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Does adapted physical activity-based rehabilitation improve mental and physical functioning? A randomized trial.

Short title: Effect of physical activity-based rehabilitation

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Abstract

BACKGROUND: Persons with chronic disabilities face a wide variety of problems with functioning that affect their level of physical activity and participation. We have limited knowledge about the effect of adapted physical activity (APA)-based rehabilitation on perceived mental and physical functioning.

DESIGN: Randomized controlled trial

SETTING: In-patient rehabilitation at Beitostølen Healtsports Center

AIM: The main aim of this study was to evaluate the effect of APA-based rehabilitation compared to waiting-list on perceived mental and physical functioning. Secondly, we wanted

to assess whether improvement in self-efficacy, motivation, pain and fatigue during rehabilitation was related to the effect of the intervention.

METHODS: Persons above 17 years (men and women) with chronic disabilities who applied for a rehabilitation stay, were randomized to an adapted physical activity-based rehabilitation intervention (n=304) or waiting-list with delayed rehabilitation. A total of 246 consented and were allocated to four week intervention or a waiting-list control group. The main outcome was physical and mental functioning evaluated four weeks after rehabilitation using the Medical Outcomes Study 12-Item Short-Form Health Survey (SF-12).

RESULTS: Compared to waiting-list the adapted physical activity-based intervention improved physical and mental functioning. Improvement in physical functioning during rehabilitation was related to reduced pain, improved motivation and self-efficacy.

CONCLUSION: The results indicate that an adapted physical activity-based rehabilitation program improves functioning. Improved efficacy for managing disability may mediate the improvement in mental functioning.

CLINICAL REHABILITATION IMPACT: Adapted physical activity-based rehabilitation should be considered during the development of rehabilitation strategies for people with chronic disabilities. Motivational and self-efficacy aspects must be addressed when organizing and evaluating rehabilitation programs.

Keywords: Rehabilitation, social participation, adapted physical activity, randomized trial, disability

Introduction

The present study was undertaken to evaluate the effect of an adapted physical activity-based rehabilitation program in persons with disabilities. Persons with chronic disabilities face a wide variety of problems, including pain and fatigue which often contribute to enhance the disability [1, 2]. They consistently exhibit reduced physical activity compared with the general population [3-6]. Reduced physical activity may lead to increased health problems [7]. Inactivity may also be associated with negative emotional responses [8, 9] . Depression seems to interplay with pain, which may further reduce physical activity [2] and result in a vicious circle in which physical capacity and quality of life deteriorate further [10]. Thus, both physical and mental functioning is reduced in subjects with chronic disability [11] [10, 12].

In response to these limitations, adapted physical activity (APA)-based rehabilitation programs have been developed to facilitate participation in physical activities among people with disabilities [13]. This program is based on the assumptions that APA-based rehabilitation contribute to the experience of self-efficacy [14]. Self-efficacy is defined as the ability to mobilise motivation and perform tasks to achieve control over given events and to manage daily life demands [15]. Self-efficacy is considered to consist of several constructs that are important to rehabilitation [16] . The concept may be related to physical, social and health dimensions [17] and is often targeted in physical activity-based programs [18]. Self-efficacy is closely linked to motivation, where particularly the autonomous component is assumed to facilitate increase in physical activity over time [19]. Nevertheless, to our knowledge, neither the effectiveness nor the influence of changes in self-efficacy or motivation has been evaluated in randomised controlled trials in any of the programs based on APA [20, 21]. Prospective studies have also indicated positive effects of APA on physical and mental functioning [21]. However, randomized trial evaluating the effects has not to our knowledge been conducted.

The main aim of this study was to evaluate the effect of an adapted physical activity-based rehabilitation program compared to waiting-list on perceived mental and physical functioning. Secondly, we wanted to assess whether improvement in self-efficacy, motivation, pain and fatigue during rehabilitation was related to the effect of the intervention.

Methods

Design

The study had an interventional, double-blinded design. The study was approved 27th of December 2008 by the Regional Medical Committee for Research Ethics in Norway (S-08837c 2008/21144) and registered with ClinicalTrials.gov (number NCT01788397).

Setting

Beitostølen Healthsports Centre (BHC) is part of the public rehabilitation services in Norway. 4-week in-patient rehabilitation is offered to patients referred to the Centre.

Randomisation

The subjects were randomised to in-patient rehabilitation or a waiting-list control group. The control group did not receive any intervention during the waiting period, but were assigned to receive in-patient rehabilitation after the primary outcome evaluation of the study. Sequentially numbered, opaque, and sealed envelopes were prepared according to the randomisation scheme generated by the web site Randomisation.com. Randomisation was performed in blocks of 30. A secretary who was blinded to the intention of the study enrolled the participants according to the information in the envelopes. The randomisation was concealed from the participants, the researchers and the staff members who treated the

participants. The randomisation code was broken after the data analyses were finalised (i.e., after the primary outcome was assessed).

Participants and procedures

All subjects above 17 years who were referred by their physician to BHC between July 1, 2010 and August 1, 2012 without major cognitive or language problems were eligible for the study ($N = 321$). About one third of the patients referred to BHC have painful musculoskeletal problems including rheumatic diseases, half of the patients have various neurological problems with cerebral palsy, multiple sclerosis, inherited motor neuron disorders as the most frequent diagnostic entities. Twenty percent have other disabilities such as cerebrovascular diseases, spinal cord injuries and visual impairments. Written invitation containing information about the study was sent to the participants after randomization without revealing if they were assigned to the in-patient rehabilitation or waiting list control group. The coordinator for admission at BHC included the subjects who accepted the invitation and signed an informed consent form.

Questionnaires

A written questionnaire was administered by mail to the participants at home before the rehabilitation stay (baseline) and again four weeks after the rehabilitation stay or waiting-list period. In addition, the intervention group were assessed at admission and discharge from BHC.

Rehabilitation program at BHC

The rehabilitation program at BHC is based on the adapted physical activity (APA) [13] approach, which uses physical activities that take into account the specific presuppositions and preferences of each individual.

The aim of the APA based rehabilitation is to facilitate participation in activities according to goals of the patients.

The team and the patient created a detailed goal-oriented plan for both the rehabilitation at BHC and the follow-up period. The rehabilitation program includes social and cultural activities and the extensive use of natural outdoor facilities on a year-round basis. A wide range of services is offered, including adaptations of environmental factors, assistive technology and individual instruction. The range of activities that the rehabilitation centre offers includes swimming, cross-country skiing, alpine skiing, horseback riding, aerobics, kayaking and other activities, which allows each individual to determine the best suited activities.

All of the participants were examined by a medical doctor and a multidisciplinary team of physiotherapists, nurses, social workers and sports pedagogues upon admission. The multidisciplinary team guided the activities throughout the four week rehabilitation period. Both group based and individual based activities were included during the four week in-patient based rehabilitation.

The program includes 2-5 hours of guided physical activity every day, six days a week. In addition a targeted teaching program over four lessons is included, focusing on nutrition, intensity, total work-load during the day and discussing the challenges patients can experience in following up regular physical activity at home. The rehabilitation also includes 1-3 hours daily with social and cultural activities like i.e. handiwork, singalong and board games. However, the exchange of experiences with other participants as well as the informal social

activities during the rest of the day-time, although difficult to quantify is assumed to be important for the effect of this program.

During the stay, the individual participants' schedules are regularly assessed and adjusted when necessary, whereas no changes were conducted regarding the overall intervention scheme during the study period.

Adherence to the program was assessed as completing the four week stay. No direct monitoring of intensity or adherence to activities were otherwise included. However user involvement in goal planning is an essential part of the rehabilitation process and is directed at enhancing patient autonomy, treatment adherence and self-efficacy [22].

Demographic and medical information

Demographic and social data (age, gender, education, residence, employment and the need for social services) were recorded during an interview performed by the medical doctor upon admission to the rehabilitation centre. Diagnoses were obtained from the participant's application for the rehabilitation stay. The main reasons for disability were grouped according to disorders of the nervous system, disorders of the musculoskeletal system and other disorders.

Primary outcome

Physical and mental functioning was measured using the Medical Outcomes Study 12-Item Short-Form Health Survey (SF-12, licence number QM 027126), Norwegian version [11, 23]. The SF-12 consists of 12 items and yields a Physical Component Summary (PCS) and a Mental Component Summary (MCS). The SF-12 has been shown to account for almost 90 % of the variance of the SF-36; furthermore, it reflects the same dimensions as the SF-36 and is less time-consuming [11, 23]. The responses are given on a Likert scale with scores that ranges from 1

to 5 according to the various questions. The Physical and Mental Component norm-based scores for the SF-12 were calculated using the reversed scores for questions 1, 8, 9 and 10 [24].

Measurements

Pain and fatigue were measured on visual analogue scales (VAS) from zero (no pain/fatigue is no problem) to 100 mm (worst imaginable pain/ fatigue is a major problem) over the past week [25, 26].

Three separate scales were used to capture the different elements of self-efficacy. All three scales were used in Norwegian after forward and back translated and synthesis according to the guidelines [27]. Efficacy for managing chronic disease (chronic disease-efficacy) was measured with the Self-Efficacy for Managing Chronic Disease 6-Item Scale [15]. A sample item is "How confident are you that you can keep the fatigue caused by your disease from interfering with the things you want to do?" Responses were given on a ten-point Likert scale ranging from *not at all confident* (1) to *totally confident* (10). The scale has been tested for validity in a sample of 605 subjects with chronic disease. The scale demonstrated high internal consistency (0.91).

Efficacy for exercising regularly (exercise-efficacy) was measured with the three-item Norwegian version of Self-Efficacy for Exercise Regularly scale [28]. A sample item is "How confident are you that you can do aerobic exercise, such as walking, swimming, or bicycling, three to four times each week?" Responses were given on a ten-point Likert scale ranging from *not at all confident* (1) to *totally confident* (10). The scale has been tested for validity in a sample of 478 subjects with chronic disease (internal consistency 0.83, test-retest reliability 0.86).

The Norwegian version of the two-item Efficacy for Social/Recreational Activities Scale [28] was used to measure efficacy for social and recreational activities (social-efficacy). A sample item is How confident are you that you can continue to do your hobbies and recreation?" Responses were given on a ten-point Likert scale ranging from *not at all confident* (1) to *totally confident* (10). The scale has been tested for validity in a sample of 478 subjects with chronic disease (internal consistency 0.84, test-retest reliability 0.84).

Motivation towards physical activity and exercise was assessed by the 19-item Behavioral Regulation in Exercise Questionnaire (BREQ-2) [29]. The scale comprises five subscales: Amotivation with four items (e.g., "I don't see why I should have to exercise"), external regulation with four items (e.g., "I exercise because other people say I should"), introjected regulation with three items (e.g., "I feel guilty when I don't exercise"), identified regulation with four items (e.g., "I value the benefits of exercise"), and intrinsic motivation with four items (e.g., "I exercise because it's fun"). The items are scored on a five-point Likert scale ranging from 0 "Not true for me" to 4 "Very true for me. The two BREQ-2 subscales "Identified regulation" and "Intrinsic regulation" were merged into the variable autonomous motivation "External regulation" and "Introjected regulation" were merged into the variable controlled motivation [30]. Mean item score is reported for each subscale. The scale was originally tested in a sample with 194 subjects, demonstrated to have an acceptable internal consistency and reliability was confirmed with Cronbach Alpha scores ranging from 0.73-0.86 for each item. The instrument has recently been tested in a Norwegian population [31].

Sample size

The sample size was determined according to the change in mental and physical functioning (SF-12) observed in a previous study at BHC [21] (the mean change in mental functioning was 8.26 SD 9.97; the mean change in physical functioning was 4.81 SD 7.33). With a significance level of 5 % and power of 90 %, we needed 50 people in each group, provided that there were no changes in the control group during the waiting period. Considering a possible 20 % improvement as a result of positive expectations in the control group during the waiting period [32], 70 people in each group were needed. To accommodate for 25 % drop out and adjust for possible confounders in the analysis 150 subjects in each group was estimated.

Statistics

All of the data were analysed using SPSS, version 21. The baseline characteristics were summarized with descriptive statistics to check for similarity at baseline. Effect of intervention on changes in physical and mental functioning was calculated by multiple regression analysis adjusting for baseline PCS and MCS. Intention to treat analyses were conducted for subjects completing follow-up together with multiple imputation for all included subjects returning at least one questionnaire prior to the intervention.

For the intervention group changes in pain, fatigue, motivation as well as changes in exercise efficacy, social efficacy and chronic disease efficacy during rehabilitation were calculated. The impact of these changes for improvement in physical and mental functioning four weeks after rehabilitation was evaluated controlling for demographic factors and baseline PCS and MCS.

Results

Participants

The 304 eligible subjects were randomized and subsequently 246 subjects consented to participation (Fig 1). Patients not consenting to participation had a mean age of 48 years (SD 13), 53 % were females, and 30 % had musculoskeletal disorders, without statistically significant differences compared to the consenting subjects ($p>0.39$). Eight of the consenting subjects did not return the baseline forms (five in the intervention and three in the control group). No other statistically significant differences in baseline characteristics were found between the intervention and control group ($p>0.05$) (Table 1).

Additionally 36 subjects did not attend intervention or respond to the assessment four week post intervention, which resulted in 202 subjects with complete outcome data (Fig 1).

There were no statistically significant differences between the subjects completing outcome and not completing outcome assessments ($p>0.08$).

Effect of rehabilitation

Multiple regression analysis with multiple imputation of missing data revealed a significantly larger improvement in PCS as well as MCS from baseline to four week follow-up in the intervention compared to the waiting-list control group (Table 2). The same results were found when analysing the data only for the subjects completing outcome assessments (n=202). For subjects completing four week follow-up the intervention group (n=94) had improved in physical functioning (3.76 points, SD 0.93) ($p<0.001$), while no changes were observed in the waiting-list control group (-0.02 point SD 0.66) ($p=0.98$) (n=108). The intervention group had also improved in mental functioning (3.79 points, SD 1.17) ($p=0.002$). Slight improvement although not statistically significant was also observed in the waiting-list control group (1.02 point SD 0.65) ($p=0.12$).

Influence of changes in motivation and self-efficacy during rehabilitation on physical and mental functioning

During the four week in-patient period with APA-based rehabilitation, self-efficacy and motivation also increased significantly. Furthermore, pain and fatigue decreased. No such changes were observed in the waiting-list group (Table 3.).

Multiple regression analysis with demographic factors, disability group and changes in self-efficacy, motivation, pain and fatigue during rehabilitation (controlled for baseline mental and physical functioning) revealed that social efficacy was a significant predictor for improvement in physical functioning as well as mental functioning in the intervention group (Table 4). Disability category influenced improvement in physical functioning, with the largest improvement in the mixed disability category (5.32 SD 2.28).

Discussion

To the best of our knowledge, this is the first randomised trial to evaluate APA-based in-patient rehabilitation in a mixed-case population with chronic disabilities. The results indicate effect of APA-based rehabilitation on both physical and mental functioning, with stable values in the waiting-list control group.

A number of randomised controlled trials that included physical activity and exercise-based interventions have been directed toward patients with cardiovascular and other lifestyle disorders and have found that the interventions had positive effects on functioning [33-35]. Roine et al [36] reviewed 151 articles that applied exercise interventions to a wide variety of conditions and concluded that exercise improved quality of life and was cost-effective for treating both musculoskeletal and cardiac conditions. Furthermore, patients with neurological disorders seem to benefit from physical activity, and Motl et al [10] showed that increased

physical activity improved physical functioning after six months in patients with multiple sclerosis. Furthermore, physical activity was associated with better mental functioning even when controlling for physical functioning [37]. Physical activity was also associated with a reduced decline in physical functioning over a five-year period for patients with multiple sclerosis [38].

In addition to improvement in functioning, motivation and self-efficacy, pain and fatigue decreased during the rehabilitation. Such changes were not observed in the control group during the waiting-list period. The effect of physical activity on pain as well as fatigue is well documented [39, 40]. Improvement in self-efficacy is observed in other rehabilitation interventions [15, 41]. In the present study, the APA-based intervention aimed to improve self-efficacy and motivation through positive experiences with physical as well as social and cultural activities. Social-efficacy seemed to be an important factor for improvement in physical and mental functioning. This is supported by the results of earlier studies that demonstrated a relationship between health status and self-efficacy [15].

The level of physical functioning in our study population was considerably lower than the non-disabled population [11]. Furthermore, the level of physical functioning was lower than levels reported by Loza et al for subjects living with chronic disabilities in general [42], but comparable to the level of physical functioning of other patients admitted to rehabilitation [43]. The study participants' mental functioning did not differ from that of the general population [11]. The mental consequences of physical disability vary largely [44, 45], and the subjects referred to rehabilitation institutions like BHC may be selected according to better mental functioning.

The SF-36 family of instruments was developed specifically to capture the broader burden of disease reflected by the physical and mental role function and overall well-being [46]. They are the most widely used generic instruments and have been applied to more than 200 different medical conditions [47]. The SF-12 was chosen to reduce the burden of questionnaires and retain the explained variance [11, 23]. The limitation of this choice is that only physical and mental component scores can be evaluated.

The clinical relevance of improvement in physical and particularly in mental functioning can be questioned. Minimal clinically important difference (MCID) may vary across conditions and settings [24, 48]. When applying an MCID of four points [49], approximately half of the subjects were expected to have a clinically relevant improvement. The magnitude of improvement in both mental and physical functioning was also similar across the three disability groups. The effect size was moderate and quite similar for physical and mental functioning.

A priori, one would think that a program primarily designed to improve physical activity would show the greatest effect on physical outcomes. However, the stay at BHC itself and the associated social and cultural activities combined with contact with other people may have contributed to the observed improvement in mental functioning. The clinical significance of this improvement is difficult to evaluate because the participants had normal mental functioning before admission. Furthermore, the present design does not allow us to draw conclusions about the long-term effects of the program. Because the follow-up occurred four weeks after the participants had returned home, the improvement was not entirely attributable to the positive experience of the stay at BHC. Longer follow-up would of course have been preferable. However, it was not possible to withhold rehabilitation from the waiting-list group any longer without more thorough information which could have biased the blinding.

Nevertheless, all patients were followed for one year. At that time also the waiting-list control group had received rehabilitation. These data indicate that there is a long-term benefit of the APA-based rehabilitation [50].

The strength of this study is the blinded, randomised, controlled design [51]. The power of the present study was also high regarding the main outcome. To our knowledge, very few studies have evaluated rehabilitation programs with similar scientific methodology [20]. Conducting randomised trials in rehabilitation is a challenge. Conducting two different interventions at the same centre is often hampered by contamination between the interventions. Comparing with other study centres is usually flawed by differences in patient recruitment. Hence, waiting-list control is a well-recognized option [52]. This will also secure all participants equal services, in a situation where the timing of rehabilitation in chronic conditions may not be crucial.
The stable level of functioning in the control group indicates that this did not negatively affect the results. We had no information about adjuvant treatment received in the waiting period for the control group, but if received this treatment did not alter the patients functioning. A weakness is the lack of cost-effectiveness analysis. Such analysis were not conducted due to the lack of a randomized long-term follow-up.

The generalisability of the results may have been affected by the recruitment procedure because participants were recruited from a sample admitted to a rehabilitation stay. This cohort may differ from other populations with chronic physical disabilities in several ways. As an example, a more positive attitude towards physical activity can be expected because they were well informed about the treatment program at the rehabilitation institution. We also want to address the different approaches to rehabilitation between countries. This may affect the generalisability of the results across national borders. Finally, as in all studies involving

human patients, the participants were volunteers. Thus, the effects of this intervention can only be extrapolated to patients willing to take part in a fourweek group intervention.

Conclusion: The results indicate that an adapted physical activity-based rehabilitation program improves functioning. Improved self-efficacy for social and recreational activities may mediate the improvement in both mental and physical functioning.

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Table 1: Demographic and clinical characteristics at baseline for the intervention and control groups.

	Intervention (n=118)	Control (n=120)
Age (SD) years	51 (14)	51 (12)
Gender (female) %	60	55
Living in town/township %	38	50
Education (university) %	43	51
Employed %	35	39
Personal assistance (> 2 hours per week) %	15	23
Living alone %	35	35
Disability - Neurological % - Musculoskeletal % - Other %	50 27 23	45 30 24
	Mean (SD)	Mean (SD)
Exercise-efficacy Social-efficacy Chronic disease-efficacy	7.40 (2.00) 6.98 (2.32) 6.72 (1.81)	7.55 (2.19) 6.83 (2.44) 6.25 (1.86)
aMotivation	2.57 (0.39)	2.57 (0.41)
Pain	37.11 (26.15)	39.09 (28.09)
Fatigue	46.34 (31.46)	53.45 (30.09)
PCS	37.89 (9.46)	36.44 (9.53)
MCS	48.26 (9.46)	49.05 (11.35)

*p<0.05

Table 2. Multiple regression analysis with multiple imputation of missing data. Changes in physical functioning (PCS) and mental functioning (MCS) from baseline to 4-week follow-up in the intervention (n=118) and control group (n=120).

	PCS changes			MCS changes		
	β	CI	P	β	CI	P
Intervention/Control	-3.25	-5.11, -1.39	0.001*	-2.31	-4.31, -0.31	0.02*
PCS baseline	-0.31	-0.41, -0.22	<0.001*			
MCS baseline				-0.40	-0.49, -0.30	<0.001*

*p<0.05

Adjusted R^2 PCS change=0.16, Adjusted R^2 MCS change=0.22

Table 3. Changes in clinical factors during rehabilitation/waiting-list period.

	Intervention group (n=94)		Control group (n=108)	
	Mean change (SD)	P	Mean change (SD)	P
Exercise-efficacy Social-efficacy Chronic-disease efficacy	0.52 (1.78) 1.22 (1.67) 0.58 (1.53)	0.06 <0.001* <0.001*	-0.12 (1.70) 0.18 (2.03) 0.28 (1.57)	0.45 0.37 0.08

Autonomous motivation	0.08 (0.33)	0.01*	-0.005 (0.32)	0.87
Pain	-8.13 (26.62)	0.004*	-0.45 (18.73)	0.80
Fatigue	-10.82 (28.11)	<0.001*	-2.94 (20.70)	0.15

*p<0.05

Table 4. Multiple regression with demographic factors and changes in self-efficacy, autonomous motivation, pain and fatigue during rehabilitation as predictors for changes in physical functioning (PCS) and mental functioning (MCS) from baseline to 4-week follow-up in the Intervention group (n=94).

	PCS changes			MCS changes		
	β	CI	P	β	CI	P
Age	-0.09	-0.22, -0.04	0.18	0.10	-0.05, 0.25	0.19
Gender	2.54	-1.07, 6.15	0.17	-1.54	-5.73, 2.65	0.47
Disability group	2.35	0.17, 4.53	0.04*	0.25	-2.27, 2.76	0.85
Exercise-efficacy	0.57	-0.66. 1.80	0.36	0.14	-1.30, 1.59	0.85
Social-efficacy	-1.47	-2.71, -0.23	0.02*	-1.44	-2.87, -0.02	0.05*
Chronic disease-efficacy	0.50	-0.84, 1.85	0.46	-0.17	-1.73, 1.38	0.83
Autonomous motivation	1.07	-4.37, 6.51	0.07	3.17	-3.22, 9.56	0.33
Pain	-0.04	-0.11, 0.03	0.26	0.03	-0.06, 0.11	0.11
Fatigue	0.01	-0.06, 0.08	0.73	-0.00	-0.08, 0.8	0.08
PCS baseline	-0.44	-0.63, -0.24	<0.001*			
MCS baseline				-0.40	-0.49, -0.30	<0.001*

*p<0.05

Fig 1: Flow chart of participants