Self-dosed and pre-determined progressive heavy-slow resistance training have similar effects in people with plantar fasciopathy: a randomised trial

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**Abstract**

**Question:** For people with plantar fasciopathy, is a 12-week self-dosed heavy-slow resistance training program more beneficial than a 12-week pre-determined heavy-slow resistance training program?

**Design:** A randomised trial with concealed allocation, partial blinding, and intention-to-treat analysis.

**Participants:** Seventy people with plantar fasciopathy confirmed on ultrasonography.

**Intervention:** Both groups performed a repeated heel raise exercise in standing for 12 weeks. Participants in the experimental group were self-dosed (ie, they performed as many sets as possible with as heavy a load as possible, but no heavier than 8 repetition maximum). The exercise regimen for the control group was pre-determined (ie, it followed a standardised progressive protocol).

**Outcome measures:** The primary outcome was the Foot Health Status Questionnaire pain domain. Secondary outcomes included: a 7-point Likert scale of Global Rating of Change dichotomised to ‘improved’ or ‘not improved’; Patient Acceptable Symptom State defined as when participants felt no further need for treatment; and number of training sessions performed.

**Results:** There was no significant between-group difference in the improvement of Foot Health Status Questionnaire pain after 12 weeks (adjusted MD – 6.9 points, 95% CI – 15.5 to 1.7). According to the Global Rating of Change, 24 of 33 in the experimental group and 20 of 32 in the control group were improved (RR = 1.16, 95% CI 0.83 to 1.64). Only four participants achieved Patient Acceptable Symptom State: three of 35 in the experimental group and one of 35 in the control group. No significant between-group difference was found in the number of training sessions that were performed (MD – 2 sessions, 95% CI – 8 to 3).

**Conclusion:** Self-dosed and pre-determined heavy-slow resistance exercise programs are associated with similar effects on plantar fasciopathy pain and other outcomes over 12 weeks. Advising people with plantar fasciopathy to self-dose their slow-heavy resistance training regimen did not substantially increase the achieved dose compared with a pre-determined regimen. These regimens are not sufficient to achieve acceptable symptom state in the majority of people with plantar fasciopathy.


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证据发现，重力慢速阻力训练在伸展跟腱病方面优于传统训练方法，虽然该训练的强度比其他腱病的训练强度低。15,17,19

增加训练强度可以提高治疗效果。23 一种方法是提高训练的自由度，以提高患者的自我效能。24,25 另一种方法是，在患者能够完成自己的康复计划和训练计划的情况下，提高训练强度，从而提高自我效能。

因此，研究问题为：对于跟腱病患者，12周自我选择的重力慢速阻力训练计划是否优于12周预定义的重力慢速阻力训练计划？

**方法**

**研究设计**

一项随机试验被设计，以隐藏分配，以减少治疗的偏倚。该试验计划在12周内进行，12周内患者每日进行3.5次训练，每次训练间隔2分钟。康复之间的休息时间为48小时。

**随机化**

参与者随机分为实验组和对照组。研究者使用随机数字生成器和www.sealedenvelope.com网站生成了分配序列，分配比例为1:1，分为两组。所有研究者都不知道分配比例，分配后，研究者安排了随机化。

**参与者，研究者，中心**

研究参加者是通过Facebook广告或通过从他们的全科医生转介的人。电话筛选后，符合筛选标准的人被邀请到研究单位进行临床检查。主要研究者是具有6年临床经验的注册物理治疗师，负责研究的实施、训练的指导和数据收集。

**结果**

在研究结束时，参与者的症状和功能得到了改善。18,19,22

**讨论**

重力慢速阻力训练在跟腱病的治疗中显示出明显的效果。18,19,22

**结论**

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PREPARE Trial guide.30 把第一参与者的试验结果写在了clinicaltrials.gov，但试验的协议并没有公开。

**参与者，研究者，中心**

跟腱病患者被通过Facebook广告或通过他们的全科医生转介招募。电话筛选后，符合筛选标准的人被邀请到研究单位进行临床检查。主要研究者是具有6年临床经验的注册物理治疗师，负责研究的实施、训练的指导和数据收集。研究者在前6个月内没有实施任何与研究相关的治疗。研究者在对有肌骨骼疾病、妊娠、以前的脚跟手术或治疗有关的抗炎注射的患者进行筛选时也进行了筛选。18

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investigator opened a sequentially numbered, opaque, sealed envelope in which the participant’s group allocation was found.

**Interventions**

Both groups received standardised patient education, a silicone heel cup, and performed either a self-dosed or a pre-determined non-supervised exercise program. Participants were told that the trial was about exercise for treating plantar fasciopathy and that there would be two groups that performed exercises in different ways. They were blinded to which of the outcomes was the primary outcome and to the differences between the heavy-slow resistance training programs.

Both groups were informed about plantar fasciopathy in terms of risk factors, aetiology, pathology, and were informed that heavy-slow resistance training was superior to stretching in plantar fasciopathy. Participants in the pre-determined group were informed that it was important to follow the program as closely as possible, whereas participants in the self-dosed group were told that (based on research on other tendinopathies) it was believed that performing the exercise as heavily as possible, but no heavier than 8 repetition maximum (RM), and with as many sets as possible would increase the likelihood of recovery. Both groups were told that compliance with their program was very important and associated with recovery. Participants were told that pain during exercise was not associated with tissue damage and that there was no upper limit of pain during exercise, as long as it was tolerable. The aim of this was to reduce any potential fear of exercise-related pain. Participants were advised to decrease their physical activity level and slowly rebuild it depending on their symptoms. They were also advised that it was acceptable to participate in physical activities that did not exacerbate symptoms that outlasted the activity. If participants already used a foot orthosis, they were allowed to continue wearing this if they remained in the Heavy-slow resistance training regimen as randomly allocated. All participants were included.

**Outcome measures**

The primary outcome was change in the Foot Health Status Questionnaire (FHSQ) pain domain from Week 0 to Week 12. The FHSQ is a self-report questionnaire ranging from 0 (poor foot health) to 100 (optimum foot health) that assesses multiple dimensions of foot health and function across four domains with a total of 13 items and has a high reliability (ICC = 0.74 to 0.92).13 Responses were entered into the FHSQ software, which calculated scores for each domain. A validated Danish translation of the FHSQ was used.15

Secondary outcomes included: the function, footwear and general foot health domains of the FHSQ; Global Rating of Change: plantar fascia thickness measured in millimetres; exercise compliance; Pain Self-Efficacy Questionnaire; Patient Acceptable Symptom State; and physical activity level measured by the International Physical Activity Questionnaire short version. All questionnaires were completed at Weeks 0, 4 and 12. The Global Rating of Change was collected at Week 12 and was used to measure participants’ self-reported improvement on a 7-point Likert scale ranging from ‘much improved’ to ‘much worse’. Participants were categorised as improved if they rated themselves as ‘much improved’ or ‘improved’ (categories 6 or 7) and categorised as not improved if they rated themselves from ‘slightly improved’ to ‘much worse’ (categories 1 to 5). Planter fascia thickness was measured using ultrasonography at Weeks 0, 4 and 12. The participant lay prone with the toes maximally dorsiflexed on the examination table and a longitudinal scan was performed. An average of three measurements was used. This method has been found to be reliable in a previous study (ICC = 0.67 to 0.77).13 Compliance was estimated based on the number of training sessions performed throughout the intervention, according to a training diary that participants were given at baseline. Patient Acceptable Symptom State was defined as when participants achieved a self-evaluated satisfactory result and felt that no further treatment was needed; hence, it was not necessarily a measure of complete recovery.16–18 The Pain Self-Efficacy Questionnaire was used to measure change in self-efficacy; it ranges from 0 to 60, with lower scores indicating lower self-efficacy.39 A reliable Danish validated translation of the questionnaire was used (ICC = 0.89).40 The International Physical Activity Questionnaire short version was used to estimate time spent performing vigorous and moderate activities, and time spent walking during the past week measured in metabolic equivalent of task (MET)-minutes.41,42

**Data analysis**

Sample size was based on the ability to detect a minimum clinically important between-group difference at the 12-week follow-up of 14.1 points in FHSQ pain.36 Based on a standard deviation of 20 points (comparable with standard deviations found in previous studies of this population),31,44,45 a two-sided 5% significance level and a power of 80%, a sample size of 33 participants in each group was required. Taking into consideration that drop-outs may occur, 70 participants were included.

Statistical analyses were performed according to a pre-established analysis plan in consultation with a statistician and using commercial software.6 Q-Q plots were used to assess data distribution. The primary intention-to-treat analysis tested between-group difference in FHSQ pain at the 12-week follow-up using a repeated measures ANCOVA with the outcome as the dependent variable, time (4 weeks and 12 weeks) as the within-subjects factor, group allocation as the between-subjects factor, and the baseline value as the covariate.6 The same model was used to perform between-group comparisons of the other FHSQ domains, Pain Self-Efficacy Questionnaire, and plantar fascia thickness, with the respective outcome as the dependent variable. Due to the distribution of the data, the between-group difference in the International Physical Activity Questionnaire short version was investigated using Mann-Whitney U test. The between-group difference in the number of training sessions performed was tested using independent t-tests. The relative risk (RR) was calculated for the dichotomised Global Rating of Change and the dichotomised Patient Acceptable Symptom State. Associations between Pain Self-Efficacy Questionnaire score and compliance, FHSQ pain score and plantar fascia thickness, and the association between compliance and FHSQ pain score were investigated using Pearson’s correlation coefficient. In an intention-to-treat analysis, multiple imputation was used to handle missing outcome data and estimates from 10 imputed data sets were combined using Rubin’s Rules.6 A complete case analysis only including cases with no missing outcome data was performed as a sensitivity analysis.

**Results**

**Compliance with the study protocol**

All participants received the intervention (ie, prescription of their heavy-slow resistance training regimen) as randomly allocated. All
registered outcomes were measured. However, 20 of 70 training diaries could not be retrieved.

Flow of participants through the study

A total of 91 individuals were interested in participation (Figure 1). Seventy participants were enrolled from October 2017 to February 2018, and the last 12-week follow-up was conducted in May 2018. Clinical and demographic baseline characteristics of the two groups were similar (Table 2). Fourteen participants (23% of those participants who had previously been in the workforce) reported that they had taken between one and 200 days off work due to plantar fasciopathy (median 30 days). Participants had consulted their general practitioner in 48 cases (69%) and 28 participants (40%) had consulted a physiotherapist. Foot orthoses were the most common treatment that participants had tried before enrolment (37 participants, 53%), with strengthening exercises including heel raises being the second most common treatment (36 participants, 51%). A full table of treatments and healthcare practitioners consulted is in Appendix 1 on the eAddenda.

Primary outcome

There was no significant between-group difference in the improvement of FHSQ pain after 12 weeks (adjusted MD −7 points, 95% CI −16 to 2), as presented in Table 3 and Figure 2. The upper limit of the confidence interval (ie, the estimate that most favours self-
directed dosing but remains consistent with the data collected) was 2, which was below the minimum clinically important difference in the prospective sample size calculation.

**Secondary outcomes**

Almost all between-group differences were non-significant at either assessment time point for the other three domains of the FHSQ (ie, function, footwear, and general foot health), as presented in Table 3. One result did reach statistical significance (footwear domain at Week 12). This result favoured the control group (adjusted MD -6 points). The confidence interval retained effects that were very close to no effect (0.2, rounded to 0 in Table 3). Again, none of the confidence intervals contained an effect that exceeded the same clinically worthwhile threshold in favour of the experimental group. Most of the non-parametric comparisons showed statistically non-significant median differences between the groups (Table 4).

Data for the four measures derived from the International Physical Activity Questionnaire short version (ie, walking, moderate activity, vigorous activity and total activity) were not normally distributed, with most participants achieving low activity and a few achieving high activity. Most of the non-parametric comparisons showed statistically non-significant median differences between the groups (Table 4). The result for walking at Week 4 was significantly different in favour of the control group, with an unadjusted difference in medians of 759 MET (p = 0.013). However, the difference was no longer statistically significant at Week 12. Individual participant data used in the analyses in Tables 3 and 4, as well as for all the remaining experimental groups and control groups were categorised as ‘improved’. This was a non-significant difference between the groups, with a relative risk of 1.16 (95% CI 0.83 to 1.64).

Four participants improved enough to meet the Patient Acceptable Symptom State definition: three of 35 in the experimental group and one of 35 in the control group. Although the relative risk indicated that the experimental group were 3.0 times more likely to achieve Patient Acceptable Symptom State, this was not statistically significant (95% CI 0.33 to 27).

The self-dosed group completed 36 training sessions (SD 8) and the pre-determined group completed 34 training sessions (SD 12), with a mean difference of -2 sessions (95% CI –8 to 3). The lowest number of training sessions performed was three and the second lowest was 13. Both participants were randomised to the pre-determined group. The self-dosed group performed an average of 5.0 sets per training session (SD 2.8) whereas 4.5 sets per training session were prescribed in the pre-determined program.

There was no significant association observed between: baseline Pain Self-Efficacy Questionnaire and number of training sessions performed (r = -0.030, p = 0.837); change in FHSQ pain and change in plantar fascia thickness (r = -0.234, p = 0.084); or change in FHSQ pain and number of training sessions performed (r = -0.082, p = 0.570).

Four participants reported adverse events, but none related to performing the exercise. All were non-serious musculoskeletal injuries of the lower extremities.

**Complete case sensitivity analysis**

The sensitivity analysis, which included only cases with no missing 12-week FHSQ pain data, had similar results as the primary analysis (MD –7 points, 95% CI –16 to 3). The multiply imputed analysis and the complete case analysis found conflicting results in two analyses. A significant between-group difference in FHSQ footwear at Week 12 was found to be non-significant in the complete case analysis (p = 0.037). A non-significant between-group difference in the Pain Self-Efficacy Questionnaire at Week 4 was found to be significant (p = 0.039); however, the difference was less than the minimum clinically important change.48

**Discussion**

This was the first trial comparing the efficacy between a self-dosed and a pre-determined heavy-slow resistance training program. A 12-week self-dosed heavy-slow resistance training program did not reduce pain more than a pre-determined heavy-slow resistance training program that has previously been shown to be effective.49 The self-dosed program was not associated with larger improvements in self-efficacy or larger exercise dose during the trial.

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### Table 2

Baseline characteristics of all participants.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Randomised (n = 70)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yr), mean (SD)</td>
<td>Exp (n = 35)</td>
<td>Con (n = 35)</td>
</tr>
<tr>
<td>Gender, n female (%)</td>
<td>50 (10)</td>
<td>49 (12)</td>
</tr>
<tr>
<td>Height (cm), mean (SD)</td>
<td>29 (83)</td>
<td>29 (83)</td>
</tr>
<tr>
<td>Mass (kg), mean (SD)</td>
<td>95 (16)</td>
<td>90 (19)</td>
</tr>
<tr>
<td>Body mass index (kg/m²), mean (SD)</td>
<td>29.3 (6.3)</td>
<td>30.7 (5.5)</td>
</tr>
<tr>
<td>Symptom duration (month), median (IQR)</td>
<td>9 (6 to 10)</td>
<td>8 (5 to 22)</td>
</tr>
<tr>
<td>Pain severity (0 to 100), median (IQR)</td>
<td>62 (24)</td>
<td>63 (19)</td>
</tr>
<tr>
<td>Bilateral pain, n (%)</td>
<td>12 (34)</td>
<td>19 (54)</td>
</tr>
<tr>
<td>Plantar fasciopathy episodes (n), median (IQR)</td>
<td>1 (1 to 2)</td>
<td>1 (1 to 2)</td>
</tr>
<tr>
<td>Additional pain sites (n), median (IQR)</td>
<td>3 (1 to 6)</td>
<td>3 (1 to 5)</td>
</tr>
</tbody>
</table>

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### Table 3

Mean (SD) of groups and adjusted mean (95% CI) between-group differences for Foot Health Status Questionnaire, plantar fascia thickness and the Pain Self-Efficacy Questionnaire.

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Groups</th>
<th>Adjusted mean between-group difference (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Week 0</td>
<td>Week 4 minus Con</td>
</tr>
<tr>
<td>FHSQ pain</td>
<td>Exp (n = 35)</td>
<td>Con (n = 35)</td>
</tr>
<tr>
<td>(0 to 100)</td>
<td>43</td>
<td>38</td>
</tr>
<tr>
<td>FHSQ function</td>
<td>61</td>
<td>58</td>
</tr>
<tr>
<td>(0 to 100)</td>
<td>23</td>
<td>21</td>
</tr>
<tr>
<td>FHSQ footwear</td>
<td>48</td>
<td>48</td>
</tr>
<tr>
<td>(0 to 100)</td>
<td>16</td>
<td>15</td>
</tr>
<tr>
<td>FHSQ general foot health</td>
<td>51</td>
<td>55</td>
</tr>
<tr>
<td>Plantar fascia thickness (mm)</td>
<td>6.1</td>
<td>5.9</td>
</tr>
<tr>
<td>PSEQ</td>
<td>44</td>
<td>45</td>
</tr>
</tbody>
</table>

Con = control group; Exp = experimental group; FHSQ = Foot Health Status Questionnaire; PSEQ = Pain Self-Efficacy Questionnaire.

Shaded row = primary outcome.
Both groups had improvements in FHSQ pain larger than the minimum clinically important difference, but only three of 35 in the self-dosed group and one of 35 in the pre-determined group achieved Patient Acceptable Symptom State, indicating continued need for improved treatments for this long-term pain complaint.

The differences between the two exercise programs were mostly not statistically significant and the confidence intervals largely excluded effects that would be considered clinically worthwhile. The few statistically significant results could well have been Type-I errors (ie, chance findings). This aligns with the findings from a study in rotator cuff tendinopathy where a self-dosed single-exercise program had effects that were equivalent to those of usual physiotherapy, which mostly consisted of resistance exercises. Although the self-dosed approach was used with the intention of increasing self-efficacy and exercise dose, participants in the experimental group did not perform more training sessions or sets per training session (5.0 versus 4.5 sets) compared with the control group who undertook the pre-determined regimen. Both groups demonstrated high exercise compliance (on average two sessions per week). The experimental and control programs appear to be two different ways of achieving the same exercise dose and clinical results. Although previous studies have indicated an association between exercise dose and recovery, this association was not observed in the present trial; however, it should be noted that the analyses of correlations may not have been reliable due to the present trial’s sample size.

The results of the present trial raise the question of whether there is a role for heavy-slow resistance training in plantar fasciopathy management. The magnitude, frequency, and duration of cyclic strains are all important for the response and adaptation of both muscle and connective tissue such as the plantar fascia. It is possible that the load some participants used was inadequate to lead to an adaptation. If pain during exercise set an upper limit of load rather than muscular strength, adaptation could have been hampered. Pain during this specific exercise has previously been reported to be 42 mm on a 100-mm visual analogue scale and kinesiophobia is a recognised feature in individuals with plantar fasciopathy. It remains unknown if using a higher load would lead to better recovery in plantar fasciopathy.

Even though both groups improved more than the minimum clinically important difference on the FHSQ pain domain and the majority were improved according to the Global Rating of Change, few achieved Patient Acceptable Symptom State. When compared with other studies using FHSQ pain as an outcome, the level of improvement is comparable to that of foot orthoses, taping, corticosteroid injections, and even sham orthoses and placebo...
injections. Therefore, the improvement seen in the present trial could have derived from regression to the mean or the silicone heel cups or patient education that participants received. Loading programs for other tendinopathies are usually pre-determined, but our findings suggest there is no need for a standardised program if patients are advised to maximise their repetitions and load (up to 8RM) because such a self-dosed program led to similar results. Physiotherapists might discuss the two forms of exercise program prescription (self-dosed or pre-determined) to determine whether one appeals to the individual patient as being more motivating or acceptable. Heavy-slow resistance training provides clinicians with an alternative to other conservative treatments in plantar fasciopathy but the effects compared to wait-and-see and less time-consuming treatments need to be established.

Change in plantar fascia thickness and change in FHSQ pain were not associated, which is similar to previous findings of the lack of an association between pain, function, and plantar fascia thickness. Furthermore, plantar fascia thickness is not associated with progression. This indicates that repeated ultrasonography adds very little value to the patient and clinician alike and ultrasonography should only be used for diagnosing.

The conduct of the trial involved many procedures to ensure that it generated robust results, such as randomisation, sample size calculation, concealed allocation, intention-to-treat analysis, and prospective registration. Also, by blinding participants to how the exercise program was prescribed to the opposite randomised group, participants may have minimised any pressure on participants to exaggerate their improvement by knowing that they had been randomised to a group that the investigators hoped or anticipated would do better. The trial also had some limitations that ought to be considered. The validity of the training programs from which compliance was estimated may be questionable, because patients tend to overestimate their physical activity level and exercise compliance. In addition, patients may also have difficulties with replicating the exercise with an exactly correct technique when performing exercises at home. Conceivably, these issues would have applied equally to both groups and would therefore be unlikely to strongly bias the inferences made from the data. Another limitation was that the treating therapist was not blinded to group allocation, which could have introduced bias when participants were instructed.

To account for this, the patient education and instructions were that the treating therapist was not blinded to group allocation, such that the treating therapist was not blinded to group allocation, which could have introduced bias when participants were instructed.

In conclusion, advising people with plantar fasciopathy to self-dose their slow-heavy resistance training regimen does not substantially increase the dose achieved. Self-dosed and pre-determined heavy-slow resistance exercise programs are associated with similar effects on plantar fasciopathy pain and other outcomes over 12 weeks. These regimens are not sufficient to achieve acceptable symptom state in the majority of people with plantar fasciopathy.

What was already known on this topic: Heavy-slow resistance training involves repeated slow contractions through concentric, isometric and eccentric phases against a heavy load. Heavy-slow resistance training is often used for tendinopathies. Preliminary evidence suggests that heavy-slow resistance training may be more effective than stretching or eccentric exercise in the treatment of plantar fasciopathy, but the dose tested was lower than that which typically used for other tendinopathies. What this study adds: Advising people with plantar fasciopathy to self-dose their slow-heavy resistance training regimen does not substantially increase the achieved dose compared with prescribing a pre-determined regimen. Self-dosed and pre-determined heavy-slow resistance exercise programs are associated with similar effects on plantar fasciopathy pain and other outcomes over 12 weeks.

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Footnotes: * SSPP Statistics for Windows, Version 25, IBM, Armonk, USA.

Eaddenda: Table 5 and Appendix 1 can be found online at: https://doi.org/10.1016/j.phys.2019.05.011.

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