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Effectiveness of the Physical Therapy Godelive Denys-Struyf Method for Nonspecific Low Back Pain

Primary Care Randomized Control Trial

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Study Design. A simple blind, random controlled clinical trial.

Objective. To assess the effectiveness of physiotherapy treatment based on the muscular and articular chains Godelive Denys-Struyf (GDS) method for nonspecific low back pain (LBP) in primary care.

Summary of Background Data. Despite a systematic review by the European COST ACTION B13 "Low back pain: guidelines for its management," there are still many unresolved questions regarding the effectiveness of the different physical therapy treatments used for LBP. Setting: 21 physicians and physiotherapists in 7 Primary Care Centers and 6 researches in the Complutense University of Madrid (Spain). Participants: 137 patients diagnosed with nonspecific LBP.

Methods. The control group underwent 15 sessions of conventional physiotherapy in Primary Care Centers, and the experimental group received 15 GDS treatment sessions. Pain was evaluated by Visual Analogical Scale (VAS), functional disability by Oswestry questionnaire, and quality of life by the physical and mental components of SF-36 questionnaire. Outcome measures were assessed before treatment (A1), at the end of treatment (A2), and at 3 months (A3), and 6 months (A4) of follow-up.

Results. Repeated measures analysis of variance revealed that at the end of treatment and 3 months later, subjects in both groups showed less pain, reduced functional disability, and an improved quality of life, though improvements were greater in the GDS group.

Six months after treatment, patients in the GDS group continued to show reduced pain ($VAS_{(A4-A1)} = -3.54$, 95% CI: −4.18 to −2.90) while VAS scores in the control group returned to initial values ($VAS_{(A4-A1)} = 0.15$, 95% CI: −0.36 to 0.67).

Conclusion. Treatment of nonspecific LBP using the GDS method provides greater improvements in the midterm (6 months) in terms of the pain, functional ability, and quality of life perceived by patients than the conventional treatment based administered in primary care.

Key words: low back pain, primary health care, physical therapy (specialty), biomechanics. **Spine 2009;34: 1529–1538**

Low back pain (LBP) is an incapacitating disease that affects many persons worldwide. The prevalence of LBP over a lifetime is 60% to 84%[1] and the yearly incidence has been estimated at 5% to 25%, with a peak produced between the ages of 25 and 45 years. In European countries, this entity generates a cost representing 1.7% to 2.1% of a country's gross domestic product[2,3] because it is among the health problems responsible for most sick leave.[4]

The Spanish National Health Service is a universal and publicly-funded health care system. In Spain, LBP accounts for over 2 million visits to a Primary Care Centre (PCC) per year.[5]

Although nonspecific LBP is a defined clinical condition, because it is the result of a biomechanical alteration caused by postural or functional overload, countless physiotherapy strategies have been proposed to manage this type of LBP.[6] When we embarked on this study in 2005, the most relevant systematic reviews of the treatment of acute and chronic mechanical LBP indicated there was no scientific evidence (level A) supporting the effectiveness of most physiotherapeutic methods[7,8] in the absence of clinical trials of sufficient quality for their conclusions to have any clinical implications.[9]

In 2007, a practical guide to the management of LBP (COST B13)[10–12] was prepared by 14 European groups of LBP experts. Among the recommended treatments, we find most of the techniques that form the basis of the muscular and articular chains, or Godelive Denys-Struyf (GDS) method, assessed here[13–15] although no level A clinical trial has yet been performed on the GDS method itself. The muscular and articular GDS method (or muscle and joint chains GDS method) was developed by the Belgian kinesiotherapist Godelive Denys-Struyf.

Experimental Group Treatment: GDS Method

The GDS[16,17] method is based on a combination of individual manual therapy sessions and group sessions in which spinal stabilization exercises (for transversospinalis or multifidus muscles, transverses abdominis muscles)

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are performed along with exercises that work other muscles promoting spine stabilization such as those of the pelvic floor, diaphragm, *etc.* At the end of these sessions the patients are given instructions on how to perform simple maintenance exercises as part of a home exercise program of individualized exercises. The GDS method is a physiotherapy procedure classed as a specific treatment modality and is based on balancing the muscle tensions that provoke nonspecific subacute and chronic LBP through biomechanical alterations that affect lumbar-pelvic and spinal stability. The 3 different types of session (individual, group, and home care) are focus on recovering the 3 elements that confer lumbar-pelvic stability: musculoskeletal structure, musculature, and central nervous control of this musculature.[18] The muscle chains concept links these 3 elements.[19–22]

■ Materials and Methods

Study Design

The study performed was a simple blind randomized controlled trial (Figure 1) in which outcome measures were blindly assessed.

Objective

To assess the effectiveness of physiotherapy treatment based on the muscular and articular chains GDS method for nonspecific LBP in primary care.

Recruitment of Participants

Seven health centers in the Comunidad of Madrid were selected from the National Health System network. The study participants were persons attending their PCC because of LBP. We selected 160 patients from the PCC database system (OMI-AP) diagnosed with nonspecific LBP. Of these 160 patients, those not fulfilling the inclusion criteria (Table 1) or those with red flags (physical risk factors, such as nonmechanical pain, history of cancer, general unwellness), yellow flags (psychological risk factors, such as inappropriate attitudes and beliefs about back pain, inappropriate pain behavior), or irradiated LBP with signs of neurologic compromise according to the International Paris Task Force[23] were excluded.

Once these patients had been excluded 142 patients remained, who were informed of the possibility of voluntarily participating in the study. The 137 patients who finally gave their written informed consent were then randomly allocated to the experimental or control group.

The study participants all presented chronic LBP when referred to the physiotherapy unit because family physicians do not generally prescribe physiotherapy until 2 to 6 weeks after an acute LBP episode. Acute LBP is usually defined as the duration of an episode of LBP persisting for less than 6 weeks; chronic LBP as LBP persisting for 12 weeks or more.[9]

Sample Size

The program used to calculate this was SAMPLE POWER 2.0, and these data were then confirmed using the GRANMO 5.2.[24] For our study, accepting an alpha risk of 0.05 and a beta risk of 0.20 in a 2-sided contrast, 58 subjects in the first group and 58 in the second were required to detect a difference equal to or greater than 1.39 U. We assumed a common SD of 2.3 and follow-up losses of 0.25 (25% of the initial study population).

Assignment to Treatment Groups

A simple randomization procedure was used to assign patients to each treatment group. This random sequence was generated by Preventive Medicine and Public Health Department, Complutense University of Madrid, and was undisclosed until the

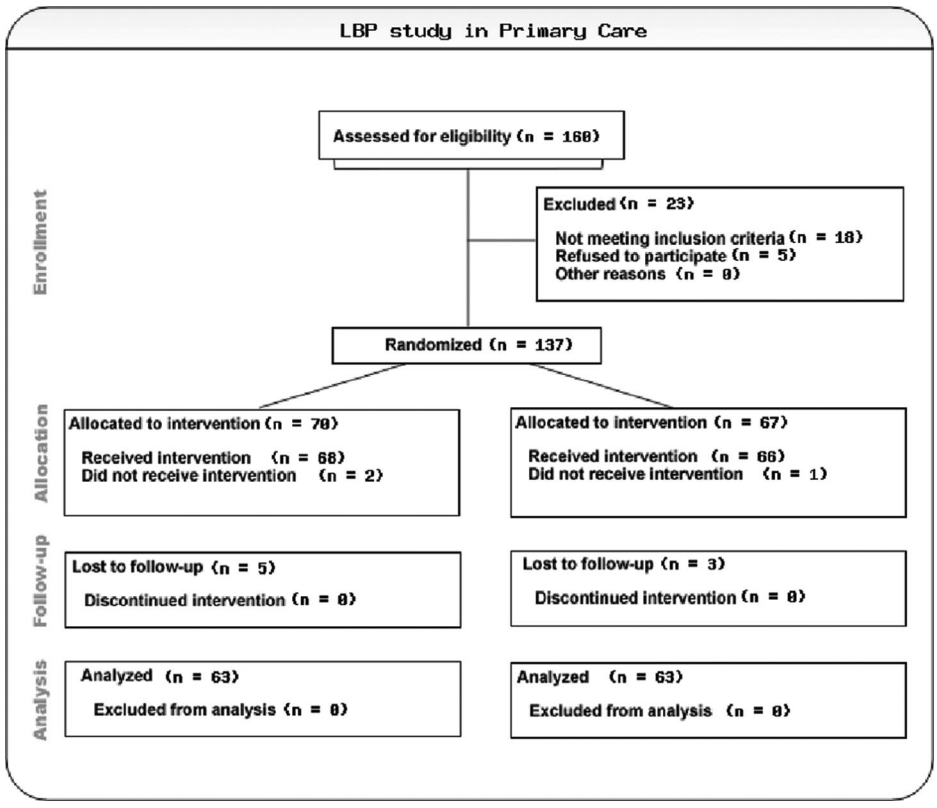

Figure 1. Flow chart showing the study design.

Table 1. Inclusion/Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
Age: participants were required to be 18 yr or older and under 65 yr	Refuse to participate or sign the informed consent
Diagnosis: nonspecific low back pain	Significant symptoms of depression
Physiotherapy prescribed by family doctor at the Primary Care Centre	Cognitive defects preventing adequate understanding of the study procedures
Patients whose LBP was caused by functional overload and/or poor postural habits with no neurological signs according to International Paris Task Force criteria	Insufficient understanding of the language to follow instructions
Patients who were not receiving treatment at the study outset and who agreed to not receive treatment in the 6 mo after the end of the study	Imminent move, lack of time, or non locatable over a yr
Patients whose LBP was subacute or chronic and of course longer than 2–4 mo according to International Paris Task Force criteria	Subjects in whom electrotherapy was contraindicated for whatever reason
	Patients showing red flags or physical warning signs
	Patients showing yellow flags or sociopsychological warning signs

interventions had been assigned. Assignments were made by 7 (one randomly selected per PCC) clinicians, who were not subsequently involved in assessing or administering treatment to the patients. Of the 137 patients, 70 were assigned to the control group and 67 to the experimental group.

Primary and Secondary Outcome Measures

The main outcome measure was pain assessed using the Visual Analogical Scale (VAS). Secondary outcome measures were functional disability and quality of life. Functional disability was estimated using the Oswestry Index for LBP disability and quality of life by the SF-36 quality of life questionnaire.

Nineteen physiotherapists were involved: 7 were full-time workers in primary care centers (they treated all the research patients; they received 10 workshops and 4 weekend courses to be able to apply the GDS treatment protocol); 7 were specializing in the GDS method (they assessed the research patients; they had between 2 years of GDS special formation in GDS method); 5 were university collaborators (they completed the questionnaires and test with the patient present; they received a course to be able to completed the test in a validated way).

The participating physiotherapists received basic training on the treatments to be used in both groups, especially the experimental treatment group. GDS describes 6 functional muscle groups which are used in normal musculoskeletal posture and movement. "Basic training" consisted of learn how to do GDS individual and group sessions procedures (Table 2) to restore the normal tone and function to this muscle groups to restore the overall equilibrium of muscles according to their biomechanical actions to maintain the normal position on bone structure.

A patient evaluation and treatment course was given by the world representative of the GDS method, along with 10 workshops for each of the activities that were to be conducted on the

Table 2. Experimental Treatment Group*

Session	Type	Content
1	Group	Understanding nonspecific LBP. Understanding and palpating body structures: acquiring personal knowledge of the columna vertebralis and region coxae
2	Individual	Treatment for normalizing biomechanical tensions in the regio perinealis, regio coxae, articulatio sacroiliaca, and columna vertebralis using techniques such as massage, pressure over painful points, balancing† muscles according to the biomechanical actions of the musculature on bone structure
3 and 4	Both individual	The same as session 2 but targeted at normalizing‡ biomechanical tensions generated by the muscles causing LBP (1, rectus abdominis/pelvic floor muscles; 2, diaphragma/iliopsoas/quadratus lumborum, transversospinalis, transverses abdominis; 3, ischium-tibialis muscles/gluteus maximus/erector spinae)
5	Group	Postural health: body knowledge to understand the body structures that could be affected in LBP and how to prevent pain through best daily practices
6	Group	Normalizing tensions in the pelvic floor muscles and rectus abdominis muscle
7	Group	Normalizing tensions in the diaphragma and stabilizing musculature of the spine (transversospinalis, transverses abdominis)
8	Group	Normalizing tensions of the most retracted musculature§ of the posterior section of the trunk and lower limbs (ischium-tibialis muscles, gluteus maximus, and erector spinae)
9	Group	Stretching all muscle chains¶
10	Individual	Same as session 2. Control session (CS)
11	Group	Same as session 6 (CS)
12	Group	Same as session 7 (CS)
13	Group	Same as session 8 (CS)
14	Group	Same as session 9 (CS)
15	Group	Self- and maintenance exercises: 4 movements or simple exercises to perform as everyday activities

*GDS sessions type and content.
†Balancing muscles = restoring the overall equilibrium of the muscles according to their biomechanical actions to maintain the normal position on bone structure.
‡Normalizing biomechanical tensions = restoring muscle tone to maintain the normal position on bone structure.
§Retracted musculature = muscles that present a tone over muscle normal tone or muscular normal tension. This limits the range of joints movement or alter its normal position.
¶Muscle chains = muscle-groups that act in unison in creating normal body posture and movement. All parts of the musculo-skeletal system are interdependent, with muscular groups linking all parts together.

study patients. These sessions were video-recorded and transcribed so that each physiotherapist could revise the procedures when necessary and specially the day before a session. At the end of the workshops all physiotherapists were evaluated.

A strict protocol was established to standardize physical examination and treatment procedures. The study coordinator was visiting different health centers in a random way to be sure that the therapists reliably applied the proposed treatment and evaluation protocol.

Interventions

Each group was subjected to an initial evaluation in which baseline main and secondary outcome measures were determined.

Control Group (C): Conventional Physiotherapy Protocol Applied in PCCs. Patients in the control group underwent 15 treatment sessions: 14 forty-minute sessions of TENS plus 10 minutes of microwave treatment and a last session in which they were given instructions for home postural health exercises. In Spanish PCC, routine clinical practice for nonspecific LBP is based on management guidelines and includes: several electrotherapy sessions (microwave and TENS treatment) and a final session in which the patient is given an instruction sheet of standard exercises to strengthen the spinal column.

The TENS treatment delivered was the conventional procedure[25] including a frequency of 150 Hz and 100-μs impulse time. Impulses were applied bipolarly using a dispersive pole (+) in the contralateral lumbar region or other muscle region close to the lumbar spine and pelvis and a (−) pole at the exit of the painful nerve root at the dermatome corresponding to the secondary hyperalgesia or the most painful point. The mA limits of intensity were set according do the patient's indication of a clear but not painful feeling.

Microwaves were delivered as pulses with a baseline frequency of 2450 MHz and power of 250 W. The peak dose for the pulse mode was calculated according to time of the first feeling of heat by the patient in a test run of increasing microwave doses. Patients underwent 2 to 3 sessions per week of an average duration of 50 minutes.

Experimental Group (GDS)-Physiotherapy for Balancing Muscular and Articular Chains in the Lumbar-Pelvic Region. Patients in the GDS group underwent 15 sessions of articular and muscular balancing of the lumbar spine and pelvis (Table 2). Each patient attended 2 sessions of an average duration of 50 minutes per week.

Patient-Assessed Outcomes

The assessments and questionnaires completed by the participants at the start and end of treatment, and 3 and 6 months after this were always the same and administered by the same groups of physiotherapists and physicians at each PCC.

Baseline (A1). Biomechanical assessment. Tests: VAS, Oswestry, SF-36, and life style.

End Treatment (A2) and Three-Month Posttreatment (A3). Biomechanical assessment. Tests: VAS, Oswestry, SF-36, and personal satisfaction.

Six-Month Posttreatment (A4). Biomechanical assessment. Tests: VAS, Oswestry, SF-36, and compliance with home exercises.

The questionnaires and tests used are LBP tools[26] that assess functional disability (Oswestry Index)[27] and 2 valid generic tests used to measure pain and assess quality of life (VAS[28,29] and SF-36[30]). These tests were selected on the grounds of their validation and use in similar clinical trials for evaluating LBP along with their rapid and easy application.

All tests and questionnaires were completed with the patient present. During the study, no adverse events occurred that could pose a physical or socio-psychological risk to the patients' health.

Masking

A simple blind study was designed in which the operators were blind to the main (pain) and secondary (functional disability and quality of life) outcome measures recorded.

The physiotherapists who treated and assessed the patients were not the same: the latter were unaware of the treatment received by each participant. To ensure the examiners were always blind to this information, another investigator selected at random was always present at the assessment sessions to prevent the patient or evaluator revealing the type of treatment received in any conversation.

Data Analysis

All statistical analyses were performed using the SAS PROC GLM program to run a repeated measures analysis of variance. The level of significance was set at $P < 0.05$. The intention to treat analysis was performed on those patients for whom complete postbaseline data were available (63 per group).

■ Results

Baseline Data

A baseline descriptive analysis was performed on the basic demographic and clinical features of each group as well as their main and secondary outcome measures. Both groups were found to be well-matched in terms of these data.

Mean age in both groups was 39 years ($CI_{(total)}$ = 37.68, 40.95). Of the 137 initial participants, 49 were men (35.77%) and 88 women (64.23%) such that the sample was homogenous in sex (P [χ^2] = 0.4838). The origin and race of the population was representative of western Europe, 121 patients (88.32%) being of Spanish or European origin.

Control Group: Conventional Physiotherapy Protocol Used at the Spanish PCC

The control group showed improved pain symptoms at the end of treatment (% change $VAS_{(A2–A1)}$ = −30.96 [95% CI: −39.47 to −22.45]) and at 3 months of follow-up ($VAS_{(A3–A1)}$ = −12.01 [−22.06 to −1.97]) (Table 3). Improvements were also recorded at these 2 time points (A2 and A3), respectively in functional disability ($Oswestry_{(A2–A1)}$ = −35.44 [−46.67 to −24.22] and $Oswestry_{(A3–A1)}$ = −25.20 [−40.29 to −10.01]) and quality of life, both in terms of its physical component ($SF\text{-}36_{physical(A2–A1)}$ = 31.40 [−21.11 to 41.68] and $SF\text{-}36_{physical(A3–A1)}$ = 23.57 [8.96–38.18]) and mental component ($SF\text{-}36_{mental(A2–A1)}$ = 41.11 [18.41–63.62] and $SF\text{-}36_{mental(A3–A1)}$ = 23.39 [8.65–38.13]).

Scores obtained in the initial assessment (A1) and at 6-month posttreatment (A4) failed to vary significantly

Table 3. Pain Changes in VAS Scores*

	Treatment Group	N	Mean	Standard Deviation	Two-Sided 95% CI (Mean)
Baseline (A1)	Electrotherapy	63	5.51	2.35	4.92, 6.11
	GDS	63	5.59	2.08	5.06, 6.11
	Total	126	5.55	2.21	5.16, 5.94
Final (A2)	Electrotherapy	63	3.66	2	3.16, 4.17
	GDS	63	2.3	1.85	1.83, 2.76
	Total	126	2.98	2.04	2.62, 3.34
3-mo follow-up (A3)	Electrotherapy	63	4.49	2.17	3.94, 5.03
	GDS	63	1.82	1.68	1.4, 2.24
	Total	126	3.15	2.35	2.74, 3.57
6-mo follow-up (A4)	Electrotherapy	63	5.67	2.09	5.14, 6.19
	GDS	63	2.04	2.03	1.53, 2.55
	Total	126	3.85	2.74	3.37, 4.34
Absolute change A2–A1	Electrotherapy	63	−1.85	2.1	−2.38, −1.32
	GDS	63	−3.29	2.12	−3.82, −2.75
	Total	126	−2.57	2.22	−2.96, −2.18
Absolute change A3–A1	Electrotherapy	63	−1.03	2.16	−1.57, −0.48
	GDS	63	−3.77	2.21	−4.32, −3.21
	Total	126	−2.4	2.57	−2.85, −1.94
Absolute change A4–A1	Electrotherapy	63	0.15	2.04	−0.36, 0.67
	GDS	63	−3.54	2.54	−4.18, −2.9
	Total	126	−1.7	2.95	−2.22, −1.17

*Main outcome measure change is represented in a repeated measures table. Outcome measure description: pain (0–10, 0 = best). Patients in the GDS and control groups showed similar starting pain intensity (A1). Differences were observed between the 2 groups at each subsequent assessment time (A2, A3, and A4), with the patients undergoing GDS treatment reporting lower pain intensities. The same results are given in Figure 1.

in terms of pain ($VAS_{(A4-A1)}$ = 24.80 [2.84–46.77]) (Table 3), functional disability ($Oswestry_{(A4-A1)}$ = −6.08 [−17.72 to 29.89]), and both components of quality of life ($SF\text{-}36_{physical(A4-A1)}$ = 0.57 [−13.49 to 14.64] and $SF\text{-}36_{mental(A4-A1)}$ = 8.69 [−7.23 to 24.61]).

Experimental Group: Physiotherapy for Balancing Muscular and Articular Chains (GDS Method)

In the experimental group, improvements were noted at the end of treatment (A2) and at 3 months (A3) and 6 months (A4) posttreatment in the outcome measures: pain (% change $VAS_{(A2-A1)}$ = −58.61 [−67.46 to −49.76]; $VAS_{(A3-A1)}$ = −67.18 [−75.24 to −59.13] and $VAS_{(A4-A1)}$ = −61.83 [−72.57 to −51.08]) (Table 3); functional disability ($Oswestry_{(A2-A1)}$ = −53.72 [−64.27 to −43.17]; $Oswestry_{(A3-A1)}$ = −63.17 [−72.77 to −53.56] and $Oswestry_{(A4-A1)}$ = −58.83 [−71.17 to −46.50]); quality of life physical ($SF\text{-}36_{physical(A2-A1)}$ = 31.40 [21.11–41.68]; $SF\text{-}36_{physical(A3-A1)}$ = 71.90 [50.72–93.09] and $SF\text{-}36_{physical(A4-A1)}$ = 72.07 [48.35–95.79]); and quality of life mental ($SF\text{-}36_{mental(A2-A1)}$ = 45.94 [24.53–67.36]; $SF\text{-}36_{mental(A3-A1)}$ = 53.48 [33.77–73.20] and $SF\text{-}36_{mental(A4-A1)}$ = 51.00 [27.90–74.11]).

Control Group Versus *Experimental Group*

To estimate the efficiency of the experimental treatment, we performed repeated measures. The results obtained indicate a greater improvement in patients undergoing GDS treatment (Table 4).

Once the null hypotheses for the 3 effects included in the model were compared, we undertook a complementary analysis to identify significant effects.

Interaction plots among pain, functional disability, and quality of life as perceived by each person were constructed according to the type of treatment received and over the 4 study months (Figures 2–5).

Table 4. Efficiency of the Experimental Treatment Performed With a Repeated Measures Analysis of Variance*

Repeated Measures Analysis	Hypothesis of No Time Effect	Hypothesis of No Time Treatment Effect	Hypothesis of Between Subjects Effect
VAS	Wilk value (0.369) *F* value, *P* value ($F[3, 122] = 69.33$, $P < 0.0001$)	Wilk value (0.369) *F* value, *P* value ($F[3, 122] = 27.53$, $P < 0.0001$)	*F* value, *P* value ($F = 42.91$ $P < 0.0001$)
Oswestry	Wilk value (0.369) *F* value, *P* value ($F[3, 122] = 42.63$, $P < 0.0001$]	Wilk value (0.369) *F* value, *P* value ($F[3, 122] = 7.77$, $P < 0.0001$)	*F* value, *P* value ($F = 11.93$, $P < 0.0001$)
SF-36 physical	Wilk value (0.369) *F* value, *P* value ($F[3, 122] = 41.84$, $P < 0.0001$)	Wilk value (0.369) *F* value, *P* value ($F[3, 122] = 11.29$, $P < 0.0001$)	*F* value, *P* value ($F = 20.79$, $P < 0.0001$)
SF-36 mental	Wilk value (0.369) *F* value, *P* value ($F[3, 122] = 18.00$, $P < 0.0001$)	Wilk value (0369) *F* value, *P* value ($F[3, 122] = 8.83$, $P < 0.0001$)	*F* value, *P* value ($F = 15.73$, $P < 0.0001$)

*The results were obtained comparing the null hypotheses for the 3 effects included in the model. *P* values obtained indicate a greater improvement in patients undergoing GDS treatment.

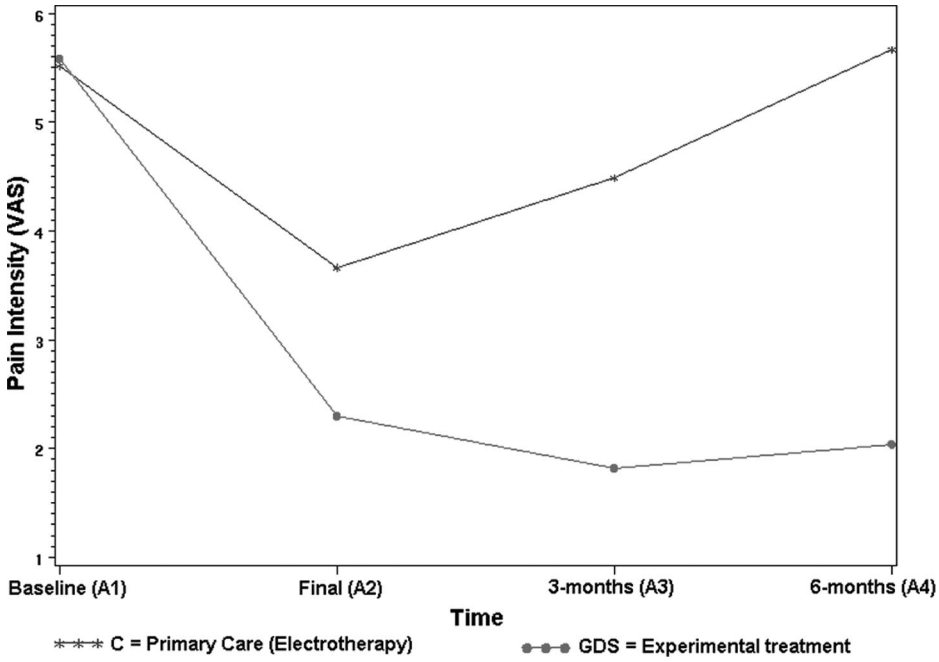

Figure 2. VAS repeated measures plot. Outcome measure description = pain (0–10, 0 = best). Patients in the GDS and control groups showed similar starting pain intensity (A1). Differences were observed between the 2 groups at each subsequent assessment time (A2, A3, and A4), with the patients undergoing GDS treatment reporting lower pain intensities.

The 2 groups showed reduced pain (VAS), improved functional disability (Oswestry), and improved quality of life (SF-36) at the end of treatment (A1 *vs.* A2) and 3 months after treatment (A1 *vs.* A3) although these improvements were significantly greater for the GDS group.

Six months after treatment, the improvements observed in the GDS group at the end of treatment (A2) persisted while VAS scores in the control group returned to pretreatment values (A1) and functional ability and quality of life scores fell to under half their starting values, especially the mental component of quality of life.

■ Discussion

Principal Findings and Meaning of the Study

At the end of treatment (A2) and 3 months later (A3), both the experimental (GDS) and control (C) treatment groups showed improvements in terms of the 3 main outcome measures pain, functional disability, and quality of life.

The most meaningful data of this study, however, appeared in the assessment performed 6 months after the end of treatment (A4), in which group C returned to almost the same state of pain as before treatment and

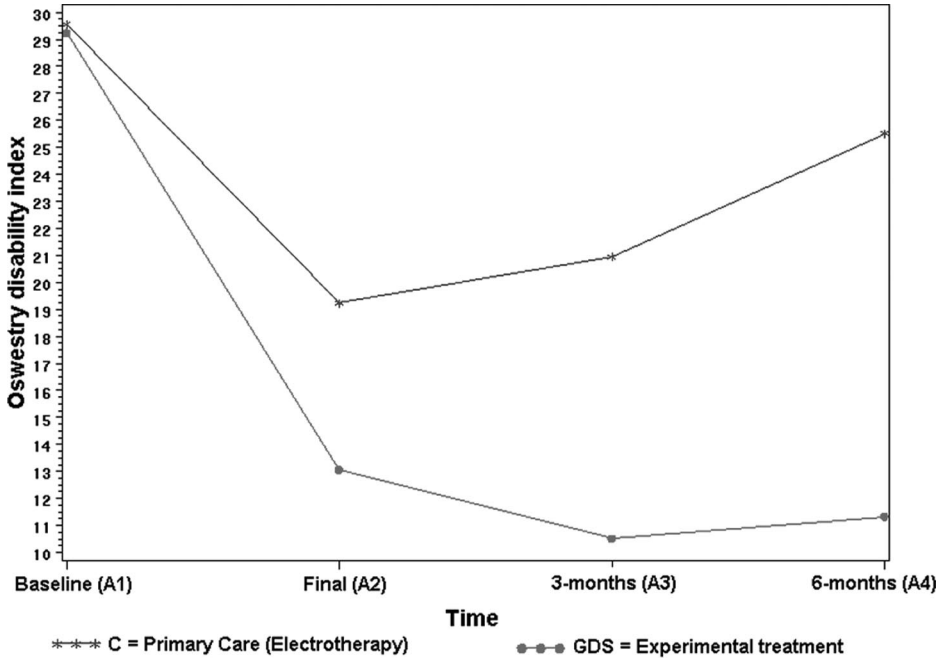

Figure 3. Oswestry disability index. Outcome measure description = functional disability (0–100, 0 = best). Patients in the GDS and control groups showed similar starting functional disability level (A1). Differences were observed between the 2 groups at each subsequent assessment time (A2, A3, and A4), with the patients undergoing GDS treatment reporting lower disability level.

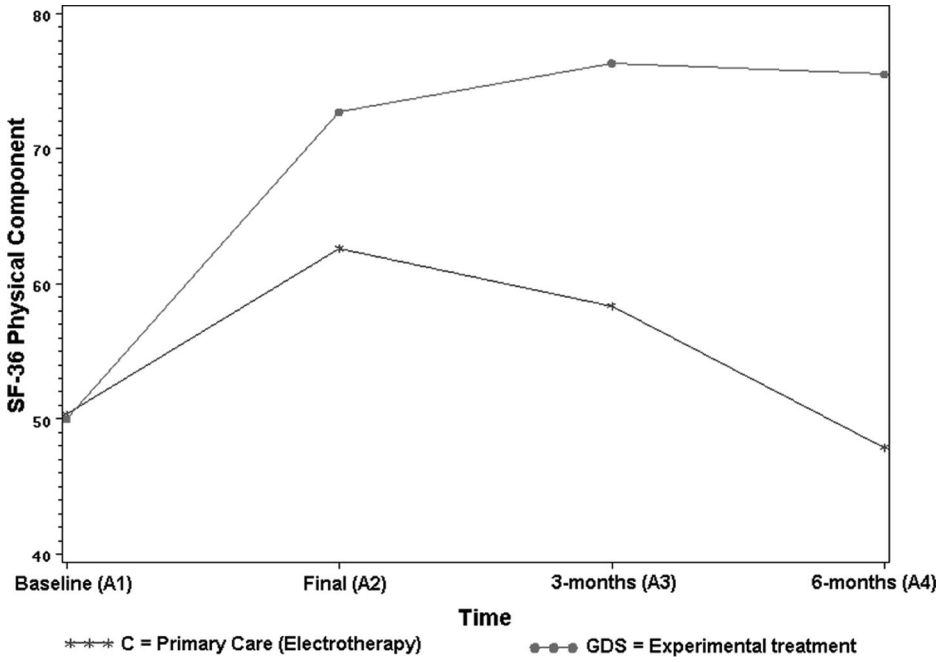

Figure 4. SF-36 questionnaire for physical component of health. Outcome measure description = physical component (0–100, 100 = best). The 2 groups improved quality of life (SF-36) at the end of treatment (A1 *vs.* A2) and 3 months after treatment (A1 *vs.* A3). At 6 months after treatment (A4), quality of life scores in the control group returned to pretreatment values (A1).

also lost over half the improvements made in functional disability and quality of life. This situation could be attributed to the difference between a treatment regimen focused on improving a symptom such as pain (C) and a therapy targeted at eliminating the cause of this pain and the consequent functional disability.

Previous studies[31] included in large systematic reviews conducted over the past few years[5] also support the improvement of patients subjected to treatment methods that incorporate physical exercises to correct the biomechanical malalignment causing pain in a given musculature through motor relearning in the person with LBP.[32] The GDS muscular chain method pursues the movement of the patient in group sessions in which the most ergonomic, adapted, and coordinated movements are recovered, contributing to maintaining spinal health. In contrast, electrotherapy sessions and give an instruction sheet of standard exercises in the last session are passive. The findings of many studies support the hypothesis that passive methods do not achieve the persistence of the changes produced in musculoskeletal structures, since they do not involve active learning[33] by the patient who determine that the nervous system automatically executes[34] "best practice" or aligned, coordinated body movements that avoid the reappearance of LBP.[35] Electrotherapy is a passive technique the patient receives

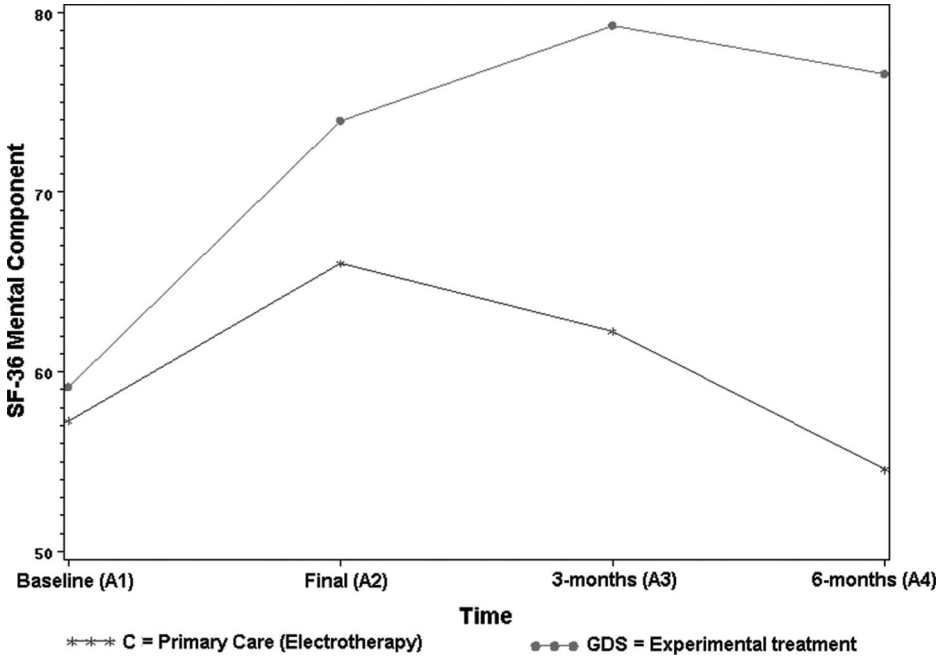

Figure 5. SF-36 questionnaire for mental component of health. Outcome measure description = mental component (0–100, 100 = best). Six months after treatment, the improvements in quality of life scores observed in the GDS group at the end of treatment (A2) persisted, while quality of life scores fell to under half their starting values, especially the mental component of quality of life.

without undertaking motor activities that will teach the body habits to replace poor body movements.

The results of the present study question the effectiveness of the treatment for nonspecific LBP currently applied in Primary Care, especially when based on electrotherapy or methods in isolation. Our findings point to a an improvement in patients receiving Primary Care treatment that does not however, persist beyond 3 months, such that these patients are likely to be readmitted to a Physiotherapy Unit in the short-term. The problem posed by this need for readmission to the National Health System needs to be examined at the cost level, including among the outcomes assessed a worsening of the mental component of the quality of life of these patients.

Our results indicate that 6 months after being treated with electrotherapy, these patients show a similar level of pain as before treatment possible explaining the poor scores obtained in the mental component of the quality of life questionnaire, which were sometimes even worse than pretreatment scores. This finding is important when assessing the repercussions of promoting treatments that achieve reduced pain in the short-term that is not maintained in the long-term. The mental state of a patient who experiences a transient improvement in quality of life only to recover the same level of pain as before treatment could increase his/her negative vision of the disease, instilling pessimism, fear of pain, and a lack of confidence in a future recovery. This type of situation may be among the main aggravating factors of the problem attempted to be solved, since at the outset we are dealing with a patient with LBP, and further on in time the patient with continued LBP is in a worse psychological condition to confront the disease.

Strengths and Weaknesses of the Study

In the present study, considerable levels of improvement were maintained for 6 months in pain, functional disability, and quality of life, unlike the results of other studies in which other manual physiotherapy methods[31,36,37] were used but that a randomized controlled trial was not conducted to provide level a scientific evidence. Notwithstanding, the effectiveness of many of the techniques used in the GDS method that are common to other manual physiotherapy methods has been confirmed with a moderate level of evidence, as reported in the COST B13 guide.

Other studies[38–41] have revealed improvements in the experimental group treated with sessions of self-exercises, group exercises, manipulation, and spine stabilization exercises, although their results do not show the significant differences observed here. This study presents the first results of a randomized controlled trial of the GDS muscular and articular chains method. This method and other techniques that pursue the same therapeutic objectives,[42] involving group sessions of 10 to 12 patients in which best practice movements and body postures are recovered, can be very useful in a public health setting. Besides shortening the waiting list, these methods promote patient participation in his/her own recovery, provoking changes in body movement that are sustainable over time.

Finally, although there are many studies[43] that have examined the use of TENS to treat chronic LBP, there is no sound scientific evidence supporting its use due to a lack of precision in the following areas: type of application, application site, length of treatment, optimal frequencies, and intensities.[44] The COST B13 guide recommends new research efforts to evaluate its effectiveness, since 6 trials of high methodologic quality revealed a tendency towards favorable results using TENS to treat subacute and chronic LBP.[45] In the present study in which electrotherapy was adequately standardized, we observed an improvement in patients treated with TENS and microwave therapy in the short-term (3 months).

The present findings should be considered in the next update of the COST B13 clinical practical guide to simple mechanical LBP because of the implications of its conclusions for everyday physiotherapeutic practice at Primary Care centers.

Limitations of the Study

The nature of this type of physiotherapeutic intervention makes it impossible to conduct a double-blind study, which is a prerequisite for the highest level in scientific evidence.

The GDS method offers a novel feature over other physiotherapeutic measures in that 5 of 6 treatment subgroups are defined according to the muscle chain causing back pain. Indeed, this feature is both the strong and weak point of the study: weak because of the specialization required of the therapist to be able to assign each patient to the appropriate treatment group, and strong because the treatment's efficacy is based on targeting the musculature triggering back pain and restoring the overall equilibrium of the muscles and joints of the body.

Unanswered Questions and Future Research

The following are our future goals:

- To undertake a study designed to evaluate the progress of these patients beyond 6-month posttreatment.
- To perform a cost/benefit analysis of the GDS method, which involves several group sessions in which 10 to 12 patients are simultaneously treated in a 1-hour session.
- To assess the possible reductions in pharmacological costs associated with the GDS method from primary care to specialized care for operations and readmissions to health centers and physiotherapy units (reduced waiting list).
- To determine the minimum number of sessions needed to achieve the improvements observed in this study in which 15 physiotherapy sessions were administered.

• To identify among the patient subgroups if there are certain muscle groups that always need treating regardless of whether a patient shows one causal set of muscles or another. For instance, the musculature described in the literature as spine stabilizing.

■ Conclusion

The findings of our study suggest that the use of the GDS method to treat nonspecific LBP leads to greater improvements in the mid term (6 months after treatment) in patient perceived pain, functional ability, and quality of life than the conventional treatment based on electrotherapy currently used in Spanish primary care.

The results of this study suggest that applying a specific physical evaluation and exercise active programs based on individual muscular deficits is an appropriate treatment for people having subacute or chronic nonspecific pain.

■ Key Points

• Trials of physical therapy for LBP have provided conflicting results. Despite a systematic review by the European COST ACTION B13 LBP: guidelines for its management and the guidelines of its Working Group of experts in the field of LBP research, there are still many unresolved questions regarding the effectiveness of the different physical treatments used for LBP.

• Numerous observational studies have suggested that the GDS method may be effective in treating back pain, but until now evidence from randomized controlled trials is lacking. The only randomized controlled trial to date is that presented here.

• The findings of our study suggest that the use of the GDS method to treat nonspecific LBP leads to greater improvements in the mid term (6 months after treatment) in patient perceived pain, functional ability, and quality of life than the conventional treatment based on electrotherapy currently used in Spanish primary care.

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