristics of stroke patients.

Characteristics	Hospitalized group n=15	Home-living group n=15	p-value for group differences
Age mean (y), SD	69.7, SD 9.7	62.5 SD 10.4	0.777
Gender female, n (%)	6 (40)	5 (33.3)	0.705
Height mean (m), SD	1.63, SD 0.08	1.70, SD 0.09	0.391
Weight mean (kg), SD	68.8, SD 12.2	81.9, SD 9.5	0.135
BMI mean (kg/m²), SD	25.9, SD 4.9	28.3, SD 3.3	0.490
Time since stroke mean (days), SD	69.1, SD 40.5	2680.4, SD 1878.3	p<0.001*
Stroke type			0.407
Ischemic, n (%)	9 (60)	6 (40)	
Haemorrhagic, n (%)	6 (40)	7 (46.7)	
Both, n (%)	/	2 (13.3)	
Lesion side			0.700
Left, n (%)	9 (60)	9 (60)	
Right, n (%)	4 (26.7)	6 (40)	
Bilateral, n (%)	2 (13.3)	/	
Stroke disability			
RMA-GF, median (P25-P75)	7 (5-11)	11 (10-11)	0.001*
FAC, median (P25-P75)	3 (2-5)	4 (4-5)	0.033*
Mobility			0.700
No use of walking aids in ADL, n (%)	4 (26.7)	6 (40)	

SD= standard deviation, BMI= Body Mass Index, RMA-GF= Rivermead Motor Assessment-Gross Function, P25-P75= Percentile 25 and 75, FAC= Functional Ambulation Categories, ADL= Activity of daily living, *= p< 0.05.

Significant differences between both groups were found in time since stroke (p<0.001), degree of loss of function (RMA-GF, p=0.001) and walking ability (FAC, p=0.033). Patients in HOM had a longer time between onset of stroke and inclusion and showed better gross function and walking ability. The demographic and clinical characteristics of included stroke patients are presented in Table 1.

Difference in amount of PA

Table 2A presents cumulated PA in the two patient groups during three consecutive days. Significant differences in PA were found between the patient groups with the pedometer (number of steps; p=0.001) and the coded activity diary (kcal/24h; p<0.001). Mean steps/day varied from 1514.3 to 3010.7 in HOS and 5691.4 to 6716.7 in HOM.

Patients in HOM performed significantly more steps than patients in HOS on Thursday (p=0.002), Friday (p=0.025) and Saturday (p<0.001). HOM patients also showed significant higher EE levels (Kcal/24h) during these three days (p=0.009; p=0.002; p<0.001, respectively) (Figure 1).

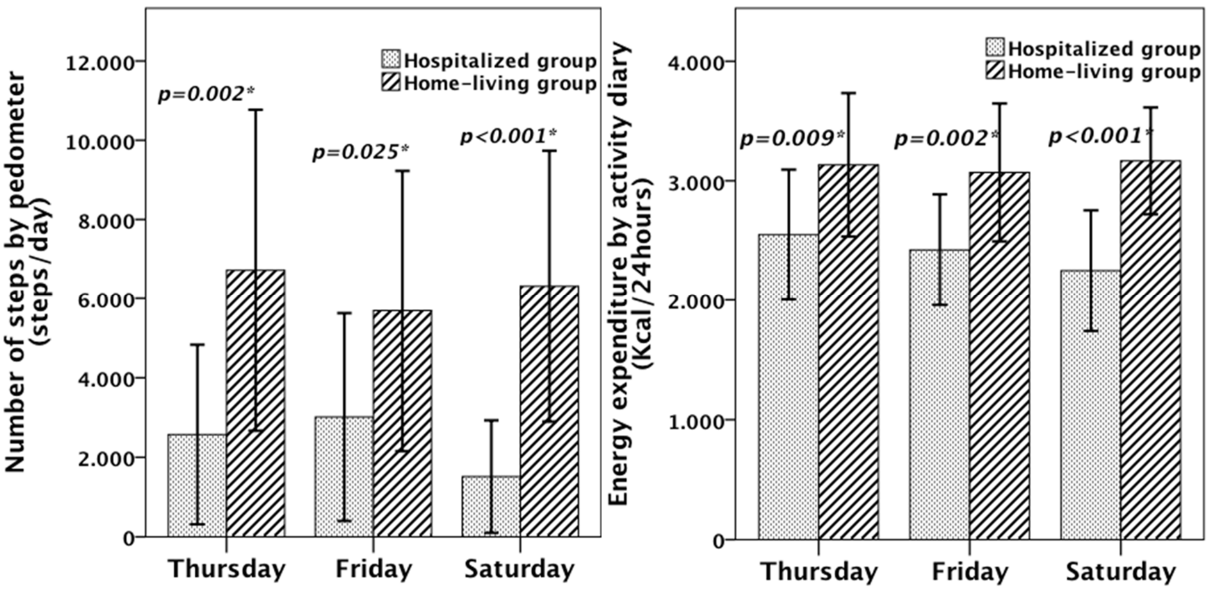

Figure 1: Post-hoc analysis with unpaired t-test by means and standard deviations to visualize significant differences in number of steps and energy expenditure between two groups of stroke patients.

Time spent on different activity levels

Four activity levels were extracted each day from the activity diary in both patient groups (Table 2B). The time spent on the moderate activity level (≥3-6≤METs) was significantly different between both groups during the three days (p=0.037). The hospitalized patients showed to be relatively more moderately active on a weekday compared to HOM ($p_{Thursday}$=0.006; p_{Friday}=0.027) (Figure 2), while on the Saturday, the differences were not significant. Sedentary behavior was mostly observed without significant differences between groups. Patients in HOM spent more time in light level activities without significant differences between groups. Vigorous activity was performed by maximum 7 patients in HOM (Median=0). Patients in HOS showed no vigorous activity.

Table 2: Difference in physical activity measured by a pedometer, activity monitor, activity diary in two groups of stroke patients.

A	Hospitalized group (n=15)				Home-living group (n=15)				
Variable	Thursday	Friday	Saturday	Total	Thursday	Friday	Saturday	Total	Repeated measures ANOVA p-value between subjects Thursday, Friday, Saturday
Pedometer (Yamax Digiwalker SW-200), mean SD									
Number of steps	2572.9	3010.7	1514.3	7097.8	6716.7	5691.4	6314.5	18722.6	0.001*
	SD 225.8	SD 2613.5	SD 1414.3	SD 5850.5	SD 4051.3	SD 3536.6	SD 3419.8	SD 10063.6	
Activity monitor (SenseWear Pro2), mean SD									
EE, kcal/24h	1815.10	3922.26	1727.40	7261.00	2100.84	4376.72	2260.00	9368.50	0.224
	SD 296.16	SD 650.46	SD 214.93	SD 1410.71	SD 376.40	SD 1069.17	SD 290.91	SD 1409.30	
Coded Activity diary, mean SD									
EE, kcal/24h	2548.22	2421.09	2246.68	5860.15	3132.88	3069.54	3166.08	7759.34	<0.001*
	SD 544.30	SD 464.40	SD 506.04	SD 1412.78	SD 600.05	SD 576.95	SD 447.04	SD 2243.04	
Total METs*min	2135.80	2033.40	1889.60	3651.30	2184.40	2183.20	2249.80	4014.90	0.051
	SD 219.86	SD 164.18	SD 294.77	SD 1040.94	SD 312.51	SD 438.25	SD 320.60	SD 977.01	
B									Mann Whitney U test p-value Total versus Total
Coded Activity diary, METs*minutes, median (P25-P75)									
Sedentary	840	930	990	2820	900	870	930	2670	0.461
	(810-1020)	(840-990)	(810-1110)	(2550-3090)	(810 -1050)	(780-990)	(750-1050)	(2340-3000)	
Light	510	570	735	1971	765	735	738	2298	0.161
	(405-669)	(438-741)	(465-864)	(1335-2181)	(504-960)	(477-1008)	(477-1011)	(1653-2718)	
Moderate	630	480	105	1434	285	285	210	690	0.037*
	(420-810)	(390-705)	(0-279)	(825-1605)	(0-585)	(105-420)	(0-510)	(315-1494)	
Vigorous	0	0	0	0	0	0	0	0	0.050
	(0-0)	(0-0)	(0-0)	(0-0)	(0-480)	(0-240)	(0-480)	(0-1440)	

A= normally distributed data, B= not normally distributed data, SD= standard deviation, EE= Energy expenditure, P25-P75= Percentile 25 and 75, *= p< 0.05.

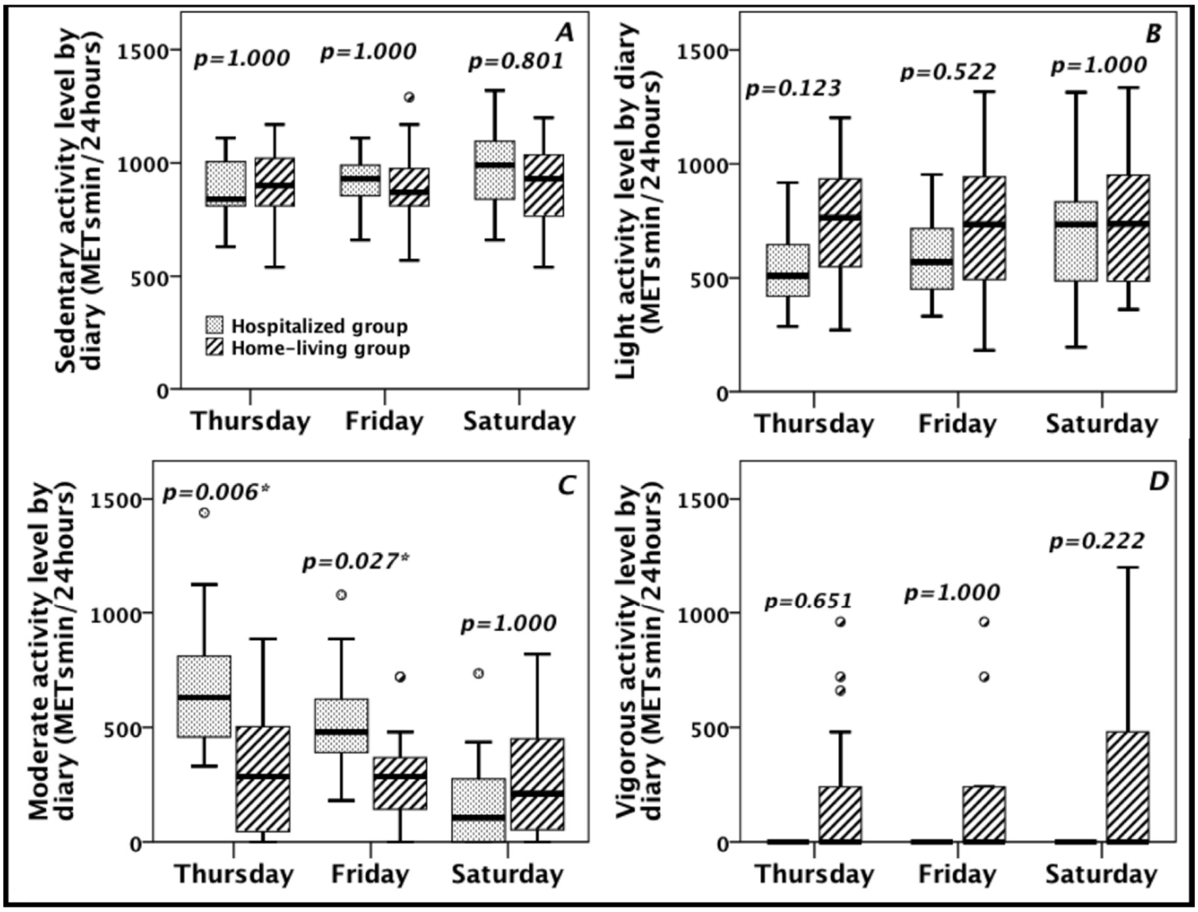

Figure 2: Time spent on four activity levels in two groups of stroke patients during three consecutive days by Medians and Interquartile ranges: A= sedentary activity level (≤1 METs), B= light activity level (>1-<3 METs), C= moderate activity level (≥3-6≤ METs), D= vigorous activity level (>6 METs).

DISCUSSION

This study examined the time spent during different activity levels and categories of PA in subacute hospitalized and chronic home-living stroke patients using objective and self-reported measures. Similar to other study results, this study showed that both groups of patients have a reduced PA with a lot of time spent carrying out sedentary activities. Patients in HOM walked significantly more steps and expended more energy during the three consecutive measurement days. The higher quantity of vigorous intensity activities was accompanied by a relatively lower amount of moderate intensity activity in the HOM compared to the HOS.

Consistent with recent research[22,23], this study demonstrated that PA is reduced after stroke with a significant difference between subacute hospitalized patients and patients in chronic phase. In HOS 13 (87%) patients on weekdays and 15 (93%) patients on a weekend day showed a walking activity that was well below the minimal level of PA recommended for adults with disabilities and chronic illness (5500 steps/day)[24], and was too little to expect health benefits. In HOM a range of 5 to 8 out of 15 patients (33% to 54%) achieved less than 5500 steps/day. In both groups no (HOS) to few (HOM, n≤3) patients performed more than 10,000 steps/day[25], recommended to improve health and wellbeing. One explanation as to why PA is generally reduced after stroke is that activity in many patients may be limited by neuromusculoskeletal impairment.[26] Another explanation might be that stroke patients have little awareness of the risk of an inactive lifestyle. A pre stroke life without sports or other formal modes of exercises may result in little motivation to increase PA after stroke.[27]

A finding of this study was that moderate activity level was significantly higher in HOS vs HOM during weekdays. A possible explanation is that in the rehabilitation center therapeutic exercises were more common than in the home environment. Further analysis of this study showed that time spent on moderate activity in both patient groups was higher in comparison to other study results one[4] to three[23] years post stroke. In the study of Baert et al. only 4% of included patients showed moderately intensive activities.[4] Possibly less severe stroke patients were included in our study in comparison to the study of Baert et al.[4] In the study of Kunkel et al. PA increased until one year post stroke, but improvements slowed down after two and three years post stroke.[23] In our study chronic stroke patients were included from six months to many years post stroke. Furthermore, in the current study, therapeutic exercises and sport activities were categorized as moderately active by the code system of the activity diary. Also, only one activity could be filled in every 30 minutes. Consequently an overestimation might have occurred when the diary was analyzed.

This study also showed that the HOS group received more intense therapy and had more impairments based on the RMA and FAC results than HOM. It could be expected that more stepping activities were performed in HOS. However, our results showed fewer steps performed in HOS patients during three days. We did not investigate what type of activities were performed in therapy sessions. An explanation might be that therapy sessions often included non-locomotor activities. In agreement with this, a systematic review reported that stroke patients were engaged in PA for less than two thirds of a total physiotherapy session duration.[28] This implicates that physical therapy goals should be altered to help promote a more active live-style.[28,29]

Aside from the intensity levels of PA, time spent in sedentary behavior should also be a point of focus after stroke. In line with other studies[30,31] sitting, lying or sleeping was frequently noticed during 24 hours (in HOS > 14.5 hours (60%) and in HOM >12 hours (50%)). These activities tended to occur less than in a study evaluating subjects one-year post stroke (81%).[4] An explanation might be that stroke severity was possibly different between studies. Furthermore, our research data was based on a self-reported coded diary whereas the study of Baert et al. used heart rate monitors.[4] It has been stated that caution is needed when self-reported measures are involved.[32,33] However, the activity diary used in the current study, proved to be valid in previous research to register sedentary behavior (r_s=0.74, p<0.01) and total EE (r_s = 0.92, p<0.01).[11] In the current study, when the diary was used to calculate total EE, significant differences were found between groups although no differences in total EE were found when analysing the SWP2A data. Recently published findings report under or overestimation of the SWP2A, possibly due to the lack of patient-specific algorithms.[8]

A major clinical implication of this study is that in subacute hospitalized as well as in chronic home-living stroke patients the amount of activities needs to be enlarged. Also in both phases of recovery the intensity of activities should be increased, whereas long-periods of sedentary behavior need to be reduced. As patients in HOM were less moderately active and only little vigorous activity was noted, patients in subacute phase should be briefed about the importance to continue moderate and vigorous activities in next phase of recovery. Therapists in early phase should explain the importance of an active lifestyle and promote sport and adapted activities to improve PA and consequently health in the chronic phase of recovery.[34] The role of the family in the chronic phase becomes crucial as the stroke patient might not be motivated or not capable of independent mobility and transport to a sport activity.

Study limitations

This study warrants some critical reflections. First, there were differences in the baseline level of impairment (RMA, FAC and use of walking aids) between the HOS and HOM populations. Also differences in time since stroke between groups might have contributed towards the findings of differences in the number of steps and activities. Due to the limited sample size, these differences were not accounted for in the analyses. An alternative study design would have been to carry out longitudinal follow-up of the HOS group. However, such a study is methodologically very challenging. Second, data was collected over a period of 3 days in comparison to 4-7 days in other studies.[13,35] Third, results of activity diary should be interpreted with caution, as this is based on self-report. Fourth, no severe stroke patients were included as inclusion criteria required that patients could move independently (with or without a walking-aid). Finally, participants were not questioned about their experience of wearing the devices or filling in the dairy. Despite the mentioned limitations, this study provided a step forward to determining PA and sedentary behavior in two phases of stroke recovery.

CONCLUSION

In chronic home-living stroke patients more steps were performed and higher energy expenditure values were measured than in subacute hospitalized stroke patients. However, participation in moderate activities was reduced and only a few therapy hours were provided in home-living patients. Monitoring PA with quantitative measures is feasible in both chronic home-living and subacute hospitalized patients with stroke.

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Part B

The effectiveness of an aerobic training program in stroke patients.

Chapter 4
Effectiveness of Active Cycling in Subacute Stroke Rehabilitation: A Randomized Controlled Trial.

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ABSTRACT

Objective To examine the effects of 3-month AT followed by coaching on A-Cap, strength and gait speed after subacute stroke.

Design Randomized controlled trial

Setting Inpatient rehabilitation center

Participants Patients (N=59; mean age= 65.4±10.3; 21 women (36%); Barthel Index≤50= 64%) with first stroke and able to cycle at 50 revolutions/minute enrolled in the study 3-10 weeks after stroke onset.

Interventions Patients were randomly allocated to a 3-month cycling group (ACG, n=33) and education or to a control group (CG, n=26). Afterward, patients in the ACG were randomly assigned to a coaching (n=15) or to a noncoaching group (n=16) for 9 months.

Main Outcome Measures Aerobic capacity, isometric knee extension strength and gait ability and speed were measured before and after intervention and during follow-up at 6 and 12 months.

Results A nonsignificant difference was found in workload ($Watt_{peak}$) ($p= 0.078$) between ACG and CG after 3 months. Furthermore after 3 months of cycling and after nine months of coaching, all groups showed significant changes over time ($p\leq0.027$) in peak oxygen consumption (VO_{2peak}), $Watt_{peak}$, leg strength and gait speed. Also, significant changes over time ($p<0.001$) were found in the ACG and the CG in patients with walking inability at baseline.

Conclusion No significant differences between training groups were found over time. Although our study did not have objective exercise data from the training device during follow-up, the 3-month active cycling (AC) program combined with education sessions seemed an applicable method in subacute stroke rehabilitation. New long-term AT interventions should focus on coaching approaches to facilitate training after a supervised AC program.

Key-words Cerebrovascular disorders, Clinical trial, Education, Exercise, Mentoring, Rehabilitation.

INTRODUCTION

Stroke patients often show impaired A-Cap indicated by VO_{2peak}.[1] Previous studies reported a reduced VO_{2peak} to 10-17mLkg^{-1}min^{-1}.[2-4] Since light ADL require 10.5 mLkg^{-1}min^{-1} and more strenuous demand 17.5 mLkg^{-1}min^{-1} in healthy persons, it seems that basic ADL in stroke are also impaired by limited VO_{2peak}.[5] It is expected that even higher energy requirements in ADL may occur because of biomechanical inefficiency.[5]

A meta-analysis[6] revealed that AT improved A-Cap by an average of 2.27 mLkg^{-1}min^{-1}. Often cycling was executed to increase A-Cap by continuous or interval training with a heart rate (HR) of 50-80% of maximum.[7] Active cycling (AC) allows a continuous repetition of movements, without the challenge of balance control, and therefore is practical in the acute phase.[8] Besides increased A-Cap, other benefits were gait endurance, gait speed, and quality of life.[9,10] However, no study investigated the effect of AT on strength. Still, AC allows reversing muscular weakness, because the less affected leg helps the affected one through coupling of the pedals.[8]

Up until now, limited data were found on AT in early and severely impaired patients. Further, no coaching studies were set up to improve physical activity after stopping the program. Resnick et al. studied motivators such as objective and verbal encouragement, social support, and psychological benefit.[11] These motivators may enhance participation in exercise and promote carryover and integration of exercise into ADL.[11]

This study aimed to determine the effects of AC followed by a 9-month coaching approach on (1) A-Cap, (2) strength, (3) gait ability and speed in subacute stroke patients. In addition, we wanted to investigate whether patients with walking inability at baseline obtain more benefit from AT.

METHODS

Participants

Patients were recruited from an inpatient rehabilitation center in Herk-de-Stad, Belgium. Potential participants were at the beginning of the study hospitalised in the center and were screened based on the following inclusion criteria: (1) first-ever stroke[12]; (2) age ≤ 80 years; (3) between 3 and 10 weeks after stroke onset; (4) able to carry out simple instructions; and (5) able to pedal a MOTOmed viva2 leg trainer[a] (at 50 revolutions/minute). Exclusion criteria were: (1) neurological disorders with impaired functionality existing prestrike; (2) prestroke Barthel Index[13] <50; and (3) absolute contraindications for exercise testing[14]. Written informed consent was obtained from the enrolled participants. All underwent a complete physical and cardiologic examination.

Study design

In a single-blind, randomized, controlled intervention patients were randomly assigned to an active cycling group (ACG) or a control group (CG) for 3 months of training in the center or at home if discharged (Supplementary Figure A). Patients were stratified after baseline according to the type of stroke, motor impairment severity, and A-Cap. They were assigned to the following 3 strata: (1) type; (2) the Rivermead Motor Assessment gross function scale (RMA-GF)[15] (group1, 0-3; group2, 4-6; group3, 7-13); and (3) decreased A-Cap, defined as VO_{2peak} <70% of age-predicted VO_{2peak} ($mLkg^{-1}min^{-1}$) (men: 60-[age X .55]; female: 48-[age X .37])[16] or increased A-Cap, defined as VO_{2peak} ≥70% of age-predicted VO_{2peak}. A permuted block design of 4 was used, created by a computer random-number generator, with an allocation ratio of 2:2. After the 3-month program, in the ACG, a second group allocation was performed based on the initial stratified randomization procedure. Concealed allocations were achieved by contacting the holder of the allocation schedule who was "offsite".

The assessor was blinded to the group assignment. Patients were aware of different programs but instructed not to inform the assessor. The protocol was approved by the Medical Ethics Committee, Antwerp University Hospital, Belgium (B30020107752).

Outcome assessments

Patients underwent a baseline assessment and re-assessments after 3, 6 and 12 months in the center.

Exercise test

The HR_{rest} was determined during a rest electrocardiogram. A maximal graded exercise test was performed on a recumbent ergometer[b] adjusted with foot shells and leg guides. The exercise test started with a 3-minute rest. Exercise began at 20Watt with 50 revolutions/min, and the workload was increased by 10 Watt/min until maximal effort or one of the predefined endpoints were reached [17]. A portable gas-analysis system[c] and an ECG-device[d] measured oxygen consumption ($mLmin^{-1}$), carbon dioxide production ($mLmin^{-1}$) and HR. The VO_{2peak} ($mLkg^{-1}min^{-1}$), HR_{peak}, and respiratory exchange ratio (RER) were calculated as the mean value during the final 20 seconds of the last completed increment in workload ($Watt_{peak}$) during the exercise test, from where a 3-minute recovery started. A Borg's ratings of perceived exertion[18] scale was used to determine perceived fatigue.

Also, the oxygen uptake efficiency slope (OUES) was calculated, which reflects the relationship between VO_2 ($mLmin^{-1}$) and total ventilation ($Lmin^{-1}$).[19] The VO_2 and total ventilation during the final 20 seconds of the last fulfilled workload were used.

Strength

Participants sat on a quadriceps pendulum bank, which is a training bench to exercise quadriceps strength or mobility of the knee joint. A mold was used to attach a reliable handheld dynamometer[20,e] on a quadriceps pendulum Bank to measure isometric knee extension strength of both legs in Newtons (N). The sensors were placed 4cm proximal and anterior to the lateral malleoli. Participants were asked a maximal isometric knee extension for 5 seconds and repeat 3 times at intervals of ≥30 seconds.

Gait ability

The Functional Ambulation Categories[21] (FACs) Scale, a 6-point scale[22], was used to evaluate the human support required when walking, regardless of whether patients used an assistive device.

Gait speed

Patients were tested with the 10-m walk[23], performed 3 times by patients walking at their usual pace and at their fastest, safe pace without running. Patients were allowed to rest in between tests and to use walking aids. Three trials were averaged to determine both gait velocities.[23]

Interventions

Phase I

The ACG and CG underwent an additional 3 months of training in addition to their individually designed multidisciplinary therapy programs.

In the ACG, patients performed an additional 3-month cycling program, seated on a (wheel)chair in front of a stationary bike that enables passive, motor-assisted or active resistive training on a MOTOmed leg trainer (Supplementary Table B). Training sessions consisted of 30 minutes of AC, progressing from interval (weeks 1-8) to continuous (weeks 9-12) training, with 3 sessions per week. Heart rate (HR) training zones were calculated ($[HR_{peak} – HR_{rest}]X[60\text{-}75\%] + HR_{rest}$)[24]. A Polar pulse watch and chest strap[f] monitored HR. Patients cycled once during 10 minutes, raising their HR into the proposed training zone to determine resistance (0-20 grade). Then $Watt_{peak}$ and training schedule were uploaded weekly on a MOTOmed chip card.[a] During training, patients were asked to reach a steady cadence (50 revolutions/minute) or when not possible, to cycle at a freely chosen frequency so the proposed HR training zone was maintained. Each session started and ended with 5 minutes of passive movement of both legs at 25 revolutions/min. Ratings of perceived exertion[18] were obtained at the end of each session.

During the 3 months, four 1-hour educational sessions were given to patients and relatives or friends to facilitate training after discharge. Within the first session, definitions, symptoms, and risk factors were discussed. In the following 2 sessions, the importance of an active lifestyle and how to improve A-Cap and physical activity during and after the 3 months of training were explained. In the last session, all the information was summarized, with an emphasis on goal-setting and problem-solving. Finally, an individual movement contract was set-up between the researcher and each patient, consisting of a written document with the patient's decision about how to continue the training.

In the CG, an additional passive mobilization[g] therapy was given for the paretic hip and knee with the patient supine, consisting of three 30-minute sessions per week during the 3 months.

Phase II

After 3 months of training, patients in the ACG were randomly assigned to receive coaching (Co-ACG) or not to receive coaching (Nco-ACG). The researcher monthly (9 times) visited the Co-ACG patients, and during the visits the movement contract and problems were discussed. They were allowed to choose the training modality (e.g. bike) to increase their A-Cap, and were asked to write down their training schedule (duration, intensity). This approach was based on the transtheoretical model of behavior change.[25] The Nco-ACG and CG patients were offered no additional therapy.

Statistical Methods

The sample size calculation was based on $Watt_{peak}$, using a 2-tailed samples t test with α=.05. We needed a minimum of 21 participants per group to have an 80% power to detect a clinically significant difference between ACG and CG of a mean ±SD of 12.20±13.70Watt.[26]

All statistical analyses were performed using SAS 9.4[h] and R 3.0.1[i] using a significance level of .05 (2-tailed). Normality was verified. To assess differences in patient characteristics between the ACG and CG different test were used depending on the type and distribution of data.

To determine differences between the training groups in phase I and over 4 time points (phase I-II) for continuous outcomes, linear mixed-effects models were used with fixed factors time and group, time-by-group interaction and a subject-specific intercept. Group-specific training effects and time effects were compared between the groups by post hoc testing. To correct for multiple testing, the Bonferroni-Holm correction was used. Similarly, a logistic-mixed effects model was used for the binary outcome variables ($FACs_{total}$=5; Borg>14). The severity of motor deficit (RMA-GF≤ 6) was also incorporated in the model as a fixed effect and interactions with time, treatment, and time by treatment were investigated.

Finally, the linear mixed-effects model was used in a subgroup of patients who could not walk 10m at baseline.

RESULTS

Participants

Between 2010 and 2013, 148 patients were screened. Of these, 80 did not meet the inclusion criteria (Figure 1). Of the remaining 68 patients, 59 entered the study. Fifty-six patients completed phase I and 53 finished phase II. Only 6 patients withdrew from the study over 1 year (Figure 1). Patient characteristics showed no significant group differences before treatment (Table 1).

During the course of the study, the following events were recorded: a new stroke (CG=1), implanted pacemakers (Nco-ACG=2), epileptic seizures (Nco-ACG=2), fall incidents (Nco-ACG=1, CG=1), respiratory problems (Co-ACG=1, CG=1), and musculoskeletal surgeries (Co-ACG=2, Nco-ACG=1, CG=2). Missing data per outcome parameter are described in a Supplementary Table C.

Treatment Effects

In phase I, no group-by-time interactions were found in exercise test parameters (VO_{2peak}, OUES, HR_{peak}, RER, Borg-outcomes) (Table 2, Supplementary Tables C-D-E). Furthermore, significant changes within time were found for VO_{2peak} and $Watt_{peak}$ (p<.001); in particular in the ACG (3mo to baseline; p<.001,) higher values were measured. In phase II, also no group-by-time interactions were detected between both groups for exercise parameters. Significant time changes were found for VO_{2peak} (p<.001), in particular in the AC groups (6mo vs baseline; p<0.01) and the CG (6mo vs baseline; p<.05), and in the AC groups (12mo vs baseline;

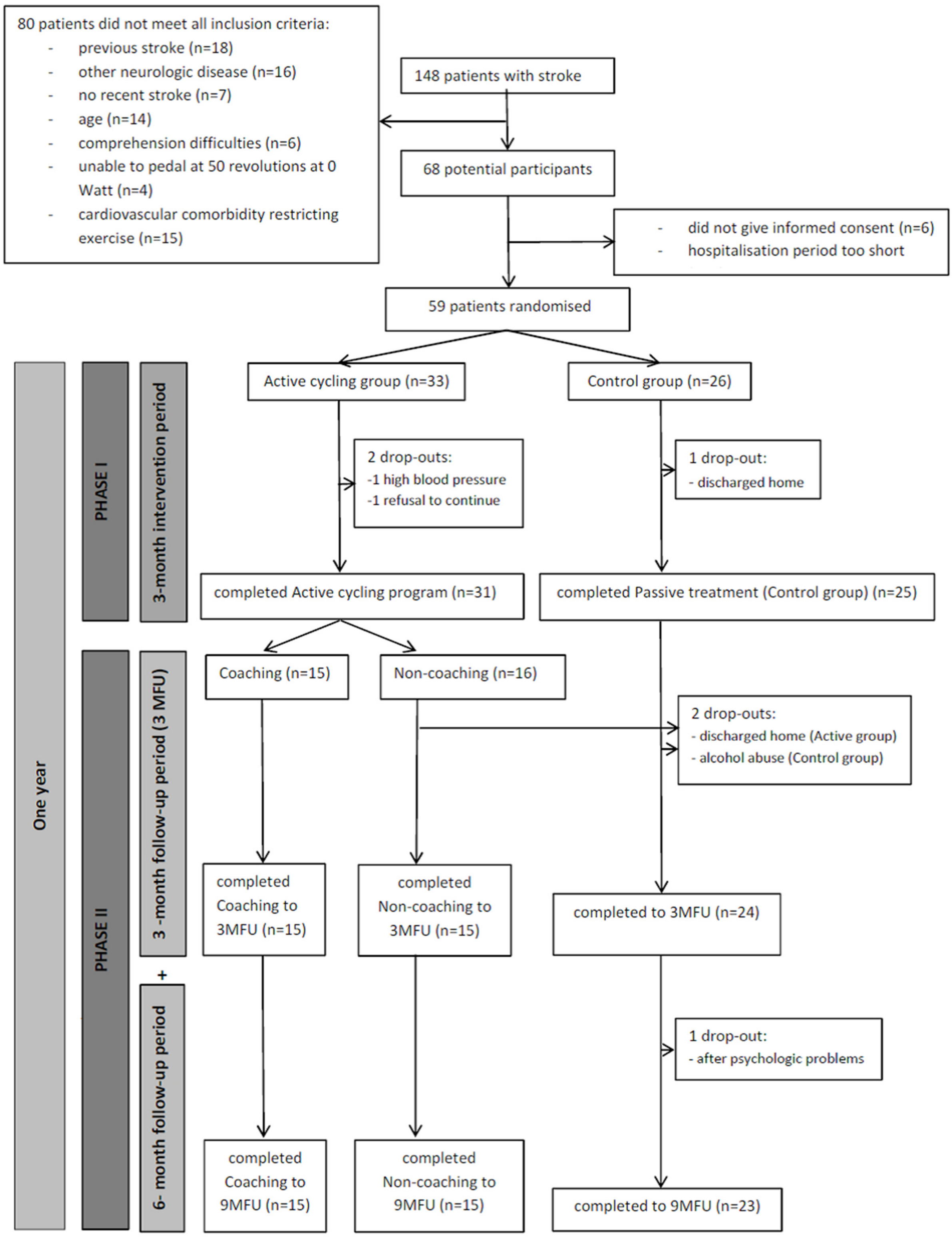

Figure 1: Flow diagram of study participants through each stage of the trial.

p<0.05). Also $Watt_{peak}$ showed significant time changes (p<.001), in particular between baseline and 6 months in the AC groups (p<.001) and the CG (p<.01) and between baseline and 12 months in the AC groups (p<.001) and in the CG (p<.05). Furthermore, no deterioration in mean VO_{2peak} values was seen in Co-ACG between 6 and 12 months when compared to other groups. Patient characteristics showed no significant group differences before treatment (Table 1).

Table 2 (see supplementary Tables C-D-E) shows no group-by-time interaction in strength, gait ability and speed in both phases. However, significant changes over time were found for all assessments, except for FAC scores in phase I (p= .081). Between 3 months and baseline, significant changes were found in the ACG (p<.001) and CG (p<.01) for paretic leg strength and for comfortable (p<.001) and maximal gait speed (ACG p<.01; CG p<.001). Between 6 months and baseline significant time changes were found for all assessments in all groups (p<.05), except for less affected leg strength and FAC scores in the ACG groups. Between 12 months and baseline, significant differences were found for all assessments (p<.05), except for the less affected leg strength in all groups and for FAC scores in the Nco-ACG. Additional significant time changes were detected for the paretic leg in Nco-ACG (12mo vs 3mo; p<.05).

Table 1: Patient characteristics at study onset.

Characteristics	ACG (n=33)	CG (n=26)	P for Group differences
Age, mean (y) ±SD	66.7 ±8.8	63.8 ±11.8	0.29[a]
Sex men, n (%)	20 (60.6)	18 (69.2)	0.49[c]
Height, mean (m) ±SD	1.7 ±0.1	1.7 ± 0.1	0.77[a]
Weight, mean (kg) ±SD	73.9 ±13.5	75.7 ±18.5	0.68[a]
Body Mass Index, mean (kg/m²) ±SD	25.8 ±4.0	26.6 ±6.3	0.53[a]
Stroke until hospitalization in rehabilitation center, median (days) (P25-P75)	21 (17-26)	18 (14-23)	0.09[b]
Stroke until intake in study, mean (days) ±SD	50.5 ±19.8	48.5 ±19.2	0.70[a]
Stroke type			0.83[d]
Ischemic, n (%)	29 (87.9)	22 (84.6)	
Hemorrhagic, n (%)	3 (9.1)	4 (15.4)	
Bilateral, n (%)	1 (3.0)	/	
Lesion side			0.68[d]
Left, n (%)	16 (48.5)	13 (50)	
Right, n (%)	17 (51.5)	12 (46.2)	
Bilateral, n (%)	/	1 (3.8)	
Ability to walk 10m, n (%)	13 (39.4)	12 (46.2)	0.27[c]
Use of walking aids			0.15[d]
No use of walking aids in ADL, n (%)	20 (60.6)	18 (69.2)	
Ankle-foot orthosis, n (%)	/	1 (3.8)	
2 wheel rollator, n (%)	/	1 (3.8)	
4 wheel rollator, n (%)	6 (18.2)	5 (19.2)	
Cane, n (%)	7 (21.2)	1 (3.8)	
Stroke disability			
RMA-GF, median (P25-P75)	5 (3-10)	5.5 (4-11)	0.75[b]
FACs, median (P25-P75)	2 (1-4)	3 (1-4)	0.96[b]
NIHSS, median (P25-P75)	5 (3-7)	5 (2-10)	0.95[b]
Barthel Index, median (P25-P75)	30 (15-70)	32.5 (15-65)	0.69[b]
MMSE, median (P25-P75)	26.5 (24-28.5)	28 (27-28)	0.29[b]

ACG= Active cycling group, CG= Control group, ADL=Activity of daily living, P25-P75=Percentiles 25-75, RMA= Rivermead Motor Assessment gross function scale, FACs= Functional Ambulation Categories, NIHSS=National Institute of Health Stroke Scale, MMSE=Mini Mental State Examination. There were no significant differences in patient characteristics at baseline between the intervention and the control groups ([a] independent samples t-test, [b] Mann-Whitney U test, [c] Chi-square test, [d] Fisher's exact test).

Table 2: Analysis of outcome parameters per treatment group based on a mixed-effects model.

	Data per Group				Mixed-Effects model					
Outcome Parameter	Phase I		Phase II		Phase I			Phase I + II		
	Baseline	3 mo	6 mo	12 mo	Time	Group	Group*Time	Time	Group	Group*Time
VO_{2peak}[a] ($mLkg^{-1}min^{-1}$)										
CG	14.17 ±4.74	15.29 ±5.10	16.51 ±5.51*	16.11 ±5.19	$F_{1,51}$= 17.83	$F_{1,51}$= 0.13	$F_{1,51}$= 2.07	$F_{3,134}$= 16.03	$F_{2,134}$= 0.24	$F_{6,134}$= 0.59
ACG	13.12 ±5.22	16.06 ±4.58***			p< 0.001	p= 0.717	p= 0.156	p< 0.001	p= 0.788	p= 0.740
Co-ACG	*[13.61±4.92]*	*[16.13 ±4.08]*	17.11 ±4.38**	17.94 ±3.71**						
Nco-ACG	*[12.71 ±5.57]*	*[15.99 ±5.15*]*	16.14 ±4.96**	15.73 ±5.53*						
Oxygen uptake efficiency slope[a] (($mLmin^{-1}$ oxygen uptake)/($Lmin^{-1}$ ventilation))										
CG	1482.04 ±445.91	1561.96 ±557.55	1623.65 ±614.39	1713.47 ±674.65	$F_{1,51}$= 3.71	$F_{1,51}$= 0.04	$F_{1,51}$= 0.02	$F_{3,134}$= 2.59	$F_{2,134}$= 0.00	$F_{6,134}$= 1.19
ACG	1503.18 ±512.91	1634.38 ±483.77			p= 0.060	p= 0.834	p= 0.887	p= 0.055	p= 0.995	p= 0.313
Co-ACG	*[1481.20 ±399.95]*	*[1673.86 ±391.98]*	1587.50 ±426.18	1605.36 ±415.28						
Nco-ACG	*[1521.50 ±602.24]*	*[1597.53 ±567.78]*	1688.73 ±444.37	1654.66 ±568.55						
Peak heart rate[a] (beats minute-1)										
CG	108.79 ±23.34	107.89 ±23.97	114.28 ±27.60	106.81 ±20.85	$F_{1,54}$= 0.00	$F_{1,54}$= 0.00	$F_{1,54}$= 0.88	$F_{3,140}$= 1.81	$F_{2,140}$= 0.11	$F_{6,140}$= 0.93
ACG	107.53 ±24.44	111.35 ±20.88			p= 0.951	p= 0.957	p= 0.354	p= 0.148	p= 0.897	p= 0.473
Co-ACG	*[107.00 ±22.70)]*	*[106.39 ±17.62]*	109.23 ±15.58	118.78 ±22.35						
Nco-ACG	*[107.97 ±26.45]*	*[116.01 ±23.13]*	116.31 ±23.60	112.25 ±21.39						
Peak workload[a] (Wattpeak)										
CG	57.20 ±25.58	63.33 ±27.77	71.43 ±29.54**	67.90 ±36.60*	$F_{1,53}$= 27.27	$F_{1,53}$= 0.01	$F_{1,53}$= 3.24	$F_{3,139}$= 22.51	$F_{2,139}$= 0.01	$F_{6,139}$= 0.73
ACG	53.33 ±30.89	68.07 ±32.50***			p< 0.001	p= 0.939	p= 0.078	p< 0.001	p= 0.991	p= 0.625
Co-ACG	*[52.67 ±25.76]*	*[64.67 ±26.96*]*	70.00 ±24.49***	73.85 ±26.63***						
Nco-ACG	*[53.89 ±35.34]*	*[71.25 ±37.57**]*	72.67 ±36.15***	72.31 ±33.95***						
Respiratory exchange ratio peak[a]										
CG	0.96 ±0.12	0.97 ±0.09	0.98 ±0.12	0.93 ±0.10	$F_{1,51}$= 1.03	$F_{1,51}$= 2.19	$F_{1,51}$= 0.05	$F_{3,134}$= 1.40	$F_{2,134}$= 0.59	$F_{6,134}$= 1.43
ACG	0.92 ±0.13	0.94 ±0.12			p= 0.316	p= 0.145	p= 0.827	p= 0.245	p= 0.556	p= 0.208
Co-ACG	*[0.90 ±0.11]*	*[0.92 ±0.11]*	0.93 ±0.12	1.01 ±0.14						
Nco-ACG	*[0.93 ±0.14]*	*[0.96 ±0.13]*	0.98 ±0.08	0.97 ±0.10						
Ratings of perceived Exertion[b], n Borg>14 (%)										
CG	10/25 ±40%	14/25 ±56%	14/22 ±64%	10/20 ±50%	$F_{1,53}$= 3.34	$F_{1,53}$= 0.01	$F_{1,53}$= 0.02	$F_{3,141}$= 2.09	$F_{2,141}$= 1.96	$F_{6,141}$= 0.71
ACG	13/33 ±39%	18/31 ±58%			p= 0.073	p= 0.939	p= 0.893	p= 0.104	p= 0.144	p= 0.646
Co-ACG	*[6/15 ±40%]*	*[6/15 ±40%]*	4/12 ±33%	3/13 ±23%						
Nco-ACG	*[7/18 ±39%]*	*[12/16 ±75%]*	10/15 ±67%	5/13 ±38%						

Table 2 continued.

Outcome parameter	Data per Group				Mixed-Effects model					
	Phase I		Phase II		Phase I			Phase I+ II		
	Baseline	3 mo	6 mo	12 mo	Time	Group	Group*Time	Time	Group	Group*Time
Maximal knee extension strength paretic leg[a] (Newton)										
CG	158.11 ±107.07	203.70 ±104.31**	222.28 ±117.84***	225.23 ±108.18***	$F_{1,54}$= 47.18	$F_{1,54}$= 0.02	$F_{1,54}$= 0.10	$F_{3,152}$= 32.94	$F_{2,152}$= 0.08	$F_{6,152}$= 0.68
ACG	163.77 ±109.29	213.63 ±128.11***			p< 0.001	p= 0.902	p= 0.755	p< 0.001	p= 0.927	p= 0.669
Co-ACG	*[167.96 ±95.30]*	*[204.63 ±96.03]*	226.01 ±97.65**	224.22 ±95.13**						
Nco-ACG	*[160.28 ±122.39]*	*[222.06 ±155.12*]*	250.59 ±165.55***	263.13 ±162.30***,+						
Maximal knee extension strength non-paretic leg[a] (Newton)										
CG	247.39 ±93.37	267.68 ±91.93	297.02 ±106.55**	295.95 ±88.47	$F_{1,54}$= 5.19	$F_{1,54}$= 0.68	$F_{1,54}$= 0.02	$F_{3,151}$= 7.72	$F_{2,151}$= 0.27	$F_{6,151}$= 0.57
ACG	271.97 ±126.33	298.57 ±124.33			p= 0.027	p= 0.414	p= 0.903	p< 0.001	p= 0.763	p= 0.757
Co-ACG	*[278.51 ±115.136]*	*[301.13 ±114.19]*	299.23 ±104.42	304.55 ±109.38						
Nco-ACG	*[266.52 ±138.04]*	*[296.16 ±136.87]*	326.76 ±154.17	309.18 ±121.60						
Functional Ambulation Categories[b], n FAC_{total}= 5 (%)										
CG	6/26 (23%)	10/25 (40%)	14/24 (58%)*	13/23 (57%)*	$F_{1,54}$= 3.16	$F_{1,54}$= 0.02	$F_{1,54}$= 0.13	$F_{3,152}$= 9.34	$F_{2,152}$= 0.01	$F_{6,152}$= 0.34
ACG	8/33 (24%)	11/31 (35%)			p= 0.081	p= 0.892	p= 0.723	p< 0.001	p= 0.991	p= 0.917
Co-ACG	*[3/15 (25%)]*	*[5/15 (33%)]*	8/14 (57%)	11/15 (73%)*						
Nco-ACG	*[5/18 (28%)]*	*[6/16 (38%)]*	8/15 (53%)	9/14 (64%)						
10-meter comfortable gait speed[a] (m/s)										
CG	0.44 ±0.44	0.63 ±0.46***	0.65 ±0.40***	0.65 ±0.39***	$F_{1,54}$= 33.74	$F_{1,54}$= 1.00	$F_{1,54}$= 0.20	$F_{3,153}$= 26.87	$F_{2,153}$= 0.97	$F_{6,153}$= 0.23
ACG	0.35 ±0.41	0.53 ±0.37***			p< 0.001	p= 0.321	p= 0.659	p< 0.001	p= 0.382	p= 0.966
Co-ACG	*[0.43 ±0.39]*	*[0.60 ±0.29*]*	0.61 ±0.24**	0.62 ±0.26**						
Nco-ACG	*[0.29 ±0.43]*	*[0.48 ±0.43*]*	0.57 ±0.41***	0.57 ±0.40***						
10-meter maximal gait speed[a] (m/s)										
CG	0.61 ±0.60	0.87 ±0.58***	0.90 ±0.59***	0.89 ±0.56***	$F_{1,54}$= 31.48	$F_{1,54}$= 0.21	$F_{1,54}$= 0.51	$F_{3,151}$= 23.19	$F_{2,151}$= 0.26	$F_{6,151}$= 0.35
ACG	0.57 ±0.68	0.78 ±0.60**			p< 0.001	p= 0.651	p= 0.479	p< 0.001	p= 0.768	p= 0.910
Co-ACG	*[0.60 ±0.62]*	*[0.86 ±0.48**]*	0.85 ±0.35***	0.98 ±0.40***						
Nco-ACG	*[0.54 ±0.76]*	*[0.70 ±0.70]*	0.83 ±0.60*	0.82 ±0.65*						

CG= control group; ACG= active cycling group; Co-ACG= ACG with coaching; Nco-ACG= ACG without coaching; *,**,*** significant to baseline (*p<0.05,**p<0.01,***p<0.001); + significant to 3 months (p<0.05). Within-subjects (Time) and between-subjects (Group) effects and Within-subjects effects X Group (Group*Time) were calculated using [a] Linear and [b] Logistic mixed effects model. Note: Values are mean ± SD except otherwise mentioned. The amount missing data per outcome parameter per group is mentioned in a Supplementary Table C.

Table 3: Analysis of outcome measures in stroke patients who could not walk 10m independently at baseline divided in 2 groups based on a linear mixed-effects model.

Outcome parameter	Data per Group				Linear Mixed-Effects model		
	Phase I		Phase II		Phase I + II		
	Baseline	3 mo	6 mo	12 mo	Time	Group	Group*Time
10-meter comfortable gait speed (m/s)							
CG	0.00 ±0.00	0.26 ±0.30**	0.32 ±0.29***	0.38 ±0.29***	$F_{3,70}$= 28.16	$F_{1,70}$= 0.08	$F_{3,70}$= 0.16
ACG	0.00 ±0.00	0.23 ±0.20***	0.32 ±0.20***	0.33 ±0.24***	p< 0.001	p= 0.774	p= 0.925
10-meter maximal gait speed (m/s)							
CG	0.00 ±0.00	0.38 ±0.44**	0.42 ±0.45***	0.42 ±0.43***	$F_{3,68}$= 20	$F_{1,68}$= 0.06	$F_{3,68}$= 0.35
ACG	0.00 ±0.00	0.27 ±0.27*	0.43 ±0.28***	0.42 ±0.34***	p< 0.001	p= 0.807	p= 0.787
VO_2peak (mL kg-1 min-1)							
CG	12.06 ±5.15	13.23 ±5.30	14.40 ±6.61	14.07 ±6.20	$F_{3,59}$= 10.03	$F_{1,59}$= 0.50	$F_{3,59}$= 0.75
ACG	9.85 ±3.94	13.15 ±4.10**	13.36 ±4.21***	14.17 ±4.98**	p< 0.001	p= 0.481	p= 0.524
Oxygen uptake efficiency slope ((mLmin-1 oxygen uptake)/(Lmin-1 ventilation))							
CG	1321.18 ±569.28	1282.27 ±544.61	1409.11 ±805.70	1440.67 ±755.78	$F_{3,59}$= 1.73	$F_{1,59}$= 0.00	$F_{3,59}$= 0.46
ACG	1246.41 ±482.83	1391.46 ±405.67	1425.62 ±348.33	1481.20 ±384.29	p= 0.171	p= 0.961	p= 0.711
Peak workload (Wattpeak)							
CG	39.09 ±21.19	47.27 ±24.12	56.00 ±31.69**	47.78 ±38.01	$F_{3,64}$= 13.61	$F_{1,64}$= 0.01	$F_{3,64}$= 1.92
ACG	35.29 ±17.00	50.67 ±24.92**	51.54 ±23.75***	58.33 ±27.58***	p< 0.001	p= 0.926	p= 0.136
Respiratory exchange ratio peak							
CG	0.92 ±0.11	0.96 ±0.10	0.97 ±0.14	0.92 ±0.13	$F_{3,59}$= 0.97	$F_{1,59}$= 0.03	$F_{3,59}$= 0.56
ACG	0.91 ±0.14	0.95 ±0.17	0.96 ±0.12	1.01 ±0.14	p= 0.415	p= 0.855	p= 0.641
Maximal knee extension strength paretic leg (Newton)							
CG	75.07 ±89.26	135.15 ±92.88	148.79 ±101.00**	174.32 ±118.01**	$F_{3,68}$= 14.97	$F_{1,68}$= 0.41	$F_{3,68}$= 0.21
ACG	103.72 ±73.79	150.17 ±106.35)	178.13 ±120.33**	184.90 ±134.17***	p< 0.001	p= 0.525	p= 0.891
Maximal knee extension strength non-paretic leg (Newton)							
CG	228.67 ±95.66	256.31 ±105.32	283.68 ±119.41	275.45 ±117.33	$F_{3,68}$= 6.16	$F_{1,68}$= 0.01	$F_{3,68}$= 0.08
ACG	225.09 ±107.60	265.11 ±103.55	285.51 ±127.04	274.06 ±104.25	p< 0.001	p= 0.922	p= 0.968

CG= control group; ACG= active cycling group; *, **, ***= significant to baseline (*p<0.05, **p<0.01, ***p<0.001). Within-subjects (Time) and between-subjects (Group) effects and Within-subjects effects*Group (Group*Time) were calculated using a Linear mixed effects model.Note: Values are mean ± SD. The amount missing data per outcome parameter per group is mentioned in a Supplementary Table C.

Because of the uneven distribution seen in Nco-ACG (RMA-GF≤6, n=12; RMA-GF>6, n= 6) compared with Co-ACG (RMA-GF≤6, n=7; RMA-GF>6, n= 8), the severity of motor deficit was incorporated in the model as a fixed effect with no significant interaction effects found.

Furthermore, no group-by-time interactions were found in phase I+II in patients who could not walk 10m at baseline (Table 3, Supplementary Tables C-F). However, significant improvements over time (p<.05) were found in both groups in gait speeds between all assessments and baseline and in paretic leg strength in 6 and 12 months compared to baseline. Additionally, in the ACG significant improvements over time (p<.01) were found in VO2peak and Wattpeak when all measurement points were compared to baseline. In the CG, an additional significant difference was found in Wattpeak (6mo vs baseline; p<.01).

DISCUSSION

This randomized controlled trial investigated the 1-year effects of AT combined with coaching on A-Cap, strength, and gait speed. No significant differences between training groups were found over time. However, throughout the 2 phases, patients in both groups showed significant improvements on these outcomes. In phase I, differences between the groups only seem to become evident on $Watt_{peak}$. In phase II, visual inspection of the data showed that the ACG continued to improve in $Watt_{peak}$, VO_{2peak}, and less affected leg strength and gait speed at 12 months, while in the Nco-ACG and CG less benefit was observed. Although visually there were changes in the figures, the differences were not statistically significant.

After the 3 months of AC, VO_{2peak} and $Watt_{peak}$ increased significantly after AT, while no significant improvements were found in the CG, which resulted in no significant group*time interactions ($Watt_{peak}$, p= .078; VO_{2peak}, p= .156). A 27.6% increase in $Watt_{peak}$ is slightly higher than the 23.4% increase found by Tang et al.[27] Also, compared to the study[26] we prioritized in our sample calculation ($Watt_{peak}$=12.20 Watt), we found more than the predefined clinical effect in Workload (Phase I= 14.74Watt). The increase of 2.94 $mLkg^{-1}min^{-1}$ in VO_{2peak} in the ACG was also higher than the 2.27 $mLkg^{-1}min^{-1}$ increase that was recently reported.[6] Also in phase I, significant improvements were found in gait speed; however, the improvements were comparable in the ACG and CG and similar to those found by Duncan et al[28]. Further, paretic leg strength improved in both groups in phase I without significant interaction.

Follow-up measurement until 6 months showed a significantly increased, VO_{2peak} and $Watt_{peak}$ in all groups. Although no group*time interactions were found, the greatest mean increase was found in the Co-ACG for VO_{2peak}, and in both ACG groups for $Watt_{peak}$. This finding might be explained by adaptations of the cardiovascular system expected after 2 to 6 weeks of training.[29] Also, recommendations are to gradually increase the intensity, as was performed in our study.

Interestingly, between 6 and 12 months, the only progress in VO_{2peak} and $Watt_{peak,}$ was seen in the Co-ACG, while

in the other groups similar results or a slight deterioration was seen. The slightly higher improvement in VO_{2peak} in the Co-ACG might be caused by coaching. The support from qualified personnel providing exercise information, ensuring safety and comfort, and providing external motivation has been previously identified to promote carryover and integration of exercise behaviors into everyday life.[11,30] Also, psychosocial factors (self-efficacy, PA beliefs, social support) appear relevant in the uptake and the maintenance of PA after stroke.[31] The most deterioration in $Watt_{peak}$ was seen in the CG. However, these differences were not significant.
Also at 12 months, significant improvements were found for strength and gait speed in all groups compared with baseline, without differences between the groups. Visual data inspection showed that between 6 and 12 months, the less affected leg strength (+5.32 Newton) still increased in the Co-ACG in contrast to the other groups. A deterioration of -17.58 Newton in less affected leg strength was seen in the Nco-ACG. This did not reach significance.
For the second aim, no significant group difference over time in severely impaired patients was found, possibly because of an uneven distribution of severity of motor deficit and small patient numbers in the ACG groups. Still, mean values showed that patients with severe walking deficits continued to increase in VO_{2peak} and $Watt_{peak}$ after AT (6mo vs 12mo), while the CG showed deterioration. This could support the assumption that more severely impaired patients gained more long-term benefit from a supervised AT program.[10] Possibly, less impaired subacute patients could benefit more from high-intensity training on an upright bike[32] or from combined AT programs with strength and balance[28].

In general, this study could not reveal group differences over time. This might be explained by spontaneous recovery in the subacute phase along with the aerobic requirements of ADL. Also in Tang's study,[27] no group differences were found after 4 weeks. However, Duncan[28] found differences in VO_{2peak} and gait speed, although in less severe patients. Katz-Leurer et al[26] found group differences for $Watt_{peak}$ after 8 weeks of AC in acute, moderately to severely impaired patients. The intensity (60%) during this 8-week study was comparable to the initial intensity (week 1-2) in our study. Here, the control was not described, with no follow-up. The results in our study may suggest that higher training intensities or more weeks of continuous training may be needed to obtain more pronounced effects. The positive effects of high-intensity training in chronic stroke on gait speed and A-Cap may support this thought.[29] Furthermore, we noticed that patients in all training groups remained at low levels of baseline AC, strength, and gait velocities when compared with healthy age-related persons[33].

This study used a stratified randomization, a blinded assessor and follow-up, which were considered as strengths. Furthermore, the additional training given to the ACG and CG, as well as the coaching approach in phase II to a part of the ACG group, was considered an asset. This study showed that the ACG approach was clinically usable for subacute patients because (1) it required little standby assistance as a results of the chip cards; (2) it was safe to execute; (3) the intensity was gradually built; (4) the approach was applicable in severely impaired patients; and (5) the caregivers were involved in the educational sessions. Further, patients were motivated to continue their AT by a self-chosen modality. Finally, patients listed no adverse effects, and only 6 patients drooped out of the study for reasons unrelated to the intervention.

Study limitations

The present study did not gather objective exercise data (e.g. Workload, HR) during the coaching period. Also, different type of aerobic exercises were chosen (treadmill, n=1; fitness, n=1; outdoor 4-wheel-bike, n=1; stationary-bike, n=12), which might have affected $Watt_{peak}$. Undoubtedly, the small sample size (phase II) contributed to not finding clinically significant group differences. A post hoc power analysis was performed. Based on an effect of 6.33 Watt in phase I (12.58 Watt [ACG]- 6.25 Watt [CG]; ±13.52 Watt), using an independent samples t test, we should include 73 patients per group to have an 80% power. At the end of phase II, an effect of 8.46 Watt (18.46 Watt [Co-ACG]-10.00 Watt [CG]; ±22.05 Watt) was found, so 108 patients per group should be included in phase II.

CONCLUSION

No significant differences between training groups were found over time. Although our study did not have objective exercise data from the training device during follow-up, the 3-month AC program combined with education sessions seemed to be an applicable method in subacute stroke. New long-term AT interventions should focus on coaching approaches to facilitate training after supervised AC.

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SUPPLIERS

a. RECK-TECHNIK GmbH & Co, KG.
b. ErgoSelect600K; Ergoline GmbH.
c. Metamax3B; Cortex Biophysics GmbH.
d. Electrocardiogram device; CUSTO-MED GmbH.
e. Microfet2; Hoggan Health Industries Inc.
f. Polar pulse watch and chest strap; Polar Electro Oy.
g. Kinetec Performa Ability One; Kinetec SAS
h. SAS 9.4 software; SAS Institute Inc.
i. R 3.0.1 sotware; R Core Team 2013. R foundation for statistical Computing.

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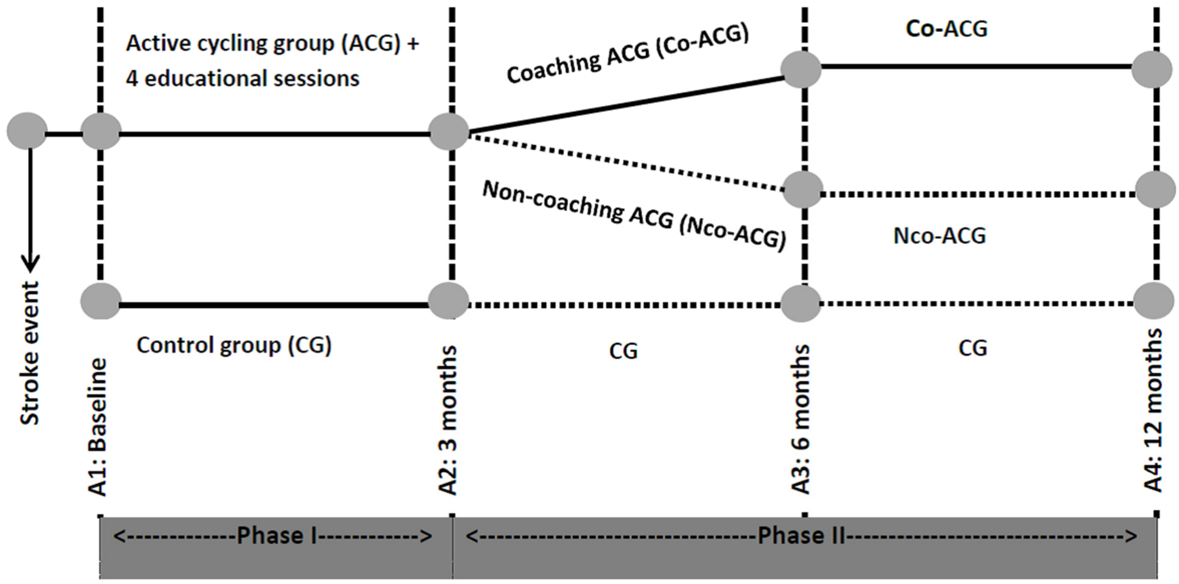
SUPPLEMENTARY FILES



Supplement A: Design of the study used in the Active cycling group (ACG) and the Control group (CG) over four measurement points (A1- A4).

Supplement B: The training program of Phase I to the Active cycling group.

Phase I (weeks)	Duration (minutes)	Intensity (%)	Training Program Active cycling group	Info sessions (60 minutes)
1	51	60	R= 3 min, AC= 6 X 5 min	
2	48	60	R= 3 min, AC= 1 X 5 min, 3 X 6 min, 1 X 7 min	
3	45	65	R= 3 min, AC= 2 X 7 min, 2 X 8 min	Week 3
4	42	65	R= 3 min, AC= 2 X 9 min, 1 X 12 min	
5	42	70	R= 3 min, AC= 2 X 12 min, 1 X 6 min	
6	39	70	R= 3 min, AC= 2 X 15 min	Week 6
7	45	75	R= 5 min, AC= 2 X 15 min	
8	45	75	R= 5 min, AC= 1 X 20 min, 1 X 10 min	Week 8
9-12	40	75	R= 5 min, AC= 1 X 30 min	Week 12

R= rest given before and after active cycling (AC).

Supplement C: Number of patients for outcome measures reported in Tables 2, 2 continued and 3.

Table 2 and Table 2 continued		
Baseline	-	CG: n=26 (n=25 VO_{2peak}, Oxygen uptake efficiency slope, Peak workload, Respiratory exchange ratio, Ratings of perceived exertion).
	-	ACG: n=33 (n=31 Maximal gait speed).
3 months	-	CG: n=25 (n=24 VO_{2peak}, Oxygen uptake efficiency slope, Peak workload, Respiratory exchange ratio).
	-	Co-ACG: n=15 (n=14 $VO_{2peak,}$ Oxygen uptake efficiency slope, Respiratory exchange ratio).
	-	Nco-ACG: n=16 (n=15 $VO_{2peak,}$ Oxygen uptake efficiency slope, Respiratory exchange ratio).
6 months	-	CG: n=24 (n=22 Ratings of perceived exertion; n=21 Peak heart rate; n=20 $VO_{2peak,}$ Oxygen uptake efficiency slope, Respiratory exchange ratio).
	-	Co-ACG: n=15 (n=14 FAC, gait speed; n=12 $VO_{2peak,}$ Oxygen uptake efficiency slope, Peak heart rate, Peak workload, Respiratory exchange ratio, Ratings of perceived exertion).
	-	Nco-ACG: n=15.
12 months	-	CG: n= 23 (n=22 Strength paretic leg, Maximal gait speed; n=21 Strength non-paretic leg; n=20 Peak heart rate, Ratings of perceived exertion; n=19 VO_{2peak}, Oxygen uptake efficiency slope, Peak workload, Respiratory exchange ratio).
	-	Co-ACG: n=15 (n=14 Maximal gait speed; n=13 Peak workload, Ratings of perceived exertion; n=12 Peak heart rate; n=11 $VO_{2peak,}$ Oxygen uptake efficiency slope, Respiratory exchange ratio).
	-	Nco-ACG: n=15 (n=14 Strength legs, FAC; n=13 VO_{2peak}, Oxygen uptake efficiency slope, Peak heart rate, Peak workload, Respiratory exchange ratio, Ratings of perceived exertion).

Table 3		
Baseline	-	CG: n= 11.
	-	ACG: n= 17 (n=15 Maximal gait speed).
3 months	-	CG: n= 11.
	-	ACG: n= 15 (n=13 VO_{2peak}, Oxygen uptake efficiency slope, Respiratory exchange ratio).
6 months	-	CG: n= 11 (n=10 Peak workload; n=9 VO_{2peak}, Oxygen uptake efficiency slope, Respiratory exchange ratio).
	-	ACG: n= 14 (n=13 VO_{2peak}, Oxygen uptake efficiency slope, Peak workload, Respiratory exchange ratio).
12 months	-	CG: n= 11 (n=10 Maximal gait speed, Knee extension strength; n=9 VO_{2peak}, Oxygen uptake efficiency slope, Peak workload, Respiratory exchange ratio).
	-	ACG: n= 14 (n=13 Maximal gait speed, Knee extension strength; n=12 Peak workload; n=10 VO_{2peak}, Oxygen uptake efficiency slope, Respiratory exchange ratio).

Supplement D: Estimates and Confidence intervals based on a mixed-effects model (Phase I) for outcome parameters reported in Table 2 and 2 continued.

	Mixed effects model (Phase I)		
	Time	Group	Group*Time
VO_{2peak}[a] ($mLkg^{-1}min^{-1}$)			
ACG	β= 1.14 (-.08 to 2.36)	β= -1.05 (-3.71 to -1.60)	β= 1.18 (-.47 to -2.83)
Oxygen uptake efficiency slope[a] (($mLmin^{-1}$ oxygen uptake)/($Lmin^{-1}$ ventilation))			
ACG	β= 71.51 (-47.84 to 190.86)	β= 21.14 (-245.51 to 287.79)	β= 11.45 (-149.65 to 172.54)
Peak heart rate[a] (beats $minute^{-1}$)			
ACG	β= -1.70 (-6.77 to 3.38)	β= -1.27 (-13.65 to 11.12)	β= 3.18 (-3.63 to 1.00)
Peak workload[a] ($Watt_{peak}$)			
ACG	β= 6.24 (.75 to 11.73)	β= -3.87 (-19.60 to 11.87)	β= 6.56 (-.75 to 13.88)
Respiratory exchange ratio peak[a]			
ACG	β= .02 (-.04 to .07)	β= -0.04 (-0.10 to .02)	β= .01 (-.07 to .09)
Ratings of perceived Exertion[b], n Borg>14 (%)			
ACG	β= 1.92 (.60 to 6.07)	β= .98 (.32 to 2.98)	β= 1.11 (.24 to 5.19)
Maximal knee extension strength paretic leg[a] (Newton)			
ACG	β= 47.60 (27.83 to 67.38)	β= 5.66 (-53.70 to 65.01)	β= -4.16 (-30.73 to 22.42)
Maximal knee extension strength non-paretic leg[a] (Newton)			
ACG	β= 18.61 (-4.53 to 41.75)	β= 24.58 (-34.87 to 84.03)	β= -1.91 (-32.99 to 29.18)
Functional Ambulation Categories[b], n FAC_{total}= 5 (%)			
ACG	β= 1.03 (.66 to 11.91)	β= .08 (.20 to 5.95)	β= -.35 (.10 to 4.94)
10-meter comfortable gait speed[a] (m/s)			
ACG	β= .19 (.10 to .28)	β= -.09 (-.31 to .12)	β= -.03 (-.15 to .10)
10-meter maximal gait speed[a] (m/s)			
ACG	β= .27 (.14 to .40)	β= -.04 (-.37 to .29)	β= -.06 (-.23 to .11)

ACG= active cycling group; Within-subjects (Time) and between-subjects (Group) effects and Within-subjects effects X Group (Group*Time) were calculated using [a] Linear and [b] Logistic mixed effects model; β= Estimate and (95% confidence interval) out of the mixed effects model.

Supplement E: Estimates and Confidence intervals based on a Mixed effects model (Phase II) for outcome parameters reported in Tables 2.

	Mixed effects model (Phase II)										
	Time			Group		Group*Time					
	3 months	6 months	12 months			3 months		6 months		12 months	
				Co-ACG	Nco-ACG	Co-ACG	Nco-ACG	Co-ACG	Nco-ACG	Co-ACG	Nco-ACG
VO_{2peak}[a] ($mLkg^{-1}min^{-1}$)											
β	1.14	2.04	1.87	-.56	-1.46	1.00	1.39	1.42	.65	.83	.57
CI Upper	-.06	.76	.57	-3.80	-4.52	-.96	-.53	-.66	-1.33	-1.31	-1.47
CI Lower	2.34	3.32	3.18	2.67	1.60	2.97	3.31	3.50	2.62	2.97	2.62
Oxygen uptake efficiency slope[a] (($mLmin^{-1}$ oxygen uptake)/($Lmin^{-1}$ ventilation))											
β	71.49	87.39	177.84	-.84	39.46	96.21	-66.11	34.57	9.19	-153.91	-62.46
CI Upper	-49.41	-41.80	46.31	-335.28	-277.08	-102.05	-260.41	-175.86	-190.38	-370.08	-269.36
CI Lower	192.39	216.59	309.36	333.60	356.00	294.46	128.20	245.00	208.76	62.26	144.43
Peak heart rate[a] (beats $minute^{-1}$)											
β	-1.65	2.87	-2.11	-1.79	-.83	1.04	5.36	.42	2.85	9.54	7.98
CI Upper	-7.57	-3.43	-8.51	-17.34	-15.53	-8.62	-4.09	-9.97	-6.98	-.92	-2.21
CI Lower	4.26	9.17	4.30	13.75	13.87	10.71	14.80	10.82	12.68	20.00	18.17
Peak workload[a] (Wattpeak)											
β	6.24	12.30	9.73	-4.53	-3.31	5.76	7.39	6.36	3.70	7.67	7.14
CI Upper	.23	5.98	3.19	-24.34	-22.05	-3.93	-2.09	-4.01	-6.11	-2.66	-3.11
CI Lower	12.24	18.61	16.26	15.27	15.43	15.45	16.87	16.73	13.52	18.00	17.39
Respiratory exchange ratio peak[a]											
β	.02	.01	-.02	-.06	-.03	.00	.02	.01	.03	.11	.06
CI Upper	-.03	-.04	-.08	-.13	-.10	-.09	-.06	-.07	-.05	.02	-.02
CI Lower	.07	.06	.03	.02	.04	.08	.10	.10	.11	.20	.14
Ratings of perceived Exertion[b], n Borg>14 (%)											
β	2.00	2.76	1.51	1.02	.97	.50	2.49	.27	1.17	.28	.65
CI Upper	.62	.80	.43	.23	.24	.07	.36	.03	.17	.03	.09
CI Lower	6.45	9.50	5.26	4.40	3.87	3.41	17.18	2.11	8.13	2.38	4.72
Maximal knee extension strength paretic leg[a] (Newton)											
β	47.54	66.89	65.85	9.84	2.17	-10.86	2.59	-8.84	12.31	-9.59	29.14
CI Upper	24.39	43.39	41.64	-65.69	-69.26	-48.70	-34.43	-46.89	-25.48	-48.08	-9.63
CI Lower	70.70	90.40	90.06	85.37	73.60	26.97	39.60	29.22	50.09	28.91	67.91
Maximal knee extension strength non-paretic leg[a] (Newton)											
β	18.60	44.93	31.66	31.12	19.13	4.02	-7.61	-24.20	-3.45	-5.62	-.05
CI Upper	-4.17	21.81	7.46	-42.17	-50.18	-33.20	-44.02	-61.63	-40.61	-43.72	-38.42
CI Lower	41.38	68.05	55.85	104.41	88.44	41.23	28.79	13.23	33.71	32.49	38.32
Functional Ambulation Categories[b], n FAC_{total}= 5 (%)											
β	3.82	13.51	13.37	.75	1.48	.83	.51	1.52	.46	3.98	.90
CI Upper	.74	2.43	2.38	.06	.14	.05	.04	.09	.03	0.21	.05
CI Lower	19.84	75.25	75.02	9.79	15.81	12.71	.02	26.75	7.06	76.19	14.84
10-meter comfortable gait speed[a] (m/s)											
β	.19	.20	.23	-.01	-.16	-.02	-.03	.02	.03	-.03	.01
CI Upper	.11	.12	.14	-.27	-.39	-.16	-.16	-.12	-.10	-.17	-.12
CI Lower	.27	.29	.31	.24	.08	.11	.10	.15	.16	.10	.14
10-meter maximal gait speed[a] (m/s)											
β	.27	.30	.29	-.01	-.07	.00	-.11	.03	-.04	.05	-.04
CI Upper	.15	.18	.16	-.39	-.44	-.19	-.30	-.16	-.23	-.15	-.23
CI Lower	.39	.42	.41	.37	.30	.19	.07	.23	.15	.24	.15

Co-ACG= active cycling group with coaching; Nco-ACG= active cycling group without coaching; Within-subjects (Time) and between-subjects (Group) effects and Within-subjects effects X Group (Group*Time) were calculated using [a] Linear and [b] Logistic mixed effects model; β= Estimate; CI Upper and Lower= 95% confidence interval out of the mixed effects model.

Supplement F: Estimates and Confidence intervals based on a Mixed effects model (Phase II) for outcome parameters reported in Table 3.

	Linear Mixed-Effects model (Phase II)						
	Time			Group	Group*Time		
	3 month	6 month	12 month		3 month	6 month	12 month
				ACG	ACG	ACG	ACG
10-meter comfortable gait speed (m/s)							
β	.26	.32	.38	.00	-.03	.00	-.05
CI Upper	.13	.19	.25	-.16	-.20	-.17	-.22
CI Lower	.38	.45	.50	.16	.14	.17	.12
10-meter maximal gait speed (m/s)							
β	.38	.42	.44	.00	-.10	.01	.00
CI Upper	.18	.23	.24	-.25	-.36	-.25	-.26
CI Lower	.57	.62	.64	.25	.15	.27	.27
VO2peak (mL kg-1 min-1)							
β	1.17	2.38	2.16	-2.21	1.66	.90	1.26
CI Upper	-.53	.56	.34	-5.97	-.63	-1.48	-1.23
CI Lower	2.87	4.21	3.98	1.55	3.95	3.28	3.74
Oxygen uptake efficiency slope ((mLmin-1 oxygen uptake)/(Lmin-1 ventilation))							
β	-38.91	47.19	104.22	-74.77	144.57	112.76	77.69
CI Upper	-230.94	-158.95	-101.92	-470.52	-114.21	-156.66	-203.11
CI Lower	153.12	253.32	310.36	320.98	403.34	382.17	358.49
Peak workload (Wattpeak)							
β	8.18	15.69	8.35	-3.80	5.45	.73	12.48
CI Upper	.03	7.25	-.41	-23.29	-5.27	-10.44	.94
CI Lower	16.33	24.14	17.10	15.69	16.16	11.90	24.02
Respiratory exchange ratio peak							
β	.03	.05	.00	-.01	.00	.00	.07
CI Upper	-.05	-.05	-.09	-.12	-.11	-.12	-.05
CI Lower	.12	.14	.09	.10	.12	.12	.19
Maximal knee extension strength paretic leg (Newton)							
β	60.09	73.73	91.44	28.65	-18.73	.31	-2.23
CI Upper	17.46	31.10	47.44	-51.56	-74.69	-56.26	-60.45
CI Lower	102.72	116.36	135.44	108.87	37.23	56.88	55.99
Maximal knee extension strength non-paretic leg (Newton)							
β	27.64	55.01	41.25	-3.58	-1.92	-6.52	6.89
CI Upper	-11.62	15.75	.72	-89.53	-53.49	-58.66	-46.78
CI Lower	66.89	94.26	81.77	82.37	49.65	45.62	60.56

ACG= active cycling group; Within-subjects (Time) and between-subjects (Group) effects and Within-subjects effects X Group (Group*Time) were calculated using a Linear mixed effects model; β= Estimate; CI Upper and Lower= 95% confidence interval.

Chapter 5

Does a cycling program combined with education and followed by coaching promote physical activity in subacute stroke patients? A Randomized Controlled trial.

Submitted as:

Vanroy C, Vanlandewijck Y, Cras P, Truijen S, Vissers D, Swinnen A, Bosmans M, Wouters K, , Feys H.
Does a cycling program combined with education and followed by coaching promote physical activity in subacute stroke patients? A Randomized Controlled trial. Disability and Rehabilitation, 2017.

ABSTRACT

Objective To investigate the effects of 3-month AC followed by coaching on PA after subacute stroke.

Design Randomized controlled trial

Setting Inpatient rehabilitation center

Participants Patients (N=59; mean age=65.4±10.3) aged ≤80 years with first stroke and able to cycle at 50 revolutions/minute enrolled 3-10 weeks post-stroke.

Interventions: Patients were randomly allocated to 3-month AC (ACG, n=33) or to a control group (CG, n=26), three 30-minutes training/week. Afterwards, the ACG was randomized into a coaching (n=15) versus non-coaching group (n=16) for 9 months.

Main Outcome Measures PA was measured by objective and self-reported measures, which were taken before/after AC and during 6/12 months, except the Baecke-questionnaire, which was used at baseline/12 months.

Results A significant difference was found in Baecke/sport (p=0.039) between the ACG and the CG, in patients with severe motor function deficits at baseline. Patients in CG performed significant less sports at 12 months (mean $Baecke/sport_{baseline}$ =3.07±1.21, mean $Baecke/sport_{12months}$ =1.43±0.98; p=0.01). Furthermore, all groups showed significant changes over time in all measures at 3 months (p≤0.024) (except: PASIPD, diary/ Mets*minutes- moderate) and 12 month (p≤0.020) and additionally in a subgroup with severe motor function deficits (p≤0.033) (except diary/ Mets*minutes-sedentary).

Conclusion When AC combined with education is used in subacute patients with severe motor function deficits before starting AT, more sports participation might be observed after 1 year. No other significant group differences were found over time. In all groups, however, patients showed significant improvement over time in PA measures. Future work should focus on facilitating coaching after an AT program.

Key-words Cerebrovascular disorders, Rehabilitation, Physical Activity, Mentoring, Coaching.

INTRODUCTION

Stroke remains a leading cause of long-term disability[1]. Patients often have low levels of PA[2] decreasing A-Cap and leading to disuse atrophy and social isolation. An inactive lifestyle also contributes to a heightened risk for recurrent stroke and other cardiovascular diseases.[1] Recent lifestyle guidelines to reduce cardiovascular risk encourages moderate to vigorous PA for at least 40 minutes per time, minimum 3 to 4 days per week.[3] Moreover, studies also advise to reduce prolonged sedentary behavior as this leads to remodeling and thickening of arterial walls.[4-6]

The minimum recommended PA level is often not reached post stroke. A review including 22 studies measuring stroke patients' number of steps per day reported attainment of less than half of age-matched normative values.[7] Our own research described more steps and higher EE values in chronic home-living than in subacute hospitalized patients.[8] However, participation in moderate activities was reduced in chronic patients and only few performed moderate activity at least 3 days per week. This was also found in a longitudinal study.[9] In current literature, little is known about the time patients spend being sedentary and how this is distributed during a day.

In stroke patients, it remains a challenge to quantify PA due to disturbed walking patterns, slow gait speeds and cognitive deficits.[4] To assess PA, several objective devices (e.g. heart rate monitor[10], pedometers[11,12], activity monitors[13]) have been described. Other measures are self-reporting questionnaires[14,15] and activity diaries[16]. Often objective and self-reported measures are used together due to their complementary character. Objective devices were found to require fewer days of monitoring in comparison to self-reported measures to gather a reliable assessment.[17] In older persons, three to four days of monitoring are needed to reliably assess PA, regardless of which instrument was used.[17]

Convincing evidence exists of the benefits of AT after stroke, including reduced neurological impairment, improved A-Cap, enhanced lower extremity function, reduced systolic blood pressure, decreased energy cost of hemiparetic gait and facilitated performance of daily activities.[18,19] However, patients experience a lack of suitable devices to continue AT after ending a program, objective and verbal encouragement, knowledge of PA and support from family.[20] Recent studies examined the effect of supervised AT programs rather than implementing an approach to guide patients in adopting this as a part of a lifestyle change.[21] In the majority of studies severely impaired patients were excluded, because test or training material was not adapted.[18]

In summary, there is still need to search for an AT program that facilitates the carryover effect of improved A-Cap to live more physically active and that is also feasible for moderate to severe motor impaired patients. A previous study conducted by our research group has investigated the effects of an AT program combined with coaching on aerobic capacity, leg strength and gait speed.[22] No significant differences between the training groups over time were found for these primary outcome measures. We hypothesized that this AT program might improve secondary measures, such as PA. Therefore, the purpose of this study is to investigate the short and long term effects of this AT program on PA by using a combination of objective and self-reported measures. Finally, we aimed to investigate if patients with severe motor functions deficits (not able to walk 10m at baseline) benefited more from the AT program.

METHODS

Participants

From April 2010 until January 2013 stroke patients were recruited from an inpatient rehabilitation center in Herk-de-Stad, Belgium. The criteria for inclusion are described elsewhere.[22] Informed consent was obtained from all patients.

Design

A single-blind, randomized, controlled design was used. From the start, patients were randomized into two 3-month groups: an ACG and a CG. After the 3-month program, the ACG was subdivided into a Co-ACG and a Nco-ACG. Detailed information on the group assignment, the concealed allocations and the blinding to the group assignments were described previously.[22]

Treatment conditions

Phase I

The ACG underwent an AC program and the CG received a passive approach, each consisting of three sessions per week during 3 months. Both programs were given in addition to regular therapy.

All the ACG patients performed an AT program on a MOTOmed viva2 leg trainer[a]. Each training session consisted of 30 minutes of AC varying from interval to continuous. Heart rate training zones (THR) were calculated based up the Karvonen formula[23] ($THR = [HR_{peak} – HR_{rest}]X[60\text{-}75\%]+ HR_{rest}$), where peak heart rate (HR_{peak}) and rest heart rate (HR_{rest}) were determined in a maximal graded exercise test. Each training session a chip card was put into the operating panel of the MOTOmed leg trainer. Patients were asked to cycle at the proposed THR. At the beginning and the end of each training session, both legs were passively moved by the MOTOmed trainer during 5 minutes. During the 3 month program, four 1-hour educational sessions were given to patient and relatives or friends concerning different themes to prepare them to continue after ending the program.

The patients in CG received passive mobilization on a Kinetec device[b] of the paretic hip and knee in supine position, without education.

Phase II

After 3 months of training, the ACG patients were subdivided into two groups for a 9-month period. Patients in the Co-ACG trained their A-Cap by a chosen modality (eg, treadmill). They had to mark all training moments and duration of each session on a calendar. Monthly the researcher visited the patients to stimulate active behavior and therapy compliance, to discuss the training moments, and to help resolve specific problems. This approach was based on the transtheoretical model of behavior change.[24]

The Nco-ACG and patients in CG were not visited and not asked to report all training moments in phase II.

Outcome assessments

At baseline demographic and clinical data were collected, followed by reassessments after 3, 6 and 12 months. During the period of assessment patients were instructed to wear an activity monitor and pedometer and to fill in an activity diary during 3 consecutive days (Thursday–Saturday). The following day, all material was recollected and missing data in patients' diaries were completed. At this moment patients also filled in the questionnaires.

Objectively measured PA

Number of steps

The YDWP[c] is a uni-axial spring-levered pedometer and measures the number of steps. This was placed on the anterolateral side of the non-hemiplegic knee attached to a patella support strap.[12] Patients were instructed to wear the pedometer only during day hours and to write down the numbers of steps every evening. A knee-worn YDWP is proven to be a valid device in stroke patients except during high-intensity walking.[12]

Energy expenditure

The SWP2A[d] is a multi-sensor activity monitor, which was worn on the non-hemiplegic upper arm positioned on the triceps muscle halfway between acromion and olecranon during 24 h per day. Using a proprietary algorithm the data were converted into EE per minute. The SWP2A (EE) has been validated in chronic stroke patients.[25]

Self-reported PA level

A coded activity diary developed to directly measure the daily PA level was used.[16] For each activity, patients were asked to write down 1 code number every 30 minutes reflecting the activity that had taken the most time within the 30 minutes period.[16] Using the Compendium of Physical Activities Tracking Guide[26] and taking into account position and intensity, activities were converted to total Metabolic equivalent (METs) values, which were subdivided in 4 activity levels (sedentary, ≤1METs; light, >1–<3 METs; moderate ,≥3–6≤ METs; vigorous, >6 METs).[16] This diary was found to be valid in determining total METs*minutes and in sedentary and moderate activity level after stroke.[16]

The Physical Activity Scale for Individuals with Physical Disabilities (PASIPD) was used to reflect about PA during the preceding 7 days. When collecting the PA measures, the PASIPD was asked to be filled in. The PASIPD is a 7-day recall questionnaire used in individuals with visual, auditory and locomotor disabilities.[14] The Dutch version includes a 12-item questionnaire, from which a total PA score was calculated as the average daily hours multiplied by a METs-value and summed over items (METs hr per week).[27] The test-retest reliability and criterion validity was comparable to well established self-reported PA questionnaires.[27]

The Baecke Questionnaire of Habitual Physical Activity is a short and easy to fill in questionnaire, which is used to determine work, sport and leisure activities.[15] In this article, data concerning work was not analyzed, as patients were mostly beneficiaries of health insurance or retired. Patients were asked to reflect over the past month. A sport score was calculated from a combination of the intensity of played sport, time per week and the proportion of the year in which the sport was played regularly.[15] This questionnaire was only used at baseline and 12 months. Its validity and reliability was described in different populations.[15,28]

Statistical Methods

All statistical analyses were performed using SAS 9.4 software[e] and R version 3.0.1[f] using a significance level of .05 (2-tailed). The power analysis was described elsewhere.[22] Normality was verified, if required, square root transformed (pedometer, PASIPD, diary and activity levels).

To assess differences in the ACG and CG patient' characteristics, different test were used dependent on the type and distribution of data. A linear mixed-effects model was used to investigate the differences between the training groups in phase I and over 4 time points (Phase I-II) for all outcomes with fixed factors time and group, time-by-group interaction, and a subject-specific intercept. Group-specific training and time effects were compared between the groups by post hoc testing. To correct for multiple comparisons, the Bonferroni-Holm correction was used. The severity of motor deficit was also incorporated in the model as a fixed effect and interactions with time, treatment, and time by treatment were investigated. Finally, in a subgroup of patients who could not walk 10m at baseline, the same mixed-effects model was used to determine differences in PA level between the ACG and CG patients.

RESULTS

Participants

No significant differences were observed in patients' characteristics between groups at baseline. The flow of participants and drop-outs through the study was described elsewhere.[22] To summarize, 59 patients were included (ACG, n=33; CG, n=26) and 56 patients completed the 3-month program (ACG, n=31; CG, n=25). At the start of phase II, the ACG-patients were divided in the Co-ACG (n= 15) and the Nco-ACG (n= 16). At the end of phase II, 53 patients finished the entire program (Co-ACG, n=15; Nco-ACG, n=15; CG, n=23).

Treatment effects

In phase I, no group by time interactions were found in PA parameters between the ACG and CG (Table 1, Supplementary Tables A-B-C). However, significant time changes were found for all assessments, except SWP2A, PASIPD, diary and moderate activities. In particular in the ACG more steps ($p<.001$) were measured, due to more steps in the subgroup Nco-ACG ($p<.05$). In the other subgroup of ACG (Co-ACG; $p<.01$) more light activities were reported. In phase I and II, also no group by time interactions were found between the AC groups and CG. Again, significant time changes were found for all assessments ($p\leq.02$). In particular, when 6 months measures were compared to baseline, more light activities were reported ($p=.01$) in the Co-ACG and steps ($p<.05$) were measured in the CG. When 6 months were compared to 3 months, lower SWP2A (Nco-ACG) and PASIPD (CG) scores were found ($p<.05$). Interestingly, in 12 months compared to baseline, a deterioration was seen in CG for PASPID ($p<.001$) and Baecke (sport/leisure) scores ($p<.01$) and in the AC groups a significant increase was noted in light

Table 1: Analysis of outcome parameters per treatment group based on a Linear mixed-effects model.

Outcome parameter	Data per Group				Linear mixed-effects model					
	Phase I		Phase II		Phase I			Phase I + II		
	Baseline, Mean ±	3 mo, Mean ±	6 mo, Mean ±	12 mo, Mean ±	Time	Group	Group*Time	Time	Group	Group*Time
Pedometer (Yamax Digiwalker SW-200), (Number of steps)										
CG	3154.8 (1078.5-4417.3)	4789.0(1458.3-7036.3)	5694.8 (1366.8-8316.8)*	3722.3 (804.6-6810.0)	$F_{1,52}$= 27.65	$F_{1,52}$= .44	$F_{1,52}$= .59	$F_{3,149}$= 11.33	$F_{2,149}$= .32	$F_{6,149}$= .50
ACG	2657.3 (1145.8-4909.8)	5340.3 (2304.3-9417.5)***			p< .001	p= .512	p= .447	p< .001	p= .727	p= .805
Co-ACG	[2569.5 (1634.3-3730.5)]	[2569.5 (2184.3-6065.1)]	5013.2 (926.5-7211.3)	5635.5 (1876.5-8096.8)						
Nco-ACG	[2745.0 (650-5594.6)]	[2745.0 (2324.7-10572.3)*]	4346.0 (2520.3-10044.0)	5018 (1182.5-8170.0)						
Activity monitor (SenseWear Pro2), (EE, kcal/24h)										
CG	1945.43±426.88	2035.85±569.63	1939.03±606.98	2143.44±662.55	$F_{1,41}$= 8.66	$F_{1,41}$= .12	$F_{1,41}$= 1.56	$F_{3,130}$= 4.65	$F_{2,130}$= .01	$F_{6,130}$= .76
ACG	1906.58±394.24	2189.87±667.19			p= 0.005	p= 0.736	p= 0.218	p= 0.004	p=0.992	p= 0.600
Co-ACG	[1929.49±407.78]	[2136.11±513.22]	1973.34±487.93	1955.88±420.70						
Nco-ACG	[1887.96±395.31]	[2232.87±784.40]	1851.95±663.02⁺	2060.69±451.85						
PASIPD, total score										
CG	7.71 (7.02-9.60)	8.15 (4.78-11.01)	3.06 (1.29-9.87)⁺	3.27 (1.45-6.98)***,⁺⁺⁺	$F_{1,54}$= .61	$F_{1,54}$= .53	$F_{1,54}$= .17	$F_{3,152}$= 9.99	$F_{2,152}$= 1.67	$F_{6,152}$= 1.00
ACG	7.71 (7.71-9.33)	9.03 (6.74-10.90)			p= .438	p= .468	p= .683	p< .001	p= .191	p= .428
Co-ACG	[7.71 (7.71-10.24)]	[7.71 (4.02-9.82)]	5.15 (2.57-8.17)	6.17 (2.79-10.81)						
Nco-ACG	[8.25 (6.75-9.28)]	[8.25 (7.83-11.18)]	7.15 (4.14-8.63)	6.88 (3.85-11.95)						
Coded Activity diary, (METs*minutes)										
Sedentary activities										
CG	1040 (873-1153)	1020 (830-1080)	910 (810-1050)	946 (890-1020)	$F_{1,52}$= 5.39	$F_{1,52}$= .66	$F_{1,52}$= .16	$F_{3,143}$= 3.37	$F_{2,143}$= .09	$F_{6,143}$= .63
ACG	990 (920-1080)	920 (830-1050)			p= .024	p= .423	p= .692	p= .020	p= .910	p= .708
Co-ACG	[1000 (950-1080)]	[1000 (790-1030)]	885 (800-1088)	850 (768-1070)						
Nco-ACG	[970 (865-1134)]	[970 (875-1090)]	940 (880-1050)	910 (815-1035)						
Light activities										
CG	379 (294-586)	484 (298-702)	471 (342-771)	635 (450-775)	$F_{1,52}$= 9.49	$F_{1,52}$= .21	$F_{1,52}$= .70	$F_{3,143}$= 14.41	$F_{2,143}$= .49	$F_{6,143}$= 1.61
ACG	410 (294-586)	517 (373-730)			p= .003	p= .645	p= .406	p< .001	p= .613	p= .148
Co-ACG	[410 (295-525)]	[410 (430-840)**]	679 (473-834)**	752 (538-837)**						
Nco-ACG	[430 (296-600)]	[430 (348-576)]	660 (461-789)	715 (419-869)*						
Moderate activities										
CG	345 (260-524)	370 (270-660)	510 (230-810)	305 (120-515)	$F_{1,52}$= .03	$F_{1,52}$= .00	$F_{1,52}$= .28	$F_{3,143}$= 3.87	$F_{2,143}$= .33	$F_{6,143}$= .65
ACG	390 (295-510)	420 (265-588)			p= .857	p= .991	p= .596	p= .011	p= .717	p= .690
Co-ACG	[400 (305-580)]	[400 (270-590)]	407 (214-498)	330 (174-489)						
Nco-ACG	[315 (260-508)]	[315 (246-610)]	348 (203-470)	246 (160-438)						
Baecke (Sport scores)										
CG	2.46±1.24			1.57±0.82**				$F_{1,51}$= 6.43	$F_{2,51}$= 1.75	$F_{2,51}$= 2.47
ACG	2.48±0.91							p= 0.014	p= 0.184	p= 0.095
Co-ACG	[2.45±0.86]			2.28±0.73						
Nco-ACG	[2.50±0.98]			2.31±1.14						
Baecke (Leisure scores)										
CG	2.63±0.75			2.08±0.46**				$F_{1,51}$= 9.99	$F_{2,51}$= .96	$F_{2,51}$= 2.10
ACG	2.65± 0.69							p=0.003	p= 0.388	p= 0.132
Co-ACG	[2.63±0.76]			2.57±0.67						
Nco-ACG	[2.67±0.65]			2.34±0.69						

P= percentile; ±= Standard deviation; CG= control group; ACG= active cycling group; Co-ACG= ACG with coaching; Nco-ACG= ACG without coaching; PASIPD= Physical Activity Scale for Individuals with Physical Disabilities; EE= energy expenditure; *,**,*** significant to baseline (*p<.05,**p<.01,***p<.001); ⁺, ⁺⁺⁺ significant to 3 months (⁺p<.05, ⁺⁺⁺p<.001); Within-subjects (Time) and between subjects (Group) effects and Within-subjects effects X Group (Group*Time) were calculated using a Linear Mixed Effects model. The amount missing data per outcome parameter is mentioned in a Supplementary Table C.

Table 2: Analysis of outcome measures in stroke patients who could not walk 10m independently at baseline.

Outcome parameter	Data per group: Phase I, Baseline, Mean ±	Phase I, 3 mo, Mean ±	Phase II, 6 mo, Mean ±	Phase II, 12 mo, Mean ±	Linear mixed-effects model, Phase I + II: Time	Group	Group*Time
SenseWear Pro2 Activity monitor (EE, kcal/24h)							
CG	1782.08±451.29	1984.23±672.97	1664.63±672.74	2035.84±853.91	$F_{3,59}$= 4.53	$F_{1,59}$= .02	$F_{3,59}$= .72
ACG	1813.65±359.88	2171.16±878.32	1666.41±602.00^{+}	1867.16±403.02	p= .006	p= .883	p= .544
Baecke questionnaire (Sport scores)							
CG	3.07±1.21			1.43±0.98**	$F_{1,24}$= 14.83	$F_{1,24}$= .00	$F_{1,24}$= 4.75
ACG	2.46±0.92			2.02±1.01	p< .001	p= .962	p= .039
Baecke questionnaire (Leisure scores)							
CG	2.75±0.73			1.91±0.41**	$F_{1,24}$= 19.98	$F_{1,24}$= .20	$F_{1,24}$= 2.17
ACG	2.65±0.58			2.23±0.64	p< .001	p= .660	p= .153
	Median (P25-P75)	Median (P25-P75)	Median (P25-P75)	Median (P25-P75)			
Yamax Digiwalker SW-200 pedometer, (Number of steps)							
CG	1105.0 (731.7-3091.7)	2495.0 (1078.3-4789.0)	1400.0 (1018.3-5485.0)	1296.8 (472.3-6398.4)	$F_{3,67}$= 3.10	$F_{1,67}$= .30	$F_{3,67}$= .06
ACG	2075.7 (519.6-3964.4)	2884.2 (1691.3-5378.3)	3642.0 (1150.0-5948.6)	3142.0 (828.8-5069.8)	p= .033	p= .586	p= .980
Physical Activity Scale for Individuals with Physical Disabilities (PASIPD), total score							
CG	7.71 (7.71-10.0)	8.67 (7.98-11.15)	3.17 (1.29-8.60)$^{*,++}$	3.27 (1.57-5.04)$^{**,+++}$	$F_{3,69}$= 14.45	$F_{1,69}$= .13	$F_{3,69}$= .97
ACG	7.71 (5.79-8.56)	9.25 (7.71-9.91)	6.66 (3.86-7.98)	6.03 (3.20-7.53)$^{+}$	p< .001	p=.718	p= .413
Coded Activity diary, Sedentary activities (METs*minutes)							
CG	1020 (880-1160)	1030 (900-1110)	1045 (848-1205)	963 (928-1033)	$F_{3,64}$= 1.09	$F_{1,64}$= .14	$F_{3,64}$= .61
ACG	1020 (920-1160)	1005 (843-1090)	1020 (850-1115)	950 (853-1068)	p= .361	p= .709	p= .613
Coded Activity diary, Light activities (METs*minutes)							
CG	375 (295-588)	458 (253-565)	418 (266-608)	653 (463-797)$^{*,+,\dagger}$	$F_{3,64}$= 10.36	$F_{1,64}$= .66	$F_{3,64}$= 1.92
ACG	328 (265-505)	471 (337-625)	580 (335-785)	688 (452-904)***	p< .001	p= .421	p= .135
Coded Activity diary, Moderate activities (METs*minutes)							
CG	370 (260-580)	350 (270-705)	365 (88-705)	183 (70-324)	$F_{3,64}$= 5.87	$F_{1,64}$= .03	$F_{3,64}$= .30
ACG	390 (260-510)	408 (268-563)	273 (165-433)	230 (119-311)	p=0.001	p= 0.874	p= .826

CG= control group; ACG= active cycling group; Co-ACG= ACG with coaching; Nco-ACG= ACG without coaching; EE= energy expenditure; *,**,*** significant to baseline (*p<.05,**p<.01,***p<.001); $^{+}$, $^{+++}$ significant to 3 months ($^{+}$p<.05, $^{+++}$p<.001); Within-subjects (Time) and between-subjects (Group) effects and Within-subjects effects X Group (Group*Time) were calculated using a Linear mixed effects model. The amount missing data per outcome parameter is mentioned in a Supplementary Table C.

activities (Co-ACG, $p<0.01$; Nco-ACG, $p<0.05$). Interestingly, in 12 months compared to baseline, a deterioration was seen in CG for PASPID ($p<.001$) and Baecke (sport/leisure) scores ($p<.01$) and in the AC groups a significant increase was noted in light activities (Co-ACG, $p<0.01$; Nco-ACG, $p<0.05$). This deterioration in PASIPD scores was also found in 12 to 3 months ($p<.001$).
The severity of motor deficit was also incorporated in the model as a fixed effect and interactions with time, treatment and time by treatment were investigated with no significant effects found.
Additionally, we investigated if patients with severe motor functions deficits benefited more from the AT program. Results showed one group by time interaction in Baecke (sport) scores ($p=.039$) in patients who were unable to walk 10 meter at baseline (Table 2, Supplementary Table C-D). Furthermore, in this subgroup, significant improvements over time were found in all outcome parameters ($p\leq.033$).
Additionally in the ACG, a decrease in SWP2A and PASIPD scores (6mo vs 3mo, $p<.05$; 12mo vs-3mo, $p<.05$) was found and an increase in light activities (12mo vs baseline, $p<.001$).
In the CG a deterioration was found in PASIPD scores (6mo vs baseline, $p<.05$; 6mo vs 3mo, $p<.01$). This deterioration over time in CG was further confirmed in PASIPD and Baecke (sport/leisure) scores (12mo vs-baseline, $p<0.01$; 12mo vs 3mo; $p<.01$). When 12-month measures were compared to baseline, 3 and 6 months, an increase in light activities was found in the CG ($p<.05$).

DISCUSSION

In this study no significant differences between groups were found, except in a subgroup of patients with severe motor functions deficits at baseline. Here, the AT program might facilitate patients to practice sport 1-year after a stroke event. Furthermore, significant differences over time were found in almost all objective and self-reported measures.

Although in the complete group of ACG and CG no group over time differences were detected in phase I and II, significant improvements were found over time in the ACG. At the end of phase I, an increase in number of steps per day was found in the ACG and Nco-ACG and in light activities in the Co-ACG. Presumably the training experience combined with education contributed to these results.
Throughout phase II, significantly more activities of light intensity were performed in the Co-ACG (6-12 months) and in Nco-ACG (12 months) as compared to baseline. Light activities (>1–<3 METs e.g. grooming, light household activities) are generally considered to be of low intensity and therefore, not suitable for reducing mortality.[29] However, this may provide a sufficient training stimulus for persons whose functional capacity is less than 6 METs.[30]

Besides this, it is recommended to reduce time spent in sedentary behavior as it is associated with increased mortality.[3] The AT program did not influence sedentary behavior. Except improvements over time within the AC-groups, also in the CG a significant increase was found in pedometer and total diary results at 6 months. It has been proven in cardiac patients that pedometers motivate patients as they make steps visible and so provide feedback on walking.[31]

Perhaps this also influenced the diary recordings. At 12 months, this significant difference disappeared, possibly because of the long period after ending the 3-month intervention. We believe that the CG patients were more active than normal during 3 days of monitoring because the self-reported PASIP scores showed a significant deterioration in reported PA per week at 6 and 12 months and the Baecke (sport) participation decreased compared to baseline. Maybe, more habitual PA will be explored, when monitoring for more than 3 days. Remarkably, in AC groups only one significant deterioration was found over time, namely in the Nco-ACG in the SWP2A results between 3 and 6 months, which disappeared at 12 months. Further, in the AC groups no significant deterioration over time was found, which is in favor of our intervention approach.

One-year after the start of the AT approach, patients with severe motor function deficits showed significantly more sport participation than the CG patients (p=.039). In this subgroup, 12 out of 15 AC patients declared to practice sport at 12 months compared to 2 out of 11 CG patients. At baseline, 5 out of 17 ACG patients and 3 out of 11 in CG declared not to practice sport pre stroke. Presumably, the cycling and education experience, and for some patients followed by coaching might have facilitated sport participation in patients with severe motor deficits. However, considering the most conservative Bonferroni correction of multiplying p-values by 3 (because we reused the data in phase I, phase I+II and in a subgroup) we notice that this significant difference in sport participation in this subgroup of patients disappears (p=.117) and thus this result needs to be interpreted with caution. Also significance disappeared when all patients in the ACG and CG were compared (p=.095). Previous research confirmed that long-term sport participation is low among patients with disabilities as a result of person related factors (e.g. reduced mobility), environmental factors (e.g. transport) and availability of equipment.[32] In particular, attention needs to be given to these patients to facilitate the transition from a supervised AT program to an active lifestyle.[32] Future research should consider patients' functional limitations, as well as the individual's personal preferences as also stated by Billinger et al[3].

In general, relatively low sport participation scores were found in all groups at baseline, which were comparable with another study (mean Baecke/sport=2.3 ± 0.8)[33]. An explanation might be that patients often have a pre stroke life without sports, which may result in little motivation to increase PA post stroke.[34] This is in contrast with recent guidelines in stroke prevention, which recommend to train 3 to 5 days per week large-muscle activities (e.g. walking, cycling).[3]

Evidence exists that an AT program needs to be implemented during inpatient rehabilitation, as lifestyle changes should be formed prior to patient discharge, spontaneous recovery is greatest and it increases self-efficacy and knowledge about exercise.[35] In Biasin's study[36], 4 out of 6 participants, who did not exercise regularly pre stroke declared to continue exercising after discharge. Yet, it is not explored which approach is preferred to improve training compliance after ending the program. Touillet et al[37] showed that 3 months after an AT program combined with PA education sessions, 8 of 9 patients did not maintain their PA level after discharge. Also in another study, participation in an inpatient AT did not increase PA after discharge.[38] An explanation might be that participants may not feel confident in continuing the program without the support of a trained professional.[39] Also a lack of adapted training equipment was described as a barrier. In our study, the coaching approach attempted to facilitate further training. We did not register the reasons why patients increased or decreased their PA.

The strengths of our study include the stratified randomization, the long term follow-up, the use of a blinded assessor and the unique training approach which was clinically applicable in subacute patients with severe motor function deficits. Furthermore, detailed information about different PA levels was obtained using validated instruments.

Study limitations

When interpreting the results of this study, some considerations should be taken into account. There is a lack of data of exercise sessions and data concerning objective PA measures should be transmitted without patients having access. Additionally, the small sample size in phase II may have influenced the results. Finally, the SWP2A device showed frequent malfunctioning or loosening at the nonparetic arm, which could often not be resolved with the paretic arm.

CONCLUSION

When AC combined with education is used in subacute patients with severe motor function deficits before starting AT, more sports participation might be observed after 1 year. No other significant group differences were found over time. In all groups, however, patients showed significant improvement over time in PA measures. Future work should focus on facilitating coaching after an AT-program.

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SUPPLEMENTARY FILES

Supplement A: Estimates and Confidence intervals based on a mixed-effects model (Phase I) for outcome parameters reported in Table 1.

	Linear mixed-effects model (Phase I)		
	Time	Group	Group*Time
Pedometer (Yamax Digiwalker SW-200), (Number of steps)			
ACG	β= 12.88 (4.43 to 21.34)	β= 1.97 (-11.78 to 15.72)	β= 4.40 (-7.12 to 15.91)
Activity monitor (SenseWear Pro2), (EE, kcal/24h)			
ACG	β= 109.41 (-89.27 to 308.09)	β= -37.20 (-318.30 to 243.91)	β= 161.72 (-99.38 to 422.82)
PASIPD, total score			
ACG	β= .15 (-.23 to .53)	β= .16 (-.22 to .54)	β= -.10 (-.62 to .41)
Coded Activity diary, sedentary activities, (METs*minutes)			
ACG	β= -.66 (-1,67 to .35)	β= -.27 (-1,49 to .94)	β= -.27 (-1.65 to 1.11)
Coded Activity diary, light activities, (METs*minutes)			
ACG	β= 1.45 (-.45 to 3.35)	β= -0.04 (-2.54 to 2.46)	β= 1,08 (-1,51 to 3,67)
Coded Activity diary, moderate activities, (METs*minutes)			
ACG	β= .83 (-2.60 to 4.26)	β= .61 (-2,78 to 3.99)	β= -1.24 (-5.91 to 3.43)

ACG= active cycling group; Within-subjects (Time) and between-subjects (Group) effects and Within-subjects effects X Group (Group*Time) were calculated using a Linear mixed-effects model; β= Estimate and (95% confidence interval) out of the mixed-effects model.

Supplement B: Estimates and Confidence intervals based on a mixed-effects model (Phase II) for outcome parameters reported in Table 1.

Outcome parameter	Linear mixed-effects model: Time			Group		Group*Time					
	3 mo	6 mo	12 mo			3 mo		6 mo		12 mo	
				Co-ACG	Nco-ACG	Co-ACG	Nco-ACG	Co-ACG	Nco-ACG	Co-ACG	Nco-ACG
Pedometer (Yamax Digiwalker SW-200), (Number of steps)											
β	12.90	13.63	7.92	-.56	4.20	3.13	6.49	1.00	.89	8.54	.79
CI Upper	4.30	4.91	-1.06	-18.58	-13.13	-11.14	-7.49	-13.34	-13.17	-5.96	-13.43
CI Lower	21.50	22.35	16.89	17.46	21.54	17.39	20.48	15.35	14.96	23.04	15.02
Activity monitor (SenseWear Pro2), (EE, kcal/24h)											
β	131.77	-33.26	158.66	9.89	-45.85	52.10	199.16	93.7695	-19.7254	-119.88	-9.49
CI Upper	-73.38	-224.15	-36.11	-345.68	-386.66	-285.66	-112.13	-229.80	-325.97	-451.96	-318.17
CI Lower	336.92	157.62	353.42	365.46	294.96	389.86	510.45	417.34	286.52	212.19	299.19
PASIPD, total score											
β	.15	-.52	-.75	.21	.11	-.35	.11	-.20	.28	.23	.53
CI Upper	-.23	-.91	-1.15	-.33	-.40	-.99	-.52	-.85	-.35	-.42	-.10
CI Lower	.54	-.13	-.36	.76	.62	.29	.73	.45	.91	.88	1.16
Coded Activity diary, sedentary activities, (METs*minutes)											
β	-.65	-1.10	-1.09	.10	-.62	-.96	.40	-.21	1.04	-.30	.55
CI Upper	-1.62	-2.10	-2.12	-1.45	-2.14	-2.55	-1.21	-1.84	-.61	-1.95	-1.12
CI Lower	.32	-.10	-.06	1.65	.89	.64	2.01	1.42	2.69	1.35	2.22
Coded Activity diary, light activities, (METs*minutes)											
β	1.44	1.5	4.19	-.46	.36	2.97	-.91	3.34	1.45	.59	-.39
CI Upper	-.41	-.39	2.23	-3.57	-2.68	-.06	-39.75	.24	-1.70	-2.54	-3.57
CI Lower	3.29	3.41	6.15	2.64	3.41	5.99	2.15	6.44	4.59	3.73	2.79
Coded Activity diary, moderate activities, (METs*minutes)											
β	.79	1.33	.75	.47	-1.75	.47	-.52	-4.82	-4.25	-1.11	-1.26
CI Upper	-2.71	-2.26	-3.98	-4.16	-7.49	-4.16	-6.29	-10.69	-10.17	-7.04	-7.25
CI Lower	4.29	4.92	5.47	5.10	3.99	5.10	5.26	1.04	1.67	4.82	4.72
Baecke (Sport scores)											
β			-.91	-.01	.05					.75	.72
CI Upper			-1.42	-.65	-.56					-.06	-.06
CI Lower			-.41	.65	.66					1.56	1.51
Baecke (Leisure scores)											
β			-.57	-.01	.02					.51	.24
CI Upper			-.88	-.44	-.39					.01	-.25
CI Lower			-.26	.42	.43					1.00	.72

Co-ACG= active cycling group with coaching; Nco-ACG= active cycling group without coaching; Within-subjects (Time) and between-subjects (Group) effects and Within-subjects effects X Group (Group*Time) were calculated using a Linear Mixed Effects model; β= Estimate; CI Upper and Lower= 95% confidence interval out of the Mixed Effects model.

Supplement C: Number of patients for outcome measures reported in Table 1 and Table 2.

Table 1

Baseline	CG: n=26 (n=25 Activity monitor).
	ACG: n=33 (n=32 Pedometer; n=31 Activity diary; n=29 Activity monitor).
3 months	CG: n=25 (n=18 Activity monitor).
	ACG: n=31 (n=29 Pedometer, Activity monitor, Activity diary; n=28 Activity monitor
6 months	CG: n=24 (n=23 Activity monitor, Activity diary).
	Co-ACG: n=14 (n=13 Activity monitor, Activity diary).
	Nco-ACG: n=15 (n=14 Activity monitor, Activity diary).
12 months	CG: n= 23 (n=22 Pedometer; n=21 Activity monitor, Activity diary)
	Co-ACG: n= 14 (n=13 Activity monitor; n=12 Activity monitor).
	Nco-ACG: n=15 (n=14 Pedometer, PASIPD, Activity diary).

Table 2

Baseline	CG: n=11.
	ACG: n=17 (n=16 Pedometer; n=15 Activity monitor, Activity diary).
3 months	CG: n=11 (n=10 Activity monitor).
	ACG: n=15 (n=14 Pedometer, Activity diary; n=11 Activity monitor).
6 months:	CG: n=11 (n=10 Activity monitor, Activity diary).
	ACG: n=14 (n=13 Activity diary; n=12 Activity monitor).
12 months	CG: n= 11 (n=10 Pedometer, Activity monitor, Activity diary).
	ACG: n=15 (n=13 Pedometer, PASIPD; n=12 Activity monitor, Activity diary).

Supplement D: Estimates and Confidence intervals based on a mixed-effects model (Phase II) for outcome parameters reported in Table 2.

Outcome parameter	linear mixed-effects model (Phase II)						
	Time			Group	Group*Time		
	3 mo	6 mo	12 mo	ACG	3 mo ACG	6 mo ACG	12 mo ACG
SenseWear Pro2 Activity monitor (EE, kcal/24h)							
β	193.45	-126.12	245.03	31.53	176.52	-7.10	-173.66
CI Upper	-150.77	-470.35	-99.20	-450.53	-292.49	-469.44	-636.41
CI Lower	537.68	218.11	589.26	513.59	645.53	455.24	289.10
Baecke questionnaire (Sport scores)							
β			-1.59	-.59			1.15
CI Upper			-2.43	-1.40			.06
CI Lower			-.75	.22			2.24
Baecke questionnaire (Leisure scores)							
β			-.84	-.13			.42
CI Upper			-1.29	-.60			-.17
CI Lower			-.39	.35			1.00
Yamax Digiwalker SW-200 pedometer, (Number of steps)							
β	11.63	10.22	8.22	3.17	.94	3.65	.60
CI Upper	-2.16	-3.56	-5.99	-16.31	-17.37	-14.66	-18.24
CI Lower	25.41	24.01	22.44	22.64	19.26	21.97	19.43
Physical Activity Scale for Individuals with Physical Disabilities (PASIPD), total score							
β	.09	-.79	-.07	-.19	.14	.41	.52
CI Upper	-.42	-1.31	-1.58	-.76	-.53	-.27	-.17
CI Lower	.61	-.28	-.55	.38	.81	1.09	1.20
Coded Activity diary, Sedentary activities (METs*minutes)							
β	-.04	.49	-.85	.13	-.74	-1.03	.10
CI Upper	-1.49	-1.01	-2.35	-1.78	-2.67	-3.03	-1.91
CI Lower	1.42	1.99	.65	2.04	1.20	.96	2.12
Coded Activity diary, Light activities (METs*minutes)							
β	-.17	-.02	4.52	-0.64	2.31	4.08	.81
CI Upper	-2.83	-2.77	1.77	-4.18	-1.24	.43	-2.88
CI Lower	2.49	2.73	7.27	2.89	5.85	7.73	4.50
Coded Activity diary, Moderate activities (METs*minutes)							
β	.56	-1.95	-6.59	.66	-1.12	-2.92	.13
CI Upper	-469	-7.35	-11.99	-5.06	-8.09	-10.08	-7.11
CI Lower	5.80	3.45	-1.19	6.38	5.85	4.24	7.37

ACG= active cycling group; Within-subjects (Time) and between-subjects (Group) effects and Within-subjects effects X Group (Group*Time) were calculated using a Linear Mixed Effects model; β= Estimate; CI Upper and Lower= 95% confidence interval.

General discussion

INTRODUCTION

Here, I will review the five research questions of this doctoral thesis, and discuss the main findings. Furthermore, clinical implications and methodological issues will be highlighted. Finally, recommendations for future research will be formulated.

The general aims were to gain insight in the assessment of PA in stroke patients and to explore the short and long-term effects of a new AT program in subacute stroke patients. Consequently, this thesis consisted of two major parts (Part A: Assessments of PA and Part B: The effects of an AT program) and 5 research questions as described in Table 1.

Table 1: Schematic overview of the hypotheses and research questions in the doctoral thesis.

Part	Chapter	Hypothesis	Research question
Part A: Assessment of PA	1	A YDWP is more valid and reliable then a hip-worn in stroke patients.	Which measurement technique is the most accurate to determine physical activity after stroke: a left or right arm-worn SWP2A or a hip or knee YDWP?
		A SWP2A, worn on the non-paretic arm instead of the recommended right arm, is an accurate device to detect the intensity of PA.	
	2	A 3-day coded-activity diary, is easy to use and of low cost, and valid in reporting activity levels together with daily EE in subacute stroke patients.	How to determine the activity levels together with the daily EE in stroke patients at a low cost?
	3	A detailed information about PA is obtained when using objective devices combined with a self-reported measure and when this is used in different phases of recovery.	How physically active are hospitalized and home-living stroke patients?
Part B: Effects of an AT program	4	A supervised AT program started in the subacute phase of recovery and combined with education, and followed by coaching might have a positive effect on A-Cap, leg strength and walking speed on the long-term.	What are the effects of an AT program on A-Cap, strength of the quadriceps muscle and gait speec in subacute stroke patients?
	5	A supervised AT program combined with education and followed by coaching facilitates stroke patients to life more physically active.	What are the effects of an AT program on PA in subacute stroke patients?

AT= aerobic training;; EE= energy expenditure; HOM=Home-living patients ; HOS= hospitalised patients; PA=Physical activity; SWP2A= SenseWear Pro2 accelerometer; YDWP = Yamax Digi-walker SW-200.

DISCUSSION OF RESEARCH QUESTIONS AND MAIN FINDINGS OF PART A CONCERNING THE ASSESSMENT OF PA AFTER STROKE

Chapter 1 - Which measurement technique is the most accurate to determine PA after stroke: a left or right arm-worn SenseWear Pro2 accelerometer or a hip or knee Yamax Digi-walker SW-200 pedometer?

The importance of increasing PA after stroke has been well documented and encouraged by clinical guidelines.[1-3] Despite this, PA levels are not routinely measured after stroke. To quantify PA, we need accurate devices that take into account certain characteristics of this population such as asymmetry, slow gait speed and use of walking aids.[4,5]

In literature, a StepWatch Step Activity Monitor was already proven to measure steps more accurately than a hip-worn YDWP in stroke patients.[6] A StepWatch Step Activity Monitor placed at the ankle does not implicate a standardized position when a patient wears high orthopedic shoes. Also it needs programming and is visible while wearing. This device was therefore less applicable and together with a high cost, we decided not to study further its clinimetric properties.

Although several studies have reported the usage of a spring-levered hip-worn YDWP in stroke patients, it is not recommended for patients with gait speeds below 0.5 m/s. Here it do not detect steps. Pedometers work more accurate at gait speeds above 0.5 m/s. However, it still tends to undercount in particular with more undercounting while walking slower.[6-8] It has been proven that spring-levered pedometers need a vertical acceleration of the joint where the pedometer is attached, to cause contact of the lever arm with the electrical contact.[9] Consequently, it is expected that patients with short strides or shuffling gait perform more vertical acceleration at the knee than at the hip. Maybe this type of pedometer, which is affordable and simple in usage, could measure more accurately when positioned at the knee than at the hip.

Another device, the SWP2A, is placed at the upper limb and therefore might be less sensitive to gait disorders after stroke. As this device was already proven to be valid in healthy persons[10], we decided to explore this further. Also, the developer's manual recommended wearing the device at the right arm, which could be at the hemiparetic side.

Therefore, we studied the clinimetric properties, by means of validity and reliability, of a left and right-worn SWP2A and a hip and knee-worn YDWP to determine which device is preferred to measure EE after stroke (Chapter 1).

We used an elastic patella support strap to position the pedometer at the knee, position which was well tolerated by the included participants. ***We found that this device was more valid in measuring steps positioned at the knee than at the hip in slower gait speeds on the treadmill and on flat surface at normal and increased speed. (Hypothesis confirmed)*** This opens perspectives in stroke research to monitor patients with short strides or shuffling gait in clinical trials.

The SWP2A was not valid in representing the number of steps at both arms. Furthermore, this multi-sensor activity monitor correlated fair to poor in resting conditions with indirect calorimetry, and varying results were found in other activities. (Hypothesis not confirmed) Possibly the 4-minutes of time registration was too short to measure EE correctly as stated in previous reports.[11] Also it was not clear if patients achieved sufficient arm swing during each 4-minutes test, which may have impacted the accuracy of the accelerometer. We concluded that the SWP2A should not be used to measure step counts in stroke patients. This conclusion was in accordance with a recent study of Manns et al.[12] We decided to use the SWP2A in the following studies only for the measurement of EE, during longer periods and in a free-living environment. We decided to publish the SWP2A data in the following studies, because in a study of St-Onge et al.[10] the SWP2A was proven to be valid in free-living adults. We are aware that we still need to take the SWP2A results with caution and that the validity needs to be further explored in free-living stroke patients.

The test-retest reliability of both measures at different locations was proven to be good, which means that both devices measure consistently. (Hypothesis confirmed) Based upon the results of this study, we decided to use the YDW (steps) and the SWP2A (EE) as outcome measures in other studies (Chapter 3-5).

Chapter 2 - How to determine the activity levels together with the daily energy expenditure in stroke patients at a low cost?

After a systematic literature search[13], we concluded that accelerometry-based measures were broadly described. A combination of different measures was needed to identify PA patterns to guide intervention strategies. Consequently, we chose to develop one low-cost measurement technique, a coded PA diary, which gave detailed information about the type and executed activities, the position in which these were executed and the daily EE. We preferred a self-reported measure, because this could help patients to become more aware of their activity level and increase their daily PA. Also we preferred to fill in 30 minutes blocks, as we wanted to use it in hospitalized patients in which activities of shorter duration occur rarely. A list of codes was used to indicate the PA. This was time efficient and easy to fill in so it could also be used by patients with writing problems.

We assessed the concurrent validity in measuring activity levels and total EE of the diary in hospitalized subacute patients***. The diary revealed to be valid in determining sedentary, moderate and total PA and in quantifying daily EE in subacute stroke patients. (Hypothesis confirmed)*** We expected a higher validity for the activity levels because two identical methods were compared. Possibly when shorter time periods were used, more activities can be observed and as a consequence a higher validity might be found.

During this study we noticed that family and nursing care helped the patients who could not fill in the dairy by themselves. The activity diary is applicable in a clinical environment and therefore offers a good alternative for observational methods, which are frequently used in inpatient settings. However, they are described as obtrusive, time and labor intensive, do not capture the intensity of an activity and can over- or underestimate the amount of activity performed due to the low sampling rate.[14] Based upon recent literature, we found it an improvement that we developed a measurement technique that determined different activity levels such as sedentary periods, because long periods of this behavior lead to remodelling and thickening of arterial walls.[15,16] New results show that this could not be reverted by regular moderate to vigorous activities, as was thought first.[15]

Based upon this knowledge, we decided to use the diary as one of the outcome measures in our RCT, in which we included subacute stroke patients and patients that were monitored in more free-living conditions. In this latest group, we have to interpret the diary results with caution, because the diary is not validated in patient in this stage of recovery.

Chapter 3 - How physically active are hospitalized and home-living stroke patients?

Although the consequences of PA on health, well-being and stroke prevention were frequently described in recent years[17,18], stroke patients are generally deconditioned, sedentary and inactive for long periods of time[14,19]. Consequently, researchers focused on using pedometers, accelerometers, self-reported questionnaires, observational methods or video-recordings to quantify PA.[4,13] Often only one or a combination of a few different PA measures were used, which resulted in an incomplete report.[4] Since only few studies[19,20] reported on this matter, the evolution of PA over long-term needs more investigation. In future, standardisation of measurement methods is advised in order to make results more comparable.[4] Also, there is lack of research focusing on type of activities, duration at different levels and awareness of patients with regards to PA.

Thus, we conducted an observational study to measure PA, in hospitalized subacute patients and home-living patients (Chapter 3). With this study we explored the use of the combination of three measures validated in patients with stroke (Chapter 1 and 2) to get a detailed PA report. We decided to include patients from two consecutive phases of recovery, namely subacute and chronic phase. We explored the use of the validated measures prior to an RCT-study starting in subacute phase and with long-term follow-up (Chapter 4 and 5). ***Contrary to our expectations, we concluded that home-living patients walked significantly more steps and expended more energy during three consecutive days compared to hospitalized patients. (Hypothesis confirmed)*** We believed that patients attending inpatient rehabilitations were more active, thus taking more steps and showing higher EE values. However, we overestimated the amount of time stroke patients spent engaged in active therapy. Also in literature, therapists were found to be inaccurate in their estimations of the time stroke survivors spent in physiotherapy sessions, and particularly inaccurate in estimating the time stroke patients were engaged in active task practice during therapy sessions.[21] In particular, measuring PA during therapy sessions in different phases of recovery should be continued and the results should be implemented in treatment strategies.

Patients in both groups showed a reduced PA with a significant amount of time spent carrying out sedentary activities. Also the higher quantity of vigorous intensity activities was accompanied by a relatively lower amount of moderately intensity activity in the home-living compared to the hospitalized patients.

Hereby, we emphasized the importance of measuring different aspects of PA, with special focus on the activity levels and duration of the activities. Recently, it became more important to detect sedentary behavior as it has a deleterious effect on health, independent of the amount of PA.[15,22] For instance, a patient is classified as inactive and therefore not meeting the recommended guidelines for PA. However, this patient had spent little time in seated postures, compared to another patient who was classified to be physical active (e.g. cycling for 30 min per day) despite prolonged periods of sitting.[23] Therefore, reducing or changing sedentary behavior, by means of interventions, may present a new potential therapeutic goal for secondary prevention and rehabilitation of stroke patients.[23,24]

It is also important to report free-living activities during a few consecutive days to reliably assess PA. We chose to monitor for minimum 3 days, as advised in literature for older individuals[25]. Moreover we believed it was more clinical relevant with minimal inconvenience for patients. Therefore, this study was prior to the RCT-study, in which we used our findings to report in detail on PA (Chapter 5).

DISCUSSION OF RESEARCH QUESTIONS AND MAIN FINDINGS OF PART B CONCERNING THE EFFECTS OF AN AT PROGRAM IN STROKE PATIENTS

Chapter 4 - What are the effects of an AT program on A-Cap, strength of the quadriceps muscle and gait speed in subacute stroke patients?

Previously we discussed measurement techniques, relevant to a study in which we want to explore the effects of AT. Here we will discuss the main findings of an RCT-study on A-Cap, strength of the quadriceps muscle and gait speed in subacute stroke patients. Furthermore, the effects of this study in patients with walking disability at the start of the study will be demonstrated.

Included in the analysis were 59 patients who participated in a 3-month AT program. One group cycled on a Motomed device with chip card system combined with information sessions given throughout a 3-month period. Another group underwent a passive mobilisation treatment of the paretic leg also 3 days/week during a 3-month period. After three months the cycling group was divided in a coaching and non-coaching group for a period of nine months. Results indicate that throughout one year, patients in both groups improved on A-Cap, strength of the quadriceps muscle and gait speed. After 3 months of training, differences between both training groups seem to become evident on $Watt_{peak}$. ***No significant long-term between group differences were found. (Hypothesis not confirmed)***

When these results were compared with similar reports, also no group differences over time were found in an AT program of 4 weeks[26], 8 weeks[28] and 12 weeks[27]. We found progress over time, which was in line with previous research, who found an increase of 23.4% in $Watt_{peak}$[26], 2.27 mLkg-1min-1 $VO2_{peak}$[29] and 0.18 m/s gait speed[27] compared to respectively 27.6%, 2.94 mLkg-1min-1 and 0.18 m/s in our study after 3 months of AT. In long-term follow-up measurements, the only progress was found in VO_{2peak}, $Watt_{peak}$, non-paretic leg strength and gait speed in the coaching group. In other groups no progress or even a deterioration was found when 12-month measures were compared to previous ones. We acknowledge that the follow-up approach concerned a feasibility study, due to the small patient numbers after dividing the cycling group and to a lack of objective exercise data. This coaching approach needs to be refined in further research. For example, a wireless system for data transfer might contribute to the evaluation of an AT program. Telephone calls instead of home-visits are recommended to make it more applicable for clinical practice.

To the best of our knowledge, we are the first who combined AT with educational sessions followed by coaching for a long period of 9 months. Up till now, very traditional center-based, supervised treatment sessions rather than assisting patients were performed in adopting AT as a part of a lifestyle change.[29] One study combined AT with PA education sessions, in which 8 of 9 stroke patients did not maintain their activity level 3 months after ending an AT program.[30] Education added to exercise does not seem to be sufficient. Attention needs to be given on the lack of ability that patients experience to continue AT after ending the program, objective and verbal encouragement, PA beliefs and social support from family.[31] Besides education, this was additionally needed to maintain their activity level at follow-up.

We consider it an asset that the Motomed cycling program with chip card revealed to be applicable with little stand-by help for all included patients, in particular in the severely motor impaired persons. Also the recumbent cycle ergometer test with foot shells and leg guides revealed to be safe and feasible for all subacute patients, which was comparable with the results found by Tang et al[32]. Medical pre-screening was performed by a cardiologist as also advised throughout literature.[26] Besides continuous improvement in VO_{2peak}, $Watt_{peak}$, until 12 month and a decrease in the placebo group, we could not prove that patients had more benefit from the cycling approach than from the placebo therapy. In recent literature, it has already been stressed that future research should focus also on AT modalities applicable in severely motor impaired subacute patients and how to supervise them further after the hospitalisation period.[33] Possibly, differentiation of aerobic exercise programs is needed in subgroup of stroke patients, because one AT approach might not serve all patients. In this study, it was a strength that we included severely motor impaired patients as these patients were often excluded in previous research, but also it was seen as a weakness because this made the included population more heterogeneous.

Besides this, we want to emphasize that this RCT-study started in the subacute phase, during which spontaneous recovery is still ongoing. Therefore, the results found in this RCT-study, are in addition to a spontaneous recovery of peak aerobic capacity of 16.9% that occurs during the first 6 months after stroke[34]. In our study mean values of VO_{2peak} (cycling group= 13.12 mL kg-1 min-1; control group=14.17 mL kg-1 min-1) within 3 to 10 weeks after stroke were low compared to age and gender related persons[35] and that 10 mL kg-1 min-1 is required for light instrumental activities during all ADL[36], a small improvement of VO_{2peak} could lead to a large functional carryover. Further, we have to consider that individuals with stroke need a higher $VO2_{peak}$ for basic ADL functions such as walking due to their impairments[37]. These findings confirm the importance of increasing VO_{2peak} as much as possible.

Chapter 5 - What are the effects of an aerobic training program on physical activity in subacute stroke patients?

Besides the effects of the AT program on aerobic capacity, strength of the quadriceps muscle and gait speed (Chapter 4), we also investigated the effects on PA by use of objective and self-reported measures.

One-year after the start of the AT program, we found that patients with gait inabilities prior to the AT program showed more sport participation determined by reflecting over the past month. (Hypothesis partly confirmed) Patients with gross motor function deficits have fewer abilities in sport modalities (e.g. recumbent bike) and need more guidance to come to sport participation. In our training approach, we focused on increasing daily PA and sport participation in the educational sessions during the 3-month AC program and in the coaching approach after ending the program. Also in a recent review, it has been advised to give individual counselling about PA and sports or combine this with supervised exercise programs to improve long-term PA participation and functional exercise capacity after stroke.[38]

Besides higher sport participation in a subgroup one-year after the start of our study, we found rather low sport participation scores in all groups pre stroke. This strengthens the idea that education and coaching is needed after stroke to meet the recommended health guidelines in stroke prevention[39]. Promotion of PA should be implemented in rehabilitation early after stroke, to tend to influence long-term PA lifestyle behavior.

The cycling approach with education stimulated the performance of light activities, e.g. grooming, light household activities, in cycling groups on the long-term. It has been stated that performing activities of too low intensity has no impact on reducing mortality rate.[40] However, these activities might have a training effect in patients with a functional capacity of less than 6 METs.[41] This needs to be further examined.

Unfortunately, we noticed that our AT approach did not have an impact on the many sedentary activities performed in all groups. It is described that long periods of this behavior have a negative influence on the remodelling and thickening of arterial walls.[15] Future AT research in stroke should also focus on changes in sedentary PA on the long-term.

In general, within the study in Chapter 5, we found no significant deterioration in PA measurements in both cycling groups after 1-year follow-up. This is surprising in contrast to non AT long-term follow-up studies, where a decline was found in recovery patterns after stroke rehabilitation by means of Barthel Index and Fugl-Meyer Motor assessment scores.[42-44]

Our AT approach might have slowed down the expected deterioration. This needs to be further addressed in longer follow-up research. We performed measurements at 2-year follow-up, but these results are not yet analysed. They will be discussed in future papers and are therefore not integrated in this thesis.

CLINICAL IMPLICATIONS

The studies included in this thesis have the following clinical implications for stroke patients and their caregivers:

PART A: ASSESSMENT OF PA

Chapter 1	A YDWP is a valid and reliable device to measure at slower gait speeds in stroke patients if it is worn at the knee.
Chapter 2	A coded activity diary is a valid tool to determine sedentary, moderate and total PA and to quantify daily EE in hospitalised stroke patients.
Chapter 3	Hospitalised and home-living stroke patients should be encouraged to increase their PA and spent less time on sedentary activities. In particular, hospitalised stroke patients should be motivated to increase their amount of steps and energy expenditure levels during daytime rehabilitation.

PART B: EFFECTS OF AN AT PROGRAM

Chapter 4	The evaluation of aerobic capacity, using a graded maximal exercise test on a recumbent cycle ergometer adjusted with foot shells and leg guides, is feasible and safe in the subacute stroke population. Medical pre-screening is advised. Evaluation of aerobic capacity, bilateral leg strength, and gait speed should be included in the standard protocol at rehabilitation centers and continued in the community to stimulate long-term compliance. The Motomed AC therapy combined with chip card revealed to be applicable in subacute stroke patients with only little stand-by help of a therapist. An aerobic AC program is applicable in the subacute phase of recovery during inpatient rehabilitation. It was applicable for mild to moderate motor impaired patients and even in severe motor disabled patients. A coaching approach is helpful to support patients during the first months after a supervised training period. Based upon our feasibility study we advise the use of wireless and wearable activity tracking systems to coach stroke patients.
Chapter 5	Evaluation of the amount of PA should be included in the standard protocol at rehabilitation centers and be continued after discharge to stimulate long-term compliance. An AT program is best combined with educational sessions for stroke patients and caregivers to optimise chances for continued PA after ending the program.

METHODOLOGICAL ISSUES

Patient enrolment

Patients included in the RCT-study were not restricted to communicate with other patients during their hospitalisation i.e. about the tests and the different treatment methods. This may have indirectly influenced behavior of all patients, in particular patients in the control group got no educational sessions.

An a priori power calculation in the first 3 months of the RCT-study (Part B: Chapters 5 and 6) resulted in 21 patients per group. This to obtain a power of 80% (using a two sample t-test with alpha=0.05) to detect a clinically significant difference between the cycling and the control group of 12.2 Watt (assuming a standard deviation of 13.7 Watt). This calculation was based on $Watt_{peak}$. Considering dropouts, the goal was to include

25 participants per group. Therefore, 6 years passed to include this number of patients and to finalise all treatments and measurements.

In the second part of the RCT-study, we performed a posteriori power analysis. This revealed that this part of our study did not have enough power, as we needed a total of 73 patients per group to obtain a power of 80% to detect differences using an independent samples T-test (mean difference $Watt_{peak}$: Control group=6.25 Watt; Cycling group= 12.58 Watt; mean standard deviation= 13.52; effect= 12.58-6.25=6.33). This indicates that we have to interpret the results of the second part of our study with caution and that more research needs to confirm these results. However, this part of the study represents a clinical applicable coaching approach, which might help future study designs.

The use of a control group

A placebo therapy was provided to patients in the control group. They underwent a passive mobilisation of the hemiparetic knee on a continuous passive motion device, 3 times a week for 30 minutes. This therapy was given in addition to regular therapy. This might have caused higher motivation and other indirect effects, which could have influenced their outcomes.

Measurements

In every study in this thesis we used a SWP2A, to measure EE per minute. In the study in Chapter 1, this revealed less valid in a lab setting. This was in conflict with the results of St-Onge[10] et al in 2007, where the SWAP2A showed reasonable agreement with double labelled water in measuring total EE in free-living adults. Thus, the accelerometer might improve in accuracy in free-living situations and over longer period of time registration. Therefore, we kept on using them in the next studies as a secondary outcome measure. We therefore acknowledge that the results of these accelerometers should be interpreted with caution.

Patients might have executed more activities than normal during the 3 days of monitoring.

Also they were aware of their levels of PA by writing down the pedometer results every evening and by filling in the diary every 30 minutes. This could have motivated them to live more physically active the following days. This might have influenced the results in ACG patients, who got PA education sessions during 4 sessions. In the CG a deterioration was found in reported PA/week (PASIPD) at 6 and 12 months and in the Baecke/sport participation, which strengthens the idea that these patients were more physically active during 3-days of monitoring but not in their habitual PA. Therefore, it might be better to use objective and self-report measures over 5 days, as recommended in a recent study in older adults[25], which reflects more the habitual PA and sedentary behavior.

In Chapter 2, we did not determine the reliability of the coded activity diary. Only the validity was set in hospitalized patients, but not in other stages of recovery. Therefore, we need to take the diary results in home-living environment with caution (Chapter 3 and 5). Here, we expect that more activities of short duration were performed and that the diary might be more valid when 10-minute time interval were used.

Although the current study shows the feasibility of a graded maximal exercise test on a recumbent bicycle in subacute stroke patients, the issue remains whether or not stroke patients achieved peak levels or true maximum levels of exercise according to the criteria for VO2max[32]. In our study, this test was sometimes stopped for nonaerobic issues for example, mask discomfort, leg fatigue, leg pain or discomfort due to premorbid conditions (e.g. knee pain). We advise to evaluate the A-Cap in subacute stroke patients on a recumbent bike, in which the intensity could be initiated at 0 Watt instead of 20 Watt. Also 1 practice trial is recommended before the actual evaluation is performed.[32] Thus, if adapted devices are used in the selection of testing protocols, most stroke patients who are declared stable for PA can undergo exercise testing. For patients for whom an exercise test is recommended but not performed, lighter-intensity exercise should be prescribed.[1] The reduced exercise intensity may be compensated by increasing the training frequency, duration, or both.[1]

Previously, it has been advised that submaximal, rather than maximal, exercise testing protocols should be used in the early post stroke period.[1] However, Kelly et al.[45] reported that in a sample of 17 subacute stroke patients extrapolated VO_{2peak} values from submaximal exercise tests were higher than those achieved during maximal exercise tests. Valid measures of aerobic capacity early post stroke must be established to avoid the possibility of overtraining or undertraining patients in this patient group.

Until now, no studies have specifically investigated how soon after a stroke a submaximal or a symptom-limited maximal test protocol can be performed safely. Until then, it is advised to follow guidelines similar to those recommended for post myocardial infarction patients and to use submaximal protocols (with a predetermined end point, often defined as a HR_{peak} of 120 beats per minute, or 70% of the age-predicted HR_{max}, or a MET_{peak} level of 5) early after stroke.[46,47]

ACG protocol

This study has shown that the ACG protocol is feasible in subacute stroke patients. However, we used one protocol for all the patients included in the ACG group. We expect that differentiation of aerobic exercise programs in a subgroup of stroke patients is needed to gain more benefits. We believe that the current ACG protocol is applicable in more severely motor impaired patients or severe deconditioned patients. Possibly, in less deconditioned patients, in moderate motor impaired patients or in chronic phase of recovery, the ACG protocol should be altered. For example, higher training intensities or more weeks of continuous training, or both may be needed to obtain more pronounced effects. The positive effects of high-intensity training in chronic stroke on gait speed and A-Cap may support this thought.[48] Also, we recommend these subgroup of patients to train on a stationary bike or a treadmill instead of a MOTOmed leg trainer.

Educational sessions and coaching approach

Educational sessions, such as the ones given to the cycling group in the RCT-study are preferably organized as group sessions and not individually, to make it less time-consuming for the therapist.

In the second part of this study, we did not gather objective exercise data (e.g. Workload, HR) and thus it is difficult to evaluate the adherence to the program. Patients were asked retrospectively about how and when they trained, the duration and their HR. Consequently, we have no certainty about frequency, intensity and duration of training. A wireless system for data transfer might contribute to the evaluation of an AT program. Besides this, the monthly face-to-face support required a lot of travel-time and effort from the coach. Results of previous studies have shown that telephone calls as well as face-to-face programs or mail-mediated programs can be effective in increasing PA and thus can facilitate implementation of coaching in clinical practice.[49,50]

RECOMMENDATIONS FOR FUTURE RESEARCH

In this doctoral thesis, we were looking to broaden the assessment of PA and the effect of AT after stroke. While our results contribute to the understanding of PA and CRF in subacute stroke patients, they incite to even more questions waiting to be addressed in further research.

Recommendations for assessments

Long-term follow-up research with measurement of different aspects of PA is vital to gain better insight in type and intensities of PA, sedentary behavior, CRF and cardio-metabolic health. We need to consider using similar methods of measurement and outcome parameters to allow pooling of data. Consensus about PA measurements would also facilitate to explore the effect of AT programs and other health-enhancing programs following stroke. In particular, the reliability of the coded activity diary should be determined in different phases of recovery and the validity should be further determined in home-living patients. It would be interesting to explore the correlations between objective and self-reported measures in subacute and home-living patients.

We recommend a cardiologic screening in stroke patients on a recumbent bicycle adjusted with foot shells and leg guides. Based on the screening an individual AT program should be added to a patient's rehabilitation program with retest on a regular basis.

Recommendations for CRF training

We advise to obtain more insights in therapy compliance during follow-up, namely in the coaching period after a 3-month exercise program. We need objective exercise recordings in outpatient settings. We prefer no physical presence of a physiotherapist during exercise, as this is time-consuming and not applicable in clinical practice for example due to travel-time and financial cost. Therefore, we advise to promote easy to apply wireless systems for data transfer with no cooperation from patients needed. A solution might be found within telerehabilitation which is defined as rehabilitation services to patients at a remote location using information and communication technologies[51-56]. In recent literature, many studies describe technical telerehabilitation systems[57-61], which still require manual data input of the patient or physiotherapist causing possible bias.

As a consequence, we performed a systematic review search to outline all available telerehabilitation devices with focus on direct PA data transfer with a thorough description of an AT program. As a result, 9 RCTs were involving 746 adults.[62-70] In 7 PA parameters significant changes were found, namely in VO_{2peak} (13.0 ±2.3 mL kg-1 min-1 to 17.2 ±3.9 mL kg-1 min-1 ($p < 0.05$)), blood pressure (systolic BP; 114.8 ±15.3 mmHg to 116.2 ±15.1 mmHg ($p<0.01$)), steps per day (increased; +19.15% ($p < 0.05$)), exercise duration (7.98 ±2.80 min ($p < 0.01$)) and 6-minute walking test ($p < 0.05$). Of all 9 included studies only 3 long-term (12 months) studies were performed.[58-60] Therefore, further long-term research within this topic is needed to clarify the effects of telerehabilitation combined with an AT program and to determine which exercise data can be wirelessly transmitted.

In addition, we recommend including more patients in AT programs, so the coaching approach could have more power.

Finally, patients with moderate to severe motor impairment are an under researched group in aerobic exercise studies. Therefore long-term benefits are not yet described. However, they are very susceptible to treatment, in particular when little stand-by help of a therapist is needed and therefore should be prioritized in further separate studies. New AT studies should focus on differentiation of aerobic exercise programs in subgroup of stroke patients, because one AT approach might not serve all patients. Also in each subgroup of patients long-term guidance should be implemented based on their needs. This to overcome barriers to participation and foster motivation to promote behavior change and support patients' long-term participation in PA.

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Summary

Physical mobility limitations are common after stroke and frequently lead to poor participation in physical activity (PA). It remains a challenge to measure accurately daily PA in stroke patients, because of their gait disturbances with associated weakness, spasticity and slow gait speeds often combined with disturbed balance and cognitive deficits.

In recent years, accumulating evidence suggested that stroke patients do not meet the recommended guidelines for cardiorespiratory fitness (CRF). In recent studies, mostly cycling exercises were described to increase CRF, because patients are often unable to perform a safe gait. However, severe motor impaired patients were often excluded, and long-term follow-up is lacking. Currently, increasing CRF is rarely implemented in stroke rehabilitation, because regaining physical function is a primary focus. Also many clinicians have limited experience with CRF testing or exercise prescription after stroke.

The first scope of this thesis was to gain better insight in the assessment techniques evaluating PA. Secondly, the effects of an AT program on CRF and other primary and secondary outcome measures were explored in subacute stroke patients.

The assessments of PA were addressed in Part A of this thesis, in which a knee-worn Yamax Digi-Walker SW-200 pedometer (YDWP) was proven to be more valid in slower gait speeds on a treadmill and on a flat surface at normal and brisk speed (Chapter 1). This device also showed a good test-retest reliability. Consequently, this opens perspectives to monitor stroke patients with short strides or shuffling gait. Another device, the SenseWear Pro2 Accelerometer (SWP2A) worn at the upper arm, should be used with caution in the measurement of energy expenditure (EE) (Chapter 1). To evaluate activity levels combined with EE, a coded activity diary was developed (Chapter 2). The diary revealed valid in determining sedentary, moderate and total PA and in daily EE. We found it a strength to have developed an assessment technique that determines also sedentary periods, as in recent literature it is described that long of these periods' leads to remodelling and thickening of arterial walls.

Finally, we explored the use of the knee-worn YDWP, the SW2PA and the diary in hospitalized subacute patients and home-living patients (Chapter 3). We found that home-living patients walked more steps and expended more EE during three consecutive days compared to hospitalized patients. In both patient groups a reduced PA was noted with a lot of time spent in sedentary activities, whereas in hospitalized patients more moderate activities were listed.

The second part of this thesis (Part B), reports the effects of a 3-month active cycling (AC) program combined with education and followed by a 9-month coaching approach. In Chapter 4, the primary outcome measures, A-Cap, leg strength and gait speed, were analyzed. The secondary parameters, concerning PA, were reported in Chapter 5. In general, no significant differences between the training groups were found over time. However, in sub analysis more sport participation is observed after 1 year in subacute patients with severe motor function deficits who followed the AC program. Furthermore, in all groups significant improvements over time were found. In the coaching group progress was found after 1 year in VO_{2peak}, $Watt_{peak}$, non-paretic leg strength and

gait speed compared to no progress or deterioration in non-coaching and control group. Additionally, a significant deterioration was found in the control group in the PA questionnaires.

Although our study missed objective exercise data from the training device during the coaching period, the AC program with chip card system combined with education sessions seemed an applicable method in subacute stroke. New long-term AT interventions should focus on coaching approaches to facilitate training after supervised AC.

In conclusion, this doctoral thesis made a vulnerable contribution to the assessment of PA and developed an AT program applicable for subacute stroke patients, in particular in more severely motor impaired patients.

Samenvatting

Motorische beperkingen komen vaak voor na een beroerte en leiden frequent tot een verminderde deelname aan fysieke activiteit. Het blijft een uitdaging om de dagelijkse fysieke activiteit nauwkeurig te meten bij patiënten met een beroerte, vanwege hun afwijkend gangpatroon met bijbehorende zwakte, spasticiteit en trage wandelsnelheden vaak gecombineerd met verstoorde balans en cognitieve tekorten.
De laatste jaren werd er meermaals aangetoond dat patiënten met een beroerte niet voldoen aan de aanbevolen richtlijnen voor cardiorespiratoire fitheid. In recente studies, werden vooral fiets trainingsprogramma's beschreven om de cardiorespiratoire fitheid te verhogen na een beroerte, omdat de patiënten vaak niet in staat zijn om veilig te stappen. Frequent worden patiënten met ernstige motorische uitval geëxcludeerd en ontbreekt ook een lange-termijn follow-up. Op dit moment is het verhogen van de cardiorespiratoire fitheid zelden geïmplementeerd in de revalidatie na een beroerte, omdat het herwinnen van de fysieke functie een primaire focus is. Bovendien hebben veel artsen weinig ervaring met het testen van de cardiorespiratoire fitheid of met het voorschrijven van lichaamsbeweging na een beroerte.

De eerste doelstelling van dit proefschrift was om meer inzicht te verwerven in de meetmethoden om fysieke activiteit na een beroerte te rapporteren. Daarnaast, werden de gevolgen van een aeroob trainingsprogramma op de cardiorespiratoire fitheid en andere primaire en secundaire uitkomstparameters onderzocht bij subacute beroerte patiënten.
De meetmethoden om fysieke activiteit weer te geven, werden behandeld in Hoofdstuk 1 van dit proefschrift. Een aan de knie aangebrachte Yamax Digi-Walker SW-200 pedometer bleek valide in het weergeven van het aantal stappen tijdens trage wandelsnelheden op een loopband en op een vlakke ondergrond bij normale en snelle wandelsnelheden. De betreffende stappenteller bleek ook een goede test-hertest betrouwbaarheid te hebben. Bijgevolg opent dit perspectieven om beroerte patiënten te meten met een verkort stappatroon of met een schuifelende gang. Een ander apparaat, de SenseWear Pro2 Accelerometer dient met de nodige voorzichtigheid te worden geïnterpreteerd bij het bepalen van de hoeveelheid energieverbruik. Om het activiteiten niveau alsook het energieverbruik te evalueren, werd een gecodeerde activiteiten dagboek ontwikkeld (Hoofdstuk 2). Het dagboek bleek valide te zijn bij het bepalen van het dagelijks energie verbruik, alsook bij sedentaire en matige activiteiten en bij de berekening van de totale fysieke activiteit. Het werd gezien als een sterkte om over een evaluatie methode te beschikken, welke sedentaire perioden registreert. Immers, vanuit de recente literatuur wordt beschreven dat lange ononderbroken periodes zorgen voor een remodellering en verdikking van de arteriële wanden.
Tot slot hebben we de aan de knie gedragen Yamax Digi-Walker SW-200 pedometer, de SenseWear Pro2 Accelerometer en het dagboek gebruikt bij gehospitaliseerde subacute en thuiswonende beroerte patiënten (Hoofdstuk 3). We concludeerden dat de thuiswonende patiënten meer stappen zetten en meer energieverbruik vertoonden gedurende drie opeenvolgende dagen ten opzichte van gehospitaliseerde patiënten. In beide patiëntengroepen werd een verminderde fysieke activiteit vastgesteld, waarbij veel tijd besteed werd aan sedentaire activiteiten, terwijl in het ziekenhuis opgenomen patiënten meer activiteiten vertoonden met een matig energieverbruik.

Het tweede deel van dit proefschrift, rapporteert de gevolgen van een 3 maanden actief fietsprogramma in combinatie met educatie sessies en gevolgd door een 9 maanden durende coaching aanpak. In Hoofdstuk 4 werden de primaire uitkomstparameters, zoals aerobe capaciteit, quadricepskracht in de beide benen en loopsnelheid geanalyseerd. De secundaire parameters met betrekking tot fysieke activiteit werden beschreven in Hoofdstuk 5. Geen significante verschillen werden gevonden tussen de trainingsgroepen. Echter, in een sub-analyse van subacute patiënten met een ernstige motorische functie stoornis werd meer sportdeelname waargenomen na 1 jaar. Verder worden in alle groepen aanzienlijke verbeteringen vastgesteld in de tijd. In de fietsgroep met coaching werd een verbetering in de waarden van $VO_{2\ piek}$, $Watt_{piek}$, kracht in het niet-paretische been en de wandelsnelheid waargenomen in vergelijking met geen vooruitgang of zelfs achteruitgang in de niet gecoachte fiets- en de placebogroep. Daarnaast werd in de placebogroep een significante achteruitgang in fysieke activiteit gevonden op basis van data verkregen uit twee vragenlijsten.

Desondanks dat onze studie niet beschikte over objectieve trainingsdata verkregen uit de trainingstoestellen tijdens de coaching periode, bleek het 3 maanden fietsprogramma met chip kaart systeem en gecombineerd met educatie sessies een toepasbare methode in de subacute fase na een beroerte. Nieuwe lange-termijn aerobe trainingsstudies dienen te focussen op coaching manieren om trainingen na het beëindigen van een gesuperviseerd programma efficiënter te kunnen verderzetten.

Tot slot, verschaft dit proefschrift inzicht in de evaluatie van fysieke activiteit in subacute beroerte patiënten, alsook illustreert het hoe deze patiënten aeroob kunnen getraind worden en opgevolgd, met focus op patiënten met ernstige motorische beperkingen.

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Christel, 5 Juni 2017

Curriculum Vitae

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Accepted Grants

2010-2012	"Het effect van aerobe training op de fysieke fitheid en zelfredzaamheid na een cerebrovasculair accident" Grant funded by the BOF UA & Hogescholen Oproep Samenwerkingsoproepen 2010.
2008-2013	"Het effect van aerobe training op de fysieke fitheid en de zelfredzaamheid bij CVA-patiënten", PhD-grant funded by the research counsil of Artesis Hogeschool Antwerpen.

Workshop

- "Fysieke activiteit en fysieke fitheid na een CVA", Symposium Interdisciplinaire aspecten van beroertezorg, Middelheim Ziekenhuis, Antwerpen, 18 Februari 2011.

Member

- Member of the Paramedic Board, Belgian Stroke Council.