Mari Gunnes

Adherence to a long-term follow-up programme after stroke

A prospective longitudinal study assessing adherence to the intervention applied in a randomised controlled trial

Master's Thesis in Clinical Health Science
Applied Clinical Research

Trondheim, May 2014

Norwegian University of Science and Technology (NTNU)
Faculty of Medicine
Department of Public Health and General Practice

NTNU

Acknowledgements

I would like to express my very great appreciation to my supervisor and Associate Professor Torunn Askim for her valuable support and professional guidance during the planning and development of this research work. Her willingness to share her time, experience and extensive knowledge so generously has been very much appreciated.

Further, I would like to thank Walburga Schroeter, physiotherapist and co-worker in the LAST-trial, for constructive discussions and for bringing me necessary documents at breakneck speed. I would also like to thank Grethe Albrektsen, Professor at the Department of Cancer Research and Molecular Medicine, for her advices and instructive discussions according statistical analyses applied in the present study.

My grateful thanks are also extended to all the stroke patients who contributed to this study. This work could not have been done without their willingness to spend time and effort in participating in the study.

Finally, I would like to acknowledge the support provided by my family, friends and colleagues during the preparations of my Master's thesis. Special thanks to my husband, Christian, who has motivated and enthusiastically encouraged me throughout the complete Master Programme, besides reminding me of the importance of life outside work. I promise to take my share of renovating our house from now on! Lastly, I highly appreciate the effort performed by my sister, Thea, and my friend, Marte, in contributing to language revisions, in addition to my parents who always and unconditionally reminds me that everything will be alright.

Abstract

Background: Adherence to rehabilitation programmes is considered an important area of interest in the wake of optimising long-term participation in physical activities after stroke. **Purpose:** Investigating to what extent patients were adherent to a long-term follow-up programme, applied in a randomised controlled trial. **Material and methods:** This was a prospective, longitudinal study, following patients for 52 consecutive weeks. The intervention consisted of regular sessions of coaching by a coordinating physiotherapist, aiming to motivate patients to adhere to at least 30 minutes of daily physical activity and 45 minutes of weekly exercise. Patients' self-reports in training diaries, in addition to adherence reported by the physiotherapist reviewing these, were combined and assessed as the primary outcome measure. Borg's scale of perceived exertion and Goal attainment scaling were secondary measures. **Results:** 41 community-dwelling stroke patients (mean age 75.2 years (SD 7.7)), mild to moderately disabled, were included. An average of 47.5% (SD 8.8) and 62.1% (SD 5.0) were adherent to the prescribed amounts of physical activity and exercise, respectively. The amount of exercise increased from the beginning to the end of the follow-up programme ($p = 0.039$), while a stable amount of physical activity were observed over time ($p = 0.604$). The majority of training was performed at moderate levels of intensity, while goals were poorly achieved over time. **Conclusions:** The present findings indicate that stroke patients participating in a long-term follow-up programme demonstrated good adherence to exercise and moderate adherence to physical activity over time. Whether activity levels were permanently established beyond the current time of observation is yet to be explored in future research.

Relevance

Due to the increasing prevalence of stroke, in addition to research confirming benefits from long-term participation in physical activities and exercise for stroke survivors, improved knowledge of adherence within this particular patient group is required. Hopefully, the present study will contribute to extended knowledge of adherence among stroke patients in a long-term perspective, by systematically assessing adherence of physical activity and exercise over time. Further, the present findings emphasize the importance of assessing what the patients actually do in terms of establishing effective long-term rehabilitation programmes in clinical practice.

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1 Introduction

Stroke is defined by the World Health Organization as "rapidly developing clinical signs of focal (at times global) disturbance of cerebral function, lasting more than 24 hours or leading to death with no apparent cause other than that of vascular origin", including both ischaemic and haemorrhagic stroke (1). In Europe, stroke is the largest single cause of long-term disability among adults (2), and in Norway approximately 11 000 first-ever strokes and 3 500 recurrent strokes are expected annually (3). In addition to possible profound and persisting functional impairments, stroke has socioeconomic consequences estimated to an average lifetime cost of 600 000 NOK per patient. Furthermore, total stroke-related public costs are approximately 7-8 billion NOK annually (4).

During the last decades, stroke-related clinical care has improved considerably in the Western part of the world. Advanced medical treatment methods, in addition to improved diagnostic tools and multidisciplinary teams are implemented in comprehensive stroke unit care, which is considered the gold standard concerning acute treatment of stroke today. Consequently, stroke-related mortality is declining, and the possibility of returning back to one's own home has improved extensively (3, 5, 6). Nevertheless, patients surviving stroke are in risk of experiencing long-term impairments, limitations of activities and reduced participation (7). In addition, family members might experience both emotional and physical strain when they are expected to act as caregivers when patients are discharged to home (8, 9). Further, an aging population, unchanged or small changes in stroke incidence, in addition to larger survival rates, increase the prevalence of stroke. Thus, there is a present need of health care services in the future (3).

Approximately one third of stroke patients will remain disabled, thus, post-stroke rehabilitation is required (10). Stroke rehabilitation is a dynamic process with the overall goal of reducing stroke-related disability. In that regard there should be a requirement for collaboration across medical specialities, finance and administrative systems in terms of establishing chains of care (11). Despite the fact that the main attention on stroke research still remains focused at the acute management of stroke, the rehabilitation process plays a key role in successfully reducing the long-term effects of stroke and achieving optimal functional recovery for community re-integration (12).

The extensive progression during the past ten years in the number of clinical trials involving rehabilitation indicates an increased interest in rehabilitation research and evidence-based care among clinicians (13). Early supported discharge, which emphasises rehabilitation within the basis of

the patient's home, is a well-documented component of stroke care. This has proven to reduce long-term dependency and admission to institutional care as well as shortening hospital stays (14, 15). Further, high-intensity, repetitive task-specific practice with feedback on performance, in addition to sufficient amount of training during the first three to six months after onset of stroke, has proven to be important in the process of motor recovery (7). Goal setting is also widely recognized as an integral part of stroke rehabilitation, aiming to enhance patient motivation, adherence and autonomy, likewise improving their satisfaction with rehabilitation (16-18). A systematic review suggests that goal setting appeared to positively influence patients' perceptions of participation and self-care ability, in addition to have an impact on their performance and goal achievement (19).

Evidence concerning the effect of long-term follow-up after stroke, however, is still scarce. A study following stroke survivors indicated that a deterioration of activities of daily living (ADL) and motor function, besides increased dependence on relatives, were apparent at one year and critical after four years of follow-up (20). In addition, the decrease in function seemed to be larger than one would expect in the average population of elderly (21). In order to keep muscle strength, endurance and postural control, it has been proven that stroke patients require regular physical training to maintain ADL and motor function (22, 23).

Knowing that motor impairments and lack of motor skills probably are one of the most significant barriers to an active lifestyle (24), it is a pronounced and important challenge for the health care system to improve the long-term follow-up care to ensure maintenance of motor function for this group of patients. Recovery can continue for months, even years, after stroke – usually far beyond the formal rehabilitation period (13). It is of great importance to support stroke survivors in the best and most effective way once they stop accessing formal services (13). Consequently, research on how to clearly define the effect of specific rehabilitation interventions in a long-term, routine clinical setting are still warranted (12, 13).

In order to meet the need for further research within this field, a prospective, multisite randomised controlled trial, Life Late After Stroke (LAST), has been designed. The LAST-trial is presently performed at the Stroke Unit at St Olav's Hospital together with the Stroke Unit at Bærum Hospital. In addition, the trial is conducted in close cooperation with the primary health care services in the municipalities related to these hospitals. The main objective of the LAST-trial is to develop a long-term follow-up programme for maintenance of motor function after stroke as high as possible for as long as possible. Furthermore, the intention is to assess the effects of the programme compared to standard care on function, disability and health. Participants in the intervention group receive regular coaching on physical activity and exercise by a coordinating physiotherapist for 18 consecutive

months after inclusion, and are encouraged to perform “45-60 minutes of physical exercise once a week and 30 minutes of physical activity every day”. During exercise, participants are encouraged to reach levels of high intensity. Additionally, goal setting and evaluation of goals are included to ensure adherence to the training programme (25).

In the wake of health service moving towards the goal of implementing evidence-based interventions, there is a need to select, adapt and evaluate the feasibility of interventions under actual conditions (26). In line with this, considerations on how to optimize adherence to evidence-based exercise programmes are required (27). Adherence of patients should be measured and evaluated before the results of a clinical trial are interpreted. This aims to avoid situations where poor adherence, that is undetected in a clinical trial, may result in invalid results. In addition, this might avoid an intervention being labelled as ineffective when it might actually be effective for certain populations under certain conditions (28). Further, an improved understanding of barriers to training adherence may assist in designing and administering optimal exercise programmes (29). In contrast, there is neither much published research systematically registering stroke patients’ adherence to interventions, nor research looking at factors predicting adherence and dropout from exercise in the case of this specific population (27).

Investigations of patients’ adherence to the intervention tested in the LAST-trial will hopefully contribute to a better understanding of the results when the evaluation of the trial is accomplished. Likewise, it is of great importance to explore what the patients actually did in order to draw conclusions of the intervention’s effect. Furthermore, the results might give indications of future practice concerning an increase in patients’ adherence to long-term follow-up programmes for those recovering from stroke, ultimately contributing to a better outcome and quality of life for the current population.

To address the issues presented above, the overall aim of this study was to assess the feasibility of the intervention tested in the LAST-trial; hereby investigating participants’ adherence to the treatment protocol. Moreover, the study aimed to identify aspects of participants’ adherence to physical activity and exercise in depth, in addition to the effect of using goal attainment scaling to achieve the prescribed recommendations. The scientific questions were as follows:

Primary question

1. To what extent did stroke patients randomised to the intervention group of the LAST-trial adhere to the prescribed amount of time spent on physical activity and exercise, respectively, throughout a period of 52 consecutive weeks?

Secondary questions

1. To what extent did stroke patients randomised to the intervention group of the LAST-trial adhere to the prescribed levels of intensity during physical activity and exercise throughout the period under evaluation?
2. To what extent did the participants achieve their primary goals related to physical activity and exercise?
3. To what extent was adherence to training per protocol and goal achievement associated?

It was hypothesized that participants receiving the intervention applied in the LAST-trial would be adherent according to both the recommended amount and intensity of physical activity and exercise, respectively. Concerning goal attainment, one would expect that goal setting, followed by evaluation of goal achievement, would work as a useful tool to enhance adherence to physical activity and exercise required per protocol. Hence, the participants were hypothesized to reach their goals. Finally, it was hypothesized that participants who were highly adherent to physical activity and exercise were more likely to achieve goals related to physical assignments compared to those who were less adherent.

2 Theoretical background

The theoretical framework of the research topic is presented in what follows. This includes definitions and adaptions of key concepts applied in the study. In addition, long-term participation and determinants of adherence after stroke are introduced, as well as behavioural and motivational aspects of long-term adherence.

2.1 Feasibility and adherence of interventions

Concerning the process of evaluating randomised controlled trials to fit in clinical settings, making judgements about the feasibility of possible interventions should be emphasised. However, the published literature does not propose standards to guide the design and evaluation of feasibility studies. Nevertheless, the choice of an optimal research design depends upon the selected area of focus, and this premise holds equally for feasibility studies as for other kinds of research (26).

Bowen and colleagues describe how the term feasibility study is not only covering investigations on how to prepare for full-scale research, e.g. a pilot study, but it might serve as a precursor for testing the effect of an intervention as well (26). In other words, the multifaceted purposes of a feasibility study might involve elements like these examples: Exploration of participants recruitment and retention, willingness of clinicians to recruit patients, assessments of the suitability and variability of outcome measures used, investigation of application and fidelity of a programme, exploration of the acceptability of an intervention to patients, caregivers and professionals, or, as chosen as the main attention in the current study; evaluation of patients' adherence to an intervention (30).

2.1.1 Defining adherence

Adherence in general medicine and health may broadly be reported as the degree to which patient behaviours coincide with the recommendations of healthcare providers (31). Further, a widely accepted definition of adherence among practitioners who use exercise as physiotherapy rehabilitation is "an active, voluntarily collaborative involvement of the patient in a mutually acceptable course of behaviour to produce a desired preventative or therapeutic result" (32). Besides, it is of importance to bear in mind that adherence behaviours are dynamic, and not static; understood as patients adhering to some aspects of their physiotherapy and not others, and that these behaviours may fluctuate over the course of the treatment (33). In line with these definitions, adherence in the current study is defined as patients demonstrating behaviours that coincide with the recommended components of their daily physical activity and weekly exercise prescribed, yet jointly developed, by the coordinating physiotherapist.

It should be noted that it is common practice in the literature for the words adherence and compliance to be used interchangeably (34). They can both be defined according to which extent the patients undertake the clinic-based and home-based prescribed components of their physiotherapy programme (32). However, adherence is used in preference to compliance in the present study because it is considered to imply active voluntarily involvement of the patients in the planning and implementation of the treatment, whereas compliance is regarded as abiding obediently by the practitioner's prescribed treatment protocol (32). This is in accordance with the intention of the intervention tested in this study, where participants are encouraged to be actively involved in both planning and executing the prescribed training throughout the long-term follow-up programme.

2.1.2 Measuring adherence

Given the lack of a consistently agreed-on definition of adherence to physiotherapy rehabilitation in the literature, there does not exist a gold standard on how to rate or measure adherence (33). Bassett suggests that patients' self-reports, such as exercise diaries and questionnaires, are the most ideal method of evaluating adherence to the home-based physiotherapy (35). Further, it is suggested that the preferred method of administering self-reports is by personal interviews, as participants completing questionnaires or diaries by self-administration might skip some questions or occasionally lack reports (36). Hence, multiple measures seem to be necessary to capture the range of behavioural demands that constitute adherence to rehabilitation (37, 38).

2.2 Physical activity and exercise

Like the concepts of adherence and compliance, physical activity and exercise are terms commonly used interchangeably. According to the World Health Organization, physical activity is defined as "any bodily movement produced by skeletal muscles that result in energy expenditure" (39). Physical activity in daily life can be categorized into occupational, sports, conditioning, household, or other activities. Exercise is, however, a subcategory of physical activity that is planned, structured, repetitive and purposeful in the sense that the improvement or maintenance of one or more components of physical fitness is the objective (39). In the present study, physical activity and exercise are treated as separate variables according to the referred definitions. Furthermore, the term training is used when physical activity and exercise are referred to in combination.

According to the American Heart Association Scientific Statement, stroke survivors are often deconditioned and predisposed to a sedentary lifestyle that limits performance of activities of daily living and increased risk for falls (40). Consequently, this may contribute to a heightened risk for recurrent stroke and cardiovascular disease. The latter is in addition the leading cause of death in long-term stroke survivors (41). Thus, patients can benefit from participation in physical activity and exercise. A frequency of training three to seven days a week, with a duration of 20 to 60 minutes a

day of continuous or accumulated exercise are recommended for stroke survivors according to the US guidelines (40). In Norway, however, it is recommended that stroke patients exercise at 60 to 80% of maximal heart rate for 10 to 60 minutes, two to five days a week (42). Regardless, it appears that the actual levels of physical activity in community-dwelling stroke survivors are far below the recommendations (43-45). Common features in several of the referred studies demonstrate that many stroke survivors perform minimal, if any, physical activity on a regular basis.

2.3 Long-term effects and participation after stroke

In traditional stroke rehabilitation, intensive physiotherapy generally occurs within the first three months after onset of stroke, when greatest capacity for recovery is believed to exist (46). Evidence of benefits from longer-term therapeutic activity, however, is evolving. With the aim of reducing disability, restoring and maintaining physical function and independence in ADL, several trials have proven task-oriented therapeutic activities assessed for six months and longer after stroke to be effective (47-50). Despite the developing empirical evidence of physical and functional benefits for stroke survivors from long-term engagement in a range of physical activities, long-term participation in physical activity and exercise is low for this group of patients, and maximum benefits are not being achieved (51).

In general, lack of adherence to physical activity programmes is a common problem across different populations, with many people withdrawing from exercise before any personal health benefits are achieved (52). Results from a survey of testing a model of post stroke behaviour, reports that approximately 68% of chronic stroke survivors undertake exercise activity less than three hours per week, with 42% never undertaking activity or participating less than once per week. This leaves only 31% of stroke survivors in activity four times a week, compared with 45% of age-matched healthy individuals (53).

2.4 Determinants of adherence

In general, determinants of adherence consist of a diverse range of physical, psychological and situational factors that are likely to operate simultaneously. Meichenbaum and Turk categorize determinants of adherence into patients' personal characteristics, disease or injury variables, treatment variables and the interaction between the patient and the clinician (32). Further, several studies have indicated that self-efficacy and outcome expectations exert an influence on physical activity and exercise behaviour among the elderly (54-56). Additionally, disease severity seems to be affecting patients' motivation to adhere to a clinical trial. Hence, there are indications that patients with mild forms of a disease tend to comply less than patients with moderately severe disease (28).

Similarly, patients with extremely severe, or even terminal disease, usually comply less than the moderate group (28).

The factors affecting adherence to physical fitness programmes among stroke survivors are, however, not yet clearly defined (57). Although some disability studies have included stroke survivors, the proportion has generally been small (58, 59). This makes it difficult to draw conclusions for this group of patients. One study, however, reported that musculoskeletal issues, fatigue and lack of motivation were identified by at least 50% of stroke survivors as preventing them from completing their home-based exercise programmes (57). Another study demonstrated that self-efficacy and outcome expectations of exercise, physician's recommendation to exercise, and exercise history before stroke explained 33% of the variance in exercise behaviour in a sample of stroke survivors (53). Further, findings from a retrospective analysis of constraint-induced movement therapy applied on stroke patients, indicates that close supervision might be a reason for the good and consistent adherence found during in-laboratory time (60). Some of the mentioned determinants explaining adherence are potentially modifiable. This is raising the possibility that interventions designed to educate stroke survivors regarding outcome expectations and to strengthen self-efficacy, may improve activity behaviours (53).

2.5 Improving long-term adherence

Interventions designed to enable stroke survivors to overcome barriers and engage in self-directed physical activities of long-term perspectives, should be developed. In general, a variety of psychological techniques of behaviour modification and cognitive behavioural methods have had some success in reducing the dropout rate of exercisers (61). For instance, individually adapted treatment tailored to fit the person's stage of behaviour, have showed some promising effect in enhancing adherence (62). However, these studies have sparsely included stroke survivors, making it difficult to draw conclusions for this patient group (51). In addition, physical activity and exercise are composed of a complex set of behaviours, making it difficult to pinpoint the factors contributing to, or interfering adherence to, a physical activity programme (63). Nevertheless, general methods to improve patients' adherence can be divided into educational and behavioural strategies. The latter are found to be more effective than educational techniques, focusing more directly on changing the behaviours involved in adherence (61). A variety of techniques show promising effect. Among others, there are growing interests in health coaching as an approach to improve a healthy lifestyle in patients with chronic diseases (64). This concept is aiming to enhance the well-being of individuals and to facilitate the achievement of their health-related goals (65). However, the intervention is sparsely tested on stroke patients and well-designed studies are warranted (66).

Motivational interviewing is an approach encompassed in health coaching, objecting to help patients exploring and resolving their ambivalence toward behaviour change, and subsequently facilitating positive behaviour change in the individual (67). Despite that the concept originated within substance abuse treatment (67), motivational interviewing is accepted as a structured, patient-focused and cost-effective intervention that has been increasingly used in several areas of medicine, including stroke (68-71). Although sparsely tested on stroke survivors in a long-term perspective, the technique may contribute to help building up patients' confidence in their ability to adjust and adapt to identify realistic personal goals for their recovery (69).

Goal setting is another central strategy that is found useful in the promotion of adherence to physical activity (63). From one perspective, Dishman argues that whether or not exercise goals can be reached is dependent upon adherence (72). On the other hand, there is some evidence which supports that adherence is dependent upon goal attainment or expected goal attainment (72). The referred research indicates that goal attainment and training adherence are interrelated in a somehow reciprocal relation to each other. Moreover, there is appearing evidence that goals are more likely to be achieved if patients are involved in setting them. There is also evidence that using goal attainment scaling may have positive therapeutic value in encouraging the patients to reach their goals (73). Goal set in collaboration by patient and therapist is considered an integral part of the intention of stimulating to an active, educational, solution oriented and patient focused process in stroke rehabilitation (17, 19). A systematic review indicates, however, that this is minimally adopted in practice (74).

With the intention of maintaining motivation and adherence to training over time, results from a randomised controlled trial indicates that a follow-up programme on consultative basis with self-initiated training might be just as beneficial as a compulsory training programme for stroke patients (75). According to the researchers of the study, the results were probably due to high motivation of all participants regardless of group allocation, and they hypothesized that this high motivation was triggered by the test occasions and regular contact with a physiotherapist initiating higher exercise levels in the control group. On the contrary, a multicentre, multinational, randomised clinical trial by Boysen and colleagues (76) demonstrated that an intervention consisting of repeated encouragement and verbal instructions every three months over a period of 24 months did not result in a measurable increase in long-term physical activity among stroke survivors. They concluded that more intensive strategies seem to be needed to promote physical activity after ischaemic stroke. As indicated, this research field is still contradictory, implicating that there is a need for more randomised trials assessing the impact of more compelling interventions designed to improve long-term physical activity and exercise among stroke survivors.

3 Material and Methods

3.1 Design of study

This was a prospective, longitudinal follow-up study as part of the ongoing LAST-trial (Clinical-trials.gov: NCT01467206), in which patients were enrolled at the outpatient clinic and consecutively block randomised 10 to 16 weeks after onset of stroke (25). The longitudinal follow-up design of the present study allowed accumulation of data through intensive documentation of change on the same individuals. Hence, the direction, as well as the magnitude of change over time for the data collected, were analysed (77). The flow chart (Fig.1) presented in the result section, also illustrates an overview of the design of the study. Although the LAST-trial continued for 18 consecutive months, the present study was limited to evaluate the first 52 weeks of the follow-up programme.

3.2 Participants and recruitment

Patients admitted to the stroke unit at St. Olav's Hospital and Bærum Hospital were screened for inclusion into the LAST-trial according to the criteria listed in Table 1. Furthermore, patients were stratified according to recruitment site, stroke severity (modified Rankin Scale (mRS) 0-2 or mRS 3-4) and age (above or below 80 years). Only patients recruited at St Olav's Hospital, randomised to the intervention group in the LAST-trial, were included in the present study.

Table 1. Criteria for participation in the LAST-trial.

Inclusion criteria:
- Diagnosis of stroke - 0-4 points on modified Rankin Scale (mRS) - Mini Mental State Examination (MMSE) > 20, or > 16 for patients with aphasia - Patient discharged from hospital or inpatient rehabilitation, and community-dwelling - Capable of providing informed written consent
Exclusion criteria:
- Serious medical morbidity with life expectancy < 6 months - Medical assessment showing contraindication to participate in motor training - Other serious impairments that would have significant impact on functional outcome - Already included in another intervention study - Insufficient communication/Norwegian skills to participate in assessment and intervention

3.3 Intervention per protocol

Patients included in the present study were receiving a long-term follow-up programme. This aimed to include an amount of training corresponding to at least 30 minutes of daily physical activity, in addition to exercise corresponding to at least 45 minutes weekly. The amounts of training are

equivalent to the originally recommended amount per protocol. However, slight modifications were made by allowing the total amount of physical activity and exercise to be distributed throughout the week as preferred by the individual participant. To accomplish the prescribed levels of training, coaching was offered by a coordinating physiotherapist from the primary health care of Trondheim. The physiotherapist's main purpose was to motivate and encourage the patients to follow an individually adapted training programme, developed in collaboration between the patient and the therapist. The meetings were arranged every four weeks, preferably set at the patients' home. From the 8th appointment, the frequency of physical meetings was allowed to reduce to every 12 weeks, in which the remaining appointments were set by telephone.

The content of both the daily physical activity and weekly exercise were individually adapted depending on the patient's level of fitness and motor function. Examples of daily physical activity could include walking, climbing the stairs or common domestic tasks, such as making the bed, preparing meals, cleaning or vacuuming. There were no prescribed criteria concerning intensity of physical activity per protocol, however, the patients were asked to report levels of perceived exertion. Moreover, the weekly exercise was aiming for a score on Borg's scale of perceived exertion between 15 and 17 points, i.e. high intensity. The patients were encouraged to take advantage of already established local training facilities in terms of the weekly exercise. Patients who preferred participation in group training were joining groups adapted to their functional levels, and in cases where the functional level were too low to fit into any groups, individual therapy was offered.

Patients were responsible of conducting the daily physical activity and weekly exercise themselves. The training programme, including both physical activity and exercise, was evaluated every four weeks during the course of the follow-up programme. When necessary, the therapist and patient had the opportunity of revising the content of the physical activities and the exercise programmes.

Specific assessment tools were applied for the patients to achieve the recommended amounts and intensity of physical activity and exercise prescribed. During the first meeting between the physiotherapist and the patient, the survey Exercise Preference Questionnaire (EPQ) was completed and discussed. EPQ is a questionnaire specifically designed for the stroke population, and intends to identify patients' preferences and routines in relation to physical activity (78). Furthermore, Goal Attainment Scaling (GAS) was used to set activity goals (73). In accordance to setting realistic goals, definitions and expected levels of achievement were negotiated with the patient. The criteria for a successful outcome for each individual were discussed with the patient before commencing the intervention, with the aim of both patient and therapist to have realistic expectations of what was likely to be achieved and worth striving for. One to three goals were preferably defined as a feasible

number to capture the patient's key priorities. The individually adapted goals were evaluated at every third appointment after the onset of intervention, with the same process repeated to continue or setting new goals.

3.4 Outcome measures

In line with the definition of adherence, described in chapter 2.1.1, participants' degree of adherence to the intervention per protocol was defined as the independent variable. Hence, the dependent variables consisted of three different aspects of adherence; 1) reported time spent on physical activity and exercise, respectively, 2) reported intensity level of physical activity and exercise, respectively, and 3) patients' degree of goal attainment. The dependent variables were mainly analysed and discussed separately in the present study, with the aim of systematically exploring each component of participants' degree of adherence per protocol.

Age, gender, living condition, side of hemiparesis, type of stroke and medical history were recorded for each patient at baseline. Severity of stroke was assessed by the Scandinavian Stroke Scale (79), and patient's degree of dependence was evaluated by the modified Rankin Scale (80). The Barthel Index (81) was used to assess the patient's ability to perform activities of daily living, in addition to the Mini Mental Status Examination (82) assessing cognitive function.

3.4.1 Primary outcome variable

Patients' adherence to time spent on physical activity and exercise was assessed by two different measurements. These two were; (I) participants' self-reports of daily physical activity and weekly exercise in training diaries (appendix I), and (II) an overall estimation of patients' adherence assessed by the physiotherapist in adherence forms (appendix II). The latter was completed by the physiotherapist when reviewing training diaries together with each participant at their regular appointments. The two measurements were combined and expressed as a single value comprising participants' amount of time spent on physical activity and exercise, respectively.

Training diaries were undertaken by the patients on a daily basis and completed directly after the end of each training session, before they were returned to the physiotherapist every four weeks. Different aspects of training behaviour were reported in the diaries. However, the amount of time spent on physical activity and exercise, were of specific interest in relation to the primary aim of the study. The individual's preferences of what was considered the content of physical activity and exercise according to the definitions (cf. chapter 2.2) were jointly decided by the therapist and patient in advance of the following four weeks and documented in the diaries. Hence, assurances of time spent on physical activity and exercise reported separately were accounted for.

The adherence form was intended as the training diaries' assurance of quality, and thus regarded as a supplement to the diaries. It was aimed at the physiotherapist to report an estimation of participants' adherence behaviour based on their regular conversations. Hence, the therapist was able to either confirm or disprove the participants' amount of training compared to the recommendations per protocol. Besides, the therapist could add information about patients' routines of physical activity and exercise if the patient were lacking reports in their diaries. However, suspicions of overestimations of training were not reported.

Time spent on physical activity and exercise conducted by each participant was summed and plotted in statistical programmes as weekly amounts. No lower limit was set for the recording of training, i.e. every registration was recorded regardless of small bouts of training. Considering the presentations of data, the weekly amounts of training were aggregated as total sums undertaken during four weeks, presented in 13 consecutive time intervals. This was comparable to the design of the primary outcome variable, in addition to contributing to a more manageable and perspicuous presentation of the data. Hence, the required amount of time spent on physical activity at the constructed time interval was equivalent to a total of 840 minutes (i.e. 30 min/day × 7 days/week × 4 weeks), while a total of 180 minutes (i.e. 45 min/week × 4 weeks) represented the required amount of time spent on exercise at each time interval.

Both time spent on physical activity and exercise were categorized and presented in subgroups. The chosen cut-offs regarding physical activity were as follows: (I) ≥ 30 min 7 days a week, in accordance with the amount required per protocol, (II) 30 min 5-6 days a week, less than required per protocol, but still corresponding to levels of activity recommended for adults and elderly by the Norwegian Directorate of Health (83), (III) < 30 min 5 days a week, representing amount below recommendations, and (IV) 0 min, representing both those who reported no activity or were unable to estimate (missing). With regards to exercise, the amount of time were distributed into the following classifications; (I) ≥ 45 min weekly, corresponding to required amount per protocol, (II) 20-44 min weekly, below requirements per protocol, but still within the Norwegian recommendations of exercise for stroke patients (42), (III) 1-19 min weekly, representing amount below recommendations, and (IV) 0 min, representing both those who reported no exercise or were unable to estimate (missing).

With no gold standard for what defines satisfactory versus poor adherence across health behaviours, adherence must be defined according to the specific situation of study (31). Categorizing patients as being either adherent or non-adherent is often not a sufficient approach, as adherence is not fundamentally a dichotomous variable. Ideally, the clinical or research goals should drive the

definition of satisfactory adherence (31). With regards to the present study, 30 minutes of daily physical activity and 45 minutes of weekly exercise are rated as excellent adherence (100%). However, excellent adherence throughout 52 consecutive weeks is potentially unattainable in practice. The strength of adherence in the present study is classified as follows: <20%: Poor, 21-40%: Less-adequate, 41-60%: Moderate, 61-80%: Good, 81-100%: Very good adherence.

3.4.2 Secondary outcome variables

Borg's scale

To measure participants' intensity levels of both physical activity and exercise, the Borg Rating of Perceived Exertion 6-20 Scale (Borg's scale, appendix III) were applied (84). The scale is based on the physical sensations a person experiences during activity, including increased heart rate, respiration, sweating and muscle fatigue, ranging from 6 (no exertion at all) to 20 (maximal exertion). A person's exertion rating may provide a fairly good estimate of the actual heart rate during physical activity (85), and it is an accepted method for subjective estimates of effort during exercise and intensity in both healthy people and patient populations (85-87).

Like the presentation of the primary outcome variable, participants' reported intensity levels during physical activity and exercise were presented in 13 consecutive time intervals, each consisting of four weeks. The mean values at each time interval was calculated by summing the mean values from the corresponding weeks for physical activity and exercise, respectively, and then dividing the sum by the number of weeks with valid mean values. The chosen cut-offs separating intensity-levels into light (6-10 points), moderate (11-14 points) and high intensity (15-20 points), were set in accordance to prior research and the clinical application of the scale (86, 88).

Goal Attainment Scaling

Goal Attainment Scaling (GAS, appendix IV) was assessed to score the extent to which patient's individual goals were achieved in the course of the intervention. Although the technique has its critics, a systematic review has shown an extensive literature base to support the validity, reliability, and responsiveness of GAS as an outcome measure for rehabilitation (89). GAS identifies and quantifies individual goals of treatment, enabling comparison between patients. Additionally, it allows the achievement of each goal to be measured on a 5-point scale ranging from -2 to +2, where 0 represent the expected outcome level. -1 or -2 denotes a little or much less than the expected level of attainment, respectively, and +1 or +2 correspondingly denotes a little or much more than the expected outcome (90). In addition, the approach encompasses weighting of goals to reflect the opinion of the patient on the personal importance of the goal and the difficulty of achieving the goal, respectively (73). Each goal was weighted with a number from 1 to 5, where 5 assigned to extremely important or difficult, and 1 to not important or difficult at all. Despite the fact that the scale of 1 to 5

utilised in the current study differed from the originally suggested scale of 0 to 3, there is an overall acceptance that the obtaining of weights is of little consequence as far as the scoring procedure is concerned; i.e. the range of values to be used as weights is unimportant, as long as the same range is used consistently (91, 92). This allows the calculations of an aggregated T-score, which takes into account the attainment of several goals as well as their relative weights (90).

In the present study, goal attainment was evaluated approximately 13, 25, 37 and 49 weeks after inclusion for each patient, and the overall GAS's T-score was calculated according to the algorithm presented by Turner-Stokes (73). This method gives a numerical T-score which is normally distributed around a mean of 50, assuming the goals are achieved precisely, with a standard deviation of 10, if the goals are over- or underachieved (73). Hence, a score of 50 represents the preferred level of performance. Correspondingly, a score < 50 reflects goal achievement below the expected level of performance, while > 50 reflects performance above the expected level.

3.5 Sample size

The sample size was determined by the timeframe given by the present Master's thesis. Eligible participants included in the present study were recruited from October 2011, i.e. the onset of including patients in the LAST-trial, until January 2013. With the start of the intervention defined as the participants' first meeting with the coordinating physiotherapist, the last enrolled patient possible to include in the present study reached 52 weeks of follow-up at 6th of February 2014. Approximately 40 patients were expected to be recruited within the defined timeframe which was considered justified in line with the study's design and purpose. In addition, this was in accordance with the recommended sample size for similar feasibility studies which is between 24 and 50 participants (93, 94).

3.6 Statistical analyses

Statistical analyses were run in Statistical Packages for the Social Sciences (SPSS), version 21.0, and Microsoft Excel 2010 for Windows. Both demographic and clinical data were tested for normality by QQ-plots and Shapiro-Wilk's tests. Subsequently, non-parametric statistics were chosen for variables not meeting the assumptions of normal distribution, in addition to variables measured on nominal (categorical) or ordinal (ranked) scales (95).

Baseline characteristics were presented separately between the patients who completed the intervention and the patients who withdrew the study, the latter referred to as the dropouts. Demographic data were analysed by descriptive statistics, and Fisher's Exact tests were used to detect significant differences between the two groups at baseline regarding gender, living condition, medical history, type- and severity of stroke. Further, independent-samples t-tests, or Mann-Whitney

U-tests, were run to detect the remaining variables for significant differences between the two groups at baseline. A significance level of 0.05 was chosen.

To assess differences for within-group changes from the first time interval (week 1-4) to the last time interval (week 49-52) in (a) participants' adherence to the recommended amount of physical activity and exercise, (b) intensity levels and (c) goal achievement, Wilcoxon singed rank test or paired-samples t-test were used. Further, McNemar's test of paired proportions was performed to investigate whether there were changes in the proportions of the sample adhering to the recommended amount of physical activity and exercise, respectively, in the beginning of the intervention programme (week 1-4) and at the end (week 49-52). The same test was used to assess changes in proportions of the sample achieving goals at the first (13^{th} week) and the last (49^{th} week) evaluation.

The relationship between participants' GAS –scores and adherence to physical activity and exercise were examined by Chi-Square tests or Fisher's exact tests. The latter was performed when assumptions concerning 0 cells with count less than 5 were not met. The procedure of these tests was performed as follows: The achievement of goals was dichotomized into "< 50 points; not meeting set goals" and "≥ 50 points; achieving or exceeding goals". Participants' adherence to physical activity were dichotomized the same way, with "adherent" defined as reporting a minimum of 30 min of physical activity seven days a week, while "non-adherent" was defined as reporting less than the recommended level of physical activity per protocol. Considering exercise, this was dichotomized into "adherent" defined as reporting a minimum of 45 minutes of exercise weekly, while "non-adherent" was defined as reporting less than the recommended level of exercise per protocol. Finally, the participants were dichotomized into those who fulfilled both categories of recommended physical activity and exercise per protocol, and those who only fulfilled one or none of the prescribed amounts of training.

All of the patients were included in the presentations and analyses of data, regardless of deviations of the treatment protocol. Dropouts were consecutively excluded at the time they chose to withdraw from the study. Hence, observations up until withdrawal were included in the descriptive presentations. Subsequently, the presentations of results in Tables 3-5 and Figures 2-8, cf. chapter 4, involve data from every patient until they were lost to follow-up.

When training diaries were either incomplete or missing, amounts of physical activity and exercise were conservatively reported as "0", unless described differently in the adherence form completed by the physiotherapists. If reports of amount of training was missing from one week in the training diary, and the therapist reported "adherence as usual" but lacked description of specific amounts,

these values were imputed with the mean of the remaining values from the previous and following week. Nevertheless, only a maximum of 30 minutes of daily physical activity and 45 minutes of weekly exercise were imputed if the estimated mean values exceeded the required amount per protocol. Missing values of Borg's scale were not imputed, and are presented in the results.

3.7 Ethical aspects

The study was approved by the Regional Committee of Medical and Health Research Ethics (REC no. 2013/1354, appendix V), and was conducted in accordance with ethical standards given by the Norwegian National Committee for Medical and Health Research Ethics (96). Participants enrolled in the study had already agreed to participate in the LAST-trial. Thus, the need to renew the written informed consent was considered unnecessary, also approved by REC. Further, it was expected that the information collected about each participant were satisfactorily clarified in the already approved patient information (appendix VI).

Only patients who were judged by a physician at the stroke unit at St Olav's Hospital to tolerate the intervention were included in the study. Although the effect of the intervention is still unknown, it is unlikely that it would increase the risk of adverse events. Serious adverse events, such as severe fall or sudden cardiovascular death, were recorded during the follow-up period.

3.8 Recourses and author's role

Expenses of the present study, beyond what was already spent on the LAST-trial, involved nothing else than relevant office supplies.

Employed as a research assistant in the LAST-trial from the beginning of the study, the author of this thesis has been collecting the data utilised in the current study. Main responsibilities have been screening participants for inclusion, testing and randomising eligible patients, in addition to collecting, organizing and manually plotting relevant data in statistical programmes.

3.9 Time schedule

This Master's thesis was planned and written during the third and fourth semesters of the Master's Programme in Clinical Health Science at The Faculty of Medicine, NTNU. Data were collected continuously and completed in February 2014, and the final thesis was finished by the submission date of 1st of June 2014.

4 Results

4.1 Baseline characteristics

A total of 41 stroke patients were included in the present study. The flow chart (Fig. 1) illustrates the flow of participants through the study, including the time of withdrawal for each of the patients who dropped out. Seven (17.1%) participants of the total sample chose to withdraw at some point during the 52 weeks of follow-up. Median time of participation from inclusion to drop out was 25 weeks (IQR; 5-33), ranging from 2 days to 46 weeks. One patient deteriorated severely and was lost to follow-up due to transfer to a nursing home 27 weeks post inclusion. Hence, a total of 33 patients (80.5%) completed the follow-up programme of 52 consecutive weeks.

Baseline characteristics of the sample are reported in Table 2, divided between participants who completed the trial and those who withdrew from the study during follow-up. The dropouts did not differ significantly from those who remained in the study at any of the baseline characteristics.

The total sample, with a mean age of 75.2 years (SD 7.7), involved participants affected by mild to moderate stroke (median Scandinavian Stroke Scale score 50 (IQR 38.5-54.0)), moderately disabled (median mRS score 3.0 (IQR 2.0 – 4.0)) and mild to moderately dependent in activities of daily living (median Barthel Index score 77.5 (IQR 40.0 – 95.0)), assessed at hospitalisation.

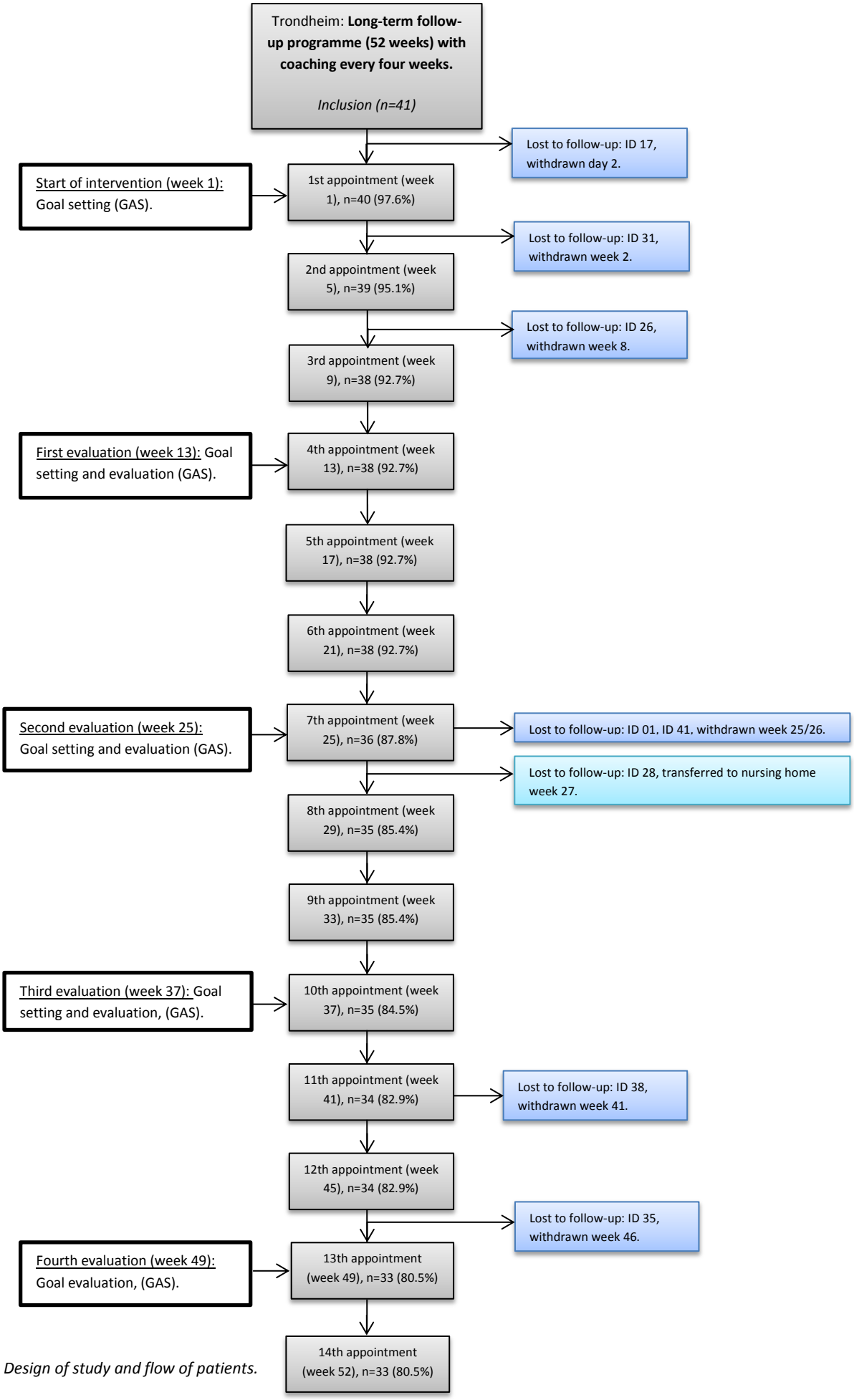

Figure 1. Design of study and flow of patients.

Table 2. Participants' demographics and clinical characteristics at baseline.

	Participants completing the study (n=34)	Dropouts (n=7)	Group differences (p-value)
Age (years)			
Mean (SD)	75.5 (7.5)	73.6 (8.7)	0.55[1]
Range	61- 91	61 - 87	
Gender, *n* (%)			
Female	21 (61.8)	3 (42.9)	0.42[2]
Living condition, *n* (%)			
Alone	12 (35.5)	0 (0)	0.09[2]
Together with someone	22 (64.7)	7 (100)	
Side of hemiparesis, *n* (%)			
Right	18 (52.9)	6 (85.7)	0.21[2]
Type of stroke, *n* (%)			
Ischemic	31 (91.2)	7 (100)	1.00[2]
Haemorrhage	2 (8.8)	0 (0)	
Medical history, *n* (%)			
Stroke	9 (26.5)	1 (14.3)	0.66[2]
Transient ischaemic attack (TIA)	8 (23.5)	0 (0)	0.31[2]
Myocardial infarction	6 (17.6)	2 (28.6)	0.61[2]
Heart failure	2 (5.9)	0 (0)	1.00[2]
Atrial fibrillation	11 (32.4)	2 (28.6)	1.00[2]
Hypertension	18 (52.9)	3 (42.9)	0.70[2]
Diabetes mellitus	6 (17.6)	2 (28.6)	0.61[2]
Lung disease	5 (14.7)	1 (14.3)	1.00[2]
At admission to hospital:			
Modified Rankin Scale, range 0-6			
Median (IQR)	3.0 (2.0-4.0)	3.5 (1.75-4.0)	0.96[3]
Scandinavian Stroke Scale (SSS), max = 58 points			
Median (IQR)	50 (34.5-54.0)	50 (45.5-55.3)	0.50[3]
Severity groups, n (%)			
Mild stroke (SSS 45 – 58)	19 (55.9)	5 (71.4)	0.38[2]
Moderate stroke (SSS 30 – 44)	8 (23.5)	1 (14.3)	1.00[2]
Severe stroke (SSS 0-29)	6 (17.6)	0 (0)	0.56[2]
Missing	*1 (2.9)*	*1 (14.3)*	
At inclusion:			
Modified Rankin Scale, range 0-6			
Median (IQR)	2.0 (1.0-3.0)	2.0 (1.0-3.0)	0.80[3]
Barthel Index, max = 100 points			
Median	95.0	95.0	0.72[3]
(IQR)	(90.0-100.0)	(90.0-100.0)	
Mini Mental Status Examination (MMSE) max = 30 points			
Median (IQR)	29.0 (28.0-30.0)	29.0 (24.0-30.0)	0.57[3]

[1] Independent-samples t-test
[2] Fisher's Exact test
[3] Mann-Whitney U-test

Table 3. Amount of training. Median (25-75 percentiles) minutes of time spent on physical activity and exercise during 52 weeks are presented in 13 consecutive time intervals, each consisting of four weeks.

TIME	Week 1-4 (n=39)	Week 5-8 (n=39)	Week 9-12 (n=38)	Week 13-16 (n=38)	Week 17-20 (n=38)	Week 21-24 (n=38)	Week 25-28 (n=35)	Week 29-32 (n=35)	Week 33-36 (n=35)	Week 37-40 (n=35)	Week 41-44 (n=34)	Week 45-48 (n=34)	Week 49-52 (n=33)	Overall
Physical activity[1] (min)														
Median (25-75 percentile)	835.0 (420.0-1729.0)	821.0 (300.0-1275.0)	952.5 (591.3-1278.5)	916.5 (640.0-1433.8)	848.5 (442.5-1343.0)	800.0 (541.8-1603.8)	935.0 (595.0-1460.0)	930.0 (380.0-1530.0)	945.0 (495.0-1785.0)	785.0 (430.0-1330.0)	824.5 (362.5-1170.0)	799.5 (270.0-1293.8)	675.0 (330.0-1194.0)	**848.5 (462.5-1383.5)**
Exercise[2] (min)														
Median (25-75 percentile)	240.0 (0.0-570.0)	260.0 (0.0-655.0)	325.0 (0.0-631.3)	420.0 (172.5-697.0)	472.5 (112.5-821.3)	330.0 (167.5-712.8)	390.0 (155.0-630.0)	360.0 (155.0-845.0)	455.0 (60.0-800.0)	335.0 (135.0-820.0)	345.0 (176.3-536.3)	307.5 (0.0 - 680.0)	400.0 (162.5-742.5)	**360.0 (90.0-695.0)**

[1] Physical activity: Recommended amount of physical activity per protocol is 30 min/day = 840 min per time interval (à four weeks).
[2] Exercise: Recommended amount of exercise per protocol is 45 min/week = 180 min per time interval (à four weeks).

Table 4. Intensity of training. Mean (SD[1]) and range of perceived exertion parameters are presented as ratings on Borg's scale (6-20) in 13 consecutive time intervals, each consisting of four weeks.

TIME	Week 1-4 (n=39)	Week 5-8 (n=39)	Week 9-12 (n=38)	Week 13-16 (n=38)	Week 17-20 (n=38)	Week 21-24 (n=38)	Week 25-28 (n=35)	Week 29-32 (n=35)	Week 33-36 (n=35)	Week 37-40 (n=35)	Week 41-44 (n=34)	Week 45-48 (n=34)	Week 49-52 (n=33)	Overall
PA[2] (Borg's scale)														
Mean (SD)	12.6 (1.4)	13.2 (1.6)	13.3 (1.7)	13.5 (1.5)	13.1 (1.2)	13.3 (1.5)	13.5 (1.4)	13.5 (1.7)	13.7 (1.8)	13.5 (1.9)	13.8 (1.7)	13.4 (1.7)	13.3 (1.8)	**13.3 (1.6)**
Range	8.8-15.6	10.2-18.8	9.3-18.5	11.0-17.0	11.0-16.0	9.7-16.1	11.0-16.3	11.0-17.9	9.4-16.9	9.8-16.7	10.3-16.7	9.3-16.6	9.6-16.2	**8.8-18.8**
E[3] (Borg's scale)														
Mean (SD)	14.0 (1.6)	13.8 (1.6)	14.4 (2.2)	14.5 (1.5)	14.1 (1.7)	14.3 (1.7)	14.4 (1.6)	14.3 (1.9)	14.6 (1.9)	14.5 (1.5)	14.8 (1.8)	14.3 (2.2)	15.0 (1.6)	**14.4 (1.8)**
Range	11.7-17.4	11.0-17.0	7.5-17.7	11.5-17.3	11.3-17.9	10.1-17.0	11.3-17.0	10.3-17.0	9.0-17.4	11.2-17.0	10.6-17.0	8.7-18.3	12.0-18.0	**7.5-18.4**

[1] SD: standard deviation.
[2] PA: physical activity.
[3] E: Exercise.

4.2 Adherence to time spent on physical activity and exercise

Table 3 shows participants' median (25-75 percentiles) amount of time spent on physical activity and exercise during the follow-up programme of 52 weeks, presented in 13 consecutive time intervals, each consisting of four weeks. Further, Figure 2 illustrates the differences between the median amount of reported time spent on physical activity and exercise, respectively, from the recommended amount of time per protocol during the corresponding time intervals. Time spent on physical activity and exercise required per protocol is represented by the reference value 0%. Correspondingly, the positive values (above 0%) represent reported amount of training above recommendations, while negative values (below 0%) represent reported amount of training below recommendations.

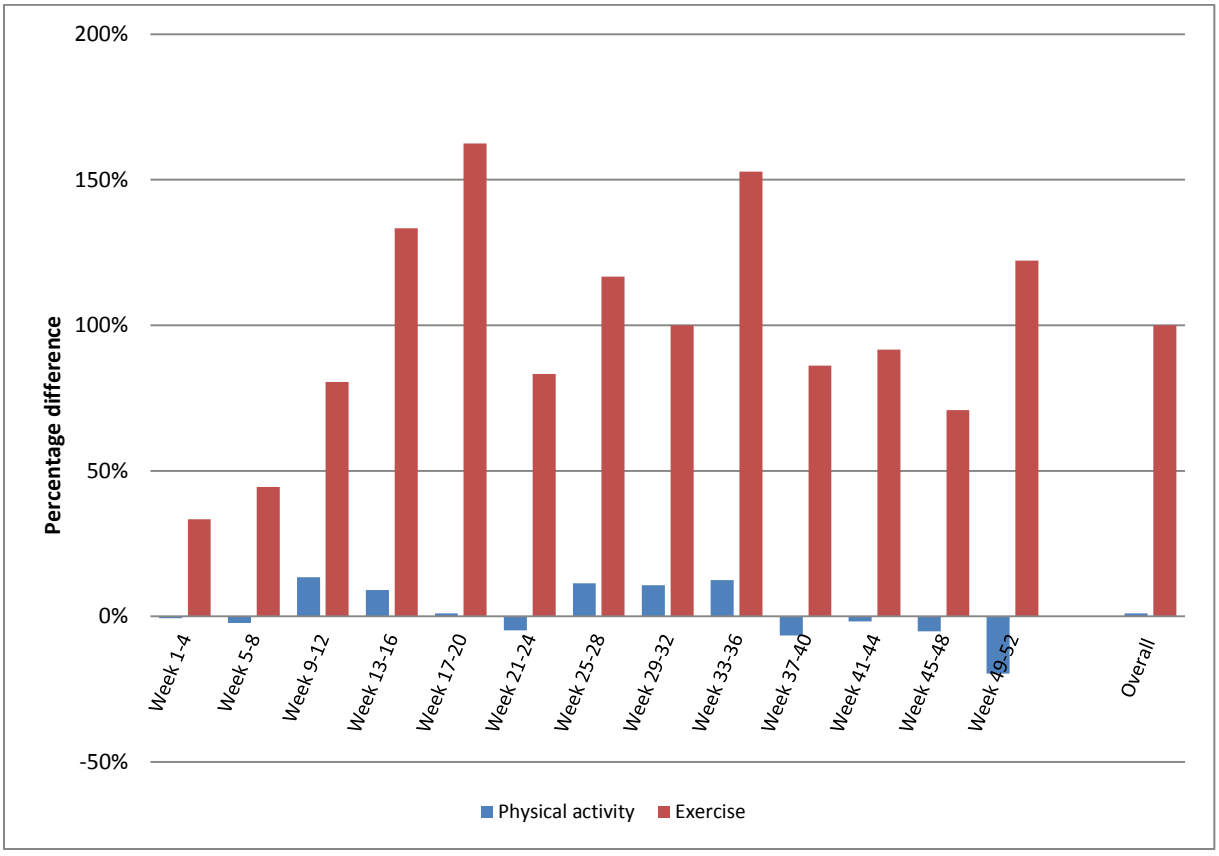

Figure 2. Differences between reported median amount of physical activity and exercise, respectively, from amount required per protocol. The latter is represented by the value 0%. Values above 0% imply amounts of training above recommendations, while values below 0% correspondingly imply amounts of training below recommendations per protocol.

4.2.1 Adherence to physical activity

With reference to Figure 2, the samples' median amount of time spent on physical activity were ranging from a maximum of 13.4% above the required amount in the third time interval (week 9-12), to a minimum of 19.6% below the recommended level at the last time interval under evaluation (week 49-52). In general, the median amount of time spent on physical activity was, however, fairly stable around the required level per protocol. The overall adherence to physical activity was 1% (IQR -44.9 – 64.7%, Fig.2) above the amount required per protocol, which corresponds to 8.5 (IQR -377.5 – 543.5) minutes above prescribed amount of physical activity per time interval. Nevertheless, there were indications that time spent on physical activity was slightly declining over time. This was primarily observed during the final part of the follow-up; from time interval 10 (week 37-40) to 13 (week 49-52). From the beginning of the study to the end, the median amount of time spent on physical activity decreased from 835 (IQR 420 – 1729) to 675 (IQR 330 -1194) minutes. No statistically significant reduction was observed (p = 0.604). Nevertheless, a reduction of 160 minutes from the beginning to the end of the follow-up indicates a decrease in adherence to physical activity of about 40 minutes on a weekly basis.

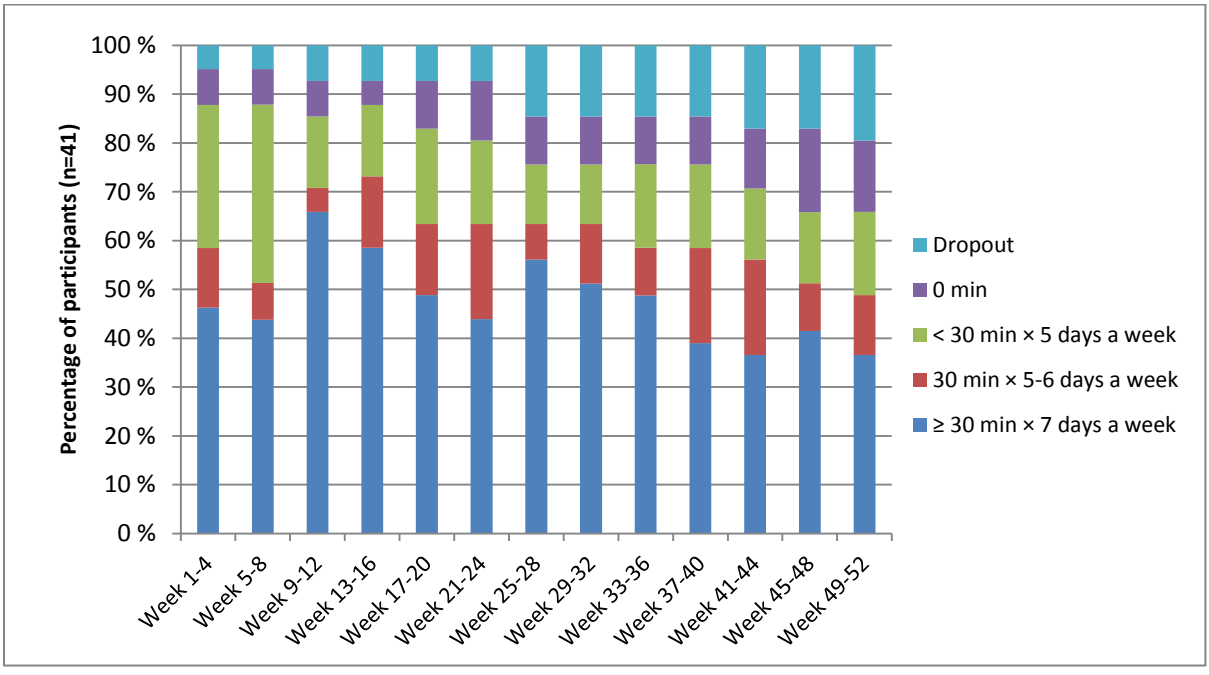

Figure 3. Reported amount of time spent on physical activity distributed in subgroups.

Figure 3 displays the distribution of reported amount of time spent on physical activity at each time interval, categorized into subgroups. Overall, a mean of 19.5 (SD 3.6) patients, equivalent to 47.5% (SD 8.8%), reported time spent on physical activity according to the required amounts per protocol. The number of participants who were adherent to the required amount of time ranged from 27 (65.9%) patients during week 9-12, to 15 (36.6%) during week 41-44 and week 49-52, indicating a

decline over time. This was in line with the increasing number of participants reporting no time spent on physical activity ranging from 2 (4.9%) patients during week 13-16 to 7 (17.1%) during week 45-48.

McNemar's test revealed no statistical significant difference in the paired proportion of participants (n=33) adhering to the prescribed levels of physical activity in the beginning of the treatment and at the end of follow-up (16 (48.5%) vs. 15 (45.5%), p=1.000).

4.2.2 Adherence to exercise

With references to both Table 3 and Figure 2, participants' median amount of time spent on exercise was larger than the recommended amount per protocol during each time interval of the follow-up programme. An overall median value of 180 (IQR -90 – 515) minutes above recommended level, demonstrated that the sample in general reported twice the amount spent on exercise than required per protocol. Furthermore, participants' median amount of time spent on exercise ranged from 33.3% (week 1-4) to 162.5% (week 17-20) above the required amount of exercise, illustrated in Figure 2. Additionally, a statistically significant increase in participants' adherence to exercise from the beginning and to the end of the follow-up programme was revealed (p = 0.032), with a median adherence to exercise increasing from 240 minutes (IQR 0-570) to 400 minutes (IQR 162.5-742.5) per time interval.

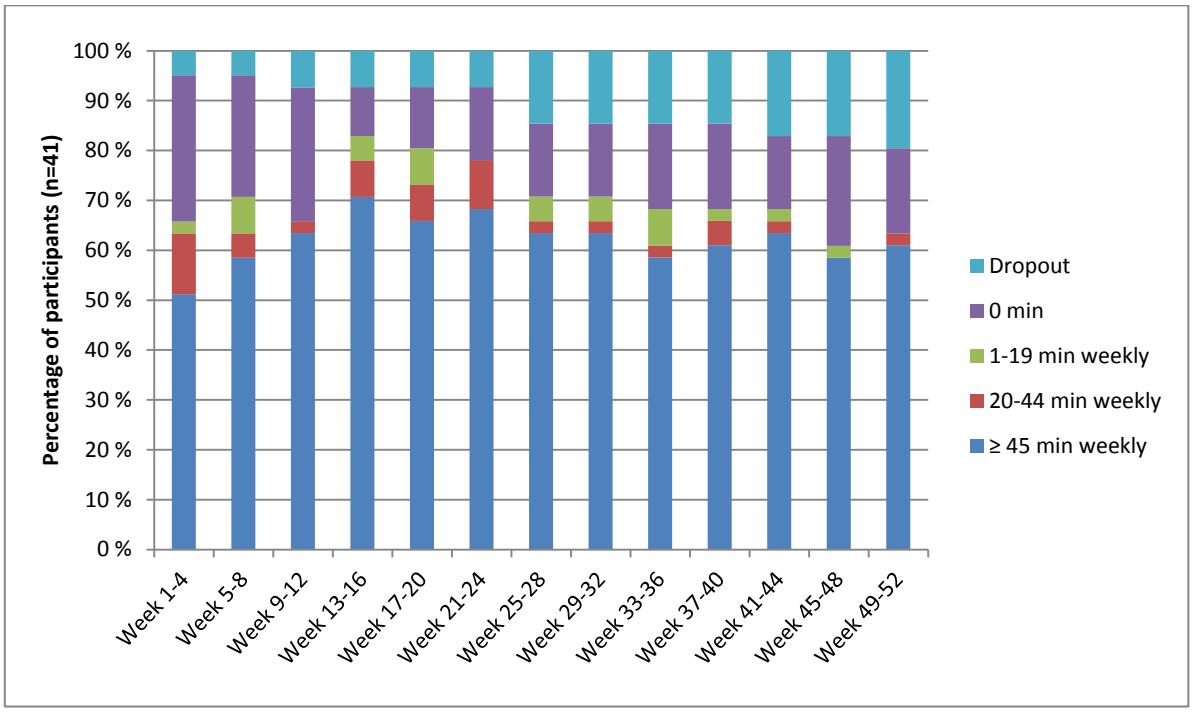

Figure 4. Reported amount of time spent on exercise distributed in subgroups.

Figure 4 illustrates the reported amount of time spent on exercise distributed in subgroups. The average proportion adherent to the recommended amount of exercise was 25.5 (SD 2.0) patients, equivalent to 62.1% (SD 5.0), ranging from 21 (51.2%) patients during week 1-4 to 29 (70.7%) during week 13-16. The number of participants reporting no time spent on exercise decreased from 12 (29.3%) at the beginning (week 1-4) to 7 (17.1%) at the end (week 49-52). An average of 18% (SD 5.7%) reported no exercise.

McNemar's test demonstrated that the paired proportion of participants (n=33) adhering to the prescribed amount of exercise significantly increased from the beginning to the end of follow-up (17 (51.5%) vs. 25 (75.8%), p=0.039). Thus, an increase in adherence to exercise of 24.3% among patients who completed the follow-up programme were observed, revealing that three-quarters of the participants were conducting their exercise as required or more when tested at 52 weeks follow-up.

4.3 Adherence to intensity levels during physical activity and exercise

Mean (SD) and range of perceived exertion parameters during physical activity and exercise, respectively, are presented as ratings on Borg's scale (6-20) in Table 4. An overall mean of 13.3 (SD 1.6) points during physical activity and 14.4 (SD 1.8) points during exercise were observed. Ratings varied from 12.6 (SD 1.4) points (week 1-4) to 13.8 (SD 1.7) points (week 41-44) during physical activity, whereas mean ratings during exercise varied from 13.8 (SD 1.6) points (week 5-8) to 15.0 (SD 1.6) points (week 49-52). Paired-samples t-tests revealed only minor increases of mean intensity from the beginning to the end of the follow-up for both physical activity (0.59 points) and exercise (0.48 points). Further, no statistically significant changes in intensity levels from the beginning to the end of follow-up for neither physical activity ($p = 0.176$) nor exercise ($p = 0.357$) were observed.

Figure 6 and 7 illustrate the distribution of intensity levels during physical activity and exercise among the participants, divided into levels of light (6-10 points), moderate (11-14) and hard intensity (15-20). In addition, the relative frequencies of missing values at each time interval are presented. Overall, a mean of 23.1 (SD 5.1) of participants reported moderate levels of intensity during physical activity, equivalent to 56.3% (SD 12.4%). Regarding exercise, the average number of patients reporting intensity at moderate levels was 16 (SD 3.2), equivalent to 38.3% (SD 7.8%). A mean of 9.3 (SD 2.0) patients (22.7% (SD 5.0 %)) reported exertion levels corresponding to Borg's scale of 15-17 points as recommended per protocol. Further, an average of 12.3 (SD 3.8, 30% (SD 9.2%)) and 14 (SD 2.8, 35.3% (SD 6.9%)) patients were missing reports of exertion parameters during physical activity and exercise, respectively.

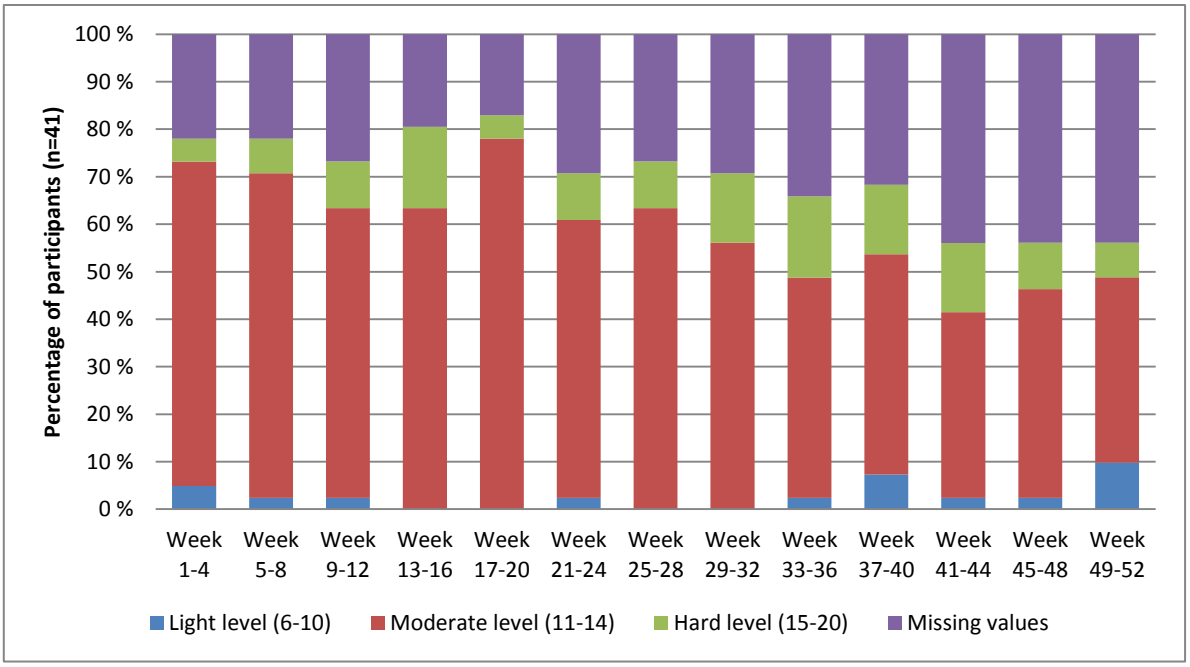

Figure 6. Levels of intensity during physical activity, measured with Borg's scale.

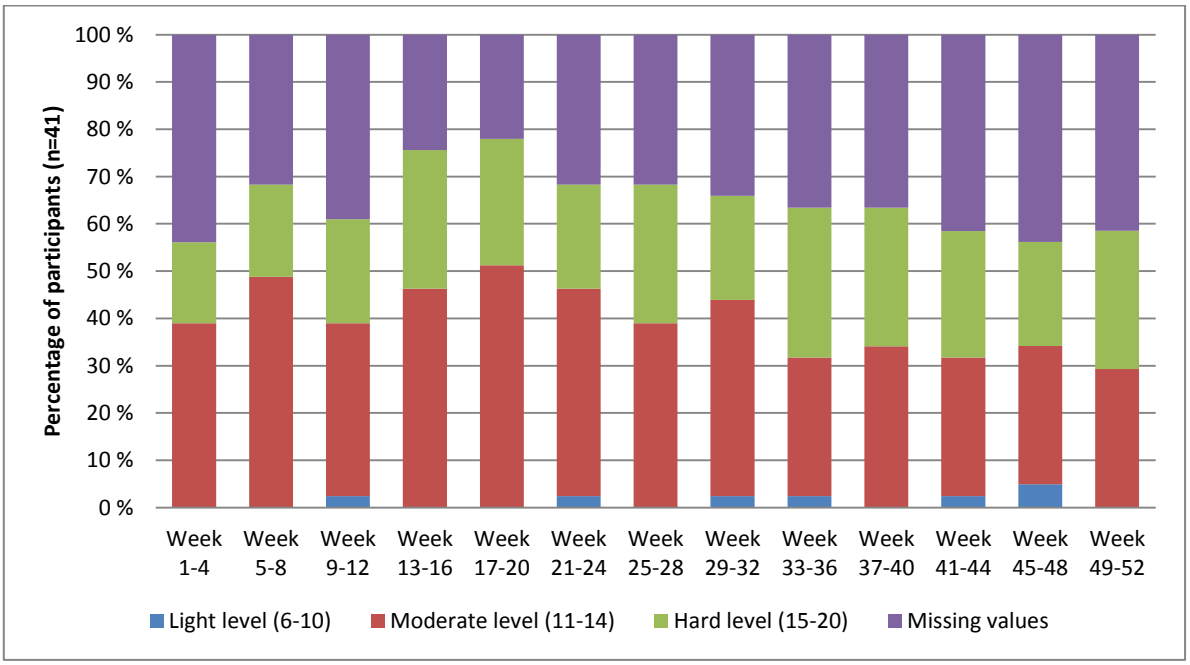

Figure 7. Levels of intensity during exercise, measured with Borg's scale.

4.4 Goal attainment and its relation to adherence

Table 5. Degree of goal attainment at each evaluation.

Goal Attainment Scaling (GAS); *sessions of evaluations*	**First evaluation at 13th week** (n=37)	**Second evaluation at 25th week** (n=32)	**Third evaluation at 37th week** (n=31)	**Forth evaluation at 49th week** (n=27)
No. (%[1]) of patients achieving or exceeding their set goals[2]				
- 50-59 points	12 (32.4)	9 (28.1)	6 (19.4)	7 (25.9)
- 60-69 points	2 (5.4)	2 (6.3)	0 (0)	1 (3.7)
- 70 ≤ points	2 (5.4)	0 (0)	1 (3.2)	1 (3.7)
- **Total**	**16 (43.2)**	**11 (34.4)**	**7 (22.6)**	**9 (33.3)**
No. (%[1]) of patients not meeting their set goals[2]				
- 40-49 points	9 (24.3)	8 (25.0)	10 (32.3)	4 (14.8)
- 30 ≥ points	12 (32.4)	13 (40.7)	14 (45.2)	14 (51.8)
- **Total**	**21 (56.7)**	**21 (65.7)**	**24 (77.5)**	**18 (66.6)**
Overall GAS-score, median (25-75 percentile)	43.8 (30.6 – 50.0)	40.0 (31.7 – 50.0)	40.0 (30.0 – 43.8)	37.7 (31.4 – 50.0)

[1]: % = Valid percent.
[2]: Score <50 reflects goal achievement below the expected level, score =50 is the expected level of performance, and score >50 reflects performance above the expected level.

Table 5 presents an overview of number of participants with goals, in addition to the participants' degree of goal attainment, at each evaluation during the follow-up programme. In accordance with what was presented in the flow chart (Fig. 1), goals were evaluated at four sessions. Numbers of patients with goals were declining, for unknown reasons, from 37 of 39 participants with goals at the first evaluation to 27 of 33 participants with goals at the last evaluation. As seen from Table 5, the median GAS-score were below the level of what was expected (50 points) at every evaluation, declining from 43.8 points at the first evaluation to 37.7 points at the last evaluation. The decrease in scores of 6.1 points did not reach statistical significance (p = 0.44).

Figure 8 displays the proportion of participants who achieved goals (≥ 50 points) versus those who did not (< 50 points), in addition to the dropout rates and the proportion of participants missing goals at each evaluation point. Although the McNemar's test revealed that the proportion of participants achieving goals was slightly larger at the first evaluation compared to the last evaluation (39.0% vs. 22.0%), the difference did not reach statistical significance (p=0.105).

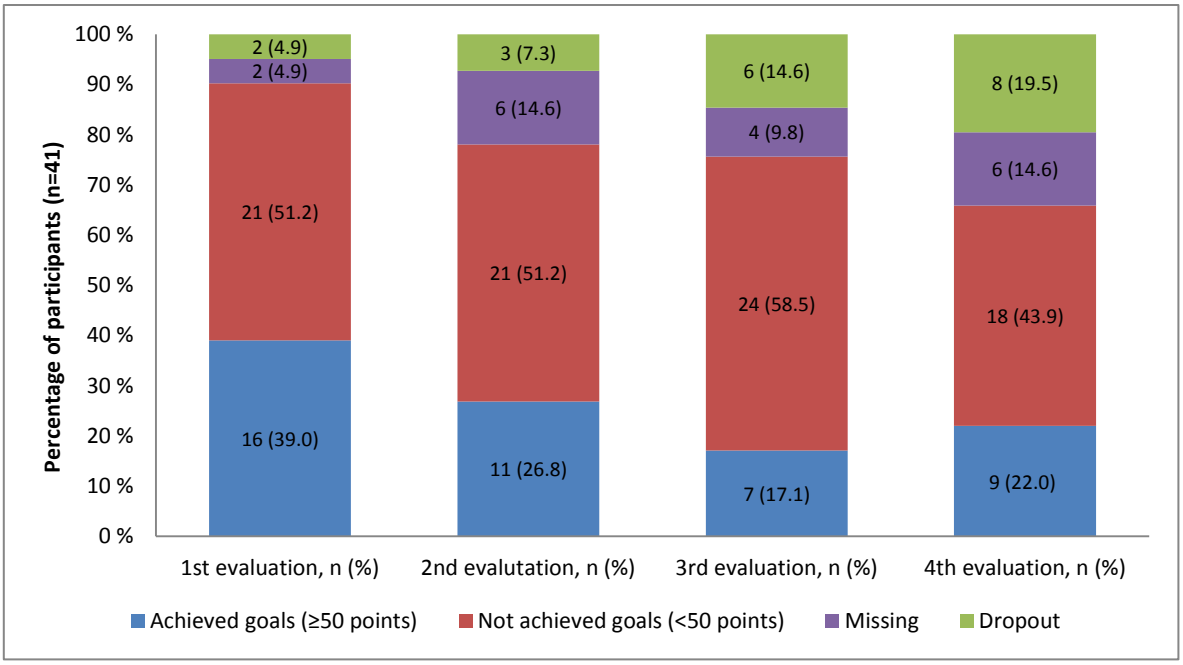

Figure 8. Goal achievements at each evaluation.

4.4.1 Association between GAS and adherence to physical activity and exercise

None of the evaluation points tested proved statistically significant relationships between achieving goals and adherence to physical activity and exercise per protocol. However, there were minor indications of more frequent goal achievement among participants who reported 100% adherence of both physical activity and exercise, compared to the participants who failed to reach the recommended time on both physical activity and exercise. The first evaluation assessed after thirteen weeks of the follow-up programme revealed that the proportion of participants who completed at least 30 min of daily physical activity and 45 minutes of weekly exercise, were more likely to achieve their goals than participants who failed to reach the recommended levels of physical activity and exercise (58.3% vs. 33.3%, p = 0.151). Similar patterns were observed during the evaluations after 25 weeks (42.9% vs. 27.8%, p = 0.465), 36 weeks (35.3% vs. 7.1%, p = 0.094) and 49 weeks of the follow-up programme (45.5% vs. 25.0%, p = 0.411).

5 Discussion

The present study is unique in that it is the first study systematically assessing adherence to physical activity and exercise among stroke survivors over 52 consecutive weeks. The main results revealed an overall good strength of adherence to the prescribed amount of exercise, while the adherence to physical activity should be regarded as moderate. However, levels of intensity during both physical activity and exercise were primarily corresponding to scores on Borg's scale equivalent to a moderate degree of perceived exertion, i.e. 11-14 points. This left a small average of 22.7% of the reported amount of exercise to have been performed within the prescribed levels of high intensity, i.e. 15-17 points on Borg's scale. Further, goals related to the individuals' training programmes were poorly achieved over time. There were, however, slight indications of more frequent goal achievement among highly adherent patients, compared to those who were non- or partly adherent.

5.1 Adherence to physical activity and exercise

Overall, the median amounts of reported physical activity in this study were approximately corresponding to the recommended activity levels per protocol during the first twelve time-intervals (week 1-48) of the follow-up programme (Fig. 2). Small differences in both directions were observed with reference to the prescribed levels of activity. Nevertheless, from time interval 10 (week 37-40) a minor, yet increasing, decline was observed. This was primarily noticeable in time interval 13 (week 49-52). The decrease in activity observed over time in the present study is in line with earlier research indicating that the majority of stroke patients may cease or reduce their activity levels over time (51). However, the decline detected in the present study did not reach statistical significance, and at the end of the follow-up programme the median amount of physical activity still corresponded to levels of 30 minutes of physical activity five days a week. This is in accordance with the levels of activity recommended for adults and elderly by the Norwegian Directorate of Health (83).

On the contrary, the median amounts of reported time spent on exercise proved to reach levels beyond what was intended per protocol (Fig. 2). In addition, the reported amount of exercise significantly increased from the beginning to the end of the follow-up programme. The most reasonable explanation of this finding is that the increase in time spent on exercise was achieved as a consequence of the participants' improved physical fitness levels. Further, this might have enhanced motivation and improved the ability to exercise as intended. However, one might speculate whether the increasing amount of exercise was compensated for by the decrease in physical activity. This suggestion is in line with the results of Meijer and colleagues (97), who have shown that in the elderly an exercise training programme with moderate intensity resulted in an increase in exercise, which was compensated for by a decrease in non-training physical activity. They propose that elderly

anticipate exercise by reducing their physical activity before the exercise sessions, possibly by resting more to save energy, which might have been the case concerning the participants in the present study as well.

5.1.1 Expected levels of activity and exercise

To our knowledge, few studies have investigated self-reported adherence to both physical activity and exercise among chronic stroke patients in a long-term perspective. This limits the possibilities of comparing the present findings with prior research. Alternatively, available cross-sectional surveys and longitudinal observational studies of shorter follow-up time are applicable for comparison. Hence, it gives an impression of the expected amount of physical activity and exercise undertaken by community-dwelling stroke survivors.

A large cross-sectional survey assessing levels of exercise among chronic stroke patients with self-reported questionnaires, found a proportion of 31% reporting regular exercise, in addition to 27% reporting rare or no exercise (53). Although a slightly different definition of exercise limits the possibility of direct comparison, the results of the present study indicate larger rates of exercise, in which a mean of 62.1% was found to be adherent to exercise in a long-term perspective, while an average of 18% reported no exercise.

Furthermore, studies measuring physical activity by the use of accelerometers or other electronic devices among stroke survivors (43-45), found significantly lower proportions of patients meeting the recommendations of 30 minutes of daily physical activity compared to the findings of the present study. One longitudinal follow-up study, investigating physical activity over six months after stroke, reported very low activity levels during the time under evaluation (44). Moreover, a study operating with similar sample size and recommended levels of physical activity as the current study, revealed that only 15% of the participants met the recommended physical activity levels (43). It is also shown that the ambulatory activities of stroke patients are well below both the recommended levels and activity levels of sedentary age-matched adults, including those with disabilities (45, 98).

Compared to healthy individuals, findings from a population-based Norwegian survey assessing activity levels with the use of a self-reported questionnaire, suggested that an average of 46.7% of the population, across all age groups, achieved the activity levels corresponding to 30 minutes of activity seven days a week (99). These results indicate activity levels approximately concurrent with the present result. However, the referred survey lacked age-distributed results. The physical activity level for older adults tends to decline with age, thus, one can assume that levels of activity among elderly in the referred study were below the average findings of the present study. This is confirmed by a recent population-based Norwegian survey, measuring physical activity by the use of

accelerometers, showing relatively stable activity levels in adulthood up to 70 years of age (100). Moreover, a significant decrease in activity levels was observed among those >70 years, in which only 15% reached the recommended levels of 30 minutes of daily physical activity. For both men and women, the decrease was especially pronounced after the age of 75 (100).

As addressed above, prior research show conflicting findings, and there are large discrepancies between studies based on self-reported data versus objectively measured physical activity and exercise. Methodological differences limit the possibilities of direct comparison between the referred research and the present study. Still, the results of the present study suggest increased activity- and exercise levels compared to what is reported in the referred research. Although beyond the scope of the current study, it should be mentioned that combining the addressed parameters, i.e. assessing patients' degree of adherence to both physical activity and exercise of required intensity levels, would probably give lower strengths of adherence than found in the present study.

5.1.2 Elements contributing to enhanced activity levels

Without collecting amounts of daily physical activity and exercise reports from the control group in the LAST-trial, it is not clear if the intervention per se accounted for the activity levels observed among the participants in the present study included from the experimental group. Nevertheless, there are reasons to believe that several elements of the follow-up programme might have promoted the participants' adherence to physical activity and exercise. For instance, the training diaries were emphasised as an essential part of the intervention in the present study to ensure compliance (25). Evidence indicates that self-monitoring, i.e. the process of attending to and recording one's behaviour, is an effective technique for producing behavioural change (37, 101). In addition, it is evidence demonstrating that counselling to exercise by a healthcare provider can influence patient's behaviour. Regarding stroke survivors, Shaughnessy and colleagues (53) found that being told to exercise by a primary healthcare provider had an important influence on the outcome expectations and directly influenced exercise behaviour. Furthermore, essential patient-centred counselling techniques, e.g. motivational interviews, utilised in the present study, have proven to lead to an improvement in patients' confidence in their ability to engage in rehabilitation and improve recovery (69), thus contributing to increased adherence to the intervention. However, the overall effect of these elements will be tested thoroughly in the LAST-trial.

5.1.3 Variability between participants

According to our pre-defined classification of adherence, the reported time spent on physical activity ranged from less-adequate to moderate adherence, while the time spent on exercise ranged from moderate to good adherence. However, the interquartile range revealed large variability between participants. Special attention should be given to participants reporting no time spent on physical

activity, which in the present study increased from 7.3% in the beginning to 14.6% in the end of the follow-up programme. The findings regarding exercise, revealed a decline in non-adherers over time from 29.3% in the beginning to 17.1% at the end, which is still a large proportion. Failure to maintain adequate levels of post-stroke training may cause cardiovascular deconditioning, physical deterioration and reduced function (40). Hence, it is of great importance to investigate the reasons why some patients fail to reach the intended physical activity and exercise levels of a rehabilitation programme.

With respect to aetiology, severity and disability, stroke is heterogeneous in its nature (13), and the findings of the present study might be a reminder of why individualised rehabilitative programmes are demanded after stroke. When applicable tools are used to assess the individual for physiological and emotional barriers to continue recovery, each patient is best prepared to reach their optimal state of function and well-being (40). Although the follow-up programme of the present study aimed to individualise the treatment tailored to suit individual challenges, one might question its overall success. As emphasised by Meichenbaum and Turk, determinants of adherence is, among others, dependent on treatment variables (32). For instance, one should question whether coaching every four weeks for those who were not adherent to the intervention is considered as an adequate frequency of visits to achieve and maintain adherence over time. Although results from a recent RCT indicate that long-term follow-up on consultative basis with self-initiated training might be just as beneficial as compulsory training (75), one should question whether this happened due to the Hawthorne effect. This phenomenon suggests that subjects in behavioural studies change their performance in response to being observed, regardless of an independent variable (77) . Hence, degrees of closer supervision or more intensive strategies, as demonstrated by Kaplon and colleagues (60) and by Boyson and colleagues (76), might be necessary to enhance adherence.

5.1.4 Dropouts

Long-term clinical trials have a great challenge in keeping participants enrolled and adherent to protocol (102). In the present study, 7 out of 41 participants were defined as dropouts. Despite lack of statistical significant differences from the participants who completed the study, further investigations disclosed that the dropouts separated in two different directions according to baseline characteristics. The two groups differed in age, cognitive levels, degree of functional disability and dependence. It appeared that the patients were either almost back to their pre-stroke functional level, or they were severely affected both physically and mentally. Disease related variables, such as chronic disorders and patients' perceptions of their symptoms, have been shown to influence adherence (34). Considering the present results, one might speculate whether the disease severity was one of the reasons for withdrawals. This corresponds with earlier research suggesting that

patients with either mild degree of a disease or those severely affected tend to submit less than patients with moderate severe disease (28). However, the sample was too small for any conclusions to be drawn. This tendency should be investigated further with the total dropouts from the sample of the intervention group in the LAST-trial. Additionally, future studies should investigate the determinants of adherence and the identification of participants who are susceptible for poor participating in rehabilitation programmes.

5.2 Adherence to intensity levels during physical activity and exercise

With regards to participants' adherence to levels of intensity, the results demonstrated the overall average to fall within moderate levels of perceived exertion, i.e. 11-14 points of Borg's scale, both during physical activity and exercise. Hence, results of the present study were in accordance with the current Norwegian guidelines (42), in addition to the recommendations by the American Heart Association (40). A moderate intensity level, in combination with sufficient amount and frequency of aerobic exercise, might be optimal in terms of achieving different health benefits. This includes increasing independency in activities of daily living (ADL), walking speed and efficiency, in addition to tolerance for prolonged physical activity, besides reducing the risk of cardiovascular disease (40).

Although good health effects can be achieved at lower intensity, high intensity is important to improve and maintain the cardiorespiratory fitness progress (103). The overall mean of 14.4 points reported during exercise in the current study, dropped just below the limits of the intensity level recommended per protocol, i.e. 15-17 points. This finding is consistent with previous studies among healthy, yet sedentary, adults, showing better adherence to moderate compared to high intensity physical activities (104-106). As opposed to exercise physiology, where high-intensity cardiorespiratory training often is referred as exercising at 77-95% of maximal heart rate (107), intensity of physiotherapy after stroke usually refers to the frequency of repetition of desired movement or amount of time dedicated to practice (108). Subsequently, data regarding effects of exercise intensity concerning stroke survivors, in relation to the physiological definition, are still scarce. Nevertheless, previous research indicates that walking and domestic work have the potential of reaching at least moderate levels of intensity due to indications of elevated oxygen costs of walking in hemiplegic patients compared with that of able-bodied subjects of comparable body-weight (109, 110). Additionally, domestic tasks are associated with considerably greater energy requirements among post stroke women than among their healthy counterparts (111). On the contrary, reaching high-intensity levels of perceived exertion still proved to be a challenge in the present study. Common motor impairments, such as hemiparetic gait and reduced balance, consequently leading to an increased risk of falling, might be barriers to conduct high-intensity training for stroke patients (40). Besides, attempts to implement a physical conditioning regimen may

be proven difficult and frustrating for patients suffering from post-stroke fatigue or depression (40). Additionally, our clinical experience indicated that some patients were afraid to push themselves beyond comfortable limits, fearing acute illness or discomfort.

Nevertheless, results from two recent pre-test – post-test intervention studies have shown that high intensity aerobic interval training, with intensity levels at 85-95% of peak heart rate during intervals, is beneficial and feasible for a selected group of stroke patients (112, 113). These studies, however, distinguish from the present study, as the contestants performed tailored treadmill training in close supervision by an experienced physiotherapist. Close supervision might trigger the motivation to exercise at a higher level of intensity, in addition to increasing the experience of training within safe surroundings. One can assume that without this advantage it would have been difficult for the participants in the present study to reach the recommended levels of perceived exertion.

5.3 Goal achievement and its relation to training adherence

The intention of using GAS as a tool to enable participants to achieve satisfactory adherence to physical activity and exercise required per protocol, appeared to give ambiguous findings. First and foremost, the results in the present study revealed overall levels of goal attainment to be substantially lower than expected. Secondly, slight declines of goal achievements were observed over time. Nevertheless, indications of a minor relationship between training adherence and goal achievement were identified.

Usually, if goals are predicted without bias, under- and over-achievement of goals are expected to occur approximately equally. Hence, the GAS's T-score would be normally distributed around a mean of 50 (73). Overall levels of goal attainment were much lower than expected in the present study, ranging from median scores of 43.8 to 37.7 (Tab. 5). This might indicate goals in the present study to have been biased, possibly reflecting a number of reasons, including; (a) the clinician's ability to predict and negotiate realistic expectations of outcome together with the patient, (b) the patient's ability and motivation to achieve goals, and (c) the degree of goals set in accordance with the content, duration, frequency and/or intensity of the physical activity and exercise prescribed per protocol.

Turner-Stokes emphasises that goal attainment scaling depends on both the patient's ability to achieve their goals and the clinician's ability to predict outcome, the latter requiring knowledge and experience (73). In the present study, an experienced physiotherapist in stroke rehabilitation, specifically trained in the trial protocol, performed the intervention. Nevertheless, one might assume that the frequency of appointments every four weeks neither gave the therapist enough time nor an optimal familiarizing context with the patient's actual abilities and preferences. In addition, an

independent physiotherapist does not have the advantage of consulting with a treatment team when negotiating goals, the latter recommended when using GAS as a tool in a rehabilitation process (114). Hence, the ability of setting realistic and individually adapted goals was challenged. The results suggest that the physiotherapist in collaboration with the patients had a tendency to incorporate over-ambiguous goals.

Furthermore, Turner-Stokes underlines how the involvement of patients with acquired brain injury presents particular challenges for GAS, as cognitive and communicative problems may limit their ability to remember and articulate goals (114). These were common challenges for some of the participants in the present study, affecting both their ability and motivation to achieve goals. This was in conflict with the fact that GAS requires a collaborative involvement both for the patient and their treating team (114).

Finally, task-specific training is a well-accepted principle in motor learning, which suggest that training should target the goals that are relevant for the needs of the patients (13). Some of the goals set in the present study were lacking a direct link between the goals and training, which might reduce the possibility of achieving goals. However, this requires further explorations. In general, the issues addressed above underlines how an exclusion of one or several of the elements that contributes to setting goals in an unbiased fashion, possibly skew the overall GAS's T-score.

Despite lack of statistical significance, there were minor indications of goals achieved more frequently among patients who were adherent to the prescribed amount of training during the current time under evaluation, compared to those who were less adherent. These indications were demonstrated at every evaluation point. Earlier research is supporting these findings, explaining that the degree of goals to be achieved is dependent upon adherence (17, 72). Additionally, goal setting is considered an integral part of stimulating to an active, educational, solution oriented and patient focused process in stroke rehabilitation (17, 19), and there are consensus of goal setting to be useful in the promotion of adherence to physical activity (63).

Due to the referred theoretical aspects, there are reasons to believe that the relationship between training adherence and goal achievement probably would have been stronger in the present study if goals were predicted without bias. Consequently, the implementation of goals as a tool of ensuring adherence to physical activity and exercise did not act entirely as intended in the study. Hence, potential adjustments with regards to the context of goal setting should be optimised.

5.4 Methodological considerations

With regards to research exploring training adherence among stroke survivors, the present study contributes with systematically registered patterns of adherence in a long-term perspective. At current date, this is scarcely reported in prior research for this patient group. Furthermore, the study emphasizes the importance of observing the different components of training, i.e. the duration, frequency and intensity, when evaluating adherence. This is especially important taking the dose-response relationship between activity levels and health benefits into consideration (115). Nevertheless, there are several limitations to the present study that are debated in the following.

5.4.1 Internal validity

Several factors might have threatened the internal validity of the findings in the present study. Issues of the longitudinal research design and outcome measures used to assess adherence, are of particular concern.

Study design

Maturation and history are examples of confounders unrelated to the therapeutic intervention that might have influenced patients' adherence (77). For instance, collecting data over 52 weeks might have increased the chances of biological or psychological changes within participants over time, which could have produced behavioural changes beyond the control of the study (116). Familial considerations, acute illness, public holidays or other irregularities in everyday life that were likely to occur during the follow-up programme might have affected the responses for the participants. Additionally, some patients might have gotten used to completing the training diaries in a certain manner over time due to daily routines and familiarity. Our clinical experience indicated that this was especially noticeable when patients were estimating exertion levels of Borg's scale, as some reported repeatedly the same intensity levels regardless of change in frequency or duration of the activity performed. Further, some patients reported that they became tired of filling in the training diaries over time, especially close to the end of the follow-up.

Outcome measurements

Measurements used to assess adherence to physical activity and exercise should be discussed. First of all, measuring physical activity is difficult due to its complex nature, and the challenge of balancing methodological feasibility with measurement accuracy is complicated by problems inherent in both self-reported measurements as for objective monitoring (117). Secondly, there is no single measure of activity at current date that provide objective, valid, and reliable data about the mode, intensity, duration and frequency of exercise in field settings (118).

All of the measurements utilised in the present study were of subjective character. Although standardized self-report instruments, such as training diaries and activity surveys, typically have been

used to assess physical activity in field settings (119-121), they are of variable validity. Mainly, they are limited by recall bias, social desirability bias and vulnerability to patient's inaccuracies (118, 122). As objective instruments, such as body-worn sensor systems, have been developed to overcome these problems, they may offer an accurate and feasible method of gathering detailed information on physical activity (123). Hence, there are reasons to believe that an additional objective component implemented in the present study would have contributed to reflect a more accurate activity pattern of individuals (124). However, despite their accuracy for measuring walking activities, they cannot evaluate other types of movement as precisely as required. Carrying heavy loads, resistance training, climbing the stairs, activities in water or riding a bike are examples of such, which may result in an underestimation of total activity levels (31, 125, 126). Additionally, it would not have been possible to wear activity monitors day and night in a long-term follow-up programme. Due to the benefits of training diaries assessing both the content, amount, frequency and intensity of training, besides being one of the simplest and least equipment-intensive methods to register adherence (118), they were accepted as a reasonable measurement in the current study.

Combined measurement

This study combines participants' self-reported time spent on physical activity and exercise with adjustments by the physiotherapist. This method has not been validated in previous research, however, a post-hoc analysis was performed to analyse the differences between participants' self-reports exclusively and the combined measurement. After adding the physiotherapist's adjustments, the results indicated only a small increase in the amount of reported activity over time (0.0%-4.2%). A few exceptions were recognised in the beginning of the follow-up, revealing a discrepancy of 26.4% and 16.4% during the second and third time interval, respectively. This indicated a lack of participants' self-reports in their training diaries compared to the combined measurement. The reasons for these observed deviations are uncertain, however, with the largest discrepancy found in the beginning of the follow-up programme one can assume that this might happened due to a familiarizing process of reporting activity in training diaries. Nonetheless, it seems that reviewing training diaries on a daily basis contributed to ensure compliance, in accordance to what was predicted in the protocol (25).

Although the combined measurement to a certain degree adjusted for participants' possible underestimations of training reported in the diaries, any uncertainties of participants might over-reporting time spent on either physical activity or exercise were not adjusted. This represents a limitation of the results, and the reported activity levels should therefore be interpreted with caution. Nevertheless, our clinical experience implicated that underestimation was a larger challenge than overestimation. In addition, recording training of shorter bouts than 10 minutes should

probably have been left unregistered, due to the fact that bouts below the referred duration are not as effective in affecting chronic disease risk factors. Moreover, there were indications of participants finding exercise easier to report than physical activities. In accordance with the definitions described in section 2.2, this might be due to the fact that exercise is a more structured and planned activity with fixed limits, compared to physical activities. The latter were probably undertaken in different and irregular situations during the day, hence, threatened by recall bias to a greater extent than exercise.

Borg's scale

The validation of Borg's scale applied on the stroke population is still insufficient. Nevertheless, a recent study by Sage and colleagues (127), examining the validity of ratings of perceived exertion (RPE) at individuals in the sub-acute stage of stroke recovery, concluded that RPE appears to be a reasonable indicator of exercise intensity after stroke at moderate (60-70% VO_{2peak}), but not at high-intensity exercise (80% VO_{2peak}). Similar findings within cardiac rehabilitation concluded that RPE resulted in an exercise intensity level below target during high-intensity interval training (128). The relative heart rate (HR), i.e. percentage of maximal HR measured with HR-monitors, provides an alternative to Borg's scale. Problems with inadequate measures, however, might occur in patients treated with beta-blockers, which lowers both the maximal heart rate and heart rate at submaximal work (42). Further, RPE is an accepted method for subjective estimates of exercise effort and intensity in both healthy people and patient population (85-87). In addition, it does not require costs or external equipment.

Goal Attainment Scaling (GAS)

GAS has shown to be suitable as an outcome measure for patients with multiple, complex rehabilitation needs (129). This includes individuals who experience disability following acquired brain injury, and among them stroke patients (130-132). Still, a number of significant limitations in using GAS within the stroke rehabilitation setting have been identified. As discovered in the present study, a potential criticism of GAS is that it depends not only on the improvements made by the patients during rehabilitation, but also in the experience and ability of the clinicians to predict outcome (73). A period of formal training in goal setting and scaling procedures prior to using GAS in both research and clinical practice is therefore necessary (133). Further, defining predetermined levels for each of the five outcome score levels is in practice time-consuming, and additionally, there is a potential risk for the use of minus figures when a goal is not achieved to be apprehended as demoralizing or discouraging for patients (73). In addition, the physiotherapist claimed that defining suitable goals was challenging. Nevertheless, GAS allows for important changes in function to be identified, which many current scales may not address (134). However, further work is needed to

assess construct validity and generalizability of findings for GAS to become a routine outcome measurement in stroke rehabilitation.

5.4.2 External validity

With regards to the external validity, the sample was limited to those individuals who were participating voluntarily in a stroke rehabilitation programme. This might have led to possible selection bias, in which the present study might reflect a higher extend of adherence to physical activity and exercise than what could be expected among those who chose not to participate. Further, the study sample consisted of stroke survivors mild to moderate affected in terms of severity of stroke. Hence, for stroke survivors more severely affected in both motor function and cognition, the results should be interpreted with caution.

With the relatively small sample size of 41 participants, one should be aware of the possibility of non-significant results due to insufficient power. Hence, the possibility of committing a Type II-error, i.e. obtaining a non-significant result when in fact the null-hypothesis is not true, is imminent (135). In addition, although data were available on dropouts until they left the programme, withdrawals of these individuals reduced the data. Consequently, those who completed the programme provided the majority of data and, thus, the application of these findings applies primarily to individuals who adhere to programmed rehabilitation. In addition, the large amount of missing data considering reports of perceived exertion during training was posing a threat to the external validity. Our clinical experiences indicated that it was hard for some stroke patients to rate their perceived exertion, especially among those with little or no training experience and those with reduced cognitive function.

5.5 Implications for clinical work

Registering adherence in relation to determine if a treatment is feasible should be emphasised among clinicians as well as researchers. Consequently, this may lead to a stronger awareness of patients in the risk of dropping out of a rehabilitation process. Additionally, this might enhance the possibility of adjusting treatment parameters to better achieve satisfactory adherence among patients who are vulnerable to poor participation in rehabilitation programmes.

Further, the rehabilitation programme presented in the current study was closely related to a clinical context as the follow-up programme was performed in stroke patients' own environment. Besides, no advanced or expensive equipment were required. This is in accordance with the well-accepted principle of context-specific training in motor learning (13). Furthermore, although beyond the scope of the present study, patients acquired to take responsibility of regular physical activity and exercise in a long-term perspective might contribute to a continuation of well-established habits, perhaps

beyond the duration of the rehabilitation programme. However, these suggestions are yet to be explored in future research.

6 Conclusions

The present findings showed that patients participating in a long-term follow-up programme after stroke demonstrated moderate adherence over time to 30 minutes of daily physical activity and good adherence to a minimum of 45 minutes of weekly exercise. These results indicate that elements of the intervention, like self-monitoring one's behaviour through training diaries, regular coaching and motivational interviews assessed by a coordinating physiotherapist, potentially contributed positively to the observed levels of adherence to physical activity and exercise. On the contrary, high intensity levels during exercise and goal attainment were only sparsely achieved. There were, however, indications of a minor relationship between goal attainment and adherence to physical activity and exercise in terms of more frequently achieved goals among highly adherent patients.

Future research should consider implementing a combination of self-reported and objective outcome measures, aiming for a more accurate and complete registration of physical activity and exercise behaviour within this patient group. Further, investigations of whether the observed decrease in physical activity happened by coincidence, or was the beginning of a significant decline, should be explored. This renders the possibility of determining to what extent levels of physical activity and exercise found in the present study was permanently established among the stroke patients. Conceivably, these suggestions would contribute to a further thorough understanding of this research field.

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Appendices

Treningsdagbok for: _____

Daglig fysisk aktivitet

Du har sammen med din koordinerende fysioterapeut blitt enig om å gjennomføre 30 minutter daglig fysisk aktivitet og du skal i løpet av de neste fire ukene velge mellom følgende aktiviteter:

1 .....

2 .....

Ukentlig trening

Du har sammen med din koordinerende fysioterapeut blitt enig om å gjennomføre 45-60 minutter trening hver uke og du skal i løpet av de neste fire ukene gjennomføre følgende treningsopplegg:

3 .....

4 .....

	Dag 1 Dato:				Dag 2 Dato:				Dag 3 Dato:				Dag 4 Dato:				Dag 5 Dato:				Dag 6 Dato:				Dag 7 Dato:			
Type aktivitet	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Antall minutter																												
Borg skala																												

	Dag 8 Dato:				Dag 9 Dato:				Dag 10 Dato:				Dag 11 Dato:				Dag 12 Dato:				Dag 13 Dato:				Dag 14 Dato:			
Type aktivitet	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Antall minutter																												
Borg skala																												

Treningsdagbok for: _____

Daglig fysisk aktivitet

Du har sammen med din koordinerende fysioterapeut blitt enig om å gjennomføre 30 minutter daglig fysisk aktivitet og du skal i løpet av de neste fire ukene velge mellom følgende aktiviteter:

1 .....

2 .....

Ukentlig trening

Du har sammen med din koordinerende fysioterapeut blitt enig om å gjennomføre 45-60 minutter trening hver uke og du skal i løpet av de neste fire ukene gjennomføre følgende treningsopplegg:

3 .....

4 .....

	Dag 15 Dato:				Dag 16 Dato:				Dag 17 Dato:				Dag 18 Dato:				Dag 19 Dato:				Dag 20 Dato:				Dag 21 Dato:			
Type aktivitet	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Antall minutter																												
Borg skala																												

	Dag 22 Dato:				Dag 23 Dato:				Dag 24 Dato:				Dag 25 Dato:				Dag 26 Dato:				Dag 27 Dato:				Dag 28 Dato:			
Type aktivitet	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Antall minutter																												
Borg skala																												

Pasient navn:_____ LAST ID:_____ Kommune:_____

Fysioterapeut:_____

					Har pasienten gjennomført det avtalte treningsopplegget?			
					JA	**Delvis**	**NEI**	**Årsak hvis nei og opplysninger om andre viktige hendelser siden forrige møte**
Dato 1. møte:	Møtested:	Tidsbruk (min): 1	2	3				
Dato 2. møte:	Møtested:	Tidsbruk (min): 1	2	3				
Dato 3. møte:	Møtested:	Tidsbruk (min): 1	2	3				
Dato 4. møte:	Møtested:	Tidsbruk (min): 1	2	3				
Dato 5. møte:	Møtested:	Tidsbruk (min): 1	2	3				
Dato 6. møte:	Møtested:	Tidsbruk (min): 1	2	3				

1= tid til direkte pasientkontakt (hjemmebesøk + tlf. samtale), 2=kjøretid, 3=tid til dokumentasjon (rapportering i Gerica/Helios + annet etterarbeid)

Dato 7. møte:	Møtested:	Tidsbruk (min): 1 | 2 | 3					
Dato 8. møte:	Møtested:	Tidsbruk (min): 1 | 2 | 3					
Dato 9. møte:	Møtested:	Tidsbruk (min): 1 | 2 | 3					
Dato 10. møte:	Møtested:	Tidsbruk (min): 1 | 2 | 3					
Dato 11. møte:	Møtested:	Tidsbruk (min): 1 | 2 | 3					
Dato 12. møte:	Møtested:	Tidsbruk (min): 1 | 2 | 3					
Dato 13. møte:	Møtested:	Tidsbruk (min): 1 | 2 | 3					

1= tid til direkte pasientkontakt (hjemmebesøk + tlf. samtale), 2=kjøretid, 3=tid til dokumentasjon (rapportering i Gerica/Helios + annet etterarbeid)

BORGS SKALA - INSTRUKSJON

I løpet av denne treningstimen vil vi at du skal være oppmerksom i forhold til hvor anstrengende du føler at treningen er. Denne følelsen skal gjenspeile totalsummen av anstrengelse og utmattelse, ved å kombinere alle følelser av fysisk stress, påkjenning og utmattelse. Ikke bry deg om hver enkelt faktor slik som smerte i bena, kortpustethet eller øvelsens intensitet, men forsøk å konsentrere deg om den totale indre følelsen av anstrengelse. Prøv å ikke undervurdere eller overvurdere din følelse av anstrengelse; men vær så presis som du kan.

BORG SKALA

6	
7	Meget, meget lett
8	
9	Meget lett
10	
11	Ganske lett
12	
13	Litt anstrengende
14	
15	Anstrengende
16	
17	Meget anstrengende
18	
19	Svært anstrengende
20	

Goal Attainment Scaling

Møte nr: _____ Navn: _____

Dato for målsetting: _____ Dato for evaluering: _____

Mål nr. 1: _____

Hvor viktig er dette målet?

Ikke viktig i det hele tatt 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ Ekstremt viktig

Hvor vanskelig tror du det er å nå dette målet?

Ikke vanskelig i det hele tatt ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 Ekstremt vanskelig

Måloppnåelse	-2	_____
(Ring rundt oppnådd	-1	_____
målsetting ved	0	_____
evalueringstidspkt.)	+1	_____
	+2	_____

Mål nr. 2: _____

Hvor viktig er dette målet?

Ikke viktig i det hele tatt 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ Ekstremt viktig

Hvor vanskelig tror du det er å nå dette målet?

Ikke vanskelig i det hele tatt ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 Ekstremt vanskelig

Måloppnåelse	-2	_____
(Ring rundt oppnådd	-1	_____
målsetting ved	0	_____
evalueringstidspkt.)	+1	_____
	+2	_____

Goal Attainment Scaling

Møte nr: _____ Navn: _____

Dato for målsetting: _____ Dato for evaluering: _____

Mål nr. 3: _____

Hvor viktig er dette målet?

Ikke viktig i det hele tatt 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ Ekstremt viktig

Hvor vanskelig tror du det er å nå dette målet?

Ikke vanskelig i det hele tatt ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 Ekstremt vanskelig

Måloppnåelse	-2	_____
(Ring rundt oppnådd	-1	_____
målsetting ved	0	_____
evalueringstidspkt.)	+1	_____
	+2	_____

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Region:	Saksbehandler:	Telefon:	Vår dato:	Vår referanse:
REK midt	Øystein Lundestad	73597507	12.09.2013	2013/1354/REK midt
			Deres dato:	Deres referanse:
			25.06.2013	

Vår referanse må oppgis ved alle henvendelser

Torunn Askim
St. Olavs Hospital

2013/1354 Fysioterapi etter hjerneslag

Forskningsansvarlig: NTNU, St Olavs Hospital
Prosjektleder: Torunn Askim

Vi viser til søknad om forhåndsgodkjenning av ovennevnte forskningsprosjekt. Søknaden ble behandlet av Regional komité for medisinsk og helsefaglig forskningsetikk (REK midt) i møtet 23.08.2013. Vurderingen er gjort med hjemmel i helseforskningsloven (hfl.) § 10, jf. forskningsetikklovens § 4.

Prosjektomtale
Prosjektet ønsker å benytte innhentede opplysninger fra den såkalte LAST-studien (Life After STroke) i en mastergrad ved Klinisk helsevitenskap, NTNU. I den studien undersøkes det om ekstra oppfølging fra fysioterapeut og tilpasset treningsopplegg gir høyere funksjonsnivå blant hjerneslagpasienter. (Kontrollgruppa får standardbehandling.) I foreliggende prosjekt ønskes det å klargjøre om pasientgruppen i intervensjonsgruppa i LAST-studien faktisk er i stand til å oppnå sine individuelle mål og til å opprettholde et individuelt tilpasset fysisk aktivitetsnivå over en periode på 18 måneder. Opplysninger fra 50 pasienter (Trondheim, Bærum) vil bli brukt i denne gjennomførbarhetsstudien.

Vurdering

Komiteen har vurdert søknad, forskningsprotokoll, målsetting og plan for gjennomføring. Prosjektet blir av komiteen oppfattet å ligge innenfor de rammer og det samtykke som ble gitt i forbindelse med deltakelse i studien "Livet etter hjerneslag" (vår ref. 2011/1427); angitt bruk av helseopplysninger fra dette prosjektet godkjennes følgelig. Prosjektet "Fysioterapi etter hjerneslag" framstår som forsvarlig, og hensynet til deltakernes velferd og integritet er ivaretatt.

Vilkår for godkjenning

1. Godkjenningen er gitt under forutsetning av at prosjektet gjennomføres slik det er beskrevet i søknaden og protokollen, og etter de bestemmelser som følger av helseforskningsloven med forskrifter.
2. Forskningsprosjektets data skal oppbevares forsvarlig, se personopplysningsforskriften kapittel 2, og Helsedirektoratets veileder for «Personvern og informasjonssikkerhet i forskningsprosjekter innenfor helse- og omsorgssektoren». Prosjektdata skal oppbevares i minimum 5 år etter prosjektslutt.

Besøksadresse:
Det medisinske fakultet
Medisinsk teknisk
forskningssenter 7489
Trondheim

E-post: rek-midt@medisin.ntnu.no
Web: http://helseforskning.etikkom.no/

Vedtak

Regional komité for medisinsk og helsefaglig forskningsetikk Midt-Norge godkjenner prosjektet med de vilkår som er gitt.

Sluttmelding og søknad om prosjektendring
Prosjektleder skal sende sluttmelding til REK midt på eget skjema senest 30.06.2016, jf. hfl. § 12. Prosjektleder skal sende søknad om prosjektendring til REK midt dersom det skal gjøres vesentlige endringer i forhold til de opplysninger som er gitt i søknaden, jf. hfl. § 11.

Klageadgang
Du kan klage på komiteens vedtak, jf. forvaltningslovens § 28 flg. Klagen sendes til REK midt. Klagefristen er tre uker fra du mottar dette brevet. Dersom vedtaket opprettholdes av REK midt, sendes klagen videre til Den nasjonale forskningsetiske komité for medisin og helsefag for endelig vurdering.

Med vennlig hilsen

Sven Erik Gisvold
Dr.med.
Leder, REK midt

Øystein Lundestad
Rådgiver

Kopi til: rek-inm@medisin.ntnu.no; siv.morkved@stolav.no; rek-midt@medisin.ntnu.no

Forespørsel om deltakelse i forskningsprosjektet

Livet etter hjerneslag – Så høyt funksjonsnivå som mulig så lenge som mulig

Bakgrunn og hensikt
Dette er et spørsmål til deg om å delta i en forskningsstudie hvor formålet er å finne ut om et langtidsoppfølgingsprogram fører til et høyere funksjonsnivå enn bare standard oppfølging for pasienter som har hatt hjerneslag. Grunnen til at du blir forespurt om å delta i dette prosjektet er fordi du nylig har vært innlagt ved Slagenheten ved St. Olavs Hospital.

Vi har etter hvert fått god kunnskap om effektiv akuttbehandling av hjerneslag og du fikk i forbindelse med ditt sykehusopphold den behandling og opptrening som vi i dag mener er den beste. Vi vet imidlertid fortsatt for lite om hva som er den beste oppfølgingen i perioden etter utskriving fra sykehus. For å skaffe oss enda mer kunnskap og utvikle enda bedre modeller for langtidsoppfølging er det nå satt i gang et forskningsprosjekt ved St. Olavs Hospital, NTNU og Trondheim kommune hvor pasienter som har hatt hjerneslag blir forespurt om å delta.

Hva innebærer studien?
Denne studien skal prøve ut om månedlig oppfølging av en rådgivende fysioterapeut, som skal motivere og legge til rette for en time trening i uken og 30 minutter daglig fysisk aktivitet, over en periode på 18 måneder, er bedre enn den standard oppfølgingen som alle pasienter får i dag. Dersom du ønsker å delta i studien vil en loddtrekning avgjøre om du kommer i gruppen som får ekstra oppfølging eller om du kommer i en kontrollgruppe som får standard behandling. Dersom du ikke ønsker å delta vil du få standard behandling med tilbud om opptrening og rehabilitering som er tilpasset ditt behov.

Alle som sier ja til å delta vil bli testet ved oppstart og 18 måneder senere. Det vil da bli gjennomført en rekke tester for å undersøke blant annet motorisk funksjon, grad av selvhjulpenhet og livskvalitet i tillegg til balanse, gangfunksjon og mental funksjon. Hver 6. måned vil du bli bedt om å svare på noen spørsmål om fysisk aktivitet. I den forbindelse vil noen av deltagerne få tilsendt en brikke som skal festes på låret og som måler fysisk aktivitet over 3-4 dager. Du vil også bli bedt om å registrere hvor mye hjelp du mottar fra helsevesenet i løpet av perioden. I tillegg vil vi be din nærmeste pårørende om å besvare noen spørsmål om sin livssituasjon.

Opplysninger om alvorlige hendelser slik som nye tilfeller av hjerte og karsykdom, brudd eller andre nye sykehusinnleggelser vil bli innhentet fra Norsk pasientregister, Norsk hjerneslag register og fra din sykejournal. Opplysninger om hvor mye hjelp du mottar fra helsevesenet vil også bli innhentet fra din pasientjournal i kommunen, mens informasjon om eventuell sykemelding vil bli innhentet hos NAV.

Mulige fordeler og ulemper
Det ingen ekstra risiko og ingen økonomisk belastning forbundet med å delta i studien og det er heller ikke noe ubehag forbundet med å gjennomføre de fysiske testene. Det kan imidlertid for noen oppleves som en ulempe å måtte reise til og fra sykehuset for å gjennomføre testing ved oppstart og avslutting av studien. Forskjellen ved å delta eller ikke er imidlertid en ekstra systematisk oppfølging og grundig vurdering av fysisk funksjon frem til 18 måneder etter oppstart.

Hva skjer med informasjonen om deg?
Informasjonen som registreres om deg skal kun brukes slik som beskrevet i hensikten med studien. Alle prosjektmedarbeidere har taushetsplikt, og alle personopplysninger vil bli behandlet konfidensielt. Alle undersøkelsesresultater og navnelister vil bli oppbevart forskriftsmessig.

Det kan være nødvendig å supplere med opplysninger fra din pasientjournal for å sikre studiens kvalitet. Ditt samtykke til deltagelse i studien, gir samtidig samtykke til innsyn i din journal.

Prosjektet avsluttes senest 31.12.2020, men av kontrollhensyn blir grunnlagsdata oppbevart forsvarlig frem til 31.12.2025. Deretter vil data bli slettet. Det er prosjektleder Bent Indredavik som er ansvarlig for datamaterialet i denne perioden. Instanser som kan tenkes å kontrollere grunnlagsmaterialet er for eksempel forskningsansvarlige, Uredelighetsutvalget for forskning og Helsetilsynet.

Det vil ikke være mulig å identifisere deg i resultatene av studien når disse publiseres.

Frivillig deltakelse
Det er frivillig å delta i studien. Du kan når som helst og uten å oppgi noen grunn trekke ditt samtykke til å delta i studien. Dette vil ikke få konsekvenser for din videre behandling. Dersom du ønsker å delta, undertegner du samtykkeerklæringen på siste side. Om du nå sier ja til å delta, kan du senere trekke tilbake ditt samtykke uten at det påvirker din øvrige behandling. Dersom du senere ønsker å trekke deg eller har spørsmål til studien, kan du kontakte; *fysioterapeut og forsker Torunn Askim, på telefon 72 57 57 88(arb)/ 995 99 235(mob)*.

Studien er godkjent av Regional komité for medisinsk og helsefaglig forskningsetikk i Midt-Norge.

Utlevering av materiale og opplysninger til andre
Hvis du sier ja til å delta i studien, gir du også ditt samtykke til at avidentifiserte opplysninger kan sendes til våre samarbeidspartnere ved Stroke Division, Florey Neuroscience Institutes, Melbourne, Australia for bearbeiding og analyser der. Våre samarbeidspartnere vil ikke ha tilgang til navnelisten som kobler opplysningene om deg til ditt navn og de vil bare kunne benytte dataene til dette konkrete forskningsprosjektet.

Rett til innsyn og sletting av opplysninger om deg
Hvis du sier ja til å delta i studien, har du rett til å få innsyn i hvilke opplysninger som er registrert om deg. Du har videre rett til å få korrigert eventuelle feil i de opplysningene vi har registrert. Dersom du trekker deg fra studien, kan du kreve å få slettet innsamlede opplysninger, med mindre opplysningene allerede er inngått i analyser eller brukt i vitenskapelige publikasjoner.

Økonomi
Studien er finansiert gjennom forskningsmidler fra Norges forskningsråd, Kontaktutvalget og Samarbeidsorganet i Midt-Norge samt Slagenhetens forskningsfond. Ingen av disse har deltatt i utformingen av prosjektet og vil heller ikke være involvert i bearbeidingen av resultatene fra prosjektet. Det er således ingen interessekonflikter knyttet til prosjektet.

Forsikring
Pasientskadeerstatningsordningen gjelder ved deltagelse i studien.

Informasjon om utfallet av studien
Resultatene fra studien vil bli publisert i internasjonalt anerkjente tidsskrift. Du vil også få informasjon om utfallet av studien dersom du henvender deg direkte til oss i ettertid.

Samtykke til deltakelse i studien

Jeg er villig til å delta i studien

(Signert av prosjektdeltaker, dato)

Stedfortredende samtykke når berettiget, enten i tillegg til personen selv eller istedenfor

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(Signert av nærstående, dato)

Jeg bekrefter å ha gitt informasjon om studien

(Signert, rolle i studien, dato)