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ScienceDirect
European Journal of Pain 11 (2007) 31–37
www.EuropeanJournalPain.com

TTM-based counselling in physiotherapy does not contribute to an increase of adherence to activity recommendations in older adults with chronic low back pain – A randomised controlled trial

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Received 12 August 2005; received in revised form 13 December 2005; accepted 16 December 2005
Available online 30 January 2006

Abstract

Aims: The present study examines the outcome of counselling in physiotherapy based on the Transtheoretical Model (TTM) in a sample of elderly individuals with chronic low back pain.
Methods: In a prospective randomised trial with concealed assignment, elderly individuals with chronic low back pain were allocated to two treatment conditions. Both contained 10 sessions of physiotherapy, each of 20 min duration. In addition, the experimental group (EG) received 10 min counselling prior to every session based on the TTM, also provided by the physiotherapist, and the control group (CG) underwent a placebo ultrasound treatment with an inactivated device to control for the additional attention given to the EG. Assessments took place prior to the treatment (t1), immediately after termination of the treatment (t2), and at a 6-months follow-up. Outcome measures were physical activity calculated from one-week activity diaries, self-reported functional capacity, and range of motion measured by ultrasound topometry.
Results: A total of 170 individuals (64% female) with a mean age of 70.3 years (SD = 4.4, range 65–84) participated in the study. The retention rate was 90%. At t3, both EG and CG showed increased physical activity and functional capacity, but no change in range of motion. Effect sizes were large. Contrary to our hypothesis, however, motivational training did not result in a better outcome compared with placebo treatment.
Conclusion: The study does not provide evidence that a short TTM-based motivation programme is superior to placebo treatment regarding adherence to activity recommendations.

Keywords: Physical activity; Low back pain; Elderly; Transtheoretical model; Adherence

1. Introduction

The American College of Sports Medicine (ACSM) published a statement of its position on exercise and physical activity for older adults (Anonymous, 1998). The authors stated that, based on the available evidence, participation in a regular exercise programme is an effective strategy to reduce functional declines associated with aging. Recently, the College updated these recommendations with special reference to the prevention of osteoporosis and fractures in old age, with a focus on weight-bearing endurance activities and resistance

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1090-3801/$32
doi:10.1016/j.ejpain.2005.12.009

exercises (Kohrt et al., 2004). Moreover, systematic reviews and randomised controlled studies inspected by the Cochrane Group underscored the importance of exercise training in the treatment of subjects with persistent pain (Van Tulder et al., 1997, 2000; Ostelo et al., 2005). This applies especially to the treatment of the elderly. As a consequence the American Geriatric Society published guidelines recommending an activity programme for every elderly patient with chronic pain under inclusion of exercises for the enhancement of endurance, strength, and flexibility (American Geriatric Association, 2002).

At present, physical exercises are a principal part of every multidisciplinary programme for the treatment of chronic low back pain. Guzman et al. (2002), also in a publication of the Cochrane Group, reported about 10 randomised controlled trials with nearly 2000 patients that provide strong evidence that multidisciplinary rehabilitation with a functional restoration approach improves function, and they provided moderate evidence that it reduces pain, when compared with inpatient or outpatient non-multidisciplinary treatments.

One problem encountered in activity programmes is the long-term compliance of the patients (Allison and Keller, 1997). Sluijs et al. (1993) found that 70% of the participants of a physiotherapeutic training for back pain did not adhere to the treatment regimen. In one of our own studies, only 30% of the participants of a back school performed the target behaviour (performance of exercises at least three times a week) at a nine-month follow-up (Keller et al., 1996). After inspection of the available literature, Blue and Black (2005) came to the conclusion that a lesson revealed from the studies is the need for the detection of effective ways to improve intervention adherence and retention and to prevent relapse.

In recent years, various researchers have devoted their work to solving this problem with different outcomes. In workers with musculoskeletal pain, Linton et al. (1996) have been able to show the superiority of a cognitive-behavioural intervention over education with regard to participation in an exercise programme. However, a difference in the pain intensity scores between those participating in the two interventions could not be demonstrated. Friedrich et al. (1998) conducted a controlled randomised study in a physiotherapy setting with a treatment offered by physiotherapists both in the experimental and the control condition. Experimental and control patients with chronic low back pain received ten 25-min sessions of an exercise programme aimed at the restoration of normal function. In addition, the experimental patients participated in a motivation programme also based on cognitive-behavioural techniques. At a 12-month follow-up, no difference was found between the motivation group and the control group with regard to exercise compliance. Despite this finding, the motivation group was superior to the control group with respect to self-reported disability and pain intensity. A follow-up after 5 years confirmed the positive results (Friedrich et al., 2005). Despite this positive outcome there remains some methodological critique that imposes limitations on the validity of these results. In contrast to good clinical practice, the authors neither focussed on one primary outcome variable nor did they correct for multiple computations. They included more than 20 variables into their statistical analysis, and it appears probable that some of these variables may have produced statistically significant results by mere chance. Moreover, what might have been the principal outcome in a training for the enhancement of motivation, namely the level of adherence to the treatment regimen, failed to differentiate between experimental and control condition. Consequently, it remains unclear why the training resulted in reduced disability and pain levels, if this effect cannot be attributed to increased long-term adherence.

Interventions based on the Transtheoretical Model (TTM) of behavioural change show the potential to be effective in shaping the motivation of the patient with regard to different target behaviours (Prochaska and Norcross, 2002). The principal idea of this model is that behaviour change is a process that unfolds over time and involves progression through a series of different stages: precontemplation, contemplation, preparation, action and maintenance. At each stage different processes of change optimally produce progress. Matching change processes to the respective stages requires that the therapy relationship be matched to the client's stage of change. In a meta-analysis on physical activity and exercise, Marshall and Biddle (2001) included 91 independent samples and found that the results support the application of the model, because core constructs differ across stages and most changes are in the direction predicted by the theory. Steptoe et al. (2001) found that the application of this model in a general practice setting improved the outcome of counselling procedures with regard to various target behaviours, among them also physical activity. Also, the application of the model by practice nurses yielded similar results (Steptoe et al., 1999). In a critical review, however, Adams and White (2003) came to the conclusion that while it is true that activity promotion interventions based on the TTM are effective in promoting activity adoption, there are not sufficient studies supporting the assumption that the initial results are maintained over a longer period of time. The authors concluded that future studies are necessary to especially address maintenance of the acquired behaviour.

In contrast to the study by Friedrich et al. (1998, 2005) we address an older population, namely individuals of at least 65 years of age, and we rely on interventions derived from the TTM to initiate and to maintain behavioural change. Previous studies on the promotion of physical activity in older individuals with pain principally included patients with arthritis or osteoarthritis (e.g., Dias et al., 2003; Petrella and Bartha, 2000; Buchner et al., 1992). Little research has been done on the promotion of physical activity in older patients with low back pain, and, in this context, there is a complete lack of research based on the TTM. We hypothesised that a TTM-based motivation training for elderly individuals with low back pain who participate in a physiotherapy treatment has a favourable impact on adherence to activity recommendations, and, consequently, also on physical function.

2. Methods

2.1. Design

In a prospective randomised controlled trial, elderly individuals with chronic low back pain were individually allocated to two groups. Computer-assisted randomisation was performed by an external institute (University Institute for Medical Biometrics) and included stratification for age and stage of change to avoid possible confounding effects (Riebe et al., 2005). Concealed allocation was ensured. Experimental patients participated in physiotherapy and counselling, control patients in physiotherapy and placebo ultrasound treatment.

Inclusion criteria were a minimum age of 65 years, diagnosis of chronic low back pain due to osteoporosis or to degenerative spine disorders with or without previous surgery to the spine, and pain at the time of inclusion. Exclusion criteria were red flags (lumbar spine pathologies) such as tumors, fractures, infections or acute inflammatory disease, spinal stenosis, or a high degree of instability. We also excluded patients who had low back surgery within the previous 6 months and those with a diagnosis of dementia.

Patients were recruited in the departments of orthopaedics and neurosurgery at the university hospital in Marburg. After the medical examination, including an X-ray assessment, those who provided informed consent received a physiotherapeutic as well as a psychological assessment utilizing a published and evaluated structured pain interview for the elderly (Basler et al., 2001). Three assessments were taken, before treatment (t1), after its termination 6–7 weeks later (t2), and at a 6-month follow-up (t3). Primary outcome measures were physical activity, functional capacity and range of motion.

Calculation of the sample size relied on the following assumptions: (1) expected effect size of the principal outcome variables in the middle range (η^2 >0.06 and <0.15, see Adams and White, 2003), (2) 5% level of significance and power of 80%, (3) number of drop-outs at follow-up 15%.

2.2. Assessment instruments

At t1, a stage algorithm allocated the patients to different stages (Basler et al., 2004; Schumann et al., 2003), which are precontemplation (PC), contemplation (C), preparation (P), action (A), and maintenance (M). The target behaviour was a minimum of 30 min of self-administered physical activity a day under inclusion of stretching, strengthening and endurance exercises. At each assessment, patients filled out a 7-day activity diary. Pictures illustrated the desired activities and thus facilitated the recordings. Previous research indicated that this is a reliable and valid instrument (Follick et al., 1984).

Functional capacity was assessed by the Hannover Functional Disability Scale (HFAQ) (Kohlmann and Raspe, 1996). This scale measures activities of daily living, e.g., ability to wash one's hair or to put on stockings without help. Raw scores are transformed to values that indicate a percentage of normal function. A value of >80% demonstrates normal capacity. The HFAQ is a frequently used instrument for the assessment of back pain disability and a scale with good psychometric properties. A comparison of the HAFQ with the Roland and Morris Scale in a German population demonstrated good internal consistency of both scales ($r > 0.85$), a retest reliability of 0.91, and an intercorrelation of both scales that amounts to 0.75 (Roese et al., 1996). Correlations with further disability measures indicate a concurrent validity of the HFAQ that is equivalent to the Roland and Morris Scale. We preferred the HFAQ because it only consists of 12 items without a loss of psychometric quality compared to the Roland and Morris Scale.

Range of motion was measured by ultrasound topometry utilizing the device CMS 20S offered by the company Zebris located in Isny, Germany. This system depicts posture and movement in three-dimensional space. Patients are requested to bend forward, while ultrasound signals measure the location of pre-defined reference points over the skeleton. The data are stored automatically for subsequent computation.

Ultrasound topometry was performed by a physiotherapist who was unaware of the treatment allocation of a patient in order to prevent detection bias.

2.3. Treatment

Over a period of 5 weeks both groups received 10 individual physiotherapy sessions in an outpatient setting. Treatment sessions were based on the ACSM recommendations, were of 20 min duration, and followed a standardised treatment manual. Each session started with stretching exercises and progressed to a treatment tailored to the specific needs of the patient. Dependent on the initial evaluation, the treatment aimed at improving trunk and lower limb muscle length, strength, endurance, flexibility and coordination. The sessions included homework assignments that were individualised for every patient accounting for personal preferences. Special emphasis was laid on Activities of Daily Living (ADL) complemented by written material in order to facilitate performance in the natural environment.

In addition, the experimental patients individually attended a standardised counselling procedure of 10 min duration prior to every physiotherapy treatment offered by the same therapist who conducted the physiotherapy treatment. The programme addressed readiness for change and implicitly integrated some of the relevant processes of change (e.g., consciousness raising through presenting stage-adjusted information about chronic back pain and the beneficial effects of physical activity). The strategies were aimed at increasing self-efficacy and at positively influencing decisional balance. Additionally, they were intended to enhance commitment, self-reinforcement and reinforcement of desired behaviour, the use of social support and constructively dealing with relapse. Counselling took into consideration the individual's stage of change that was determined during the initial assessment (Basler et al., 2004).

In order to compensate for the additional attention given to the experimental group, the control group participated in a placebo ultrasound therapy with an inactivated device. This procedure also lasted 10 min. While the physiotherapists moved the device over the painful body parts, they were free to talk to the patient without any restriction on the topic.

Four experienced physiotherapists participated in the study after an introductory class, two in the experimental group and two in the control group. Only the therapists in the experimental group, however, received information about the experimental treatment. They participated in another class of 8 h about the TTM with trial counselling sessions. They also recorded their actual behaviour during the sessions and marked every deviation from the treatment plan. Two of the authors (S.Q., U.W.) inspected these recordings regularly and supervised the physiotherapists in order to encourage adherence to the treatment protocol.

2.4. Ethical considerations

The study was positively evaluated by the ethics committee of the faculty of medicine at the University of Marburg.

2.5. Subjects

In accordance with power calculations, a total of 170 individuals participated in the study, of whom 152 provided data at follow-up (drop-out rate 10%). In experimental (EG) and control group (CG), patients discontinued participation in the study for the following reasons: deteriorated health status (EG: $n = 7$; CG: $n = 3$), withdrawal of consent after randomisation (EG: $n = 3$, CG: $n = 2$), death (EG: $n = 2$; CG: $n = 0$), and erroneous inclusion (EG: $n = 1$; CG: $n = 0$). Drop-outs because of health reasons were equally distributed in EG and CG (Fisher exact test, $\chi^2 = 0.09$; df = 1; n.s.). At t3, an additional 5% of the patients did not return the diaries. Moreover, at t1, due to a software problem of the ultrasound device, the data of 25 patients were not recorded accurately. The flow of the participants is shown in Fig. 1.

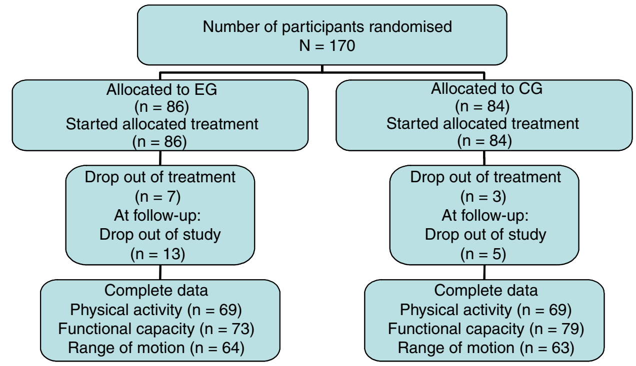

Fig. 1. Flow of participants through the stages of the trial.

2.6. Hypotheses

As a consequence of the experimental intervention, we expected a superiority of the experimental patients over the control patients with regard to the amount of time engaged in physical activity. Given the fact that physical activity corresponds with functional capacity in older adults (Riebe et al., 2005), we also expected a better function in the experimental group at the follow-up assessment.

2.7. Statistical procedures

Statistical procedures were χ^2-tests and analyses of variance. As we include three principal outcome variables, the Bonferroni correction for multiple comparisons was applied. We conducted an intention-to-treat analysis and, in addition, a per-protocol analysis, both with equivalent results. For this reason, only the intention-to-treat analysis is presented in this paper.

3. Results

Stratification for age and stage of change as possible confounders resulted in an equal distribution of these variables in experimental and control group. There were no differences between experimental and control subjects in either of the descriptive variables depicted in Table 1.

Table 1
Description of the sample

Variables		Experimental group	Control group
N		86	84
Age (in years)	Mean	70.09	70.56
	SD	4.19	4.55
	Minimum	65	65
	Maximum	79	84
Gender (%)	Male	37.2	34.5
Level and years of education (%)	Master (University)	7.0	8.3
	Bachelor[a]	3.5	6.0
	13 years[b]	4.7	6.0
	10 years[c]	20.9	26.2
	9 years[d]	62.8	52.4
	No qualification	1.2	1.2
Marital status (%)	Single	3.5	2.4
	Married	75.6	70.2
	Widowed	18.6	19
	Divorced	2.3	8.3
Place of residence (%)	Apartment/flat of one's own	95.3	95.2
	Old age residence	1.2	0.0
	Other	3.5	4.8
ICD-10 diagnoses (%)	M47 Spondylosis	49.2	51.8
	M54 Lumbago	27.0	17.9
	M42 Osteochondrosis	17.5	23.2
	Other diagnoses	6.4	7.2
Stage of change prior to treatment (%)	Precontemplation	12.8	7.4
	Contemplation	35.9	35.8
	Preparation	44.9	44.4
	Action	1.3	4.9
	Maintenance	5.1	7.4

[a] Fachhochschule.
[b] Gymnasium (Abitur).
[c] Realschule.
[d] Hauptschule.

Table 2 shows the distribution of the outcome variables over time. It becomes evident that both the experimental group and the control group showed an improvement of physical activity and self-reported functional capacity. Effect sizes are large. On the other hand, motivational training did not result in a better outcome compared with placebo ultrasound treatment. Range of motion remained unchanged throughout the observation period. Consequently, the primary hypothesis has to be rejected.

4. Discussion

Our randomised controlled prospective study showed that physiotherapy treatment for elderly patients with chronic low back pain resulted in an overall increase in time spent on physical activity and in functional capacity (large time effect). However, contrary to our assumptions, 10-min motivational counselling provided by physiotherapists prior to every physiotherapy session did not lead to better short- or long-term results than a placebo ultrasound treatment (small interaction effects). While improvements seemed minimally larger in the intervention group, neither the additional 5 min of daily physical activity nor the 4% higher functional capacity in the intervention group at t3 were large enough to be secure against statistical error. Additionally, the improvements in both groups in physical activity and self-reported function should not be over-interpreted, because our study design did not allow comparison of the results with those of an untreated control group.

These results are not in accordance with those of the previously mentioned randomised controlled study conducted in the same setting (Friedrich et al., 1998, 2005). Although experimental and control subjects did not differ with regard to exercise compliance, the experimental subjects were superior to the controls with regard to self-reported disability and pain intensity. Different from our study, the authors worked with a younger age group. Although the authors did not explicitly mention their diagnoses, they explained that the vast majority of their

Table 2
Distribution of the principal outcome variables and intention-to-treat analysis of the data

Variable		t1, *M* (SD)	t2, *M* (SD)	t3, *M* (SD)	Main effect group[a]	Main effect time[a]	Interaction effect[a]
Average duration of physical activity (minutes a day)	EG, $n = 75$	15.98 (21.1)	29.24 (14.6)	29.63 (24.2)	$F_{1,145} = 2.79$	$F_{2,144} = 27.98$	$F_{2,144} = 0.32$
	CG, $n = 72$	14.11 (15.5)	24.7 (16.3)	25.3 (19.7)	n.s.	$p < 0.01$	n.s.
					$\eta^2 = 0.019$	$\eta^2 = 0.28$	$\eta^2 = 0.004$
Functional capacity (percent of normal function)	EG, $n = 86$	67.3 (18.9)	73.7 (16.5)	72.5 (20.3)	$F_{1,168} = 1.06$	$F_{2,167} = 15.07$	$F_{2,167} = 0.975$
	CG, $n = 84$	66.3 (19.2)	70.2 (17.9)	68.9 (19.7)	n.s.	$p < 0.01$	n.s.
					$\eta^2 = 0.006$	$\eta^2 = 0.153$	$\eta^2 = 0.012$
Range of motion (degrees)	EG, $n = 74$	22.9 (9.8)	24.2 (9.1)	23.7 (9.3)	$F_{1,139} = 1.75$	$F_{2,138} = 0.44$	$F_{2,138} = 2.00$
	CG, $n = 67$	22.1 (9.6)	21.6 (9.5)	21.5 (9.1)	n.s.	n.s.	n.s.
					$\eta^2 = 0.012$	$\eta^2 = 0.006$	$\eta^2 = 0.028$

[a] Analysis of variance, EG – experimental group, CG, control group; t1 – before treatment, t2 – after treatment, t3 – 6-months follow-up; η^2 – effect size (>0.01 small effect, >0.06 medium effect, >0.14 large effect).

patients suffered from non-specific pain disorders due to physical strain, non-physiologic movements, stress or other reasons without clear explanation. In contrast, structural imaging showed that the vast majority of our patients displayed degenerative disorders of the spine. It may be more difficult to foster the motivation of these patients beyond the intrinsic motivation they already displayed by their participation in a physiotherapy programme. On the other hand, the positive results presented by Friedrich et al. may also be a consequence of statistical flaws that have been mentioned in Section 1.

In the present study, the differences in treatment between the experimental and the control treatment were obviously not big enough to impact the outcome. Although the control therapists were not trained in motivational counselling, treatment diffusion cannot be excluded. Experimental and control therapists worked in the same department and communicated with each other. Moreover, the control therapists were allowed to talk to the patients at any part of the treatment. When questioned, they admitted the inclusion of motivational aspects either at the time of the placebo treatment or later on during the exercise part. To give an example, they underscored the importance of homework assignments and reinforced reports of physical activity, which they considered represented good clinical practice in physiotherapy. In contrast to the experimental therapists, however, they did not use a structured and theory-based approach. What can be excluded is a lack of adherence of the physiotherapists to the treatment protocol. Inspection of the records and supervision of the physiotherapists by the authors of this study showed a good correspondence between the actual behaviour of the therapists and the behaviour expected of them.

Pretest effects may be a further explanation for the negative results. At every assessment the attention of the patients was focussed on physical activity, in the structured interview as well as in the activity diaries. This may also have increased adherence to the homework assignments.

Additionally, placebo effects of the ultrasound treatment need to be taken into consideration. Hrobjartsson and Gotzsche (2001) conducted a meta-analysis of clinical studies that compared placebo treatment in the experimental condition with no treatment in the control condition. They could not detect a positive outcome of the placebo treatment with respect to objectively assessed measures, but they found moderate effect sizes of the treatment with regard to subjective measures. They obtained the highest effect sizes in the assessment of pain. Following the cognitive hypothesis, expectancy beliefs are the link between placebo and positive outcome (Jäger and Lamprecht, 2003). These depend on characteristics of the placebo. Expectancy beliefs tend to be higher in invasive procedures and in those procedures that demand sophisticated technical equipment. For this reason, it cannot be excluded that the placebo treatment in the control group impacted positively on the pain experience of the patients and, as a consequence, also on self-reported functional capacity.

Finally, the characteristics of the sample may explain the non-significant interaction effects to some extent: At baseline, over 50% of both treatment groups were either already active (action or maintenance stage) or ready to exercise regularly (preparation stage). While the action-oriented intervention in our study was adequate for this highly selective sample with such characteristics, one strength of TTM-based interventions lies in addressing the motivational needs of individuals in earlier stages of change. Individuals in this sample may not have benefited from the motivational part of the intervention because they had already entered the study highly motivated for the target behaviour. The sample size is not big enough to calculate whether subjects in pre-action stages profited better from the intervention than those in the action stages.

What we consider unlikely is the existence of an attrition bias, which means the possibility of a selective drop-out rate. The number of drop-outs differed only slightly between treatment and control subjects, and the reasons for drop-out did not appear to be different.

In summary, the study does not provide evidence that a TTM-based motivation programme is superior to placebo treatment in the promotion of physical activity in elderly individuals with chronic low back pain. These findings may be attributed to a lack of validity of the model-based intervention for this age group or to an insufficient control of treatment diffusion. A strength of the study is the control of non-specific treatment effects by inclusion of a placebo treatment.

Acknowledgement

This study is funded by the German Research Society (DFG BA 793/6-1+2).

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