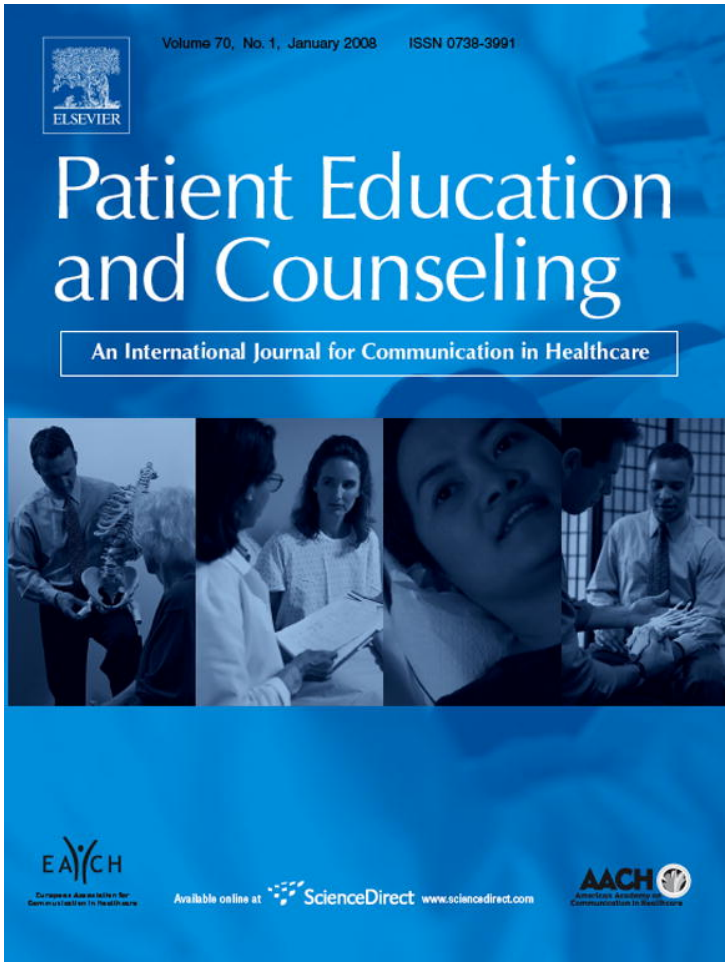

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TTM-based motivational counselling does not increase physical activity of low back pain patients in a primary care setting—A cluster-randomized controlled trial

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Abstract

Objective: To investigate the effectiveness of a TTM-based motivational counselling approach by trained practice nurses to promote physical activity of low back pain patients in a German primary care setting.
Methods: Data were collected in a cluster-randomized controlled trial with three study arms via questionnaires and patient interviews at baseline and after 6 and 12 months. We analysed total physical activity and self-efficacy by using random effect models to allow for clustering.
Results: A total of 1378 low back pain patients, many with acute symptoms, were included in the study. Nearly 40% of all patients reported sufficient physical activity at baseline. While there were significant improvements in patients' physical activity behaviour in all study arms, there was no evidence for an intervention effect.
Conclusion: The outcome may be explained by insufficient performance of the practice nurses, implementation barriers caused by the German health care system and the heterogenous sample.
Practice implications: Given the objective to incorporate practice nurses into patient education, there is a need for a better basic training of the nurses and for a change towards an organizational structure that facilitates patient–nurse communication. Counselling for low back pain patients has to consider more specificated aims for different subgroups.

Keywords: Physical activity; Low back pain; Motivational counselling; Primary care

1. Introduction

According to current evidence-based guidelines and recommendations, low back pain (LBP) patients should increase their regular physical activity or change a sedentary life style to prevent pain chronification [1–5]. Patients with an acute onset of back pain should be advised to continue with their normal physical activity during the acute phase. In case of insufficient physical activity in the patient's history, patients should be encouraged to increase their activity in future.

General practitioners (GPs) as frequent medical consultation partners provide a promising setting for physical activity promotion. However, counselling by practitioners during the normal medical consultation is often ineffective [6,7] and shows only short-term effects in behaviour change [8,9].

Internationally, there have been efforts to delegate parts of the health-promotion tasks to practice nurses because of physicians' time constraints [10]. In the United Kingdom, it has

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been shown that (behavioural) counselling for physical activity was successful when performed by practice nurses [11–13]. Practice nurses in Germany are usually primarily involved in administrative and organizational tasks. As a first step of involving practice nurses better into patient care, trained practice nurses were successfully integrated in the care of diabetes management. The effectiveness of interventions supported by practice nurses in the context of other diseases is currently under evaluation [14]. New models of nurses' involvement are necessary especially in regard to disease management programs (DMP) [15].

Systematic reviews showed that successful interventions to promote physical activity should include multiple components like provider advice, written material and behavioural interventions tailored to patients' needs as well as on-going professional support [16–18]. The reviews also point out the lack of long-term data.

Theory-based counselling is more effective than interventions not grounded in theory [19]. One of the most widely applied theories in promoting physical activity is the Transtheoretical Model (TTM) [20] often in combination with the technique of 'motivational interviewing' according to Miller and Rollnick [21–23]. Interventions based on the TTM are tailored to the patients' motivation and readiness to change. There are promising short-term effects of TTM-based interventions but the evidence for long-term adherence to increased levels of physical activity is not yet convincing [24–26]. Success of physical activity interventions should not only be shown in stage progression but also in increasing exercise levels [27].

Marshall and Biddle [25] point out that there is a clearly defined relationship between readiness for physical activity (stages of change) and self-efficacy. Self-efficacy also plays an important role in other theories of health behaviour and in the psychological determinants of exercise [28]. Self-efficacy is a potential mediator for exercise behaviour [29] and should be taken into consideration in theory-based interventions. Interventions in subacute pain patients aiming at increased physical activity can influence exercise behaviour and self-efficacy [30].

Based on these findings, the purpose of this study was to assess the effects of a TTM-based motivational counselling approach to increase physical activity in patients with low back pain in a primary care setting. In a three-armed cluster-randomized controlled trial we compared motivational counselling by trained practice nurses to general counselling by practitioners and usual care treatment. Primary outcome was the self-reported physical activity (MET hours/week), and self-efficacy was a secondary outcome variable.

2. Methods

2.1. Study design

The study was a multi-center cluster-randomized trial with three study arms within the German back pain research network (GBPRN). We used general practices as the unit of randomization. The block randomization was arranged externally by the GBPRN-chairman based on a computer-generated randomization list for each of the two study centres. General practitioners (GPs) in both intervention groups (A and B) were trained in using a German LBP guideline developed by the German Society of General Practice and Family Medicine (DEGAM). The aim of study arm A was to evaluate a guideline implementation strategy by training the GPs in three interactive 2-h quality circles and providing them with extensive information material [31]. In study arm B, practice nurses were additionally trained in TTM-based motivational counselling to promote physical activity. In the control group, the GPs received the guideline via mail which had been shown to have no effect on patient outcome [32].

Data collection from the included patients at baseline was performed with standardised questionnaires and one telephone interview 4 weeks after study inclusion. Follow-up assessments were done at 6 and 12 months by standardised telephone interviews conducted by specially trained study nurses.

All participating GPs, practice nurses and patients provided their written informed consent. The study was approved by the local ethics committees of the Universities of Marburg and Göttingen, Germany. GPs and practice nurses received monetary compensation for the recruitment of patients and the participation in training sessions.

2.2. Participating physicians

A total of 883 GPs in two German regions were invited to participate. Of all invited physicians, 52% did not respond, 34% declined because they could not fulfill the trial requirements (participation of GPs and practice nurses). Two practices dropped out after randomization. In the final trial, we included 126 physicians from 116 practices which was 14% of invited practices.

2.3. Recruitment of patients

GPs were asked for consecutive recruitment of 15–20 patients who presented with current low back pain over a time period of 11 months in the years 2003–2004.

Expecting small effects ($f = 0.1$) and a drop out rate of 25% we aimed for 1874 patients ($\alpha = 0.05$, $p = 0.80$, intracluster correlation coefficient $\rho = 0.03$, expected cluster size $n = 16$). Inclusion criteria were low back pain on the day of recruitment, written consent to participate in the study and age above 19 years. Exclusion criteria were insufficient language skills (speaking, reading, or writing), pregnancy and isolated thoracic pain.

2.4. TTM-based intervention

2.4.1. Training of practice nurses in TTM-based motivational counselling

Practice nurses in study arm B received intensive training over a total of 20 h (two full day workshops and between one

and three supervision sessions). As background information, they were introduced to the key messages of the LBP guideline and the rationale why LBP patients should increase their regular physical activity.

At the beginning the practice nurses were trained in general counselling skills like active listening, paraphrasing and verbal affirmation and reinforcement. The main focus of the training was on the TTM-based counselling approach and the motivational interviewing style.

The practice nurses learned to identify the stage of change and to use stage-specific counselling strategies. For patients with no intention to change their exercise behaviour (precontemplation), the goal was to provide information and raise interest in the topic. With patients in the contemplation stage, practice nurses were encouraged to discuss the subjective advantages and disadvantages of increasing physical activity (decisional balance). Emphasis was put on methods for strengthening the patients' self-efficacy by reinforcing small steps towards the intervention goal. Patients in the preparation stage were encouraged to make implementation plans and schedule regular times for exercise. Patients in the action and maintenance stages were taught to identify high risk situations for relapse and to re-establish regular behaviour patterns after lapses and relapses.

With regard to the style of counselling, practice nurses learned to focus on active listening, expressing empathy and identifying ambivalence in the preaction stages. In the action stages a more direct style with reinforcement techniques and direct advice was preferred. It was emphasized that the change should come from the patient and that the practice nurses should not push patients to change if they were not yet ready.

The training emphasized practical interactive exercises and role plays. Nurses received supportive material (fact sheets, wording suggestions, reminders) and copies of all written material used during the training.

The success of the training was evaluated by a paper-and-pencil test, in which the practice nurses were required to identify the correct stage of a written case and to match the stage specific counselling procedure with the stage the patient was in.

2.4.2. Motivational counselling intervention

Practice nurses were asked to invite all identified patients for up to three counselling sessions (max. 15–20 min each). The first session was to be scheduled within 3 weeks after inclusion in the study. Nurses handed out specifically designed stage-specific booklets to the patients at the end of each meeting.

The practice nurses and the GPs had a list with regional exercise opportunities and fitness clubs available.

After the first contact with the patients, practice nurses were offered two additional supervision sessions by the study coordinators in order to support their counselling efforts.

The counselling sessions were integrated into the normal course of the medical practice organization. The practice nurses had to schedule separate dates for the patient consultations. Nurses were reimbursed for their time spent for the training and for each counselling session.

2.5. Measurement

2.5.1. Instruments

The main outcome to prove the effectiveness of the motivational counselling was physical activity which was assessed by the *Freiburger Questionnaire on Physical Activity* (*FQPA*; [33]). The questionnaire uses 12 items to detect the amount of health-related physical activity. Items 9–12, which ask about sleep, recreation time and self-evaluation, were left out in the context of this study to reduce the patients' answering burden. The FQPA has satisfactory measurement properties and allows a calculation of weighted metabolic equivalent (MET) hours/week. One MET represents the amount of oxygen used by an average seated person and increases with the intensity of exercise.

The coding for the MET intensity of the different activity types is based on the compendium of physical activities from Ainsworth et al. [34]. The scores can be summarized in METs/week or in kcal/week for daily activities (low to moderate intensities), leisure time physical activity, sports activity and an overall estimate of total physical activity.

The distribution across the *TTM stages of changes* was assessed by an algorithm, in which the patients were asked whether they already perform regular vigorous physical activity for at least 20 min three times a week or have the intention to do so [35]. The stage algorithm allocates the patients to different stages of change: precontemplation, contemplation, preparation, action and maintenance. The good psychometric quality and the practicability of the algorithm have been shown in previous studies [36,37].

Self-efficacy was assessed with 14 items, originally developed as a 12-item scale by Basler et al. [36] based on a scale by Fuchs and Schwarzer [38]. Items assess the patients' confidence to perform planned physical activities across a number of adverse situations. We added two pain-specific items to the original scale (for example: ''I am confident I can perform my planned physical activity even when I have pain.''). The response format is a 5-point Likert-scale ranging from 1 (not confident at all) to 5 (very confident). Cronbach's α of the 14-item scale at baseline was 0.88.

In order to classify the *natural history of LBP* we used a modification of the von Korff procedure [39]. For grading the *severity of pain* we used the von Korff-scheme [40] in which chronic pain is classified as a function of pain intensity and pain-related disability in five grades (see Table 3). Grade 0 (pain free) did not apply to our sample.

The measures included in the study are presented in the measurement overview in Table 1.

2.5.2. Statistical analyses

We compared baseline characteristics of patients to identify possible selection bias in the three study arms and performed detailed comparisons between study dropouts and left participants. Movements within the TTM-stages

Table 1
Measures included in the study

Instruments	Questionnaire in the practice	Questionnaire at home	Second interview (6 months)	Third interview (12 months)
Sociodemographic characteristics		×		
Employment characteristics		×		
Classification of pain	×			
Chronification grade	×			
Pain intensity	×			
Days of pain in the previous 12 months	×			
CES-D (depression)		×		
Fear avoidance beliefs (FABQ)		×	×	×
Hannover functional ability questionnaire (FFbH-R)	×		×	×
Freiburger questionnaire on physical activity (FQPA), primary endpoint	×		×	×
State of change TTM		×	×	×
Self-efficacy, secondary endpoint		×	×	×

between baseline and the 12-month assessment were categorized into 'progress' (moved forward by at least one stage), 'stable' or 'regression' (moved backward by at least one stage).

To determine the effectiveness of the intervention we applied multilevel analysis because patient outcomes of one GP cannot be considered as completely independent measurements [41,42].

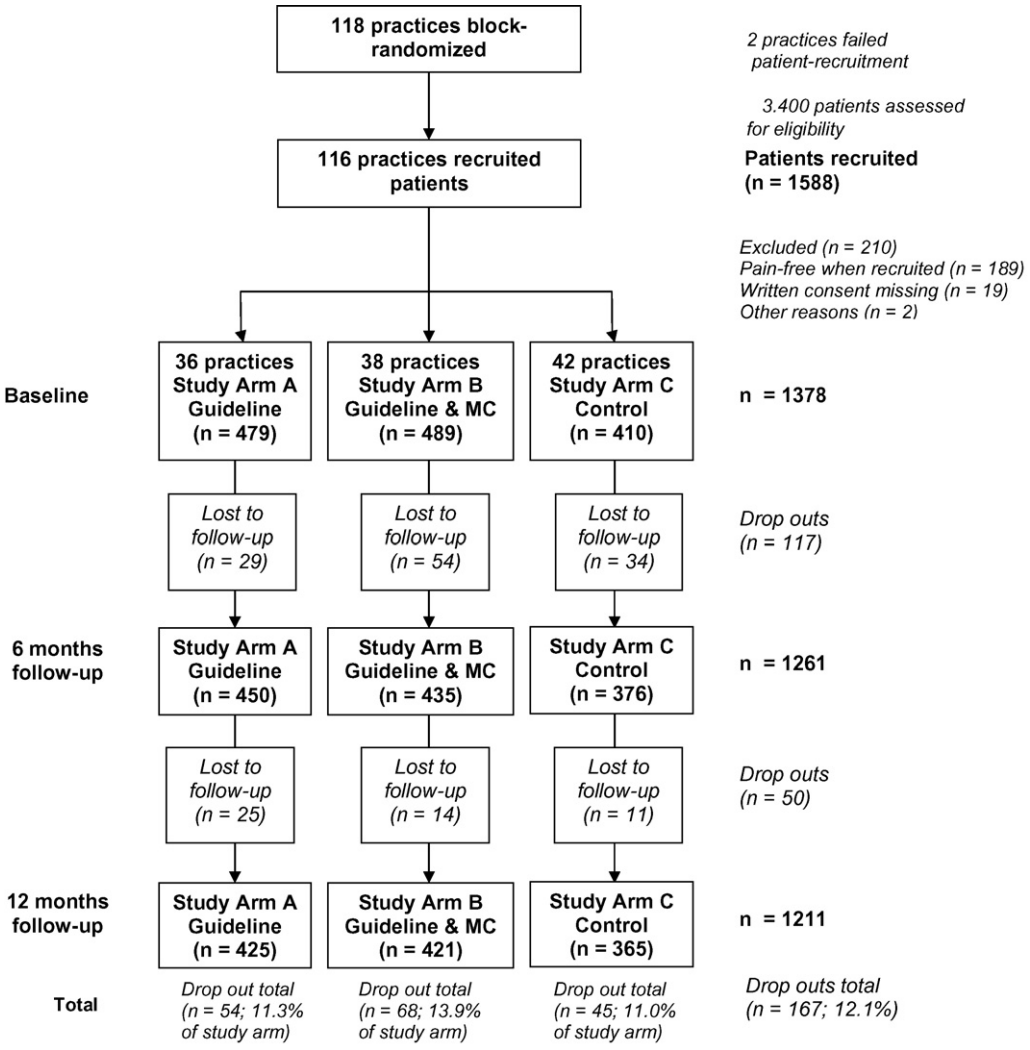

Fig. 1. Patient flowchart.

We considered as potential regressors the baseline values of the outcome measures, chronicity of pain and sex. Chronicity of pain and sex were chosen as prognostic factors for LBP patients based on the literature [2,3]. For the final model we selected significant variables in a stepwise backward procedure.

Our primary outcome was the total physical activity score in MET hours/week, as secondary outcome we defined the mean self-efficacy score for physical activity. Sensitivity analysis was performed for the primary outcome measure by replacing missing data according to the ''last value carried forward principle''.

Statistical analysis was performed with SPSS12.0 [43].

3. Results

3.1. Sample characteristics

During the period assigned to the recruitment approximately 3400 patients with LBP had been invited to participate. Of these, 1378 patients could be included in the final sample (Fig. 1). The number of patients recruited by each of the 116 practices showed a range between 1 and 27 (mean cluster size 11.88).

Of the whole sample, 58% were female with a mean age of 49 years. Most patients had acute LBP (around 60%), but one third suffered from chronic LBP.

Since the distribution of the MET hours/week was highly skewed, we report mean and median values when appropriate. We also performed an outlier correction for MET hours/week by ''winsorizing'' the distribution (values of the 98th percentile and above were set to this value).

There were no differences between the study arms in the main outcomes at baseline except for the distribution across the stages of change. Significantly more patients in study arm B were in the contemplation stage and fewer in the precontemplation stage in comparison to the other study arms ($\chi^2 = 17.89$, d.f. = 8, $p < 0.05$). Further differences in baseline and sociodemographic characteristics between the study arms are shown in Tables 2 and 3.

3.2. Dropout analysis

There was an average 12.1% dropout rate from baseline assessment to the 12-month follow-up ($N = 167$). The proportion in the study arm B (guideline implementation + MC) was the highest with 13.9% (of $N = 489$ at baseline), in study arm A (guideline implementation only)

Table 2
Sociodemographic characteristics

Variables		Study arm A (guideline only)	Study arm B (guideline and MC)	Study arm C (control group)
N (=1378)		479	489	410
Age (in years)[a]	Mean	49.1	47.4	50.2
	S.D.	13.3	13.5	14.3
	Range	21–83	20–91	20–81
Gender (*N*, %)[a]	Male	195 (41)	189 (39)	193 (47)
BMI	Mean	26.9	26.5	27.0
	S.D.	(4.8)	(4.8)	(4.4)
Marital status (*N*, %)	Single	62 (14.8)	81 (19.1)	56 (15.4)
	Married	280 (67.0)	275 (64.7)	250 (68.7)
	Widowed	24 (5.7)	26 (6.1)	20 (5.5)
	Divorced	52 (12.4)	43 (10.1)	38 (10.4)
Living with partner (*N*, %)	Yes	325 (79.5)	317 (76.2)	273 (78.7)
Level and years of education (*N*, %)	13/12 years	60 (14.4)	69 (16.2)	57 (15.7)
	10 years	132 (31.7)	126 (29.5)	104 (28.7)
	9 years	174 (41.7)	173 (40.5)	159 (43.8)
	Other graduation	47 (11.2)	57 (13.4)	42 (11.6)
	No qualification	4 (1.0)	2 (0.5)	1 (0.3)
Employment status (*N*, %)	Working full or part-time	263 (63.4)	279 (63.4)	216 (59.8)
	Housewife	38 (9.2)	7 (11.0)	35 (9.7)
	Retired	81 (19.5)	68 (15.9)	79 (21.9)
	Unemployed	19 (4.6)	19 (4.5)	17 (4.7)
	Other	14 (3.4)	22 (5.1)	14 (3.8)
Applied for a pension[a]	Total %	37	23	40
		9.2	5.7	11.8

[a] Significant difference between groups $\alpha = 0.05$.

Table 3
Baseline characteristics

Variables		Study arm A (guideline only)	Study arm B (guideline + MC)	Study arm C (control group)
Functional capacity prior to treatment (FFbH-R)	Mean (S.D.)	67.52 (21.42)	68.74 (20.99)	65.81 (21.90)
Pain intensity (NRS 0–10)	Mean (S.D.)	5.41 (1.74)	5.26 (1.66)	5.52 (1.70)
Classification of pain (*N*, %)	Acute: ≤90 days of pain per year	239 (62.2)	233 (59.3)	171 (53.9)
	Persistent: >90 and ≤182 days, one episode	7 (1.8)	12 (3.1)	9 (2.8)
	Recurrent: >90 and ≤182 days, more than one episode of pain	28 (7.3)	30 (7.6)	3 (10.4)
	Chronic: >182 days of pain per year	110 (28.6)	118 (30.0)	104 (32.8)
Days of pain in the previous 12 months	Mean (S.D.)	101 (132.02)	103 (123.91)	112 (130.96)
Chronification grade [a] *N* = 985 (*N*, %)	Low disability/low intensity (I)	101 (29.8)	118 (33.1)	84 (29.0)
	Low disability/high intensity (II)	97 (28.6)	87 (24.4)	74 (25.5)
	High disability/moderately limiting (III)	90 (26.5)	95 (26.7)	75 (25.9)
	High disability/severely limiting (IV)	51 (15.0)	56 (15.7)	57 (19.7)
Stage of change prior to treatment (*N*, %)[b]	Precontemplation	121 (28.9)	94 (21.2)	103 (28.8)
	Contemplation	79 (18.9)	113 (25.5)	68 (19.0)
	Preparation	44 (10.5)	49 (11.0)	32 (8.9)
	Action	34 (8.1)	52 (11.7)	45 (12.6)
	Maintenance	141 (33.7)	136 (30.6)	110 (30.7)
Physical activity level (energy expenditure in MET hours/week)	Median	24.00	26.17	27.83
	Mean (S.D.)	33.17 (31.74)	34.86 (32.26)	37.16 (34.22)
Self-efficacy (concerning regular physical activity – NRS 1–5)	Mean (S.D.)	3.04 (0.73)	3.07 (0.71)	2.99 (0.73)
Job satisfaction (NRS 0–10) [a] *N* = 804	Mean (S.D.)	6.18 (2.33)	6.23 (2.54)	5.85 (2.50)
Depression (CES-D)	Mean (S.D.)	15.02 (9.34)	15.82 (9.50)	15.20 (9.30)
FABQ				
Score I[c] (physical activity cause for pain)	Mean (S.D.)	17.45 (6.83)	16.76 (6.69)	18.76 (6.77)
Score II[b] (work cause for pain)	Mean (S.D.)	13.10 (8.81)	12.91 (8.23)	14.57[a] (8.72)
Score III[b] (prognostic job)	Mean (S.D.)	8.77 (8.36)	8.16 (8.05)	10.02[a] (8.70)

[a] More than 20% missings.
[b] Significant difference between groups $\alpha = 0.05$.
[c] Significant difference between groups $\alpha = 0.01$.

11.3% (of $N = 473$) and in the control arm 11% from $N = 410$ at baseline (see Fig. 1).

Dropouts had a lower energy expenditure per week with 26.59 MET hours/week (median: 17.70) compared to remaining participants with a mean of 36.09 MET hours/week (median: 26.80) at baseline ($Z = -4.62$, $p < 0.01$). Additionally, the percentage of patients in the maintenance stage at baseline was significantly smaller in the dropout-group than in the remaining participant group (20.3% versus 33.1%; $\chi^2 = 12.21$, d.f. = 4, $p < 0.05$).

3.3. Process evaluation

Seventy-two practice nurses from 39 practices completed the training sessions, but only 70 of them put the counselling into practice. The quality of the training was rated as high (mean rating 1.5 on a 1–6 scale). In case reports, 86% of the nurses were able to correctly identify a hypothetical patient's stage of change. Moreover, nurses demonstrated very good skills to match the stage-specific counselling procedures with the hypothetical patient's stage (mean 11.7 points, scale ranging from 0 to 14). Behavioural observation samples of the actual performance during the encounter with the patient could not be taken due to resistance on the part of the nurses because they did not want to violate patient confidentiality.

Overall, 80% ($n = 399$) of the patients from study arm B received motivational counselling sessions (1–2 sessions per patient).

Despite the positive evaluation after the training, verification of the match between issued stage-specific booklets and patients' self-reported stages of change revealed difficulties in the performance of the practice nurses. The proportion of stage-matched booklets was quite small, especially in the stages ''preparation'' (23.9% stage-matched booklets) and ''action/maintenance'' (33.8%). An overview can be seen in Fig. 2.

3.4. Effect of intervention on patient outcomes

In both intervention groups the LBP patients' amount of physical activity increased from baseline to the 6-month follow-up and continued to increase to the 12-month follow-up

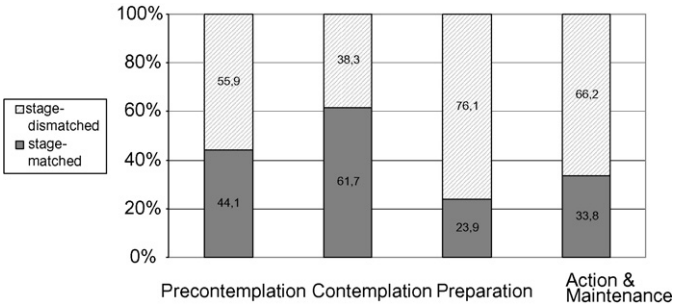

Fig. 2. Proportion of stage-matched booklets.

assessment. The control group showed reduced total physical activity after 6 months but improved to the level of the intervention groups at the 12-month follow-up.

When comparing different kinds of physical activity, it becomes obvious that in the leisure time physical activities and in the sports activities there was progress from baseline to the 6-month follow-up, but in the basic physical activities (daily activities) the patients first reduced their exercise.

Fig. 3 shows the change in the different kinds of physical activity scores over the three assessment points.

3.5. Effectiveness of motivational counselling after 6 months

The multilevel analysis for the total activity score after 6 months showed that there was no influence of sex or pain chronification (von Korff-graduation) on the amount of total energy expenditure after 6 months. Pain chronification did not improve the model and had no significant fixed effect. Due to the amount of missing values it was not taken into consideration for the final model where only the total activity score from baseline was significant as a covariate ($F_{1;\ 1234.89} = 165.51$; $p < 0.01$). There was no influence of the study arm as a fixed effect ($F_{2;\ 92.41} = 1.01$; $p = 0.37$).

Results were the same in the sensitivity analysis for missing data.

The change in self-efficacy after 6 months was similar in all three groups and the multilevel analysis revealed no effect of intervention on this outcome ($F_{2;\ 82.94} = 1.70$; $p = 0.189$). There was no effect of the other covariates with the exception of the baseline self-efficacy score ($F_{1;\ 1014.61} = 250.91$; $p < 0.01$).

3.6. Effect of intervention over the total follow-up period of 12 months

The results for the total activity score after 12 months were similar showing no intervention effect ($F_{2;\ 81.83} = 1.06$; $p = 0.35$).

The self-efficacy score declined marginally in the three groups from the 6 months to the 12 months follow-up. Again there was no effect of the intervention in the mixed model analysis ($F_{2;\ 75.23} = 0.94$; $p = 0.40$).

Details of the results with the final models are shown in Table 4.

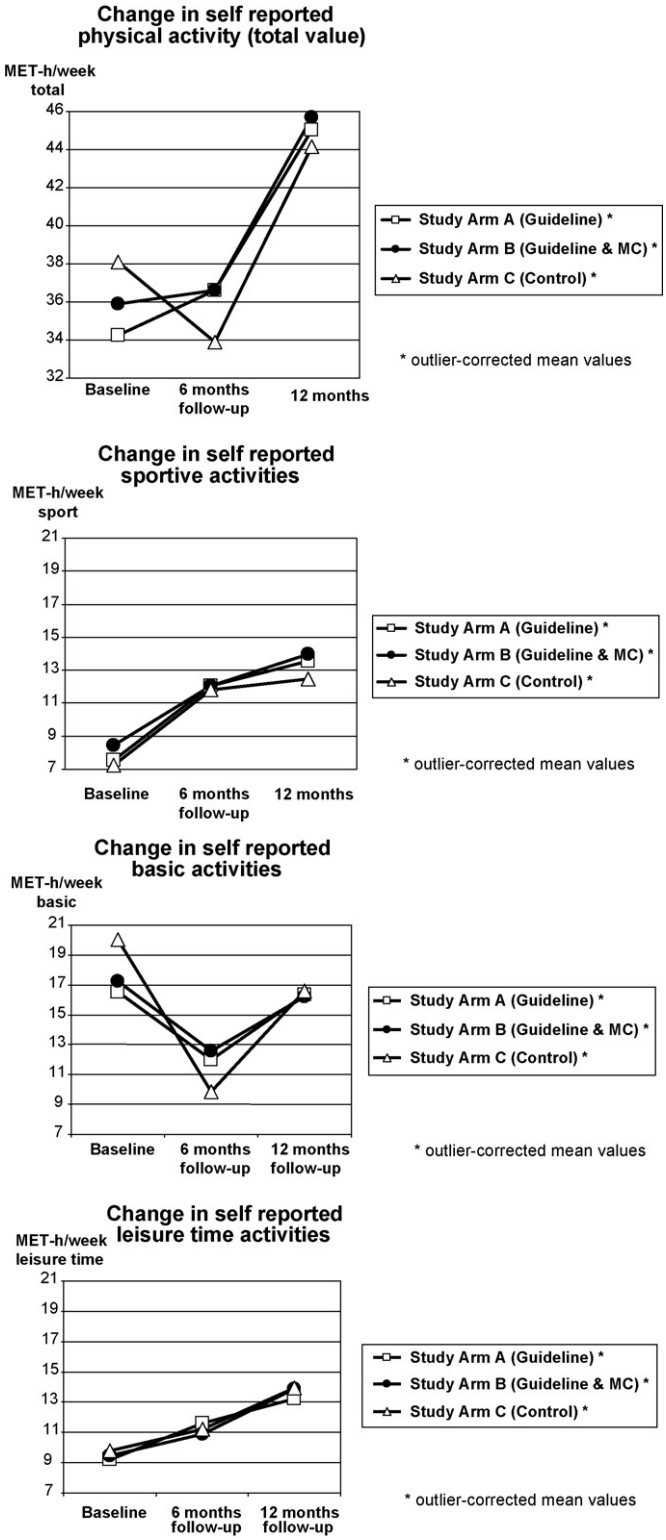

Fig. 3. Change in the different kinds of physical activity scores over the three assessment points.

At baseline there was a greater than expected proportion of patients in the population with current LBP in the action and maintenance stages in all study arms.

A χ^2-test revealed that there was no significant difference after 1 year between the study arms in stage movements

Table 4
Effectiveness of the motivational counselling intervention (values shown are adjusted for clustering of data)

	Study arm	6 months			12 months		
		Mean (95% CI)	Compared to controls		Mean (95%-CI)	Compared to controls	
			Mean difference (95% CI)	*p*-Value		Mean difference (95% CI)	*p*-Value
Total physical activity score MET hours/week	GI	36.46 (33.28–39.63)	2.95 (−1.64–7.54)	0.21	46.50 (43.06–49.92)	3.58 (−1.42–8.59)	0.16
	MC	36.27 (33.12–39.43)	2.77 (−1.81–7.34)	0.23	45.48 (42.05–48.92)	2.57 (−2.43–7.56)	0.31
	C	33.51 (30.18–36.83)	–	–	42.92 (39.2–46.56)	–	–
Self-efficacy (concerning regular physical activity) NRS 1–5	Gl	3.22 (3.14–3.30)	0.04 (−0.07–0.16)	0.47	3.22 (3.14–3.29)	0.07 (−0.04–0.18)	0.22
	MC	3.28 (3.21–3.36)	0.10 (−0.01–0.22)	0.07	3.21 (3.14–3.29)	0.06 (−0.05–0.17)	0.25
	C	3.18 (3.10–3.26)	–	–	3.15 (3.07–3.23)	–	–

GI: guideline implementation only (study arm A); MC: guideline implementation + motivational counselling (study arm B); C: controls (study arm C).

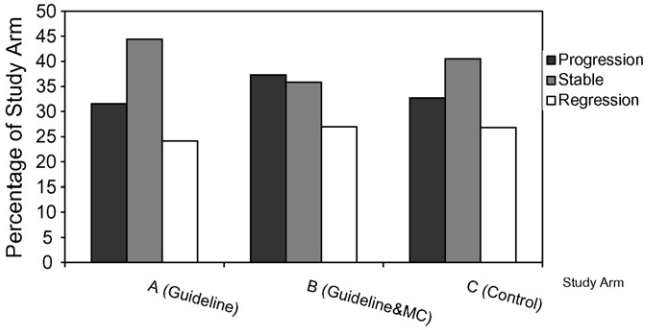

Fig. 4. Changes of stages conferring to TTM at 12 months follow-up.

(progress, stable, regression) ($\chi^2 = 6.348$, d.f. = 4, $p = 0.175$; for details see Fig. 4).

4. Discussion and conclusion

4.1. Discussion

We tested a TTM-based motivational counselling approach to increase physical activity of low back pain patients in a primary care setting. After a training session, practice nurses were able to learn the basics of the counselling procedure but the performance in practice settings was inconsistent and the effectiveness on the patient level did not exceed that of the control group conditions. In all three study arms, the amount of MET hours/week for the sportive and leisure time physical activity increased while daily activities initially decreased between baseline and the first follow-up. Effects of the intervention on physical activity or self-efficacy could not be shown in mixed models adjusted for the clustering of data and important covariates after 6 months. Sex or chronicity of pain as potential covariates did not have a substantial effect on the 6- or 12-month total amount of physical activity. There was no significant difference after 1 year between the study arms in the movements across the TTM stages of change.

Lack of differences between the outcomes of the three study arms may be attributed to different conditions. One possible explanation is the heterogeneous sample included in the study consisting of acute and chronic low back pain patients. Although chronicity of pain was not a significant covariate in mixed models, these patients are different in terms of various variables that would interact with or moderate the intervention, like fear avoidance beliefs, treatment expectations, or illness models. In another analysis we revealed fear avoidance beliefs as a significant predictor for the total amount of physical activity after 6 months only for the chronic low back pain patients [44]. Moreover, those, who already performed vigorous exercise initially, would have little opportunity to increase their physical activity due to a ceiling effect. In our sample this pertains to a considerable number of patients, many of them suffering from acute pain.

Another explanation may be the low number of counselling sessions in the current study, which might reflect local implementation barriers and skill deficits of practice nurses. Practice nurses in Germany are usually involved in administrative and organizational tasks. In the current study they had to schedule separate dates, sometimes in their spare time, for patient consultations. Although they demonstrated their knowledge after the 20 h training sessions, they very often were not able to match the stage specific booklet to the stage of the patient. One option would have been to communicate the stage allocation obtained in the initial assessment to the nurses in order to increase the number of correctly matched interventions. On the other hand, this procedure would have made it difficult to decide whether TTM-based counselling is feasible in the every day routine of a practice.

In a similar intervention targeting patients with increased risk of coronary heart disease, Steptoe et al. [11,12] successfully implemented a counselling routine performed by practice nurses. The intervention aimed at reducing smoking and fat intake and at promoting regular physical activity with a more intensive intervention than in our study. One reason why physical activity in our intervention group did not exceed the progress of those in the control groups could be an inadequate intensity of our intervention. An average of one short counselling session and a stage-specific booklet in our study were not sufficient to help people becoming more physically active than individuals in the control groups. A potential way to improve progress is to intensify the practice nurses' training in increasing the patients' motivation to participate in counselling ('therapy motivation') in addition to increasing 'behavior

change motivation', especially for patients in the earlier stages of change (precontemplation, contemplation). For those patients who are ready for behaviour change (preparation stage), it seems necessary to directly facilitate the patients' involvement in ongoing exercise programs or to refer them to exercise specialists. Similar approaches have been shown to be successful in previous studies [13,45]. While the practice nurses in our study had information about the local physical activity opportunities available, we do not exactly know to what extent they used this information during counselling.

Our data underscore that the motivational counselling approach appears ambitious for professionals not experienced with counselling and behavioural treatment. We hold the assumption that, at least in Germany, specialized health educators may be required to supplement the endeavours of the physicians [9,46].

A third explanation could be that adherence to the intervention, especially for acute patients, was not achieved within a timely fashion. Although a time frame of 3 weeks was set to administer the first counselling session, even this period may have been too long to be relevant for an acute episode of pain, and, therefore, may have reached the patient at a moment, when he or she felt it less imperative to change than at the time of the consultation to the physician.

Finally, it cannot be excluded that the results also indicate ineffectiveness of TTM as a theory. Several failed trials for exercise promotion in a primary care setting use the TTM as a theoretical background and appear to corroborate this conclusion. The results of reviews about physical activity interventions in primary care are inconsistent [8,16–18]. According to the critique of Adams and White [27], lack of effectiveness may alternatively be explained by methodological flaws. An actual stage-tailored intervention comprises of five different interventions – one for each stage. As the authors suggest, a more thorough approach to development and evaluation may require several levels of evaluation where each stage-specific intervention is contrasted against control conditions in the target group. They conclude that such an approach would obviously require substantial time and resources, but may be the only way to do justice to the TTM.

Our results are comparable to those found in other studies. Van Sluijs et al. [47] showed in a randomized controlled trial with the PACE intervention (''physician based assessment and counselling for exercise'') in general practices in the Netherlands a significant increase in physical activity for the population as a whole, but no intervention effect. Jimmy and Martin [48] found no additional effect of the extended intervention with counselling sessions by a practice assistant compared to receiving only feedback from the physician. They traced their result back to the fact that counselling was only an optional element and physicians in the control group were highly motivated. In the current study, the physicians in the other study arms were also highly motivated which can be concluded from the initial response rate of the general practitioners (14%) and the resulting selective sample of physicians interested in the topic.

Van Sluijs et al. [49] stated that (repeated) measurement of physical activity alone already affects participants' physical activity behaviour, possibly triggered by a raised awareness. That might also be the case in our study where most patients increased their physical activity up to the 12-month follow-up probably as a consequence of repeated measurements.

Despite the fact that all national guidelines for LBP treatment underscore the importance of physical activity [50], a recent review puts into question the positive effects of exercise on functional outcome [51]. The disuse- and deconditioning-hypothesis on the development of chronic low back pain is currently under discussion [52]. A low state of fitness has not been identified as a clear risk factor for LBP, although fit patients after an acute state were less likely to develop a chronic condition [53,54]. Moreover, improvements in pain and disability could not be traced back to specific back exercises or to the intensity of physical activity [2,55]. More important than specific exercises appeared overcoming fears of movement and reinjury and maintaining or initialising moderate levels of physical activity [55–57]. In our study, fear of movement might explain the decline of daily activities observed at the beginning (''kinesiophobia''; [58]) in spite of normal general fitness. Finally, there may be subgroups of LBP patients. Only certain subgroups may benefit from increased physical activity, whereas others would primarily have to address predominant psychosocial problems [59,60].

4.1.1. Limitations

Reliance on self-report data is one limitation of the study. Moreover, selection of the participants may have occurred on different levels. Considering the low response rate of the physicians, only those with a high level of motivation finally participated in the study. This could have contributed to the beneficial effects also observed in the control group. Selection for motivation may not only have influenced the composition of the physician sample, but also that of the patient sample. Informed consent favoured participation of those patients who were especially interested in physical activity. This may not only have contributed to the positive outcome in all the three groups, but also to an unexpectedly high level of MET hours/week for low back pain patients [61] at the beginning of the study. This assumption is also supported by the fact that dropouts could be characterized by low levels of activity and a high level of disability. To summarize, this is likely to be a biased sample of participating physicians, nurses, and patients due to their high level of motivation. On the other hand, this bias is inherent in all three study arms. Although motivation is a prerequisite for behavioural change, doing the right thing at the right time is necessary to favour stage progression. Given the different methods of intervention used in the three study arms, there should also be a difference in the expected outcome.

Although blinded therapists and blinded patients are a prerequisite for medication trials, this is hardly feasible in educational interventions. Because of cluster randomization, physicians had to give their informed consent in being randomized in one of the three study arms. The patients had no information about practice allocation and the interventions in the other study arms. Blindness could be assured regarding the assessment of the data, too. The study nurses did not have

any knowledge about the allocation of the patients during the telephone interviews.

4.2. Conclusion

Summarizing our findings, improvement in the total physical activity is most probably due to the initially high motivation for participating in a physical activity study, both in the group of the physicians and in the group of the patients. Despite possible alternative explanations for the failed attempt to promote physical activity like the heterogeneous sample, a possible lack of timely interventions, or a failure of the TTM as a theory, we think it is most probable that the nurses have not been able to put their knowledge into practice and to provide adequate state-of-the-art interventions. One reason may be that the basic professional training of German practice nurses in the past has concentrated too much on administrative skills and too little on skills needed for the management of patients.

4.3. Practice implications

The situation might change in the future. Due to a reform of the vocational training in 2006, practice nurses in Germany now also have to study professional communication and patient education. This might be the basis for a better incorporation of nurses into future endeavours to improve the health behaviour of the patients. There is also a need for a change towards an organizational structure that facilitates patient–nurse communication to give practice nurses more time and opportunities for self-managed activities.

Counselling for low back pain patients has to consider the complex correlations between physical activity and pain experiences and the predominance of psychosocial problems for certain subgroups.

Further studies in the field of patient counselling have to control the process quality in practice by video or tape.

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