

Effectiveness of the Godelieve Denys-Struyf (GDS) Method in People With Low Back Pain: Cluster Randomized Controlled Trial

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Background. The Godelieve Denys-Struyf method (GDS) is a motor learning intervention that may be applied in group or individualized sessions.

Objective. The study objective was to compare the effectiveness of routine physical therapy, group GDS (GDS-G) sessions, and group and individualized GDS (GDS-I) sessions.

Design. This was a cluster randomized controlled trial.

Setting. The study took place in 21 primary care physical therapy units (“clusters”) of the Spanish National Health Service (SNHS).

Participants. The participants were 461 people with subacute and chronic low back pain (LBP).

Intervention. Clusters were randomized into 3 groups. All participants received medical treatment and a 15-minute group education session on active management. Additional interventions were as follows: control (fifteen 40-minute sessions of transcutaneous electrical nerve stimulation, microwave treatment, and standardized exercises), GDS-G (eleven 50-minute group GDS sessions), and GDS-I (the same 11 sessions plus four 50-minute individualized GDS sessions).

Measurements. Primary outcomes at baseline and 2, 6, and 12 months later were LBP and pain referred down the leg (separate pain intensity numeric rating scales) and disability (Roland-Morris Questionnaire [RMQ]). Secondary outcomes were use of medication and self-reported health (mental and physical component summaries of the 12-Item Short-Form Health Survey [SF-12]). Separate linear mixed models for LBP, pain referred down the leg, and disability were developed to adjust for potential confounders. Randomization, outcome assessment, and data analyses were masked.

Results. At 12 months, disability improved 0.7 (95% confidence interval [CI] = -0.4, 1.8) RMQ point in the control group, 1.5 (95% CI = 0.4, 2.7) RMQ points in the GDS-I group, and 2.2 (95% CI = 1.2, 3.2) RMQ points in the GDS-G group. There were no differences in pain.

Limitations. The amount of exercise was smaller in the control group, and GDS-I sessions were provided by junior physical therapists.

Conclusions. The improvement in disability was slightly higher with group GDS sessions than with the program routinely used in clusters within the SNHS. Adding individualized GDS sessions eliminated this advantage. Further studies should compare the GDS with other types of exercise.

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- **eAppendix:** Illustrative Examples of Activities and Exercises Performed in a Selection of Group and Individualized Godelieve Denys-Struyf (GDS) Sessions.

Nonspecific or common low back pain (LBP) is defined as pain that is located between the costal margins and the inferior gluteal folds and that is not related to fracture, direct trauma, systemic diseases, or conditions for which decompressive surgery is appropriate, such as certain cases of symptomatic spinal stenosis or disk herniation.^{1–4} Low back pain represents major health, social, and economic burden worldwide,^{5–8} including for the Spanish National Health Service (SNHS), which is the tax-funded organization providing free health care to every resident in Spain.

Many attempts have been made to classify patients with LBP into subgroups to determine the most appropriate treatments.^{9,10} The Godelieve Denys-Struyf method (GDS) is a motor control intervention that classifies muscles influencing lumbar-pelvic and spinal stability into 6 groups (“muscle chains”), according to their anatomy and role in postures and movements (Appendix 1). It builds on the assumption that balance across these muscle chains contributes to adequate neuromuscular, biomechanical, and psychomotor control, whereas unbalanced tension across them accounts for subacute or chronic LBP.^{11–14}

To balance such tensions, 11 group and 4 one-on-one, individualized sessions of manual therapy, stretching, and exercises are applied to those muscles (eg, transversospinalis, multifidus, transversus abdominis, diaphragm, and pelvic floor muscles), and patients are taught movements intended to improve central nervous system automatic control over body positions and movements.^{11–14} In practice, the main differences between group GDS sessions and other types of exercise and motor control interventions relate to the type, order, and intensity of movements and exercises performed and the muscle

groups involved (Appendix 2 and eAppendix, available at ptjournal.apta.org). The GDS was shown to be more effective at improving pain and disability than the physical therapy program routinely used within the SNHS,¹³ which comprises transcutaneous electrical nerve stimulation, microwave treatment, and standardized exercises.^{15–17}

“Active management” of LBP includes avoiding bed rest, keeping as physically active as possible, and resuming a normal life as quickly as possible.¹⁸ A short education program on active management, comprising a 15-minute talk and distribution of a booklet to all participants, was shown to lead to clinically and statistically significant improvements in LBP and disability.^{19,20} However, despite these results and recommendations in evidence-based guidelines,^{21–24} this program is currently not included in routine clinical practice within the SNHS.

High-quality systematic reviews have shown that exercise is effective for treating LBP.^{25–27} However, adding an exercise program similar to the one offered within the SNHS to the short education program was shown to not significantly improve the results obtained with the latter.¹⁹ Nevertheless, GDS-type exercises are different and may improve results when added to the education program. In previous randomized controlled trials (RCTs) of the GDS, very few highly trained experts applied group and individualized GDS sessions.¹³ Individualized sessions increase costs, and it is not known whether they improve results. The learning curve for therapists also is not known. Determining these aspects of the GDS could contribute to optimizing the routine physical therapy management of LBP within the SNHS.

Therefore, the objective of this study was to test the following 3 hypotheses: (1) the results of a short education program are improved to a greater extent when complemented by GDS sessions than when complemented by the physical therapy program routinely used within the SNHS, (2) complementing group GDS sessions with individualized GDS sessions improves results, and (3) a 40-hour training course is sufficient to enable physical therapists to obtain results similar to those reported in studies in which senior practitioners delivered individualized GDS sessions.

Method

Design Overview

Recruitment started in May 2010, and outcome assessment was completed in April 2012.

Setting and Participants

The Institutional Review Boards in charge of primary care within the SNHS in Madrid selected 5 (of 11) primary care areas that—for operational reasons—were more suitable for participation in this trial. They covered a population of 3,532,799, approximately 54.3% of the total population in the region. The 43 physical therapy units belonging to the SNHS in Madrid in those areas were invited to join the study. The first 21 units that accepted were included.

Participant inclusion criteria were an age of 18 to 65 years, having requested care for LBP from a primary care physician, having been referred for physical therapy by the primary care physician, and signing the informed consent form to participate in the study. Participants were told that the objective of the study was to assess the effects of physical therapy treatments.

Exclusion criteria were pregnancy; diagnosis of cancer, fibromyalgia, or

inflammatory disease (eg, rheumatoid arthritis or spondylitis); criteria for referral to surgery (urgent [signs suggesting cauda equina syndrome] or not urgent [severe sciatica for >6 weeks if caused by disk herniation or >12 weeks if caused by spinal stenosis])²⁻⁴; “red flags” of systemic disease (eg, fever or unexplained loss of >10% of body weight)^{1,24}; having received physical therapy treatment during the preceding 12 months; and an inability to complete written questionnaires in Spanish.

Randomization

In this study, because we assessed interventions that were provided to groups of participants (as opposed to participants individually), we anticipated a high risk of contamination between participants within the same physical therapy unit. Therefore, at the design phase, we decided to randomize at the physical therapy unit (“cluster”) level.

Randomization was performed in a masked fashion on the basis of the chronological sequence with which each physical therapy unit joined the study. A coordination office prepared consecutively numbered, opaque, sealed envelopes, each containing a number extracted from a random numbers table.²⁸ When a physical therapy unit joined the study, the study coordinator (M.J.D.A.) opened the corresponding envelope and assigned the physical therapy unit to one of the intervention groups on the basis of the allocation number it contained.

Only the study coordinator (M.J.D.A.) and the person responsible for the coordination office (F.M.K.) knew to which group each physical therapy unit had been assigned. At the end of the study, the study coordinator verified that the sequence of randomization matched that determined by the random numbers table and the dates on which each physical therapy unit

was included and compared the list of participants who were recruited in each cluster with the list of participants who received each kind of treatment.

Interventions

Primary care physicians managed LBP in their patients in accordance with routine practice within the SNHS, which includes advice, drug treatment, potential request for diagnostic procedures, or potential referral to physical therapy, rehabilitation, orthopedic surgery, neurosurgery, rheumatology, or pain units.²³

This trial was conducted only with people referred to physical therapists. At the physical therapy units, all participants attended a short education program on active management, comprising a 15-minute talk given to groups of no more than 15 participants and the delivery of the Spanish version of the “back book.”¹⁹ All of the talks in all of the groups were given by 1 of 3 physicians, who had no links with the physical therapy units or the primary care centers. They had received 2 hours of training for this purpose from a senior medical lecturer in this field (M.G.) and were unaware of the group to which the participants attending each talk had been assigned. Other studies have shown that this short education program is effective under these application conditions.^{19,20}

The additional treatments provided in the physical therapy units depended on the group to which each one had been assigned. In the control group, the physical therapy regimen implemented was the one routinely used within the SNHS in Madrid; it consisted of fifteen 40-minute sessions, applied twice per week, for a total of 600 minutes across 7.5 weeks, and included microwave treatment, transcutaneous electrical nerve stimulation, and

standardized exercises. The exercises were implemented progressively across sessions, in accordance with the physical therapist's criteria, and expected to be continued at home.¹⁵⁻¹⁷ Participants were treated collectively, in groups of 5 to 7, depending on the numbers of microwave and transcutaneous electrical nerve stimulation devices available at each physical therapy unit.

In the GDS-G group, 11 collective GDS sessions were provided to groups of 10 to 12 participants. These sessions focused on the muscle imbalances that are most commonly found in patients with LBP.¹¹⁻¹⁴ Two 50-minute sessions per week were conducted, for a total of 550 minutes across 5.5 weeks (Appendix 2 and eAppendix).

Participants in the GDS-I group received the collective sessions provided to the GDS-G group. Additionally, each participant was physically examined for 20 minutes and received 4 additional 50-minute individualized, one-on-one sessions of manual therapy, stretching, and massage focusing on the muscle groups (chains) determined to require more attention in that particular case. Participants in the GDS-I group received physical therapy care for a total of 770 minutes across 7.5 weeks (Appendix 2 and eAppendix).

Physical therapists in the GDS-G and GDS-I groups had written reminders summarizing the order in which the exercises were to be done during each session, the duration of each exercise, and details regarding execution. The content of each session in both groups and examples of exercises implemented in each one are shown in Appendix 2 and the eAppendix.

The control and group GDS sessions (for both GDS-G and GDS-I groups) were conducted by the physical

therapists working at the physical therapy units. Those providing the GDS group sessions had attended a 40-hour course offered by a GDS-certified senior physical therapist.

The individualized GDS sessions in the GDS-I group were implemented by a different set of physical therapists, who had attended an additional 40-hour course on individualized GDS sessions offered by the same senior physical therapist. These therapists attended the physical therapy units only to conduct these sessions. The existence of individualized GDS sessions was not mentioned in the course on group GDS sessions and vice versa.

Because of the nature of the treatments being compared, the therapists and the participants could not be kept unaware of the type of physical therapy treatment (routine physical therapy, GDS-G, or GDS-I). However, they were not aware that other types of treatment were being implemented, and the therapists were not present during the outcome assessments.

Outcomes and Follow-up Assessments

Outcomes were established at the cluster level. Primary outcomes were pain (LBP and pain referred down the leg [RP], measured separately) and disability, assessed at 2, 6, and 12 months with 11-point pain intensity numeric rating scales (PI-NRSs)²⁹ and the validated Spanish version of the 24-item Roland-Morris Questionnaire (RMQ), respectively.³⁰⁻³² Secondary (or exploratory) outcomes were self-reported health and use of other treatments.³²

Variables assessed only at baseline were pain duration (number of days, categorized as acute, subacute, or chronic, with cutoff points of 14 days, 14-89 days, and ≥ 90 days, respectively)^{33,34}; sex; age (years);

height (centimeters) and weight (kilograms), combined at the analysis phase as the body mass index^{35,36}; academic level (less than primary school, primary school, secondary school, or university); employment status (self-employed, employed, unemployed, disabled, retired, student, or homemaker); employment benefits (not on sick leave, on sick leave for LBP, on sick leave for other reasons, disabled because of LBP, disabled for other reasons, or not applicable [eg, not qualifying for employment benefits]); physical activity (sedentary, minimally active, moderately active, active, or extremely active); number of LBP episodes in the preceding 2 years (0, 1, 2, or >2); comorbidities (other musculoskeletal conditions, other nonmusculoskeletal pain conditions, epilepsy, or other); having undergone physical therapy for LBP in the past; having undergone diagnostic tests for the current episode (radiography, computed tomography scan, magnetic resonance imaging, electromyogram, blood test, other, or none); and current treatments other than drugs (physical therapy, neuroreflexotherapy, psychological treatment, or surgery).

Variables assessed at baseline and 2, 6, and 12 months later were severity of LBP and RP (measured with separate PI-NRSs)³⁰; disability (measured with the RMQ)³¹; self-reported health (measured with the 12-Item Short-Form Health Survey [SF-12], including the Physical Component Summary [PCS] and the Mental Component Summary [MCS])³⁷; and drug treatment (classified as "yes" or "no" and assessing separately drugs, such as nonsteroidal anti-inflammatory drugs [NSAIDs], analgesics, muscle relaxants, steroids, antiepileptics, and psychoactive drugs [anxiolytics and antidepressants], and other). Value ranges were 0 to 10 for the PI-NRSs³⁰ and 0 to 24 for the RMQ.³¹ The PCS and the MCS have been nor-

malized for the Spanish general population ($\bar{X}=50$, $SD=10$); score ranges were 2.86 to 71.67 for the PCS and 11.61 to 71.24 for the MCS. Higher scores on the PI-NRSs, RMQ, PCS, and MCS reflected more severe pain, disability, and self-reported health. At each follow-up assessment, any adverse events attributed by participants to physical therapy were recorded.

The research staff conducting the assessments (assessors) was unaware of the intervention group to which each cluster had been assigned. Assessors had been told that they were going to assess the clinical course of participants undergoing physical therapy (but not that different types of physical therapy were being compared). They had received 4 hours of specific training offered by the study coordinator on the use of the validated instruments for measuring each variable (PI-NRSs, RMQ, and SF-12) and the exact operational definition of each variable. Assessors were 12 physical therapist students, who were not linked to the physical therapy units and who had no contact with the clinical staff at the units or the rest of the research staff, except for the study coordinator. Assessors attended the physical therapy units only when participants had been scheduled for assessment and were never present when the treatments were applied. For assessment of whether masking had been successful, at the end of the study, the participants were questioned about the types of treatments the participants had received.

Participants completed all of the self-administered questionnaires on their own, unaccompanied by health care staff or third parties, but they could ask the assessors questions. Scores for the PI-NRSs and the RMQ were calculated at each physical therapy unit by the assessors, whereas those

for the SF-12 PCS and MCS were calculated at the analysis phase.

Procedure

Physical therapists working at the participating physical therapy units consecutively screened for inclusion all patients who had LBP and who had been referred for physical therapy by their primary care physicians. Those who met the inclusion criteria were scheduled for a specific day, when an assessor considered the exclusion criteria, explained the details of the study, and responded to participant queries. Inclusion became effective when participants signed the informed consent form.

Each participant was then scheduled for a talk on active management. After the talk, clinical staff at the physical therapy units scheduled treatment sessions, and assessors scheduled assessments. Participants' attendance at treatment sessions and attendance at follow-up assessments were recorded separately by the study coordinator and the assessors, respectively.

At each assessment, the completed questionnaires were collected by the assessors, who stapled them to the participants' data forms and sent them to the coordination office. Only the assessors and the clerical staff at the coordination office had access to the questionnaires and forms.

At the coordination office, data were entered into a database by 2 administrative assistants, who verified that the data entered coincided with the participants' ratings on the PI-NRS, RMQ, and SF-12 questionnaires. When the database was completed, it was used for statistical analysis.

Data Analysis

Assumptions for sample size calculations were an intracluster correlation of .2; LBP baseline severity of 5.6

PI-NRS points; baseline disability of 7.2 RMQ points, with a standard deviation of 4; and mean improvements in pain and disability of 2.0 PI-NRS and 2 RMQ points throughout the follow-up period. These assumptions were based on previous studies assessing physical therapy treatments for LBP within the primary care centers of the SNHS and on clinically relevant minimal changes in pain and disability.^{13,19,38} Accepting type I and II errors of 5% and 20% and anticipating 20% losses to follow-up and a mean cluster size of 22, we established a sample size of 462 in 21 clusters.³⁸

Statistical analysis was performed by a team of statisticians, who were unaware of the treatment applied in each group and who had no contact with the rest of the staff involved in the study. The analysis followed the CONSORT (Consolidated Standards of Reporting Trials) rules for non-pharmacological cluster randomized trials^{39,40} and was performed on an intention-to-treat basis with linear mixed models.⁴¹ The median and the interquartile range were used to describe numerical variables, and absolute and relative frequencies were used for categorical ones. At the cluster level, the mean and the 95% confidence interval (CI) were used to show the scores for the PI-NRSs for LBP and RP, RMQ, and SF-12 MCS and PCS as well as the use of drug treatment at each assessment.

Because the objectives of this study pertained to the cluster level, linear mixed models were used to deal with clustering effects and with repeated measurements from each participant during follow-up. Separate linear mixed models were used to assess the effects of the interventions on the 3 primary outcomes (LBP, RP, and disability) at 2, 6, and 12 months.^{42,43} For each variable, "effect" was defined as the differ-

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Table 1.
Predictive Values Obtained From the Regression Models^a

Outcome	Control Group Estimate (95% CI)	GDS-I Group Estimate (95% CI)	P ^b	GDS-G Group Estimate (95% CI)	P ^b
LBP ^c			.292		.273
2 mo	1.4 (0.8, 1.9)	1.7 (1.2, 2.2)		1.7 (1.2, 2.2)	
6 mo	1.4 (0.9, 2.0)	1.0 (0.5, 1.5)		1.6 (1.1, 2.1)	
12 mo	1.0 (0.5, 1.6)	1.0 (0.5, 1.5)		1.9 (1.4, 2.4)	
RP	2.6 (1.7, 3.5)	2.0 (1.1, 2.8)	.117	2.9 (2.0, 3.8)	.426
Disability	0.7 (-0.4, 1.8)	1.5 (0.4, 2.7)	.252	2.2 (1.2, 3.2)	.024

^a GDS-I group=participant group receiving group and individualized Godelieve Denys-Struyf method sessions, GDS-G group=participant group receiving group Godelieve Denys-Struyf method sessions, CI=confidence interval, LBP=low back pain, RP=only pain referred down the leg.

^b P values relate to the comparison between each group and the control group.

^c An interaction between treatment group and time was found in the regression model for LBP. Potential confounders included in the models were age, sex, pain duration, employment benefits, comorbidities, degree of physical activity, use of nonsteroidal anti-inflammatory drugs (NSAIDs), use of analgesics, and use of muscle relaxants. Variables that remained as confounders in the models were as follows: for LBP, sick leave, use of NSAIDs, and comorbidities; for RP, sick leave, use of NSAIDs, comorbidities, baseline severity of RP, sex, physical activity, and use of analgesics; and for disability, only comorbidities and physical activity.

ence between the score at baseline and the corresponding score at the assessment at each time point, with positive values reflecting improvement. Centered baseline scores were included as covariates in each model. Treatment group (education, GDS-G, and GDS-I), assessment (at 2, 6, and 12 months), and interactions between treatment group and assessment were introduced into the models as fixed effects. Because the cluster design increases the risk of baseline characteristics being unbalanced across treatment groups,⁴⁴ potential confounders were defined both clinically and by unbalance across groups at baseline (Tab. 1).

A nonautomatic backward elimination strategy was followed to remove variables that did not have confounding effects. Confounding was considered when the estimates of the coefficients of the study arms changed by more than 10% when a variable was removed from the model. Physical therapy units and participants were introduced as random effects. Estimated effects and 95% CIs were reported.

To estimate the numbers that would need to be treated for a single participant to benefit from GDS-G and GDS-I, we subtracted the scores for LBP, RP, and disability at baseline from the corresponding scores at the follow-up assessment at which losses to follow-up were the smallest.⁴⁵ Three categories were subsequently established⁴⁵: worsening (result from the subtraction, <0), no change (result, 0), and improvement (result, >0).

Models also were used to estimate intraclass correlation coefficients for each of the primary variables at the cluster level (ie, for participants treated within the same physical therapy unit) and at the participant level (ie, for measurements taken at different time points from the same participant).

The statistical software used was Stata version 12.0 (StataCorp LP, College Station, Texas).

Role of the Funding Source

This study was funded by the Kovacs Foundation, a not-for-profit institution specializing in neck and back

pain research and with no links to the health industry. The funding institution had no role in the design and conduct of the study; data collection; management, analysis, and interpretation of the data; preparation, review, and approval of the manuscript; or the decision to submit the article for publication.

Results

Inclusion and Randomization

Of the 572 people screened, 111 were excluded for having received physical therapy during the preceding 12 months (97 participants), having criteria for referral to nonurgent surgery (26) or fibromyalgia (18), being unable to understand written Spanish (9), having red flags for systemic disease (4), or refusing to sign the informed consent form (2). For 39 people, there was more than 1 reason.

The median age of the 461 participants was 47 years. Most were women (78%) with subacute (45.8%), moderate to severe LBP (median, 6 PI-NRS points) and mild disability (7 RMQ points), although 14 had an RMQ score of 0. Table 2 shows the baseline characteristics of the participants. Seven clusters each were assigned to the control, GDS-I, and GDS-G groups, with 120, 132, and 209 participants, respectively.

The main baseline differences across groups were related to the degree of physical activity, comorbidities, LBP-related sick leave, and use of NSAIDs, analgesics, and muscle relaxants (Tab. 2). Therefore, the variables included in the regression models were age, sex, pain duration (dummy variable categorized as acute [reference category], subacute, or chronic), employment benefits (dummy variable categorized as not on sick leave [reference category], on sick leave, or disabled), comorbidities (dummy variable categorized as none [reference cate-

Table 2.
Baseline Characteristics of the 461 Participants in the 21 Clusters^a

Variable	Control Group (n=120)	GDS-I Group (n=132)	GDS-G Group (n=209)
Cluster level			
No. of physical therapy units	7	7	7
Median cluster size (minimum–maximum)	17 (13–20)	19 (16–21)	21 (18–67)
No. of physical therapists	7	7	10
Individual level			
Sex, men	24 (20.3)	38 (28.8)	37 (17.8)
Age, y ^b	44 (36, 55)	48 (38, 55)	48 (40, 54)
BMI, kg/m ² . ^b	26.1 (23.1, 29.7)	25.6 (23.8, 28.7)	25.9 (23.4, 28.4)
Academic level			
Less than primary school	4 (3.3)	5 (3.9)	8 (4.1)
Primary school	42 (35.0)	38 (29.2)	69 (35.0)
Secondary school	55 (45.8)	50 (38.5)	78 (39.6)
University	19 (15.8)	37 (28.5)	42 (21.3)
Employment status			
Self-employed	10 (8.4)	10 (7.6)	31 (14.9)
Employed	70 (58.8)	79 (59.9)	102 (49.0)
Unemployed	13 (10.9)	16 (12.1)	28 (13.5)
Disabled	1 (0.8)	0 (0.0)	1 (0.5)
Retired	9 (7.6)	9 (6.8)	5 (2.4)
Student	2 (1.7)	1 (0.8)	7 (3.4)
Homemaker	14 (11.8)	17 (12.9)	34 (16.4)
Employment benefits			
Not on sick leave	63 (52.5)	63 (47.7)	128 (66.7)
On sick leave for LBP	16 (13.3)	18 (13.6)	37 (19.3)
On sick leave for other reasons	4 (3.3)	12 (9.1)	4 (2.1)
Disabled because of LBP	1 (0.8)	1 (0.8)	1 (0.5)
Disabled for other reasons	1 (0.8)	4 (3.0)	3 (1.6)
Not applicable ^c	35 (29.2)	34 (25.8)	19 (9.9)
Physical activity			
Sedentary	35 (29.2)	34 (25.8)	83 (39.7)
Minimally active	2 (1.7)	1 (0.8)	1 (0.5)
Moderately active	10 (8.3)	6 (4.5)	15 (7.2)
Active	18 (15.0)	24 (18.2)	38 (18.2)
Extremely active	55 (45.8)	67 (50.7)	72 (34.4)
No. of episodes in previous 2 y			
0	4 (3.5)	7 (5.4)	8 (3.9)
1	11 (9.7)	16 (12.4)	19 (9.1)
2	14 (12.4)	12 (9.3)	29 (13.9)
>2	84 (74.3)	94 (72.9)	152 (73.1)
Duration of pain			
Acute, <14 d	33 (27.5)	28 (21.2)	58 (27.8)
Subacute, 14–89 d	54 (45.0)	62 (47.0)	95 (45.4)
Chronic, ≥90 d	33 (27.5)	42 (31.8)	56 (26.8)

(Continued)

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Table 2.

Continued

Variable	Control Group (n=120)	GDS-I Group (n=132)	GDS-G Group (n=209)
Had received physical therapy in preceding 12 mo	46 (38.3)	61 (46.2)	114 (54.6)
Treatment for current episode			
Drug treatment			
NSAIDs	76 (63.3)	78 (59.1)	117 (56.0)
Analgesics	35 (29.2)	48 (36.4)	84 (40.2)
Muscle relaxants	18 (15.0)	28 (21.2)	59 (28.2)
Steroids	0 (0.0)	2 (1.5)	11 (5.3)
Antiepileptics	6 (5.0)	1 (0.8)	5 (2.4)
Psychoactive drugs	13 (10.8)	8 (6.1)	10 (4.8)
Other	2 (1.7)	9 (6.8)	10 (4.8)
Neuroreflexotherapy	0 (0.0)	2 (1.5)	0 (0.0)
Denervation	0 (0.0)	1 (0.8)	0 (0.0)
Psychological treatment	0 (0.0)	1 (0.8)	4 (1.9)
Spine surgery	0 (0.0)	4 (3.0)	6 (2.9)
Comorbidities			
Musculoskeletal conditions	14 (11.7)	37 (28.0)	76 (36.4)
Pain conditions, nonmusculoskeletal	9 (7.5)	4 (3.0)	10 (4.8)
Epilepsy	0 (0.0)	0 (0.0)	1 (0.5)
Other	55 (45.8)	42 (31.8)	82 (39.2)
Diagnostic procedures			
Radiography	90 (75.0)	83 (62.9)	144 (68.9)
Scanning	1 (0.8)	2 (1.5)	4 (1.9)
Magnetic resonance imaging	11 (9.2)	12 (9.1)	12 (5.7)
Electromyogram	0 (0.0)	0 (0.0)	1 (0.5)
Blood test	0 (0.0)	1 (0.8)	0 (0.0)
Other (eg, scintigraphy)	0 (0.0)	0 (0.0)	1 (0.5)
Severity of LBP, PI-NRSs ^d	5.7 (2.3)	5.4 (2.4)	5.4 (2.3)
Severity of RP, PI-NRSs ^{d,e}	5.5 (2.6)	5.4 (2.3)	5.1 (2.4)
Disability, RMQ ^d	7.5 (4.1)	7.0 (4.3)	7.4 (4.8)
Physical Component Summary of SF-12 ^d	42.1 (5.8)	43.1 (5.8)	42.1 (5.3)
Mental Component Summary of SF-12 ^d	33.6 (7.9)	33.8 (8.0)	33.7 (7.3)

^a Data are reported as number (percentage) unless otherwise indicated. GDS-I group=participant group receiving group and individualized Godelieve Denys-Struyf method sessions, GDS-G-group=participant group receiving group Godelieve Denys-Struyf method sessions, BMI=body mass index, LBP=low back pain, NSAIDs=nonsteroidal anti-inflammatory drugs, PI-NRSs=11-point pain intensity numeric rating scales, RP=pain referred down the leg, RMQ=24-item Roland-Morris Questionnaire, SF-12=12-Item Short-Form Health Survey.

^b Median (25th percentile, 75th percentile).

^c Student, homemaker, or unemployed.

^d Mean (standard deviation).

^e Baseline scores for RP were restricted to the 319 participants who had this type of pain (ie, baseline score of ≥ 1 PI-NRS point).

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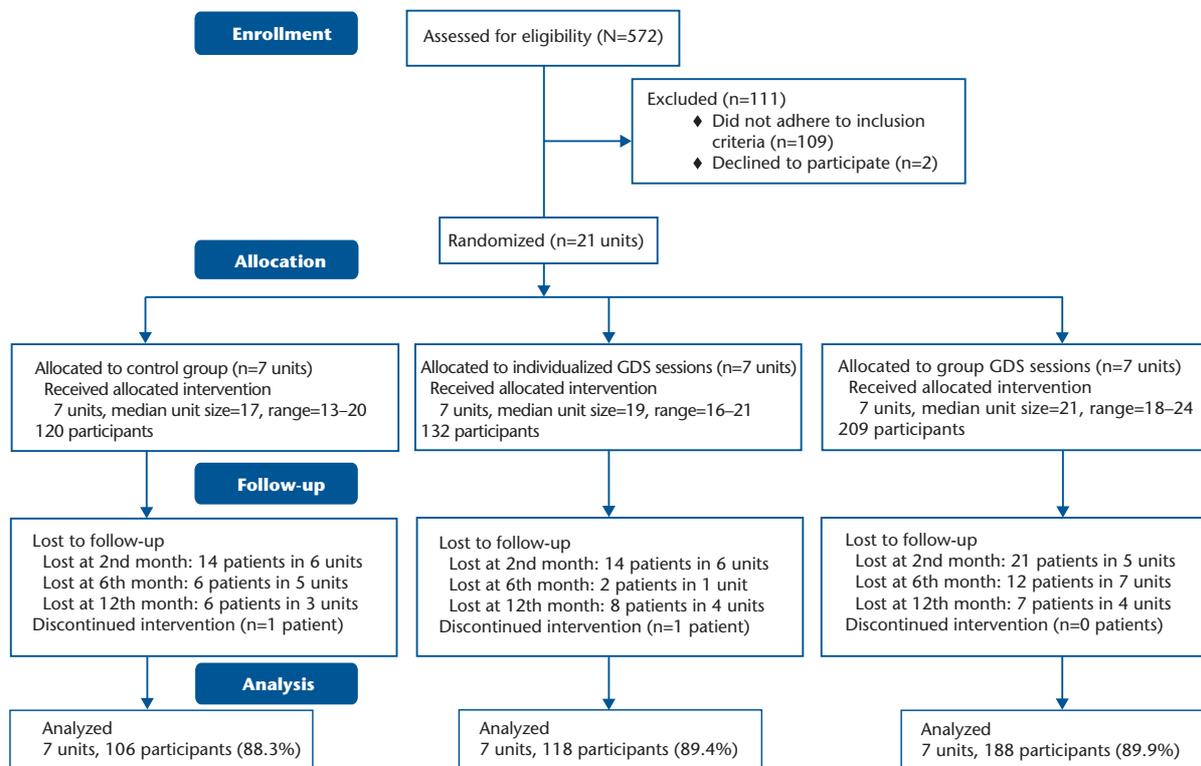


Figure 1.

Flow diagram of the study. All participants for whom data from the baseline assessment and at least one follow-up assessment were available were included in the analysis. The number of participants attending all of the follow-up assessments was 94 (78.3%) in the control group, 108 (81.8%) in the GDS-I group (participant group receiving group and individualized Godelieve Denys-Struyf method sessions), and 169 (80.1%) in the GDS-G group (participant group receiving group Godelieve Denys-Struyf method sessions).

gory], musculoskeletal comorbidities, or other comorbidities), degree of physical activity (dummy variable categorized as sedentary [reference category], minimally and moderately active, or active and extremely active), and use of NSAIDs, analgesics, and muscle relaxants.

Interventions and Clinical Course

No participant allocated to a given treatment group crossed over to a different one. The numbers of participants who did not attend at least one of the physical therapy sessions for the control, GDS-I, and GDS-G groups were 74, 23, and 26, respectively. In the control group, among the 1,800 possible session attendees (120 participants attending 15 ses-

sions), there were 174 absences (9.7%). The corresponding values for the GDS-I and GDS-G groups were 38 (1.9%) and 52 (2.3%).

During the 12-month follow-up period, 90 participants (19.5%) were lost to follow-up; 26 (21.7%), 24 (18.2%), and 40 (19.1%) were from the control, GDS-I, and GDS-G groups, respectively. Among these participants, 49 (10.6%) were lost to follow-up before the first follow-up assessment; 14 (11.7%), 14 (10.6%), and 21 (10.0%) were from the control, GDS-I, and GDS-G groups, respectively. Figure 1 shows the flow diagram of the study. According to the intention-to-treat principle, data from all participants were intro-

duced into the linear mixed models.⁴¹

Throughout the follow-up period, the clinical courses of LBP, RP, disability, the MCS score, and drug intake were similar across groups; an improvement in the PCS score was observed only in the GDS-G group (Tab. 3). An interaction between treatment group and time was detected only in the regression model for LBP, reflecting that the clinical course of LBP across time varied across groups (Fig. 2). However, differences across groups were minimal and not significant (Tab. 1).

The variables that remained as confounders in the models were as fol-

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Table 3.

Evolution of Outcomes Across Groups (Analysis at the Cluster Level)^a

Assessment	Control Group		GDS-I Group		GDS-G Group	
	n	\bar{X}^b (95% CI)	n	\bar{X}^b (95% CI)	n	\bar{X}^b (95% CI)
LBP score						
Baseline	120	5.5 (5.2, 5.7)	132	5.4 (4.7, 6.1)	209	5.4 (5.0, 5.8)
2 mo	105	4.6 (3.9, 5.2)	117	4.0 (3.6, 4.4)	188	4.2 (3.7, 4.6)
6 mo	100	4.4 (3.7, 5.2)	116	4.7 (4.1, 5.3)	176	4.3 (3.9, 4.6)
12 mo	94	4.7 (3.9, 5.5)	108	4.8 (3.9, 5.7)	169	4.0 (3.6, 4.3)
RP score ^c						
Baseline	85	5.2 (4.9, 5.6)	90	5.3 (4.9, 5.7)	144	5.0 (4.6, 5.3)
2 mo	72	3.6 (2.6, 4.5)	78	3.9 (3.2, 4.5)	125	3.0 (2.5, 3.4)
6 mo	67	3.2 (2.6, 3.9)	77	3.9 (3.1, 4.7)	110	3.0 (2.4, 3.6)
12 mo	61	3.2 (2.1, 4.3)	71	4.2 (3.0, 5.4)	114	2.8 (2.3, 3.3)
Disability score ^d						
Baseline	119	7.7 (6.4, 9.0)	132	6.9 (6.3, 7.6)	207	7.3 (6.5, 7.8)
2 mo	102	5.9 (4.6, 7.2)	117	4.7 (4.2, 5.2)	187	5.1 (4.1, 6.2)
6 mo	97	6.7 (4.7, 8.7)	115	5.3 (4.5, 6.2)	175	5.1 (4.1, 6.1)
12 mo	91	6.4 (4.6, 8.2)	107	5.8 (4.4, 7.1)	166	5.0 (4.0, 5.9)
PCS score						
Baseline	120	42.2 (41.0, 43.5)	130	43.0 (42.1, 43.9)	206	42.1 (41.0, 43.2)
2 mo	105	43.6 (41.4, 45.7)	116	43.3 (42.0, 44.6)	186	45.1 (44.1, 46.1)
6 mo	100	43.1 (41.8, 44.4)	116	43.2 (41.9, 44.4)	176	45.2 (43.9, 46.5)
12 mo	92	42.1 (40.3, 43.9)	106	42.8 (41.8, 43.9)	165	45.2 (44.5, 45.9)
MCS score						
Baseline	120	33.7 (32.1, 35.2)	130	34.0 (32.5, 35.5)	206	34.1 (32.8, 35.4)
2 mo	105	35.9 (34.4, 37.3)	116	37.7 (36.5, 39.0)	186	36.1 (34.6, 37.6)
6 mo	100	37.3 (36.3, 38.2)	116	37.2 (35.5, 39.0)	176	36.7 (35.2, 38.1)
12 mo	92	36.8 (35.2, 38.5)	106	36.8 (35.0, 38.6)	165	36.8 (34.9, 38.7)
Drug intake ^e						
NSAIDs						
Baseline	120	0.63 (0.52, 0.75)	132	0.59 (0.51, 0.67)	209	0.56 (0.47, 0.65)
2 mo	106	0.44 (0.34, 0.55)	118	0.32 (0.18, 0.46)	188	0.35 (0.29, 0.42)
6 mo	100	0.40 (0.29, 0.51)	116	0.33 (0.23, 0.44)	176	0.35 (0.31, 0.40)
12 mo	94	0.30 (0.25, 0.35)	108	0.32 (0.23, 0.41)	169	0.27 (0.15, 0.38)
Analgesics						
Baseline	120	0.29 (0.17, 0.41)	132	0.36 (0.26, 0.47)	209	0.40 (0.30, 0.50)
2 mo	106	0.17 (0.10, 0.23)	118	0.14 (0.05, 0.22)	188	0.20 (0.14, 0.25)
6 mo	100	0.16 (0.07, 0.25)	116	0.18 (0.10, 0.27)	176	0.22 (0.14, 0.29)
12 mo	94	0.18 (0.06, 0.31)	108	0.25 (0.06, 0.31)	169	0.18 (0.10, 0.25)
Muscle relaxants						
Baseline	120	0.15 (0.10, 0.20)	132	0.21 (0.12, 0.31)	209	0.28 (0.18, 0.38)
2 mo	106	0.05 (0.02, 0.12)	118	0.08 (0.03, 0.12)	188	0.07 (0.04, 0.10)
6 mo	100	0.07 (0.04, 0.09)	116	0.07 (0.04, 0.10)	176	0.08 (0.04, 0.12)
12 mo	94	0.09 (0.04, 0.14)	108	0.08 (0.04, 0.12)	169	0.09 (0.04, 0.14)

^a GDS-I group=participant group receiving group and individualized Godelieve Denys-Struyf method sessions, GDS-G group=participant group receiving only group Godelieve Denys-Struyf method sessions, CI=confidence interval (distribution of means across clusters), LBP=low back pain (severity on an 11-point pain intensity numeric rating scale [PI-NRS]), RP=pain referred down the leg (severity on a PI-NRS), PCS=Physical Component Summary of SF-12, MCS=Mental Component Summary of SF-12, NSAIDs=nonsteroidal anti-inflammatory drugs.

^b Mean across clusters.

^c Data on the evolution of RP were restricted to participants who showed it at baseline (ie, baseline score of ≥ 1 PI-NRS point).

^d As determined with the Roland-Morris Questionnaire.

^e Proportion of participants using each type of drug across clusters within each group.

lows: for LBP, sick leave, use of NSAIDs, and comorbidities; for RP, the same variables plus baseline severity of RP, sex, physical activity, and use of analgesics; and for disability, only comorbidities and physical activity.

The results from the models confirmed that the clinical courses of LBP and RP were similar across groups. The improvement in disability in the control group (0.7 RMQ point; 95% CI=-0.4, 1.8) also was similar ($P=.252$) to the improvement in the GDS-I group (1.5 RMQ points; 95% CI=0.4, 2.7). However, the improvement in disability in the GDS-G group (2.2 RMQ points; 95% CI=1.2, 3.2) was higher than that in the control group ($P=.024$) and remained so during the entire follow-up period (Tabs. 1 and 3).

There were no significant differences between the clinical course of LBP and disability in the GDS-I and GDS-G groups ($P=.968$ and $P=.297$, respectively), whereas the improvement in RP in the latter group was larger ($P=.010$).

On the basis of the results at 2 months, the numbers that would need to be treated for a single participant to benefit from GDS-G were 26 for LBP, 62 for RP, and 15 for disability. The corresponding values for GDS-I were 14, 444, and 11. No adverse events were reported by any participant in any group.

Intraclass correlation coefficients at the participant and cluster levels are shown in Table 4. As expected, there was a moderate correlation between repeated measurements for the same participant. However, there was virtually no correlation between different participants treated within each physical therapy unit ($1.09e^{-15}$ -0.07) (Tab. 4).

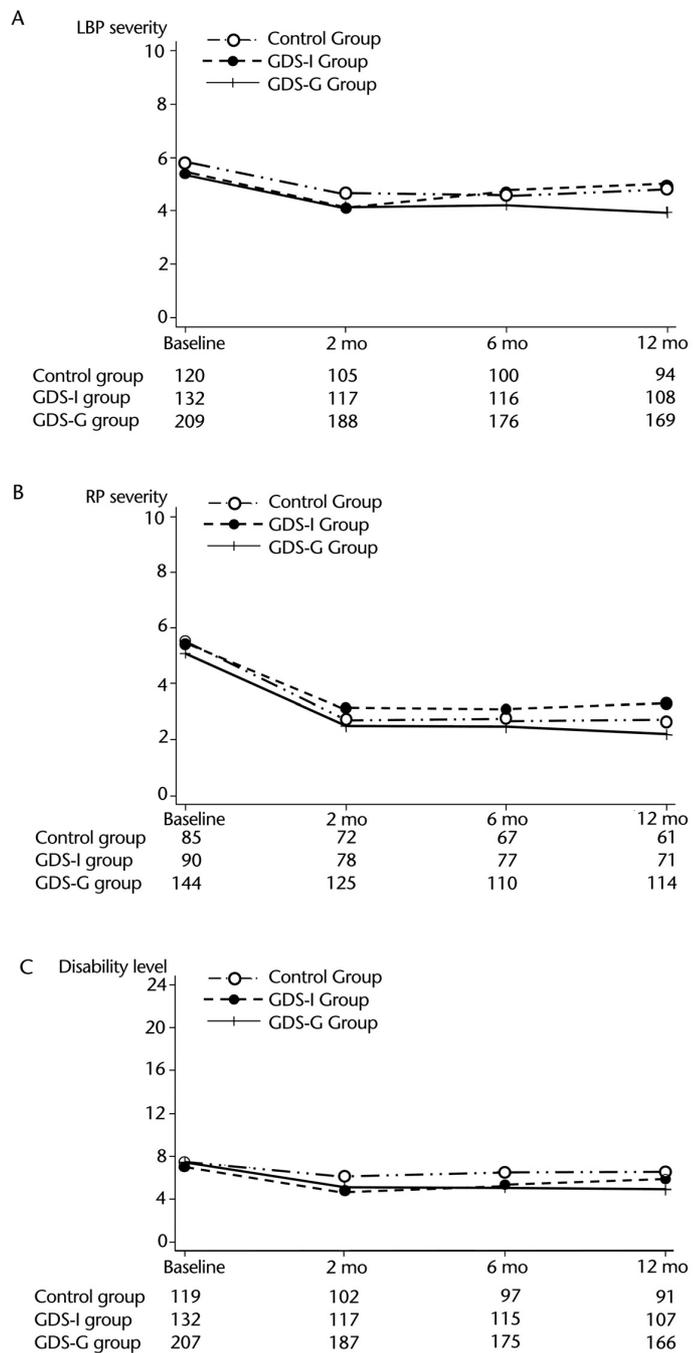


Figure 2. Clinical course of pain and disability across groups. (A) Variations in low back pain scores across groups (11-point pain intensity numeric rating scales) (mean and 95% confidence interval). (B) Variations in scores for referred pain across groups (11-point pain intensity numeric rating scales) (mean and 95% confidence interval). (C) Variations in scores for disability across groups (24-point Roland-Morris Questionnaire) (mean and 95% confidence interval). GDS-I group=participant group receiving group and individualized Godelieve Denys-Struyf method sessions, GDS-G group=participant group receiving group Godelieve Denys-Struyf method sessions.

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Table 4.

Intracluster Correlations Estimated by Regression Models^a

Outcome	ICC (95% CI)	
	Physical Therapy Unit	Participant
Low back pain	1.09e ⁻¹⁵ (1.09e ⁻¹⁵ , 1.09e ⁻¹⁵)	.44 (.37, .50)
Referred pain	.02 (.00, .17)	.31 (.23, .40)
Disability	.07 (.03, .17)	.43 (.36, .50)

^a ICC=intracluster correlation coefficient, CI=confidence interval.

Discussion

The results of the present study suggest that group sessions of the GDS improved disability (but not pain) slightly more than the physical therapy treatment routinely used within the SNHS, even when participants in both groups (GDS-G and control) were benefiting from an effective education program.¹⁹ The mean baseline disability score in participants in the present study was approximately 7 RMQ points (Tabs. 2 and 3), and the improvement in disability attributable to GDS-G was 2.2 RMQ points (95% CI=1.2, 3.2) (Tab. 1). The latter value reflects a small improvement; the cutoff value for clinical relevance is 30% of the baseline score, with a minimum value of 2.5 RMQ points.³⁷ However, this benefit lasted for up to 12 months (Tabs. 1 and 3)—a result that is uncommon among physical therapy treatments for LBP.^{21-27,46-49} In contrast to what was hypothesized, complementing GDS group sessions with individualized sessions provided by physical therapists specifically trained for 40 hours did not improve results; in fact, it eliminated the positive effect of the group sessions. These results suggest that the use of GDS-I should be discontinued, at least when provided by specialists with the training implemented in the present study.

In this cluster randomized trial, treatment allocation, participants' assessments, and statistical analyses were masked, and statistical methods

were used to adjust results for potential confounders. Physical therapy procedures involving more contact time between patients and therapists are usually associated with better results.^{19,50} However, in the present study, contact times in the control and GDS-G groups were similar. All of these factors contributed to the reliability of the results of the present study.

Moreover, the SNHS provides free health care to every resident in Spain, physical therapy practice is largely consistent across different areas, and experimental physical therapy protocols are standardized.¹⁶ Therefore, the generalizability of the results of the present study to the SNHS does not seem to be a major concern.

However, the present study has several limitations. Masking was not possible for the physical therapists providing the treatments. Nonetheless, this is the case in virtually all RCTs on supervised exercise,^{25,26,46-50} and the physical therapists providing GDS-G and GDS-I were not aware that another GDS treatment existed and was being assessed.

The intervention implemented in the control group included procedures for which evidence on effectiveness is lacking.^{21-24,51} This strategy reduced the amount of time available for exercise and may have worsened the results. However, the present study

focused on effectiveness, not efficacy, and the treatment implemented in the control group was the standard one applied within the SNHS.¹⁵⁻¹⁷ Moreover, the physical therapist is responsible for deciding the proportion of each session devoted to each form of treatment, and exercise is considered to be the main therapeutic component.^{25-27,46-49} It is recommended that exercise be progressively expanded across sessions, and at least the last 2 sessions are usually entirely dedicated to exercise.¹⁵⁻¹⁷ It would be safe to assume that, on average, at least 340 minutes (of 600) are devoted to exercise. Nevertheless, it may be argued that more time was spent on exercise in the GDS groups (eAppendix) and that this factor accounted for the results. The results of the present study do not allow any conclusions on the efficacy of the different types of exercise used in each group to be drawn.

The perception that the GDS is a new treatment may have triggered a more powerful placebo effect or greater adherence of participants, as suggested by the fact that the number of participants failing to attend the physical therapy sessions was larger in the control group. This fact should be kept in mind because, although assessors were unaware of the treatments and remained unaware of the physical therapy techniques being assessed, most variables were self-assessed by participants. However, the fact that the duration of the superiority of GDS-G over the control treatment with regard to disability was consistent at all assessments during the 12-month follow-up period (Tabs. 1 and 3) suggests that nonspecific effects were not likely to be the only explanation for the findings.

No differences across groups were found for pain-related variables (Tab. 1). This result cannot be attributed to a lack of statistical power

because the intracluster correlation for these variables was much lower ($<.02$) than anticipated at the design phase (.20). This result may have been due to the fact that the intracluster correlation was based on a previous study in which recruitment took place at the primary care physician level, as opposed to the physical therapy unit level, to which patients are referred from different physicians and primary care areas.¹⁹

In the present study, the proportion of men was only 22%, probably because of the higher prevalence among women of LBP, reporting of LBP, seeking care for LBP, and referral for physical therapy within the SNHS.^{1,29} However, linear mixed models showed that sex did not influence the results.

The physical therapy treatments in the present study did not include any psychological treatments. However, this practice is standard within the SNHS, and the psychological variables influencing the prognosis of patients with LBP specifically in the Spanish cultural setting have yet to be identified; to date, the influence of those that have been assessed has been shown to be clinically irrelevant or null.^{19,52-54}

The trial registration (NCT01060280) was updated to indicate that the present study did not assess cost-effectiveness, despite our initial intentions. Before recruitment started, it became evident that the bureaucratic requirements imposed by current Spanish regulations would make it impossible to gain access to data on work-related costs in the time frame allocated for the present study. Two additional minor differences with regard to what was described in the original protocol, on which the trial registration was based, are as follows: We had originally planned to recruit only people with subacute and chronic pain because they account for

most of the clinical, social, and economic burdens associated with LBP.⁶⁻⁸ Before launching the study, we decided to include people with acute pain because the underlying biological rationale might explain the effectiveness of GDS in their case as well and because recruiting them would make it possible for us to assess potential differences in effectiveness associated with pain duration (Tab. 1). Finally, the numbers that would need to be treated were presented in accordance with the recommendations of a reviewer and an editor, who suggested that this information would make it easier for clinicians to interpret the results of the present study.

Treatments considered to be complementary or alternative, such as acupuncture or homeopathy, were not registered as cointerventions in the present study. However, they are not used within the SNHS; patients willing to undergo these treatments should seek them in private care and pay for them out-of-pocket, which rarely happens; the use of treatments other than drugs by the participants was anecdotal (Tab. 2); and there is no reason to suspect a potential unbalanced use of alternative treatments across groups. Moreover, the available evidence shows that their effect—if any—is minimal for LBP and even smaller for disability.²⁰⁻²⁴

The results of the present study are generally consistent with those of previous studies on the effect of motor control exercise.^{47,49,50,55-57} However, they are in contrast to those of a previous RCT in which GDS-I led to significant improvements in pain in comparison with the physical therapy program routinely used within the SNHS (Tabs. 1 and 3).¹³ Three reasons may account for this discrepancy. First, the previous RCT compared GDS-I and routine physical therapy without education, but the education program implemented in the present study

has been shown to lead to significant improvements in pain^{19,20} that do not increase when physical therapy is added.¹⁹ These data may account for the fact that the differences found in the present study were not significant (Tabs. 1 and 3). Second, in the previous RCT, both individualized and group GDS sessions were provided; thus, the possibility that the results might have been better if only the latter had been used cannot be ruled out. Finally, in the previous RCT, the GDS was applied by highly trained experts, whereas in the present study, individualized sessions were provided by recently certified physical therapists after they had taken a 40-hour course. As is the case with other physical therapy methods in which an assessment process is used to establish subgroups of patients with LBP,⁵⁸⁻⁶² in GDS-I, classification determines the specific treatment to be applied. Practitioners of the GDS assume that the most shortened muscle chain in a given patient is the one that should be specifically treated and should be identified as the one that is most restrictive of the movement of antagonists when not opposed to gravity.^{11,14} The success of individualized GDS treatment depends on the accuracy of this identification. Given this rationale, insufficient training may lead to erroneous identification of the muscle chain responsible for pain, inappropriate treatment, and worsening of outcomes. In the present study, the results in the GDS-I group were worse than those in the GDS-G group, despite the fact that participants in the former had received the same group procedures and had more contact time with therapists, attention, and techniques.

Although the amounts of physical therapist time required for GDS-G and routine physical therapy were similar (550 versus 600 minutes), the participant groups in the former were larger (12 versus 5-7 mem-

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bers). These data suggest that GDS-G may have lower application costs and may prove to be more cost-effective than routine physical therapy. This idea should be explored in future studies. Future studies also should gather data on the learning curve for GDS-G and compare the data with those for other types of exercise and with those for GDS-I when the latter is provided by highly trained specialists.

In conclusion, the present study shows that, compared with the physical therapy program routinely used within the SNHS, group GDS sessions led to small improvements in disability and PCS scores but not in pain. Adding individualized GDS sessions eliminated this advantage of small improvements in disability and PCS scores. Studies confirming the effectiveness of group GDS sessions and assessing their cost-effectiveness are needed before generalization of this procedure in routine practice can be considered.

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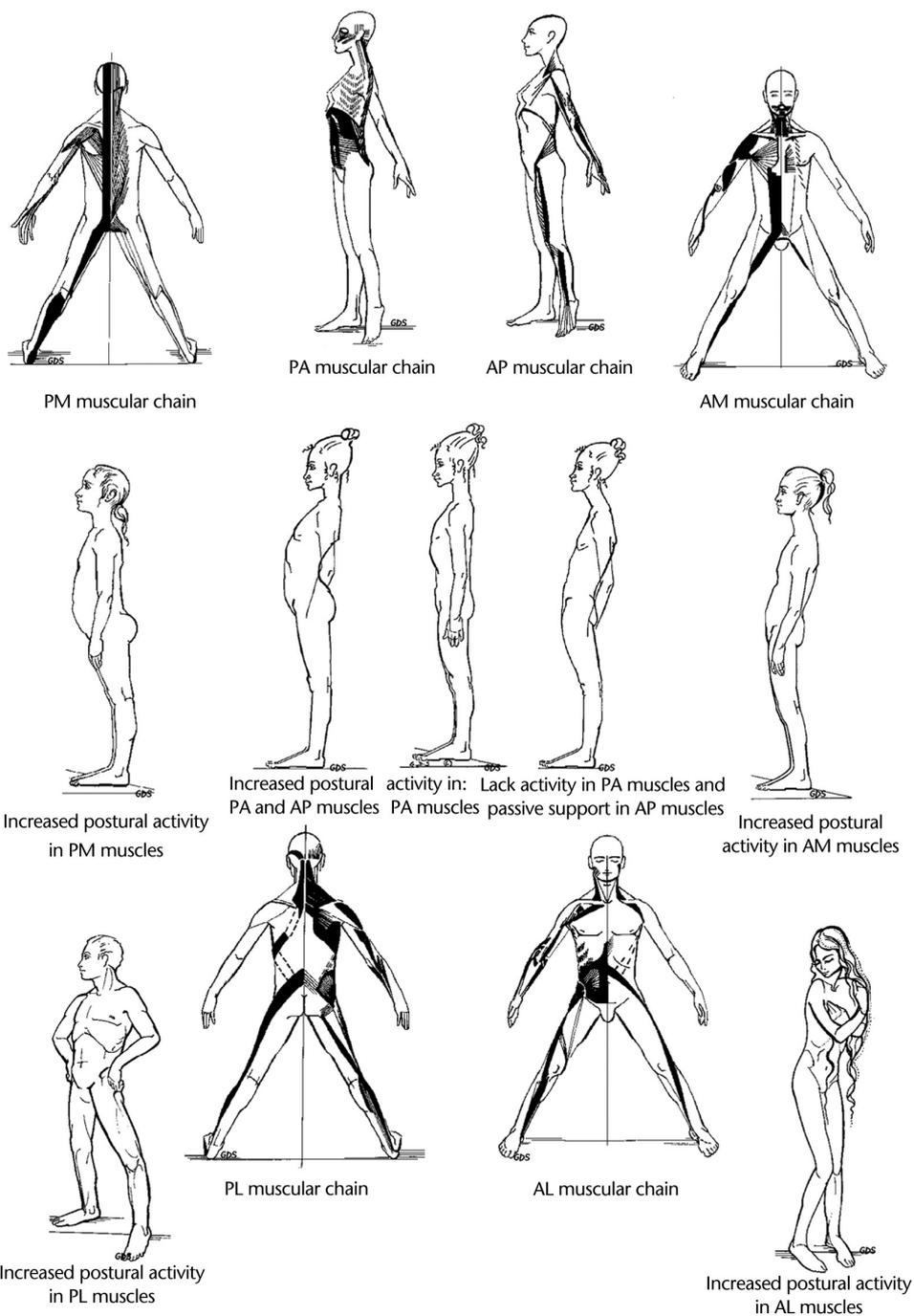
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Appendix 1.

Muscles Influencing Lumbar-Pelvic and Spinal Stability According to Their Anatomy and Role in Postures and Movements Using the Godelieve Dunys-Struyf Method^o



^o PM=postero-median, PA=postero-anterior, AM=antero-median, PL=postero-lateral, AL=antero-lateral.

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Appendix 2.

Content of the GDS-G and GDS-I Sessions^a

Session	Type	Content	Description
1	Group	Initial "cognitive" phase 1	(a) Palpation of the spine and hip joints (b) Increasing body consciousness to identify and correct bad postures and movements in daily activities
2	Group	Initial "cognitive" phase 2	Same as session 1, part b
3	Group	Postural and movement correction	Balancing tensions across muscle chains ^b by using body positions and movements to decrease/increase muscular activity in the low back and adjacent areas
4	Individualized	Postural and movement correction	Identifying tensions in all muscle chains and restoring balance ^c by using manual therapy techniques
5	Group	Functional activities	Balancing tensions along the most retracted muscles ^d of the back and lower limbs (ischial-tibial, gluteus maximus, and erector spinae muscles)
6	Group	Functional activities	Same as session 5, but focusing on the diaphragm and stabilizing the musculature of the spine (transversospinalis [multifidus] and transversus abdominis muscles)
7	Individualized	Postural and movement correction	Same as session 4, but targeted at balancing biomechanical tensions ^e generated by the "causal muscle chain(s)" and antagonist muscle chain reaction/inhibition
8	Group	Postural and movement correction	Same as session 3
9	Group	Functional activities	Same as session 5, but focusing on the rectus abdominis, piriformis, pelvic floor, and adductor muscles
10	Group	Functional activities	Same as session 5
11	Group	Functional activities	Same as session 6
12	Individualized	Postural and movement correction	Same as session 7
13	Individualized	Postural and movement correction	Same as session 4
14	Group	Postural and movement correction	Same as sessions 3 and 8
15	Group	Home exercises	Participants are taught simple movements and exercises to be performed daily; activities and movements learned in previous sessions are reviewed

^a Participants in both the GDS-G and the GDS-I groups received the group sessions. Only participants in the GDS-I group received the individualized sessions.

^b Muscle chain=group of muscles that act in coordination during body postures and movements.

^c Restoring balance=restoring the balance in tension across muscles and muscle chains.

^d Retracted muscles=muscles with increased tone or tension that alters body postures and limits range of motion.

^e Balancing biomechanical tensions=restoring the (increased or decreased) muscle tone to support normal body posture.