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The Sustainable Effectiveness to Avoid Chronification in Non-Specific, Non-Chronic Back Pain

Die nachhaltige Wirksamkeit zur Vermeidung von Chronifizierung bei unspezifischen, nicht chronischen Rückenschmerzen

ORIGINALIA

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Summary

- **Non-specific low back pain (NLBP)** affected every fourth Swiss citizen in 2018. The aims of this prospective randomized controlled trial were to determine which therapeutic strategy is most effective and sustainable to reduce NLBP and avoid chronification of non-chronic NLBP in patients in Switzerland.
- **The therapy effects** were compared between a combination of progressive exercise and two counseling units (ECG, N=22 / 59% women) and a combination of two counseling and nine units each with mobilization of the lumbar spine, the sacroiliac joint, and a massage of the back muscles (MCG, N=22 / 41 % women). Intensity of disability and pain were measured (NRS = Numeric Rating Scale, ODI = Oswestry Disability Index) after the first, fifth, ninth treatment and after weeks six and 16.
- **The first three measurements** did not show any effects, but the last two measurements showed significant positive therapy effects ($p < 0.05$) for both measuring instruments (NRS, ODI) for the ECG.
- **This study** should help to better understand the physiotherapeutic possibilities of sustainable therapy in patients with non-chronic NLBP under realistic conditions adapted to the Swiss healthcare system. The ECG showed sustainable therapy effectiveness and beneficial approaches to avoid chronification. Further long-term research seems to be particularly important in this respect.

KEY WORDS:
Cognitive Behavioural Factors, Progressive Exercises, Counseling, Manual Therapy, Treatment Costs

Zusammenfassung

- **Unspezifische Rückenschmerzen (NLBP)** betrafen 2018 jeden vierten Schweizer Bürger. Die Ziele dieser prospektiven, randomisiert kontrollierten Studie waren herauszufinden, welche therapeutische Strategie am effektivsten und nachhaltigsten zur Reduktion von nicht chronischen NLBP ist und welche sich davon als wirksamer zur Vermeidung der Chronifizierung bei Patienten in der Schweiz zeigt.
- **Die Therapieeffekte** wurden zwischen einer Kombination aus progressiven Übungen mit zwei Beratungseinheiten (ECG, N=22 / 59% Frauen) und einer Kombination aus neun Einheiten mit Mobilisationen der Lendenwirbelsäule, des Iliosakralgelenks und je einer Massage der Rückenmuskulatur sowie zwei Beratungseinheiten (MCG) verglichen (N = 22 / 41% Frauen). Die Intensität der Behinderung und der Schmerzen wurde nach der ersten, fünften, neunten Behandlung und nach den Wochen sechs und 16 gemessen (NRS = Numeric Rating Scale, ODI = Oswestry Disability Index).
- **Die ersten drei Messungen** zeigten keine, die letzten beiden Messungen jedoch signifikant vorteilhafte Therapieeffekte ($p < 0,05$) bei beiden Messinstrumenten (NRS, ODI) für die ECG.
- **Diese Untersuchung** soll helfen, ein besseres Verständnis für die physiotherapeutischen Möglichkeiten einer nachhaltigen Therapie bei Patienten mit nicht chronischen NLBP unter realistischen Bedingungen, die an das Schweizer Gesundheitssystem angepasst sind, zu entwickeln. Die ECG zeigte dabei im Vergleich zur MCG eine nachhaltige Therapieeffektivität und wirkungsvolle Ansätze zur Vermeidung der Chronifizierung. Weitere Langzeituntersuchungen scheinen in dieser Hinsicht besonders wichtig zu sein.

SCHLÜSSELWÖRTER:
Kognitive Verhaltensfaktoren, progressive Übungen, Beratung, manuelle Therapie, Behandlungskosten

Introduction

Non-specific back pain (NLBP) is prevalent, affecting every 4th Swiss citizen in 2018 (24). Switzerland recorded the direct and indirect cost of 13.4 percent of total annual medical costs for musculoskeletal conditions such as low back pain (LBP), osteoarthritis etc. (20). The recurrence rate of back pain in Switzerland is 4 times higher after the 1st occurrence (20). More than 85% of back pain does not correspond to any specific structural disease, and less than 1% of back pain is due to serious diseases such as tumors, fractures, or infections (20). From a variety of validated research projects, the NLBP treatment recommendation can be derived, in particular on the activating forms of treatment, e.g. counseling units (COU), which are a part of cognitive behavioral therapy (CBT), pain neuroscience education (PNE) and exercises (EX) (1, 3, 7, 8, 10, 17). Manual Therapy (MT) such as massage (MA) and mobilization (MO) is also effective in some research projects (2, 6, 11, 23). Combined interventions between COU, and ›

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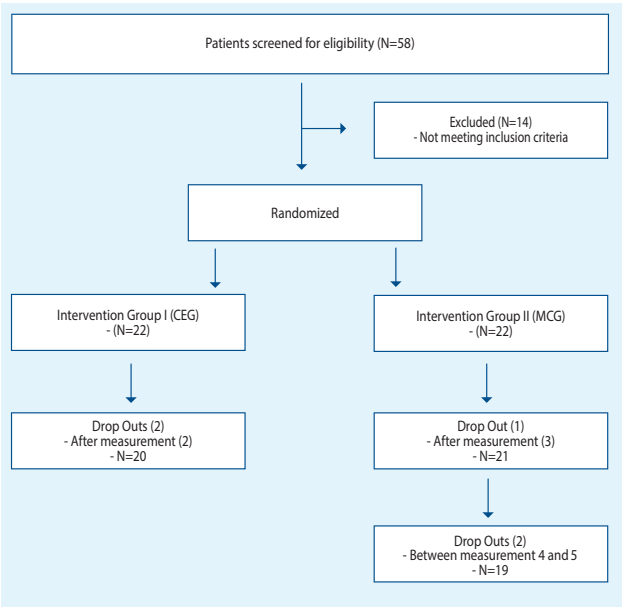

Figure 1

Methodical course. M=measurement; I=intervention.

either a manual or an activating type of therapy, have been little researched. The persistence of non-chronic pain in the patients included in this study was up to 12 weeks (22). Two different treatment methods were compared. The first involved progressive EX combined with COU (ECG), the second was a combination of COU, MA and passive MO of the sacroiliac joint (SIJ) and the lumbar spine (MCG).

Current knowledge largely supports how important it is to distinguish pain inducing influences (5, 12, 21). The development of pain by psychosocial influences seems to be much closer to the cause of the NLBP problem than the purely structural presumption of cause. The combination of sensitivity, influenced by negative experiences, and the absorption of stimuli from the environment intensifies the interpretation of pain. The risk of developing cognitive beliefs through these influences can also work towards pain reduction (19). The pain and associated perception can depend on the size of the disability in terms of functional impairment and can also be influenced by a placebo reaction (19). Therapy measures, such as CBT, COU, goal-setting (GS), GA, MC, EX, etc. are based on these findings (1, 3, 7, 8, 10, 13, 14, 16, 17, 18, 22).

The aims of this prospective randomized controlled trial were to determine which therapeutic strategy is most effective and sustainable to reduce NLBP and avoid chronification of non-chronic NLBP patients in Switzerland. The focus of the research was on the legal parameters of the classical physiotherapeutic approach in Switzerland (9 units, each between 30 to 45 minutes).

Material and Methods

The methodological content of this research project was ethically evaluated by the ethics commission of the "IST University of Applied Sciences" in Duesseldorf, Germany, whose experts expressed no reservations about the implementation of the planned methodology. Four external doctors were involved and helped recruit additional patients for the Fit 4 Life physiotherapy department. All participants were examined before the intervention and tested for their suitability for the research project (Figure 1). This included the analysis of possible red flags by the doctors who prescribed the physiotherapy and specific for the study project by the responsible physiotherapists. The corresponding inclusion criteria were defined as: LBP lasting up to 12 weeks, no physiotherapy for back problems for over 1 year, NRS minimum 3, age 25-60 years, heterogeneous gender identity. The exclusion criteria were defined as: specific back injuries (disc hernia, fracture, osteoporosis etc.), steroidal drugs, other forms of therapy (i.e. osteopathy, further physiotherapy etc.) during the whole research time (1 year before unit 1 to 16 weeks after unit 9), one or more known or suspected severe spine pathology (fractures, tumors, inflammation, rheumatic diseases, or infectious diseases of the spine), planned or previous spinal surgery, and co-morbid health conditions (hypertension, pregnancy, or severe cardiovascular diseases).

All participants come from physically inactive professions (e.g. accounting, monitoring etc.). None of the patients were intensively active more than once a week (sport). The participating patients performed a random drawing to assign them to 2 different groups by the physiotherapists (Figure 1). Both groups contained 22 patients each. The proportion of women was 59% in the ECG and 35% in the MCG and the age of the patients (N=44) ranged from 25 to 60 years (mean value±SD: 43.9±10.8 years) (Table 1). Before each intervention meeting, the participants were asked about the exclusion criteria; without taking the exclusion criteria into account, this led to exclusion from the study.

The total number of drop outs was 5 without any serious cause. Two drop outs were recorded in the ECG due to use of analgesics. The 2nd drop out occurred through the voluntary termination of the intervention series of a subject of the ECG with no more complaints. The subsequent drop outs all affected the MCG and were explained by the resumption of therapy. The measurements with respect to the excluded subjects took place only up to the time of the drop outs and further measurements were not taken into consideration. In order to avoid bias that could affect the quality of the research, all participants were asked at the outset not to disclose details of the interventions.

The German version of the ODI was used to analyze the intensity of disability in relation to NLBP (15). The NRS was used to evaluate and compare the intensity of the patient's subjective pain from 0 (= no pain) to 10 (= maximum pain) (4).

Two professional physiotherapists carried out the interventions of both groups. All intervention units, with the exception of the 1st and the 9th, were 30 minutes in duration. The COU was given twice at the beginning (1st unit) and once at the end (9th unit) for 10 to 15 minutes each. The first and last treatment unit lasted 45 minutes in total. At least one day without an intervention unit was foreseen between each intervention. Each patient received minimum 2 and maximum 3 intervention units per week.

The aim of the COU was to calm the patient, explain the pain and the helpful measures, and show the positive aspects of the treatment, such as the possibility to walk and having no limiting symptoms, such as numb feelings or motoric failures (3, 8, 17, 18). Within the ECG, any communication that could point to negative structural connections was avoided.

The program of Group I was designed according to the patient's initial problematic movement, which was intended to be improved by the therapy. The quality of the function related to the movement performance and the control against resistances, such as lifting objects. The contents of the progressive EX in connection with the COU were based on parts of the GA program (14). A progressive development to rebuild the quality of movement and functionality, in relation to the criteria of the regular physiotherapy system in Switzerland (9 units).

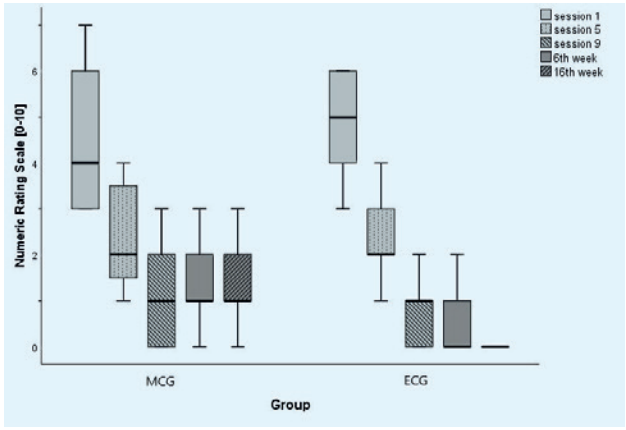

Figure 2

Group comparison of the Numeric Rating Scale over time.

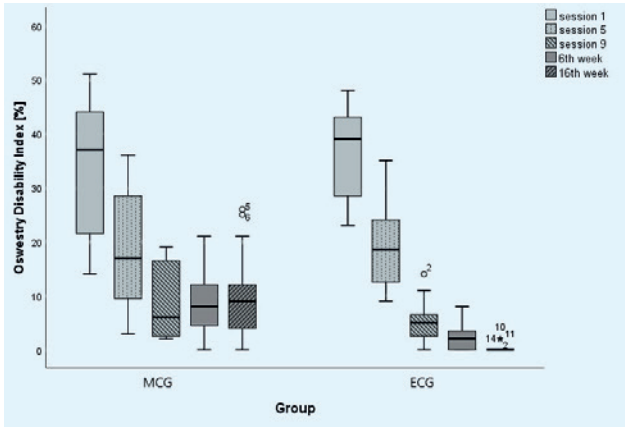

Figure 3

Group comparison of the Oswestry Disability Index over time.

The EX within the ECG were been divided into 3 specific phases, the intensities of which were changed after 3 units per phase. The desired load frame was always performed in the same way. Each EX was adapted to the patient's condition, which corresponds to the degree of disability according to the ODI. The term "severe disability" refers to a percentage between 40 and 60% according to the ODI evaluation. Below 40% corresponds to a moderate disability, and between 0-20% to a minimal disability. In addition, the data from the NRS carried out before the start of each EX were used to determine the degree of stress related to the training parameters (intensity etc.).

Depending on the patient's condition, the number of sets was between 2, for more intensive complaints (NRS between 5-6, ODI between 40 and 60%) and 3 sets per EX for less intense complaints (NRS 3-4, ODI up to 40%). The repetitions were performed between 5 and 10 times per EX within Phase 1. The duration of stimulation (time under tension) during the concentric and eccentric phases was about 1 second per phase for each of the primary muscles involved. The 1st phase includes EX such as the Superman exercise (1).

Phase 2 aimed to increase confidence in one's own motor skills, decentralise the focus on pain, build up motor and mental resilience, and reduce fear of back strain (1, 2, 10). The number of repetitions corresponded to a frequency of 8 to 12 repetitions per EX. All EX took place one after the other as a circuit. All EX should be completely painless. Positive action reflection was encouraged through communication. In the 2nd phase, EX such as the lunge, activation of the oblique trunk musculature against resistance at the cable pull, were used.

Phase 3 aimed to encourage the patient to cope with his problematic activities (e.g. lifting) and to develop autonomy (1, 2, 10, 14). The positive movement reflexion was supported by motivational hints at the end of each EX. These phase includes EX such as deadlifts.

Group II consisted of a combination of COU, MA and MO of the SIJ and the LS (2, 6, 9, 11, 23). The frequency, the measurements (NRS, ODI), the time for the regular treatment sessions and for both COU of Group II corresponded to the same set up as those of Group I. In contrast to Group I, additional information was added to the COU of Group II, because patients were informed of the possible reason for using the MT described. This included information on the importance of deblocking the SIJ, MO of the LS, and relaxation of the back muscles.

The MA took place for 10 to 15 minutes each. MA always took place in prone position and was used to treat the erector spinae, gluteus maximus, gluteus medius, gluteus minimus, latissimus dorsi, and quadratus lumborum muscles. The patients should feel relaxed, or an NRS of "0", during the massage.

For the MO of the LS, the passive intervertebral technique according to the "Maitland concept" was used. The direction of MO was anterior and in the direction of the rotations to the left and right. LS MO techniques lasted to 5 minutes. A technique similar to the "Maitland concept" was also used to mobilize the SIJ anteriorly, with the patient lying a prone starting position. This application lasted up to 5 minutes.

Statistics

All statistical analyses were performed via IBM SPSS 25. The statistical 0-hypothesis (H0.1, H0.2) was: There are no differences for the NRS between the measurement times. The H.02 was: There is no difference for the ODI between the groups. The statistical alternative hypothesis (H1.1, H1.2) was: There is a difference for the NRS between the measurement times. The H1.2 was: There is a difference for the ODI between the groups. The parameters were ordinal (alpha<5%). Subsequent non-parametric tests were performed (Table 2). The analysis includes all data from Groups I and II from the intake to the final intervention unit, minus the data of the five drop outs. The Mann-Whitney-U test was used to compare the independent variables in a group at the respective measurement times (Table 1). The groups were compared according to each of the five measurement points. Afterwards, the comparability of the dependent time points of a group was used by means of the Friedmann test. The significance level was set to (p=0.05) Effect size was calculated with r=z/square root of N (Table 1).

Results

No significant differences were found within the measurements NRS 1, NRS 2 and NRS 3 between the groups. From the 3rd measurement onwards, a tendency towards a positive development was found in connection with the ECG compared to the MCG. Between the 4th and the 5th measurements, there was a statistically significant difference ($p<0.05$) in favour of the ECG. NRS 4: $p=0.02$; effect size $r=0.52$. NRS 5: $p< 0.001$; effect size $r=0.81$. Both groups improved significantly ($p<0.05$) in total (ODI, NRS). The NRS development within the ECG was: NRS 1=5 to NRS 3=1, to NRS 4 and 5=0, and within the MCG it was: NRS 1=4 to NRS ›

Table 2

Descriptive and inference statistics. MV=mean value; SD=standard deviation; Min.=minimum; Max.=maximum; U-test=Mann-Whitney-U-Test; Sig.=significance; F=effect size.

Tests	N	MV	SD	Min.	Max.	U-test	Z	Sig.	F
DESCRIPTIVE STATISTICS (NRS)						**INFERENCE STATISTICS**			
NRS_1	44	5	1	3	7	214	-0.7	0.5	
NRS_2	43	2	1	0	4	197	-0.9	0.4	
NRS_33	41	1	1	0	4	151	-1.6	0.1	
NRS_4	39	1	1	0	3	83	-3.3	.002	0.52
NRS_5	39	1	1	0	3	30	-5.1	.000	0.81
DESCRIPTIVE STATISTICS (ODI)						**INFERENCE STATISTICS**			
ODI_1	44	35	12	9	58	209	-0.8	0.5	
ODI_2	43	19	9	0	36	213	-0.5	0.7	
ODI_3	41	8	7	0	31	143	-1.8	0.08	
ODI_4	39	5	5	0	21	73	-3.3	.001	0.53
ODI_5	39	5	7	0	26	24	-4.9	.000	0.79

3=1, to NRS 4 and 5=1 (Figure 2). The ODI development within the ECG was: ODI 1=36, to ODI 3=5, to ODI 4=2, to ODI 5=0, and within the MCG it was: ODI 1=33, to ODI 3=11, to ODI 4=8, to ODI 5=10 (Figure 3).

Discussion and Critical Comparisons

The expected H0 tends correspond to the measurement results of the research work. The results show that both methods improve the pain situation (NRS) and the intensity of disability (ODI). It is not known whether the lower proportion of women in the MCG (35% vs. 59% ECG) is decisive for the result. However, the longer the patients received the therapies, the clearer the results became. In comparison between the baseline measurements and the measurements 3, 4 and 5, the most significant results were found. The reduction in pain was more intense than the improvement in disability. Especially in the long term (measurements 4 and 5) the significant statistical results between the groups indicate that ECG is more successful than MCG in reducing pain and disability. The feasibility of this therapy combination over a short period of time also seems to be necessary in Switzerland in order to avoid the high costs associated with chronic NLBP (24).

Other studies go in line with the results of this work related to active and behavioural oriented approaches (1, 3, 7, 8, 10, 13, 14, 16-18) and their importance in the early stages of NLBP (7, 17, 22). They did not evaluate the effectiveness of combined strategies such as those described here.

The question of solutions related to the reduction of NLBP was also described in former research projects, but mostly in chronic phases (2, 14, 23). They did not refer to the situation in Switzerland.

Göhner and Schlicht (8) figured out the effects of 2 different interventions during an intervention period of 6 to 8 weeks with subacute NLBP patients in their RCT (N=47). Their control group conducted a training therapy and the intervention group conducted a CBT. The differences to this research are most evident within the CBT units. The last measurements (NRS) took place 6 months after the last unit.

Aasa et al. (1) conducted a RCT (N=70) over a period of 8 weeks and 12 units. They compared an independently practiced low MC program based on individual EX correspondent to the individual's problematic movement, with a high-load lifting program (deadlifts) in patients with recurrent NLBP. The last measurements (PSFS, VAS) took place after 12 months. The biggest difference is the measurement after 12 month.

Ulger et al. (23) investigated the effectiveness (VAS, ODI, SF36) of MT and EX in patients with chronic LBP in their randomized controlled, double-blinded research (N=113). Patients received 18 units each over a period of 6 weeks. The difference in their research are the double-blinded approach, the chronic phases of their patients, and the not usage of long-term measurements .

Authors Conclusion and Criticism

The results of this research provide the practical insights to optimize the sustainability of physiotherapeutic practice for non-chronic NLBP in Switzerland. An extension of the study is planned. In addition, the sample size should then be analysed and increased to raise the statistical power. It seems to be necessary to orient the contents of the therapy units towards the development of confidence to cope physical loads, mental stress on a daily basis such as occupational related, and intense SM in patients with non-chronic NLBP (5, 6, 8, 10, 12, 16, 17). Further studies of this kind should follow in order to transfer the results to the population.

Conflict of Interest
The authors have no conflict of interest.

Table 1

Demographic and clinical data of the participants.

NO. OF PARTICIPANTS	ECG	MCG	GENDER	OCCUPATIONAL CATEGORY	AGE	SYMPTOMS SINCE (WEEKS)
1	X		m	accounting department	56	3
2	X		m	information technology (IT)	44	2
3		X	w	retail trade (cash register)	59	1
4	X		m	administration	47	2
5		X	w	retail trade (cash register)	33	3
6		X	m	management	41	1
7	X		m	bank	53	1
8		X	m	accounting department	58	2
9	X		w	administration	37	1
10	X		w	secretary's office	58	1
11	X		w	natural science	37	1
12		X	m	graphic design	58	2
13	X		w	controlling	27	1
14	X		m	management	57	3
15	X		m	bank	25	1
16		X	m	natural science	53	2
17		X	w	IT	53	1
18		X	m	bank	36	4
19	X		w	retail trade (cash register)	45	2
20		X	w	administration	39	1
21		X	m	jeweller	54	1
22	X		w	controlling	31	4
23		X	m	insurance	59	3
24	X		m	management	37	1
25		X	w	IT	29	2
26		X	w	bank	48	1
27	X		m	IT	36	3
28		X	m	graphic design	29	1
29		X	m	natural science	34	4
30	X		w	bank	49	4
31	X		m	dentistry	37	2
32	X		w	retail trade (cash register)	54	1
33	X		w	secretary's office	56	2
34		X	m	accounting department	33	1
35		X	w	dentistry	49	3
36	X		w	bank	45	1
37		X	w	accounting department	60	3
38	X		m	natural science	25	6
39		X	m	management	41	2
40		X	w	IT	34	6
41		X	m	administration	58	5
42		X	w	retail trade (cash register)	49	1
43	X		w	dentistry	51	3
44	X		m	bank	28	1

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