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Long Term Effects of Behavioural Interventions to Increase Exercise Among Breast Cancer Patients After Medical Rehabilitation: secondary Analysis of a Randomized Controlled Trial

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title:

Long term effects of behavioural interventions to increase exercise among breast cancer patients after medical rehabilitation: secondary analysis of a randomized controlled trial

Titel:

Effekte im Zeitverlauf von Verhaltensinterventionen zur Steigerung der Bewegung bei Brustkrebspatientinnen nach medizinischer Rehabilitation: Sekundäranalyse einer randomisierten kontrollierten Studie

Authors

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Abstract:

Purpose: Physical activity (PA) as secondary prevention for breast cancer patients has many positive effects. To evaluate the effectiveness of an intervention involving behavioural and volitional strategies to increase exercise.

Materials and Methods: The study designed as a randomized controlled trail with two follow-up (6 and 12 months after rehabilitation). 1,143 participants were randomized to one of the four study groups. Group differences were analysed by multi-level-models.

Results: After rehab, patients with the combined modules, aftercare-planning (AP) and telephone-support (TS), did exercise 69 minutes per week (95% CI: 42.85; 94.90) more than the control group. Inactive patients at the beginning of the rehabilitation benefit from the combined intervention. The phone-based intervention alone did not show any effect.

Discussion and Conclusion: Rehab with the AP module combined with the TS module is associated with patients undertaking more PA.

Keywords

Breast cancer; rehabilitation; exercise; behaviour change; volition

Zusammenfassung

Fragestellung: Körperliche Aktivität als Sekundärprävention für Brustkrebspatientinnen hat positive Effekte. Ziel ist die Bewertung der Wirksamkeit einer Intervention, die Verhaltens- und Volitionsstrategien beinhaltet, zur Bewegungssteigerung.

Materialien und Methoden: Die randomisierte kontrollierte Studie wurde mit zwei Follow-ups (6 und 12 Monate nach der Reha) konzipiert. 1.143 Teilnehmerinnen wurden in eine der 4 Gruppen randomisiert. Gruppenunterschiede wurden mittels Mehrebenenmodellen analysiert.

Ergebnisse: Nach der Reha waren die Befragten, die die kombinierten Modulen Nachsorgeplanung (AP) und Telefonsupport (TS) erhielten, 69 Min./Woche (95% CI: 42,85; 94,90) körperlich aktiver als die der Kontrollgruppe. Inaktive Personen zu Beginn der Reha profitieren von der kombinierten Intervention. Die telefonische Intervention allein ist unwirksam.

Diskussion und Schlussfolgerung: Brustkrebspatientinnen profitieren von einer Reha mit dem AP-Modul in Kombination mit dem TS-Modul.

Schlüsselwörter

Brustkrebs, Rehabilitation, Bewegung, Verhaltensänderung, Volition

Backround

Physical activity as secondary prevention for patients with a diagnosis of breast cancer has been shown to decrease the total mortality (41%) and in particular the mortality due to cancer (34%) [1]. Further positive effects of physical activity include increasing the physical capabilities, decreasing adverse effects (like fatigue and lymphedema), and improving mental health [2–6]. Recommendation to cancer survivors are that they should become or stay physically active and thus as soon as possible after diagnosis. They should exercise at least 150 minutes per week, including strength exercise twice a week [7]. However, a behavioural change toward an active life style is difficult to achieve. Inactivity can be explained by a combination of personal barriers and environmental factors [8]. In that respect motivational interventions have shown only limited effectiveness on long-term behavioural change [9]. Therefore, techniques involving motivational and volitional aspects are more indicated to initiate and promote a physically active lifestyle [9–11]. Volitional methods include for example action planning, coping planning and anticipation of barriers [12, 13].

In Germany cancer patients can take part to a usually 3-week long ambulant or stationary medical rehabilitation following the primary therapy (e.g. operation, chemotherapy, radiotherapy) [14]. Every breast cancer patient has as a general rule a statutory right to a medical rehabilitation (Code of Social Law IX). The aim of a medical rehabilitation is to improve or acquire a self-determination and participation to life in society of patients. These are funded by pension insurance schemes or health insurances, according to the insurance status of the patient. Rehabilitation standardised procedures include among others exercise therapy, nutrition counselling and psychological therapy. In particular, exercise therapy in a medical rehabilitation focus on the restoration, preservation and strengthening of body functions [9, 12, 15]. Moreover exercise therapy looks into decreasing the effect of personal barriers preventing which prevent patients from exercising, thus looking to increase participation in physical activities [12].

It is known that the gains obtained during a medical rehabilitation are often not sustainable [16] because following a beneficial medical rehabilitation the patients fall back to their old habits [17, 18]. Studies show that volition based intervention, in which cognitive processes by which an individual decides on and commits to a particular course of action are the focus, can help sustain the positive effects of rehabilitation [19–21]. It has also been recommended that an aftercare plan for each cancer patient should be discussed during the medical rehabilitation together with the rehabilitation-team [22].

The aim of the INOP study (Individual Aftercare of Oncological Patients [Individuelle Nachsorge onkologischer Patienten]) that we report here, was to show the effect of volition methods on the long term quality of life of

patients with breath cancer. The primary result of the study was that quality of life measured by EORTC QLQ-C30 [23], increased by all patients after rehabilitation. Only the global quality of life and the physical functioning was significantly better than the control group for the volition based intervention when it came in combination with a telephone aftercare (see 'interventions' below for more details) [24, 25].

In the present work we perform a secondary analysis of the INOP study where we investigate the long term effects of the volition based interventions on the time spent exercising after rehabilitation.

Methods

Study design

A randomised controlled trial with three intervention and one control groups was conducted from July 2009 to December 2012. The study participants of the INOP-study were selected in five rehabilitation centres in ost-westphalia, Germany.

In the present secondary analysis the outcome of interest is the amount of exercise performed every week by cancer patients following a rehabilitation Data were collected at baseline (the beginning of rehabilitation) as well as six (t2) and 12 (t3) months after the rehabilitation by means of questionnaires.

Participants

The study included women who have been diagnosed with breast cancer (ICD-10 C50, D05, C79.81) and have obtained a medical rehabilitation in one of the participating clinics. Exclusion criteria included primary therapy not completed, palliative situation and not able to fill in the questionnaires, even with help.

Recruitment and Randomization

Patients were recruited by the physician at the time of admission; he informed the patients about the study orally and handed out a short study description. The individual randomizations occurred after written informed consent and were performed by a member of staff not involved in the study using a list which was provided to them by the study team (generated by the software programme DatInf RandList version 1.2). The participants were randomized with equal probabilities either to the control group or to one of the three interventions groups (aftercare-planning, telephone-support, combination of aftercare-planning and telephone-support).

Control

Participants in the control group received the standard rehabilitation program which does not involve any aftercare intervention [14].

Interventions

The intervention aftercare-planning (module aftercare-planning) was conceived following the principles of the VIN-CET-study (Volitional Interventions within Cardiac Exercise Therapy) by Sudeck [26] and based on behavioural and volitional strategies. The aftercare-planning-intervention consisted of three parts: i) seminar, ii) brochure and iii) one-to-one-interview. The intervention focused on promoting a physically active lifestyle in the daily routine after rehabilitation. The seminar had two aims: 1. informing about the health benefits of physical activity (motivational method), 2. providing training on how to make plans about starting, holding or increasing their physical activity including exercising (volitional method). The participants learned to generate realistic concrete "when-where-and-how-plans" about their physical activity goals. Furthermore, they learned to anticipate their personal (internal and external) barriers which may prevent them to achieve their goals and, to develop strategies to overcome these barriers. The methods used in the seminar included interactive mediation strategies like discussions. Other topics of the seminar, here not further explained, were nutrition and meditation [25, 27]. The one hour seminar was conducted in the second rehabilitation-week. The brochure provided during the seminar contained information about the health effects of physical activity as well as instructions and worksheets for the individual aftercare planning. A practical example about weekly schedule of exercises and further information concerning the intervention are available online [28]. Additionally each study participant received an individual list containing contacts of rehabilitation-sport groups, and health-sport groups and sports clubs etc. near their place of residence. In the last rehabilitation-week a circa 15 minutes one-to-one-interview was performed with the study participants during which an individual realistic aftercare plans were discussed. The intervention aftercare-transfer was a support telephone call three months after discharge (hereafter telephone-support). The aim was to identify if the participants put their planned physical activities into action. If the participants had problems with the implementation, help was provided in form of telephone counselling or written information sent by post. The third intervention combined the two interventions mentioned above. The interventions were carried out by the researchers and psychologists of the clinics. An overview about the study design and the interventions shows figure 1.

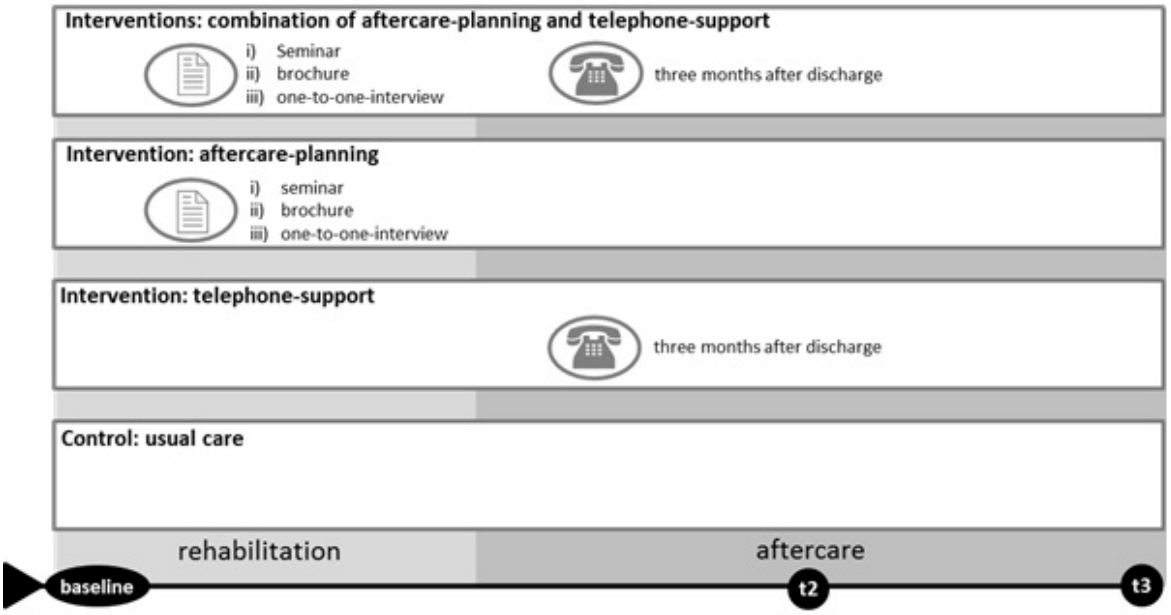


Figure 1 Overview of the interventions

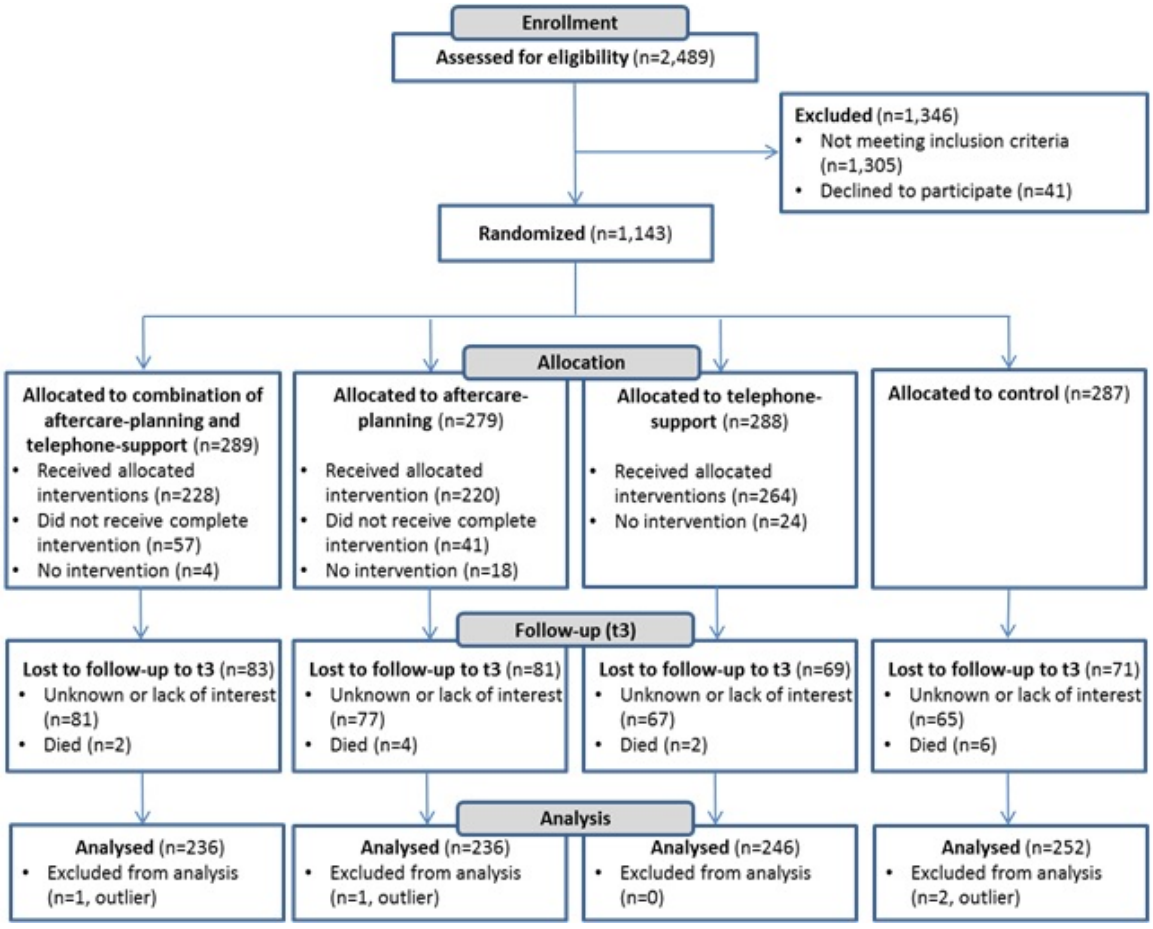
Measures

The endpoint of interest for the analysis was a self-reported measure, in minutes per week, of the duration of exercise [29, 30]. Using a questionnaire listing possible sporting activities, the participants were asked to evaluate how long and often they have been practicing each sport per week on average for the last six months with the possibility to use free text for unlisted activities. In total, four participants were excluded from the analysis, because they reported more than two hours of exercise per day. They were considered as outliers which could wrongly influence the results. The participants were defined as inactive when they reported not exercising at baseline (exercising status: active / inactive).

Statistical analysis

The differences in exercise duration between the study groups were analysed using linear multilevel models with random intercept. Model 1 provides estimates of the difference in exercise duration between t3 and t2. Follow-up for each intervention and control group using the longitudinal data with interactions study group – time-points (t2 and t3, dummy variables) controlled for age in years, body mass index (BMI) in kilograms per square metre at baseline, time since diagnosis in months and duration of exercise per week before rehabilitation (baseline-data). Model 2 tests if the exercising status (active / inactive) of participants at baseline modifies the differences obtained in Model 1 by adding interactions group / active status to Model 1. The study population consisted of

all patients with at least one measure post-rehabilitation, analysing patients in the group to which they were randomized (intention-to-treat). Analyses were conducted using Stata 12 (StataCorp. 2011).



t3: 12 months after rehabilitation

Figure 2: Flow chart

Results

Characteristics of the study participants

A total of 1,143 participants were individually randomized to one of the four study groups after informed consent was obtained. From those, 970 participants were analysed (Fig. 2). The demographic and clinical characteristics of the study participants for the four groups are described in Table 1. The study participants ware on average 59.8 years (SD=± 10.6). One-third of the participants lived alone and approx. 40 % were gainfully employed. Over 90 % of patients were diagnosed with the breast cancer from ICD-C50. Approximately one-third of the participants did not exercise at all before rehabilitation. Table 2 shows the mean duration of exercise in minutes per week at baseline, six and 12 months after rehabilitation by study group and exercising status at the beginning of the rehabilitation.

Table 1: Baseline characteristics of breast cancer patients

	Intervention			Control
	combination of Aftercare planning and telephone-support	aftercare planning	telephone-support	
	n (%)	n (%)	n (%)	n (%)
n	236	236	246	252
Age				
< 50 years	45 (19.1)	36 (15.3)	40 (16.3)	35 (13.9)
50 to 59.9 years	72 (30.5)	83 (35.2)	76 (30.9)	68 (26.0)
60 to 69.9 years	68 (28.8)	71 (30.1)	78 (31.7)	91 (36.1)
≥ 70 years	51 (21.6)	46 (19.5)	52 (21.1)	58 (23.1)
Time since diagnosis				
≤ 12 months	154 (67.0)	159 (68.2)	189 (78.8)	168 (68.9)
Body-Mass-Index				
< 24.9 kg/m^2	84 (35.9)	86 (37.2)	80 (32.9)	79 (32.6)
25.0 to 29.9 kg/m^2	95 (40.6)	76 (32.9)	105 (43.2)	108 (44.6)
≥ 30 kg/m^2	55 (23.5)	69 (29.9)	58 (23.9)	55 (22.7)
Type of rehabilitation				
follow-up-treatment	138 (59.2)	137 (61.4)	151 (62.4)	148 (61.2)
Diagnostic				
ICD-C50	212 (91.4)	203 (89.4)	226 (93.8)	218 (90.5)
Education				
≥ college/university	45 (19.5)	42 (18.3)	38 (15.8)	38 (15.4)
Living alone				
yes	60 (30.9)	78 (37.0)	68 (32.5)	83 (38.1)
Employment				
yes	95 (44.2)	106 (49.1)	96 (44.0)	90 (40.2)
Exercise				
yes	81 (38.0)	84 (38.5)	86 (37.9)	82 (35.7)

Table 2: Means and standard deviation (sd) for exercise in minutes per week at measure times at baseline, t2 and t3 stratified by study group and exercising status at the beginning of rehabilitation

	Baseline		six months after rehabilitation		12 months after rehabilitation	
	n	mean±sd	n	mean±sd	n	mean±sd
Intervention: combination of aftercare-planning and telephone-support						
total	213	72.6±125.4	196	190.0±153.8	181	186.7±130.3
inactive	132	0.0±0.0	117	152.0±145.9	111	162.2±131.7
active	81	190.9±137.1	79	246.4±148.6	70	225.7±118.9
Intervention: aftercare-planning						
total	218	82.7±148.2	199	162.0±164.6	177	164.9±150.7
inactive	134	0.0±0.0	119	126.4±154.4	108	133.3±137.3
active	84	214.5±169.6	80	214.9±166.1	69	214.4±158.3
Intervention: telephone-support						
total	227	79.4±141.0	215	149.4±147.3	191	138.4±140.4
inactive	141	0.0±0.0	133	112.6±121.3	115	98.3±111.0
active	86	209.7±158.7	82	209.0±166.0	76	199.0±158.2
Control group						
total	230	71.3±134.0	214	127.5±130.0	185	120.1±134.6
inactive	148	0.0±0.0	135	94.4±122.2	115	90.8±119.0
active	82	200.1±157.1	79	184.2±123.9	70	168.2±145.4

Intervention effects on exercise duration

Six months after rehabilitation, the intervention group "combination of aftercare-planning and telephone-support" exercised 69 minutes per week (95% CI: 42.85; 94.90) more than the control group as well as 39 minutes per week (95% CI: 12.79; 64.53) more than the intervention group "aftercare-planning" adjusted for age, BMI, time since diagnosis and exercise before rehabilitation (Table 3). The phone-based intervention "telephone-support" with 23 (95% CI: -5.54; 48.25) minutes per week did not show any statistically significant difference on exercise duration by comparison to the control group. Twelve months after rehabilitation there is no statistically detectable change in the duration of exercise compared to six months-follow-up for each study groups.

Table 3: Intervention effects of exercise in minutes per week six and 12 months after rehabilitation compared by study groups (model 1).

	ß	95% CI	p
intercept	157.32	93.56; 221.10	<0.001
Six months afterwards (t2):			
Control group	Ref.		
Combination of aftercare planning and telephone-support	68.87	42.85; 94.90	<0.001
Aftercare planning	38.66	12.79; 64.53	0.003
Telephone-support	22.85	-5.54; 48.25	0.078
Chance in group difference t3 - t2			
Control group	-9.90	-28.67; 8.87	0.301
Combination of aftercare planning and telephone-support	7.67	-18.98; 34.33	0.573
Aftercare planning	10.25	-16.46; 36.97	0.452
Telephone-support	-7.55	-33.69; 18.60	0.572

Adjusted for age, BMI, time since diagnosis and exercise at baseline; t2: six months after rehabilitation; t3: 12 months after rehabilitation; ß=coefficient of regression; 95% CI: 95% confidence interval; p: significance value; number of observation: 1.503; number of groups: 840

Intervention effects on exercise of inactive vs. active patients

The analysis stratified by active vs. inactive at baseline (Model 2; Table 4) showed that after the rehabilitation the inactive participants of the intervention group "combination of aftercare planning and telephone support" exercised on average 80 minutes per week (95% CI: 48.46; 110.67) and the intervention group "aftercare planning alone" 47 minutes per week (95% CI: 16.09; 77.76) . Both groups were thus significantly more physically active than the control group. This analysis of Model 2 was adjusted for age, BMI, time since diagnosis, exercise before rehabilitation and time in weeks. Here again, no statistically significant difference was

seen in telephone based intervention group “aftercare transfer” both inactive and active compared to the inactive respectively active control group.

Table 4: Effects of exercise in minutes per week after rehabilitation compared by study groups and exercising status at baseline (model 2)

	ß	95% CI	p
intercept	157.60	88.62; 226.57	<0.001
Inactive: group			
Control group	Ref.		
Combination of aftercare planning and telephone-support	79.57	48.46; 110.67	<0.001
Aftercare planning	46.92	16.09; 77.76	0.003
Telephone-support	13.87	-16.65; 44.39	0.373
Active in difference to the inactive			
Control group	4.60	-34.88; 44.09	0.819
Combination of aftercare planning and telephone-support	-16.83	-66.90; 33.26	0.510
Aftercare planning	-10.79	-60.44; 38.86	0.670
Telephone-support	6.02	-43.03; 55.08	0.810

Adjusted for age, BMI, time since diagnosis, exercise at baseline and time in weeks. inactive: at baseline no exercise; ß=coefficient of regression; 95% CI: 95% confidence interval; p: significance value; number of observation: 1.306; number of groups: 788

Discussion

The analysis showed statistically significant effects on the duration of exercise of the module aftercare-planning in comparison to the usual rehabilitation (control) as well as for the module aftercare-planning in comparison to the telephone-support. The phone-based-module after the rehabilitation alone wasn’t an effective intervention compared to the usual rehabilitation. Six and 12 months after the rehabilitation, the combined modules patients did exercise over an hour more per week than the control group.

This observed increased physical activity is in line with what other behavioural strategies studies showed. For example in the VIN-CET study, behavioural strategies, three months after rehabilitation lead to an exercise increase among cardiac patients. In the present study the intervention comprised a motivational intervention such as changing action recommendations, volition action, such as realizing recommendations, and volitional resource techniques [26].

Behavioural changes are explained by various theoretical models including the Social Cognitive Theory [31], Transtheoretical Model [32] or Health Action Process Approach [33]. On the quantitative side, a meta-analysis by Stacey et al. 2016 showed a small-to-medium effect of 0.3 for social-cognitive-theory-based interventions in changing physical activity by cancer survivors [34]. Husebo and colleagues found in a systematic review and

meta-analysis that the TTM and the planned behaviour were significantly associated with better exercise adherence [35]. Some studies have found that two important factors to increase the physical activity are self-efficacy and enjoyment [36] but also that individual supervising by a therapist during rehabilitation is necessary [35, 37]. In our study, patients benefited from the combined modules aftercare-planning and telephone-support but also from the module aftercare-planning alone which may infirm this later statement. The telephone-based aftercare of breast cancer patients in the study from Hass et al. also shows no additional effect [38].

What our study shows in particular is that patients who were inactive before the study began, benefited also from both the combination of aftercare-planning and telephone-support and the the aftercare-planning alone. This confirms for breath cancer patients what was already shown by the above mentioned studies, that mostly inactive patents benefited volition interventions [26, 39]. In orthopaedic rehabilitation inactive participants in the intervention group of the MoVo-Lisa-study were on average 28 minutes per week more active than those in the control group one year after rehabilitation [39, 40].

As our study shows medical rehabilitation is an ideal setting to integrate motivational and volitional strategies because of the existing infrastructure and the inpatient nature of the interventions. However there are limitations to what medical rehabilitation in the German setting can achieve. Indeed, the 3-week rehabilitation duration is too limited to support patients individually by the implementation of their aftercare goals [37]. But an individualised telephone-based support for implementation of this goals can be a sustainable solution to increase participation in physical activities. Moreover, health professionals in rehabilitation clinics must be trained to motivational and volitional behaviour strategies and techniques [41]. The short interventions developed in the INOP study or other can be well integrated in the daily routine of medical rehabilitation by sport therapist, occupational therapist or psychologist for example. Further, health professionals are advised to consider the preferences of the patients and to build up training programs comparable to the those of healthy persons [5, 37]. Besides behavioural factors and the environmental factors must also be taken into account (e.g. social support, place of residence, family status) in the planning of exercise for everyday living [42, 43].

The present study shows some limitations. The measure of exercise duration is self-reported and therefore open to (recall) bias. Due to the financial limitation of the study it was not possible to use accelerometers which would have provided more objective measures on intensity and duration of exercise.

Conclusion

In conclusion, techniques with motivational and volitional aspects have shown the possibility of promoting exercising among patients with breast cancer. The addition of a telephone-based intervention can increase the

sustainability of the increase in physical activity achieved by the rehabilitation. So, both interventions could be integrated into routine care for patients with breast cancer. Further study should evaluate the effect of such programs among other groups of oncological patients. This study was funded by Verein zur Förderung der Rehabilitationsforschung e.V. Norderney.

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