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a randomised trial

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Published in:
Journal of Physiotherapy

DOI (link to publication from Publisher):
[10.1016/j.jphys.2019.05.011](https://doi.org/10.1016/j.jphys.2019.05.011)

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Publication date:
2019

Document Version
Publisher's PDF, also known as Version of record

[Link to publication from Aalborg University](#)

Citation for published version (APA):
Riel, H., Jensen, M. B., Olesen, J. L., Vicenzino, B., & Rathleff, M. S. (2019). Self-dosed and pre-determined progressive heavy-slow resistance training have similar effects in people with plantar fasciopathy: a randomised trial. *Journal of Physiotherapy*, 65(3), 144-151. <https://doi.org/10.1016/j.jphys.2019.05.011>

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Research

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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KEY WORDS

Tendinopathy
Plantar fasciopathy
Exercise
Rehabilitation
Strengthening



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. **Registration:** [ClinicalTrials.gov](https://clinicaltrials.gov) NCT03304353. [Riel H, Jensen MB, Olesen JL, Vicenzino B, Rathleff MS (2019) Self-dosed and pre-determined progressive heavy-slow resistance training have similar effects in people with plantar fasciopathy: a randomised trial. *Journal of Physiotherapy* 65:144–151]

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Introduction

Plantar fasciopathy is one of the most prevalent musculoskeletal conditions and will affect one in every ten people during their lifetime.¹ The condition was formerly labelled as 'plantar fasciitis' but due to histological findings similar to those of tendinopathies, long-standing plantar fasciopathy is now considered a tendinopathy.^{2–4} The condition is characterised by severe and well-localised pain that often persists for several months or even years.⁵ People with plantar fasciopathy report pain during the first steps in the morning or after inactivity, which improves with ambulation and worsens during the day.⁶ Runners and 40 to 60-year-old people with low

activity levels and high body mass index are the most prone to plantar fasciopathy.^{7,8} The condition also affects mental health and as many as one in five people will have several days of sick leave due to their pain.^{9–11}

A recent systematic review and network meta-analysis evaluated the comparative effectiveness of commonly used treatments for plantar fasciopathy and none was superior to any other.¹² A new approach not included in that review is heavy-slow resistance training, which involves repeated slow contractions through concentric, isometric and eccentric phases against a heavy load. Heavy-slow resistance training is often used for other tendinopathies, despite uncertainty about the optimal regimen.^{13–17} Preliminary

<https://doi.org/10.1016/j.jphys.2019.05.011>

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Table 1
Mechanobiological descriptors of the exercise interventions.

Descriptor	Exercise programs	
	Experimental	Control
Load magnitude	As heavy as possible, but no heavier than a weight that can be lifted at least 8 times (8RM)	Week 1+2: 12RM Week 3+4: 10RM Week 5+: 8RM
Number of repetitions	≥ 8 depending on the load	Week 1+2: 12 Week 3+4: 10 Week 5+: 8
Number of sets	As many as possible	Week 1+2: 3 Week 3+4: 4 Week 5+: 5
Rest between sets	2 min	
Session frequency	3.5/week	
Duration of program	12 weeks	
Contraction modes within one repetition	3 s concentric, 2 s isometric, 3 s eccentric	
Rest between repetitions	Nil	
Time under tension	8 s/repetition, ≥ 64 s/set, ≥ 64 s/training session Total over 12 weeks: varies between participants depending on number of sets performed	Week 1+2: 8 s/repetition, 96 s/set, 288 s/training session Week 3+4: 8 s/repetition, 80 s/set, 320 s/training session Week 5+: 8 s/repetition, 64 s/set, 320 s/training session Total over 12 weeks: 13 216 s
Volitional muscular failure	Yes	
Range of motion	Full range of motion	
Recovery between sessions	48 hours	
Anatomical definition of the exercise (exercise form)	The participant stood with the forefoot on a step. A towel was placed underneath the toes to dorsiflex them throughout the exercise. With a fully extended knee, the participant performed a heel raise to maximal plantarflexion in the ankle joint and afterwards lowered the heel to maximal dorsiflexion. Support for balance by placing the hands on a wall or a rail was allowed.	

RM = repetition maximum.

evidence found heavy-slow resistance training to be superior to stretching in plantar fasciopathy,¹⁸ but the exercise dose was far lower than that prescribed in trials of other tendinopathies.^{15,17,19–22} Increasing exercise dose could lead to greater improvement in outcomes through a greater mechanobiological stimulus.²³ One way to increase dose is to prescribe a larger exercise dose, but compliance is often compromised by low self-efficacy.^{24,25} An alternative approach is to encourage patients to be in charge of their own rehabilitation and thereby increase exercise dose through increased self-efficacy.

Therefore, the research question for this randomised trial was:

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?

Method

Study design

A randomised trial was conducted with concealed allocation, partial blinding and intention-to-treat analysis. Two 12-week heavy-slow resistance training regimens – one self-dosed and one pre-determined – were compared in people with plantar fasciopathy. Prior to recruitment the trial protocol, template informed consent forms and participant information were approved by the Ethics Committee of the North Denmark Region in accordance with the Declaration of Helsinki.²⁶ People provided written informed consent before enrolment. Reporting followed CONSORT and TIDieR guidelines.^{27–29} The trial planning was performed in accordance with the

PREPARE Trial guide.³⁰ Before inclusion of the first participant, the trial was registered on clinicaltrials.gov, where the trial protocol was made publicly available.

Participants, therapist, centre

People with plantar fasciopathy were recruited through Facebook advertisement or by referral from their general practitioner. Telephone screening was performed and individuals who fulfilled the criteria were invited to a clinical examination at the Research Unit for General Practice in Aalborg, Denmark. The primary investigator – who was responsible for inclusion, exercise instructions and data collection – was a registered physiotherapist with 6 years of experience in treating patients with musculoskeletal disorders. Inclusion criteria were: history of inferior heel pain for at least 3 months before enrolment; pain on palpation of the medial calcaneal tubercle or the proximal plantar fascia; thickness of the plantar fascia of ≥ 4.0 mm; and mean heel pain ≥ 20 mm on a 100-mm visual analogue scale during the previous week.³¹ Exclusion criteria were: age < 18 years; diabetes; inflammatory systemic diseases;³¹ pregnancy; prior heel surgery; or corticosteroid injection for plantar fasciopathy within the previous 6 months.

Randomisation

After eligibility had been confirmed, participants were stratified by gender and block randomised (block sizes of two to six) at 1:1 to the experimental group or the control group. A researcher not involved in the trial generated the allocation sequence using a random number generator on www.sealedenvelope.com and was the only person who knew the block sizes. After enrolment, the primary

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 did not want to use the heel cup. No concomitant treatments were allowed. Participants were contacted either by telephone or by e-mail 2 weeks after inclusion to ask if they had experienced difficulties with the exercise and to encourage them to continue the intervention.

Heavy-slow resistance training

Both groups performed standing heel raises. Participants in the experimental group were instructed to perform the exercise with the load as heavy as possible but no heavier than 8RM and for as many sets as possible. Participants in the control group were instructed to perform the exercise according to a rigid protocol progressing from 12RM to 8RM. This progressive protocol was similar to the protocol used by Rathleff et al,¹⁸ where heavy-slow resistance training was found to be superior to plantar fascia stretching. Both groups performed exercises every second day during the 12-week intervention. The exercise descriptors are displayed in Table 1.³² If participants felt they could perform more repetitions than their load corresponded to (eg, 10 repetitions when the load was supposed to be 8RM), a backpack with books to add weight was used.

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).³³ Responses were entered into the FHSQ software, which calculated scores for each domain. A validated Danish translation of the FHSQ was used.³⁴

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). Plantar 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).³⁵ 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.^{36–38} 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.⁴³ 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.^a 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.⁴⁶ 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 non-normal 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.⁴⁷ 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

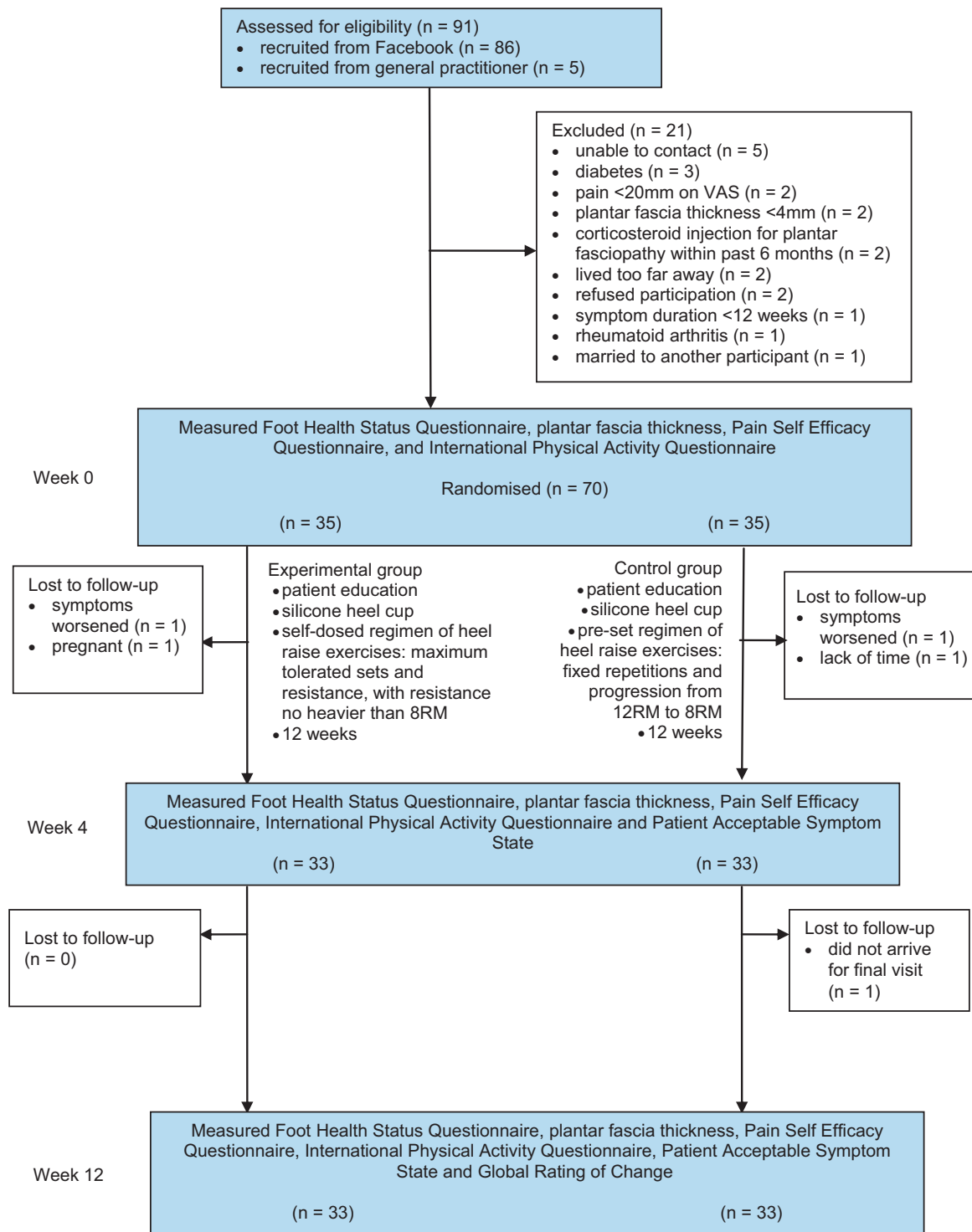


Figure 1. Design and flow of participants through the trial. RM = repetition maximum, VAS = visual analogue scale.

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-

Table 2
Baseline characteristics of all participants.

Characteristic	Randomised (n = 70)	
	Exp (n = 35)	Con (n = 35)
Age (yr), mean (SD)	50 (10)	49 (12)
Gender, n female (%)	29 (83)	29 (83)
Height (cm), mean (SD)	169 (10)	170 (8)
Mass (kg), mean (SD)	85 (16)	90 (19)
Body mass index (kg/m ²), mean (SD)	29.9 (6.3)	30.7 (5.5)
Symptom duration (month), median (IQR)	9 (6 to 30)	8 (5 to 22)
Pain severity (0 to 100), mean (SD) ^a	62 (24)	63 (19)
Bilateral pain, n (%)	12 (34)	19 (54)
Plantar fasciopathy episodes (n), median (IQR)	1 (1 to 2)	1 (1 to 2)
Additional pain sites (n), median (IQR) ^b	3 (1 to 6)	3 (1 to 5)

^a Average during previous week.

^b Includes the entire body and head, and are derived from a pain manikin that participants used during baseline assessment.⁵⁹

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. Plantar fascia thickness and the Pain Self-Efficacy Questionnaire were also not significantly different between the groups (Table 3).

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 outcomes, are presented in Table 5 on the eAddenda.

When participants provided a Global Rating of Change, 24 of 33 in the experimental group and 20 of 32 in the control group 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).

Only 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 ($p = 0.057$). 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.¹⁸ The self-dosed program was not associated with larger improvements in self-efficacy or larger exercise dose during the trial.

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.

Outcome	Groups						Adjusted mean between-group difference (95% CI)	
	Week 0		Week 4		Week 12		Week 4 minus Week 0	Week 12 minus Week 0
	Exp (n = 35)	Con (n = 35)	Exp (n = 35)	Con (n = 35)	Exp (n = 35)	Con (n = 35)	Exp minus Con	Exp minus Con
FHSQ pain (0 to 100)	43 (17)	38 (16)	58 (16)	50 (18)	70 (16)	62 (21)	-7 (-15 to 1)	-7 (-16 to 2)
FHSQ function (0 to 100)	61 (23)	58 (21)	78 (23)	75 (19)	89 (12)	84 (19)	-1 (-8 to 6)	-4 (-11 to 3)
FHSQ footwear (0 to 100)	48 (16)	48 (15)	50 (16)	48 (16)	52 (16)	46 (16)	-2 (-9 to 4)	-6 (-11 to 0)
FHSQ general foot health (0 to 100)	51 (16)	55 (18)	53 (14)	50 (15)	49 (16)	54 (14)	-4 (-11 to 2)	5 (-2 to 12)
Plantar fascia thickness (mm)	6.1 (1.2)	5.9 (1.2)	5.9 (1.3)	5.9 (1.3)	5.7 (1.3)	5.6 (1.3)	0.2 (-0.3 to 0.7)	0.1 (-0.4 to 0.6)
PSEQ (0 to 60)	44 (12)	45 (12)	50 (9)	47 (12)	54 (6)	51 (12)	-3 (-7 to 0)	-3 (-7 to 1)

Con = control group = pre-determined regimen, Exp = experimental group = self-dosed regimen, FHSQ = Foot Health Status Questionnaire, PSEQ = Pain Self-Efficacy Questionnaire. Shaded row = primary outcome.

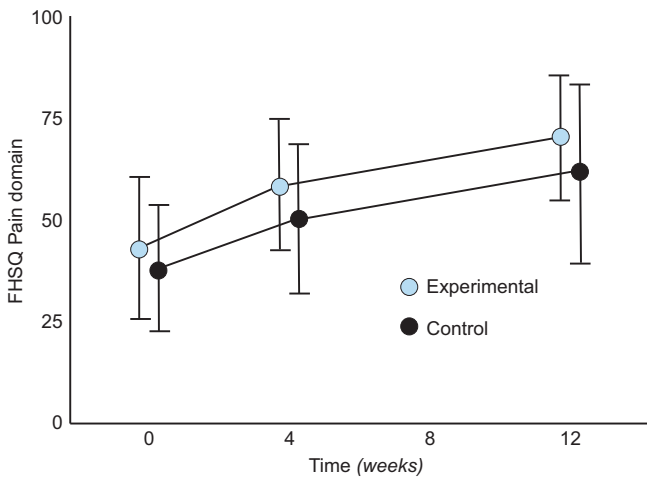


Figure 2. Pain domain of the Foot Health Status Questionnaire (FHSQ) by time. The experimental group was allocated self-dosed heavy-slow resistance training and the control group was allocated a pre-determined heavy-slow resistance training regimen. Symbols show means and error bars show standard deviations. Lines join group means at baseline and at Weeks 4 and 12. Experimental and control group data have been offset slightly for clarity.

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.⁴³ 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.²⁰ 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).^{25,49} 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,^{50,51} 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.³² 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.^{11,52} It remains unknown if using a higher load would lead to better recovery in plantar fasciopathy.

Even though both groups improved more than the nominated 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

Table 4 Median (IQR) of groups, unadjusted difference in medians, and statistical significance of the between-group difference in medians for four measures derived from the International Physical Activity Questionnaire.

IPAQ activity measure (MET-minutes/week)	Groups						Median difference ^a		Statistical significance of the difference (p)	
	Week 0		Week 4		Week 12		Exp minus Con		Week 4	Week 12
	Exp (n = 35)	Con (n = 35)	Exp (n = 35)	Con (n = 35)	Exp (n = 35)	Con (n = 35)	Week 4	Week 12	Week 4	Week 12
Walk	693 (264 to 1386)	792 (198 to 2079)	693 (198 to 1782)	1452 (594 to 2772)	990 (396 to 1739)	1155 (462 to 2079)	-759	-165	0.013	0.576
Moderate	360 (0 to 840)	0 (0 to 800)	200 (0 to 720)	480 (0 to 720)	240 (0 to 1071)	720 (480 to 1440)	-280	-480	0.643	0.096
Vigorous	480 (0 to 1680)	240 (0 to 1920)	0 (0 to 1022)	320 (0 to 1001)	720 (0 to 1500)	800 (0 to 1920)	-320	-80	0.667	0.644
Total	2678 (1344 to 5226)	2106 (792 to 6079)	2412 (1386 to 3495)	3492 (1452 to 5118)	2556 (1188 to 4212)	3582 (1215 to 5439)	-1080	-1026	0.071	0.293

Con = control group, Exp = experimental group, IPAQ = International Physical Activity Questionnaire, MET = metabolic equivalent.

^a Unadjusted for baseline difference in medians.

injections.^{31,44,45} 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.⁵³

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.^{13,15,18,21,22} 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.⁵⁴ Furthermore, plantar fascia thickness is not associated with prognosis.⁵ This indicates that repeated ultrasonography adds very little value to the patient and clinician alike and ultrasonography should only be used for diagnosing.⁵⁵

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, the trial should 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 diaries from which compliance was estimated may be questionable, because patients tend to overestimate their physical activity level and exercise compliance.^{56,57} In addition, patients may also have difficulties with replicating the exercise with an exactly correct technique when performing exercises at home.⁵⁸ 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 standardised. Finally, musculoskeletal pain conditions involve a complexity of biopsychosocial aspects; hence, there may be some aspects of plantar fasciopathy that this trial did not embrace.

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 in plantar fasciopathy, but the dose tested was lower than that 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.

Footnotes: ^a SPSS Statistics for Windows, Version 25, IBM, Armonk, USA.

Addenda: Table 5 and Appendix 1 can be found online at: <https://doi.org/10.1016/j.jphys.2019.05.011>.

Ethics approval: The Ethics Committee of the North Denmark Region approved this study. All participants gave written informed consent before data collection began.

Competing interests: Nil.

Source of support: The trial was internally funded.

Acknowledgements: Nil.

Provenance: Not invited. Peer reviewed.

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References

- Landorf KB. Plantar heel pain and plantar fasciitis. *BMJ Clin Evid.* 2015;2015.
- Lemont H, Ammirati KM, Usen N. Plantar fasciitis. *J Am Podiatr Med Assoc.* 2003;93:234–237.
- Cook JL, Rio E, Purdam CR, Docking SI. Revisiting the continuum model of tendon pathology: what is its merit in clinical practice and research? *Br J Sports Med.* 2016;50:1187–1191.
- Riel H, Cotchett M, Delahunt E, Rathleff MS, Vicenzino B, Weir A, et al. Is 'plantar heel pain' a more appropriate term than 'plantar fasciitis'? Time to move on. *Br J Sports Med.* 2017;51:1576–1577.
- Hansen L, Krogh TP, Ellingsen T, Bolvig L, Fredberg U. Long-term prognosis of plantar fasciitis: a 5- to 15-year follow-up study of 174 patients with ultrasound examination. *Orthop J Sport Med.* 2018;6:232596711875798.
- Goff JD, Crawford R. Diagnosis and treatment of plantar fasciitis. *Am Fam Physician.* 2011;84:676–682.
- Taunton JE, Ryan MB, Clement DB, McKenzie DC, Lloyd-Smith DR, Zumbo BD. A retrospective case-control analysis of 2002 running injuries. *Br J Sports Med.* 2002;36:95–101.
- van Leeuwen KDB, Rogers J, Winzenberg T, van Middelkoop M. Higher body mass index is associated with plantar fasciopathy/plantar fasciitis: systematic review and meta-analysis of various clinical and imaging risk factors. *Br J Sports Med.* 2016;50:972–981.
- Cotchett M, Munteanu SE, Landorf KB, Landorf KB. Depression, anxiety, and stress in people with and without plantar heel pain. *Foot Ankle Int.* 2016;37:816–821.
- Davis PF, Severud E, Baxter DE. Painful heel syndrome: results of nonoperative treatment. *Foot Ankle Int.* 1994;15:531–535.
- Riel H, Vicenzino B, Jensen MB, Olesen JL, Holden S, Rathleff MS. The effect of isometric exercise on pain in individuals with plantar fasciopathy: a randomised crossover trial. *Scand J Med Sci Sports.* 2018;28:2643–2650.
- Babatunde OO, Legha A, Littlewood C, Chesterton LS, Thomas MJ, Menz HB, et al. Comparative effectiveness of treatment options for plantar heel pain: a systematic review with network meta-analysis. *Br J Sports Med.* 2019;53:182–194.
- van Ark M, Cook JL, Docking SI, Zwerver J, Gaida JE, van den Akker-Scheek I, et al. Do isometric and isotonic exercise programs reduce pain in athletes with patellar tendinopathy in-season? A randomised clinical trial. *J Sci Med Sport.* 2016;19:702–706.
- Desmeules F, Boudreault J, Dionne CE, Frémont P, Lowry V, MacDermid JC, et al. Efficacy of exercise therapy in workers with rotator cuff tendinopathy: a systematic review. *J Occup Health.* 2016;58:389–403.
- Malliaras P, Barton CJ, Reeves ND, Langberg H. Achilles and patellar tendinopathy loading programmes: a systematic review comparing clinical outcomes and identifying potential mechanisms for effectiveness. *Sports Med.* 2013;43:267–286.
- Wilson F, Walshe M, O'Dwyer T, Bennett K, Mockler D, Bleakley C. Exercise, orthoses and splinting for treating Achilles tendinopathy: a systematic review with meta-analysis. *Br J Sports Med.* 2018;52:1564–1574.
- Rathleff MS, Thorborg K. "Load me up, Scotty": mechanotherapy for plantar fasciopathy (formerly known as plantar fasciitis). *Br J Sports Med.* 2015;49:638–639.
- Rathleff MS, Mølgaard CM, Fredberg U, Kaalund S, Andersen KB, Jensen TT, et al. High-load strength training improves outcome in patients with plantar fasciitis: a randomized controlled trial with 12-month follow-up. *Scand J Med Sci Sports.* 2015;25:e292–e300.
- Coombes BK, Bisset L, Brooks P, Khan A, Vicenzino B. Effect of corticosteroid injection, physiotherapy, or both on clinical outcomes in patients with unilateral lateral epicondylalgia. *JAMA.* 2013;309:461.
- Littlewood C, Bateman M, Brown K, Bury J, Mawson S, May S, et al. A self-managed single exercise programme versus usual physiotherapy treatment for rotator cuff tendinopathy: a randomised controlled trial (the SELF study). *Clin Rehabil.* 2016;30:686–696.
- Beyer R, Kongsgaard M, Hougs Kjær B, Øhlenschläger T, Kjær M, Magnusson SP. Heavy slow resistance versus eccentric training as treatment for achilles tendinopathy: a randomized controlled trial. *Am J Sports Med.* 2015;43:1704–1711.
- Kongsgaard M, Kovanen V, Aagaard P, Doessing S, Hansen P, Laursen AH, et al. Corticosteroid injections, eccentric decline squat training and heavy slow resistance training in patellar tendinopathy. *Scand J Med Sci Sports.* 2009;19:790–802.
- Khan KM, Scott A. Mechanotherapy: how physical therapists' prescription of exercise promotes tissue repair. *Br J Sports Med.* 2009;43:247–252.
- McLean SM, Burton M, Bradley L, Littlewood C. Interventions for enhancing adherence with physiotherapy: a systematic review. *Man Ther.* 2010;15:514–521.

25. Jack K, McLean SM, Moffett JK, Gardiner E. Barriers to treatment adherence in physiotherapy outpatient clinics: a systematic review. *Man Ther.* 2010;15:220–228.
26. World Medical Association Declaration of Helsinki. *JAMA.* 2013;310:2191.
27. Moher D, Hopewell S, Schulz KF, Montori V, Gøtzsche PC, Devereaux PJ, et al. CONSORT 2010 Explanation and Elaboration: updated guidelines for reporting parallel group randomised trials. *BMJ.* 2010;340:c869.
28. Hoffmann TC, Glasziou PP, Boutron I, Milne R, Perera R, Moher D, et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. *BMJ.* 2014;348:g1687.
29. Boutron I, Moher D, Altman DG, Schulz KF, Ravaud P, CONSORT Group. Methods and processes of the CONSORT Group: example of an extension for trials assessing nonpharmacologic treatments. *Ann Intern Med.* 2008;148:W60–W66.
30. Bandholm T, Christensen R, Thorborg K, Treweek S, Henriksen M. Preparing for what the reporting checklists will not tell you: the PREPARE Trial guide for planning clinical research to avoid research waste. *Br J Sports Med.* 2017;51:1494–1501.
31. McMillan AM, Landorf KB, Gilheany MF, Bird AR, Morrow AD, Menz HB. Ultrasound guided corticosteroid injection for plantar fasciitis: randomised controlled trial. *BMJ.* 2012;344:e3260.
32. Toigo M, Boutellier U. New fundamental resistance exercise determinants of molecular and cellular muscle adaptations. *Eur J Appl Physiol.* 2006;97:643–663.
33. Bennett PJ, Patterson C, Wearing S, Baglioni T. Development and validation of a questionnaire designed to measure foot-health status. *J Am Podiatr Med Assoc.* 1998;88:419–428.
34. Riel H, Jensen MB, Olesen JL, Rathleff MS. Translation and cultural adaptation of a Danish version of the Foot Health Status Questionnaire for individuals with plantar heel pain. *Foot.* 2019;38:61–64.
35. Skovdal Rathleff M, Moelgaard C, Lykkegaard Olesen J. Intra- and interobserver reliability of quantitative ultrasound measurement of the plantar fascia. *J Clin Ultrasound.* 2011;39:128–134.
36. Tubach F, Ravaud P, Martin-Mola E, Awada H, Bellamy N, Bombardier C, et al. Minimum clinically important improvement and patient acceptable symptom state in pain and function in rheumatoid arthritis, ankylosing spondylitis, chronic back pain, hand osteoarthritis, and hip and knee osteoarthritis: results from a prospective multina. *Arthritis Care Res.* 2012;64:1699–1707.
37. Tubach F, Ravaud P, Baron G, Falissard B, Logeart I, Bellamy N, et al. Evaluation of clinically relevant states in patient reported outcomes in knee and hip osteoarthritis: the patient acceptable symptom state. *Ann Rheum Dis.* 2005;64:34–37.
38. Myles PS, Myles DB, Galagher W, Boyd D, Chew C, MacDonald N, et al. Measuring acute postoperative pain using the visual analog scale: the minimal clinically important difference and patient acceptable symptom state. *Br J Anaesth.* 2017;118:424–429.
39. Nicholas MK. The pain self-efficacy questionnaire: taking pain into account. *Eur J Pain.* 2007;11:153–163.
40. Rasmussen MU, Rydahl-Hansen S, Amris K, Samsøe BD, Mortensen EL, Mortensen EL. The adaptation of a Danish version of the Pain Self-Efficacy Questionnaire: reliability and construct validity in a population of patients with fibromyalgia in Denmark. *Scand J Caring Sci.* 2016;30:202–210.
41. van Poppel MNM, Chinapaw MJM, Mookink LB, van Mechelen W, Terwee CB. Physical activity questionnaires for adults. *Sports Med.* 2010;40:565–600.
42. Craig CL, Marshall AL, Sjöström M, Bauman AE, Booth ML, Ainsworth BE, et al. International physical activity questionnaire: 12-country reliability and validity. *Med Sci Sports Exerc.* 2003;35:1381–1395.
43. Landorf KB, Radford JA. Minimal important difference: values for the Foot Health Status Questionnaire, Foot Function Index and Visual Analogue Scale. *Foot.* 2008;18:15–19.
44. Landorf KB, Keenan A-M, Herbert RD. Effectiveness of foot orthoses to treat plantar fasciitis. *Arch Intern Med.* 2006;166:1305–1310.
45. Radford JA, Landorf KB, Buchbinder R, Cook C. Effectiveness of low-Dye taping for the short-term treatment of plantar heel pain: a randomised trial. *BMC Musculoskelet Disord.* 2006;7:64.
46. Vickers AJ, Altman DG. Statistics notes: analysing controlled trials with baseline and follow up measurements. *BMJ.* 2001;323:1123–1124.
47. Marshall A, Altman DG, Holder RL, Royston P. Combining estimates of interest in prognostic modelling studies after multiple imputation: current practice and guidelines. *BMC Med Res Methodol.* 2009;9:57.
48. Chiarotto A, Vanti C, Cedraschi C, Ferrari S, Ferrari S, Ostelo RW, Pillastrini P. Responsiveness and minimal important change of the Pain Self-Efficacy Questionnaire and Short Forms in patients with chronic low back pain. *J Pain.* 2016;17:707–718.
49. Sluijs EM, Kok GJ, van der Zee J. Correlates of exercise compliance in physical therapy. *Phys Ther.* 1993;73:771–782.
50. Østerås B, Østerås H, Torstensen TA, Vasseljen O. Dose-response effects of medical exercise therapy in patients with patellofemoral pain syndrome: a randomised controlled clinical trial. *Physiotherapy.* 2013;99:126–131.
51. Rathleff MS, Roos EM, Olesen JL, Rasmussen S. Exercise during school hours when added to patient education improves outcome for 2 years in adolescent patellofemoral pain: a cluster randomised trial. *Br J Sports Med.* 2014;49:406–412.
52. Cotchett M, Lennecke A, Medica VG, Whittaker GA, Bonanno DR. The association between pain catastrophising and kinesiophobia with pain and function in people with plantar heel pain. *Foot.* 2017;32:8–14.
53. Barnett AG, van der Pols JC, Dobson AJ. Regression to the mean: what it is and how to deal with it. *Int J Epidemiol.* 2004;34:215–220.
54. Gamba C, Sala-Pujals A, Perez-Prieto D, Ares-Vidal J, Solano-Lopez A, Gonzalez-Lucena G, et al. Relationship of plantar fascia thickness and preoperative pain, function, and quality of life in recalcitrant plantar fasciitis. *Foot Ankle Int.* 2018;39:930–934.
55. McMillan AM, Landorf KB, Barrett JT, Menz HB, Bird AR. Diagnostic imaging for chronic plantar heel pain: a systematic review and meta-analysis. *J Foot Ankle Res.* 2009;2:32.
56. Sallis JF, Saelens BE. Assessment of physical activity by self-report: status, limitations, and future directions. *Res Q Exerc Sport.* 2000;71:1–14.
57. Rathleff MS, Bandholm T, McGirr KA, Harring SI, Sørensen AS, Thorborg K. New exercise-integrated technology can monitor the dosage and quality of exercise performed against an elastic resistance band by adolescents with patellofemoral pain: an observational study. *J Physiother.* 2016;62:159–163.
58. Faber M, Andersen MH, Sevel C, Thorborg K, Bandholm T, Rathleff M. The majority are not performing home-exercises correctly two weeks after their initial instruction—an assessor-blinded study. *Peer J.* 2015;3:e1102.
59. van den Hoven LHJ, Gorter KJ, Picavet HSJ. Measuring musculoskeletal pain by questionnaires: The manikin versus written questions. *Eur J Pain.* 2010;14:335–338.