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Bibliographic Data	
Authors	Robert T. Kell, Alaina D. Risi, and John M. Barden
Title	The response of persons with chronic nonspecific low back pain to three different volumes of periodized musculoskeletal rehabilitation
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Other information if relevant	No trial registration

Methods	
Aim of study	To determine which of 3 different periodized musculoskeletal rehabilitation (PMR) training volumes 1) 4 days a week 1,563 reps per week (4D), 2) 3 days a week 1,344 reps per week (3D), or 3) 2 days a week, 564 reps per week (2D) is most effective at improving strength and quality of life (QoL) and reducing pain and disability in untrained persons with chronic low back pain (LBP).
Design	Randomized clinical trial

Participants	
Population from which participants are drawn	The subjects (n = 240) recruited throughout the province of Alberta via word of mouth and advertisement were invited to participate.
Setting (location and type of facility)	Patient's choice of any local fitness facility or club in Alberta, Canada
Age	adults 18 to 50 years of age, mean age 42.5 years
Sex	Age and sex matched by group, 156 men and 83 women, total 240 at baseline
Total number of participants for whom outcome data were reported	At the primary endpoint of 6 months, 207 were analyzed
Inclusion criteria	Inclusion criteria were men and women between the ages of 18 and 50 years with a diagnosis of chronic (≥ 3 months, ≥3 days per week) nonspecific (soft tissue in origin) low back (lumbar 1–5) pain (visual analogue scale [VAS] ≥3) by a physician.
Exclusion criteria	Diagnoses of pain below the knee, spinal stenosis, herniated or ruptured disc(s), spondylolisthesis, infection in the lumbosacral area, tumor(s), scoliosis, rheumatologic disorder, osteoporosis, or previous back surgery, current use of any prescriptive or nonprescriptive pain medication, a medical history of metabolic, endocrine, cardiovascular, or neurological disease. Subjects were also excluded if they had a history of formularized resistance training experience.
Other information if relevant	There were no significant differences between groups in participants' baseline clinical characteristics, or outcome measure scores. Mean duration of back pain was 37.2 months (range 14–109 months).

Intervention Groups

Groups 1, 2 and 3	
Group name	3 different periodized musculoskeletal rehabilitation (PMR) groups only differentiated by training volumes. 1) 4 days a week 1,563 reps per week (4D) 2) 3 days a week 1,344 reps per week (3D) 3) 2 days a week, 564 reps per week (2D)
Number in group	60 in each group at baseline
Description of intervention	The intervention began with an initial 3 week familiarization period that was used to acquaint the subjects with the (a) repetition maximum protocol, (b) exercise movements (e.g., neuromuscular control), and (c) exercise order and more generally with the surroundings of their selected fitness facility. The following 13 weeks focused on the PMR program of weight training. The goal of the PMR program was to systematically and progressively overload each muscle group to maximize strength gains in a safe manner. A traditional periodized training program was used, with variation in the volume (number of reps per week) between groups, but exercise selection, general exercise order, intensity, and rest time were held consistent among the 3 groups. 13 exercises were completed each day of training. 1. Leg press 2. Leg extension 3. Leg curl 4. Bench press 5. Incline bench press 6. Lat pull 7. Low cable row 8. DB shoulder press 9. Arm curl 10. Triceps pushdown 11. Ab crunches 12. Swiss ball crunch 13. Prone superman
Duration of treatment period	3 weeks familiarization + 13 weeks PMR = 16 weeks total
Co-interventions if reported	
Additional information if relevant	Baseline testing and assessments followed the familiarization training and set the loads for each resistance exercise for the next 3 weeks. Testing occurred every fourth week throughout the study.

Group 4	
Group name	Control group (C)
Number in group	60 at baseline
Description of intervention	The controls also began with an initial 3 week familiarization period, but they stopped all resistance exercise training after this period. They were able to seek any necessary medical, physical therapy, and/or chiropractic treatment during the course of the study, but were precluded from beginning any formalized exercise (i.e., weight training) regimen.

Duration of treatment period	3 weeks familiarization + 13 weeks with no training = 16 weeks total
Co-interventions if reported	
Additional information if relevant	After completion of the study, the control subjects were offered a 12 week PMR program of their choice, either 2, 3, or 4 days per week.

Primary outcome	
Outcome name and criteria for definition	The primary outcome measures were strength, pain, disability, and QoL. The 3 tests used to monitor strength changes were (a) bench press, (b) leg press, and (c) lat pull-down measured in kilograms. Pain was measured on a 10 point VAS scale. Functional disability was measured on the Oswestry Disability Index (ODI). QoL was measured using the Short Form-36 Health Survey (SF-36).
Time points measured and/or reported	Baseline (before randomization), after 9 weeks of PMR and at the end of the 12 week PMR program at week 13.
Differences between groups	1) At baseline, there were no significant ($P \leq 0.05$) differences between the 4 groups on any of the musculoskeletal strength tests. All groups except the C group demonstrated significant ($P \leq 0.05$) increases in strength (bench press, lat pull-down, and leg press) from baseline to week 13. The effect sizes (Hedges' g) at weeks 9 and 13 were strong (ES = 1.02–2.81) in all 3 PMR groups. At both weeks 9 and 13, the 4D group was significantly ($P \leq 0.05$) stronger than all other groups, whereas the C group was significantly ($P \leq 0.05$) weaker than both the 3D and 2D groups on all strength tests over the same period. 2) At baseline, there were no significant ($P \leq 0.05$) differences between any of the groups on pain, disability, and QoL. The 3 PMR groups all demonstrated significant ($P \leq 0.05$) improvements from baseline to week 9 and from baseline to week 13 in pain, disability, and QoL. Effect sizes ranged in size from moderate to strong (ES = 0.45-1.83). The ODI scores at 9 and 13 weeks for all 3 PMR groups showed clinically important improvements. However, only the VAS score at 13 weeks for the 4D group showed a clinically important improvement (1.7 points). By week 13, the 4D showed significantly ($P \leq 0.05$) less pain and disability and improvements in the QoL as compared with all other groups. At weeks 9 and 13, the 2D and 3D groups showed significant ($P \leq 0.05$) improvements in QoL and reductions in pain and disability as compared with the C group.
Additional information if relevant	

Secondary outcomes	none

Conclusions	
Key Conclusions Of Study Authors	- This study showed that unsupervised (PMR) periodized resistance training) can be an effective musculoskeletal rehabilitation for chronic LBP and that the volume (total number of reps) of PMR exercise prescribed is important. The greater the training volume, the greater the improvement in strength, pain, disability, and QoL in those with chronic LBP. - The overall impact of the PMR weight programming was positive, improving strength and QoL, while reducing pain and disability in all training groups. The 4D PMR volume (mean of 1,563 reps per week) demonstrated the best results as compared with the 2D (mean of 564 reps per week) or 3D volumes (1,344 reps per week). - All the PMR training volumes demonstrated significant improvements in pain, disability, and QoL in those with chronic LBP over the course of 13 weeks with the 4 days a week training volume being most effective. The improvements in pain, disability, and QoL generated via the PMR were associated with moderate to large effect sizes (Hedges' g). - The findings showed that an increase in strength after whole-body PMR was associated with improved function. - This study demonstrated a substantial reduction in disability in the 3 PMR groups as determined with the ODI, thereby, improving the ability of the subjects to more easily perform their activities of daily living regardless of volume. - These findings support the use of a substantial training volume (500–1,500 reps per week) and intensity in the rehabilitation of those with chronic LBP, a volume and intensity likely comparable to that prescribed for healthy persons. The strength gains made by the 3D and 4D training groups in the present study were in most cases equal to or exceeded the strength gains made in non-CLBP populations using this training methodology. Rehabilitation specialists should not hesitate to prescribe a gradual increase in training volume eventually reaching volumes similar to those associated with healthy persons. - The present PMR rehabilitation is not only economical but also effective. - No negative effects were reported by the subjects.

Risk of bias assessment		
Domain	Risk of bias Low High Unclear	Comments
Random sequence generation *(selection bias)*	Unclear	Subjects were age and sex matched, with attempts made to match on strength and pain, and randomly assigned to one of 4 groups after baseline testing. Authors did not describe who performed the matching or how subjects were matched.
Allocation concealment *(selection bias)*	High	No mention was made of who had access to the randomization schedule or who produced it. It is not known if allocation was concealed from the trial coordinator or study outcome assessors.
Blinding of participants and personnel *(performance bias)*	High	Because of the nature of the interventions, it was not possible to blind participants. The lack of blinding does not prejudice the conclusions.
Blinding of outcome assessment *(detection bias)*	High	The authors did not describe the outcome assessors who administered all the questionnaires and performed all outcome measures at baseline and follow-ups, and so it is unknown if they were blinded to group allocation.
Incomplete outcome data *(attrition bias)*	Unclear	Thirty-three subjects dropped out of the study before completion. Authors did not detail the attrition rate per group. All participants lost to follow-up were not included in the results.
Selective outcome reporting? *(reporting bias)*	Low	The trial was not registered.
Other bias		Intention to treat analysis was not used.

Sponsorship if reported		
Study funding sources if reported	Research reported in this article was supported by the University of Alberta, Augustana Campus Research and Travel grant.	
Possible conflicts of interest for study authors	None declared	
Notes: Dr. Donald Sharpe assisted with the statistical analyses, but was not added as an author on the article.		

Comments by DOWC staff

- All 3 training volumes made significant ($P \leq 0.05$) improvements in strength, pain, disability, and QoL across time with the 4 days a week training volume consistently demonstrating the largest effect sizes for treating patients with chronic LBP.

- All the ODI scores at 9 and 13 weeks for all 3 PMR groups showed clinically important improvements in functional disability. However, only the VAS score at 13 weeks for the 4D group showed a clinically important improvement of 1.7 points.

- The improvement in strength among the participants is rather astounding. After 13 weeks of training the 4D group could bench press 25 kilograms (kg) more, the 3D group 17 kg more and the 2D group 13 kg more. After 13 weeks of training the 4D group could leg press 103 kilograms (kg) more, the 3D group 65 kg more, and the 2D group 45 kg more. Strength in the control group remained virtually unchanged. Participants' accomplishments after the 13-week program, suggests that this intervention achieved its objective of strengthening the participants.

- Several biases were potentially present in this study. The randomization and allocation concealment processes were inadequately described and could result in selection bias. It is unknown if the outcome assessors were blinded to group allocation which could result in detection bias.

- Subject compliance for the 47% of the participants that returned the exercise compliance questionnaires was 84%. Even with unclear compliance, participants still made significant improvements in all outcome measures. Inclusion of information on compliance rates by group would have been helpful in identifying any group imbalances.

- The participant drop-out rate was about 14% demonstrating its acceptability to the majority of participants. Inclusion of information on adherence rates by group would have been helpful in identifying any group imbalances.

- Study strengths included a large sample size with adequate statistical power to detect clinically meaningful effects, and generalizability to the general population.

- The main limitations were lack of blinding of assessors and patients, no long-term follow-up beyond the end of the training period, no trial registration, lack of designation of only 1 or 2 primary outcomes, and lack of information on sociodemographic characteristics of the participants.

- The authors failed to provide a flow diagram of study participation by group. No information was provided on number of drop-outs by group, number analyzed per group, or compliance rates by group.

- The authors attempted to minimize the influence of confounding variables by only varying the volume between groups and keeping exercise order, intensity, and the rest of the PMR regimen consistent among the 3 groups. However, this failed, since the 4 D group used a split routine that trained chest, back, and core on Monday and Thursday and legs, shoulders, and core on Tuesdays and Fridays. The 2D and 3D groups performed each PMR exercise on every training day. As a result of the 4Dsplit routine, the exercise order could not be identical between all groups, but was identical for the 2D and 3D groups. The 4D split routine could have confounded the outcomes for this group.

- Weight lifting is a suitable form of physical activity for the majority of the population, including individuals with LBP, being easy to do, and having little risk of injury.

Assessment by DOWC staff	
Overall assessment as suitability of evidence for the guideline ☐ High quality ☒ Adequate ☐ Inadequate	This adequate quality study provides some evidence that an unsupervised 12-week, periodized musculoskeletal rehabilitation program of weight training conducted 2, 3, or 4 days a week is effective at improving musculoskeletal strength and quality of life (QoL), and reducing pain and disability in untrained persons with chronic low back pain with the 4 days a week training volume being most effective. The volume (total number of reps) of PMR exercise prescribed is important.
If inadequate, main reasons for recommending that the article not be cited as evidence	

Additional references if relevant
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