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Inertial flywheel vs heavy slow resistance training among athletes with patellar tendinopathy: A randomised trial

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ABSTRACT

Objectives: To compare the efficacy of inertial flywheel and heavy slow resistance training in reducing pain and improving function in patellar tendinopathy.
Design: Randomised clinical trial.
Methods: Fourty two participants (1 woman, 41 men) with longstanding (>3 months) patellar tendinopathy were randomised into inertial flywheel resistance (N = 21) or heavy slow resistance (N = 21) group. Both programmes consisted of three supervised inertial flywheel or heavy slow resistance exercise sessions per week in a fitness center during 12 weeks. Primary outcome was pain and function, assessed by the Spanish Victorian Institute of Sport Assessment for Patella (VISA-P) score at 6 and 12 weeks. Secondary outcomes were activity limitation using Patient Specific Functional Scale (PSFS), health status (EuroQol-5D), patient impression of change on pain and function, adherence, adverse events, pain provocation test for the patellar tendon (numerical rating score of pain between 0 and 10), physical test, patellar tendon thickness and doppler signal on ultrasound. Secondary outcomes were taken at 0 and 12 weeks.
Results: Both groups showed significant improvements in VISA-P scores from 0 to 12 weeks but there was not statistically significant between-group difference (P = 0.506). No adverse events or side effects occurred in any of the groups during the intervention period.
Conclusions: Inertial flywheel resistance three times a week during 12 weeks resulted in similar pain and function benefit at 12 weeks compared with the heavy slow resistance training among people with patellar tendinopathy. Flywheel training is another exercise option for managing people with patellar tendinopathy.
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1. Background

Patellar tendinopathy (PT) is a common overuse injury that is characterised by load-related pain in the patellar tendon. Athletes involved in jumping, sprinting and change of direction sports such as basketball, volleyball and football are commonly affected. (Lian et al., 2005)' (Ferretti et al., 1983)' (Fredberg et al., 2008). PT results in decreased function, limited sports and activity participation and high impact on the quality of life (De Vries et al., 2017; Docking et al., 2018).

First line recommended management includes patient education, load management, and exercise therapy, especially progressive resistance training (Malliaras et al., 2015). There is no gold standard exercise program for PT, however; various approaches have demonstrated efficacy. Isolated single leg eccentric decline squat is the most investigated approach. (Visnes and Bahr, 2007)' (Young et al., 2005)' (Jonsson and Alfredson, 2005)' (Purdam et al., 2004) Positive clinical outcomes were reported with this protocol

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performed twice daily during 12 weeks, although there is lack of high-quality evidence that proves superiority to other approaches (Malliaras et al., 2013). Another popular exercise program for PT is a 12-week heavy slow resistance program performed 3 times weekly (Kongsgaard et al., 2009). Each session consists of three exercises (squat, hack squat and leg press) where, weekly, numbers of repetitions decrease, and load gradually increases. Kongsgaard et al. compared eccentric decline and heavy slow resistance exercise programs in PT and found no differences in pain and function improvement at 3 and 6 months but the latter showed superior treatment satisfaction (Kongsgaard et al., 2009).

Lower extremity strength and power is an important goal in PT rehabilitation program for individuals that participate in stretch-shortening–cycle (SSC) activities such as running and jumping (Sprague et al., 2018). There is evidence that power (jumping performance) is impaired among athletes with patellar tendinopathy, and reactive and explosive power impairments have been reported in Achilles tendinopathy (Harris et al., 2020; McAuliffe et al., 2019).

Inertial flywheel (IFR) training is a valid alternative to traditional resistance training and may be beneficial for people with PT (Beato & Dello Iacono, 2020; Romero-Rodriguez et al., 2011). It involves inertial resistance of a rotating flywheel and fast muscle contraction speeds that train and improve muscle strength and power. (Carroll et al., 2019), (Naczk et al., 2016a), (Beato et al., 2021), (Effects of flywheel train, 2021).

During maximal-effort concentric action, kinetic energy is generated through the rotation of the wheel, which is braked during the return movement, producing an eccentric overload (Norrbrand et al., 2008; Tesch et al., 2004).

The primary objective of this study was to compare the efficacy of inertial flywheel and heavy slow resistance programs on pain and function over 12 weeks in individuals with longstanding PT. Another objective was to evaluate and compare differences in activity limitation, health status, treatment effectiveness, adherence, adverse events, pain provocation test, lower limb strength and power, patellar tendon thickness and doppler signal on ultrasound.

The findings of this study may help advance exercise evidence among people with PT, particularly from the perspective of recovering lower body strength and power.

2. Methods

2.1. Study design

A prospective randomised clinical trial design was performed with a 12-week intervention period from January 2018 to March 2020. This was a superiority trial comparing the efficacy of inertial flywheel compared with heavy slow resistance program.

Given we have collected data to only 3 months, have tightly controlled the intervention delivery (by 1 highly trained therapist), and only utilized one training centre, we believe our trial conforms with an efficacy paradigm.

Participants were randomised to 1 of the trial arms with a 1-1 ratio. The study was designed and reported following the Consolidated Standard of Reporting Trials 2010 Statement (Schulz et al., 2010) and TIDier guide (Hoffmann et al., 2014). The trial was approved by the Ethical Committee at the National Clinical Hospital Córdoba, Argentina N° 3365 and prospectively registered at ClinicalTrials.gov (NCT03917849). All the subjects provided informed consent to participate.

2.2. Sample size

We estimated the standard deviation from the Kongsgaard trial (Kongsgaard et al., 2009) and calculated the effect size (0.59) based on this and the minimal clinically important VISA-P difference which is 13 (Hernandez-Sanchez et al., 2014).

To achieve 80% power with the alpha level set at 0.05 and assuming a correlation of 0.5 between baseline and follow up VISA-P, we would need a total sample of 36 people (increased to 40 to account for a possible 20% attrition rate).

2.3. Recruitment and screening

Participants were recruited from sports and orthopaedic medicine departments in Córdoba city, Argentina. Orthopaedics informed potentially eligible patients for the study and provided them with the researchers' contact details to ask for further information. Those who did were given information about the study, screened via telephone, and invited to a baseline assessment, were they potentially eligible and interested. At baseline assessment, participant eligibility was confirmed, informed consent obtained and baseline data collected.

2.4. Eligibility criteria

Men and women over 18 years old were included if they met the following criteria; had patellar tendon pain for longer than 3 months; were recreational athletes that were undertaking high patellar loading sports such volleyball, basketball, soccer or running; and they trained or played at least two times per week. Additionally, clinical diagnosis of PT where pain was localized to the inferior pole of the patellar and aggravated by activities involving high patellar tendon load (jumping, sprinting, change of direction), Victorian Institute of Sport Assessment (VISA) score <80 and tendon pathology on ultrasound imaging.

Potential participants were excluded if they had other knee injury or surgery on the currently affected side, corticosteroid injections within the last 6 months, osteoarthritis of any joint in the lower limb that required management, diabetes, inflammatory arthropathy or any other condition affecting the performance of exercise interventions (e.g. neurological and cognitive impairment).

2.5. Randomisation

Following baseline assessment, participants were allocated to one of the two intervention groups using numbered opaque envelopes containing the randomisation sequence. The sequence was created using a random number generator and put into envelopes by a researcher that was not involved in randomisation or data collection. Randomisation, data collection and intervention delivery were undertaken by a single researcher (DR). Ultrasound imaging was assessed by a blinded assessor (consultant radiologist). Participants and the outcome assessor were not blind to group allocation.

3. Study interventions

Exercise interventions were reported in accordance with Consensus on Exercise Reporting Template recommendations (Slade et al., 2016). Participants were advised to complete three exercise sessions per week with at least one day of rest in between in our study gym (part of the university). All sessions lasted approximately 50 min in total (including a standardized 10-min warm-up: cycling and dynamic mobility exercises) and were supervised by the lead researcher (DR) or an assistant physiotherapist. Some pain during and after sessions (<4/10) was acceptable (Sprague et al., 2021)· (Sancho et al., 2019)· (Silbernagel et al., 2007)· (Thomeé, 1997) but participants were instructed that any increase

in pain post-exercise should decrease to pre-exercise levels within 24 h. If this did not occur, participants were advised to adjust load in heavy slow resistance or velocity execution in inertial flywheel training and/or reduce sporting activities.

Both groups were allowed to perform sporting activities throughout the intervention period if these could be performed with minimal discomfort (defined as 30 on a visual analogue-scale (VAS) from 0 to 100, where 100 is the worst pain imaginable).

3.1. Heavy slow resistance protocol

Heavy slow resistance training has been detailed by Kongsgaard et al. (Kongsgaard et al., 2009) and consisted of three 2-legged exercises using traditional resistance equipment. Exercises included leg squat, leg press and hack squat performed on commercial exercise machines (Fox, Buenos Aires, Argentina). Participants completed four sets of each exercise with a 2–3-min rest between sets. Repetitions/load-intensity was: 15-rep maximum (RM) week 1, 12RM weeks 2–3, 10 RM weeks 4–5, 8 RM weeks 6–8 and 6 RM weeks 9–12. All exercises were performed from full extension to 90° of knee flexion. Participants were instructed to spend 3 s completing each of the eccentric and concentric phases respectively (6 s total per repetition).

3.2. Inertial flywheel resistance protocol

Exercises were performed in three custom inertial flywheel machines: 2-legged squat, leg press and knee extension (Ivolution, Sunchales, Argentina). Participants completed four 2-legged sets of 10 concentric-eccentric reps of each machine with a 2–3 min rest between sets. The first two reps of each set were aimed at accelerating the flywheel and were not considered. The subsequent 10 concentric phases of each repetitions were instructed to be performed at maximal velocity while delaying the braking action to the last part of the eccentric phase (Romero-Rodriguez et al., 2011). Each coupled concentric and eccentric actions were completed with a repetition cycle of about 3 s. Inertia loads were: 2.5 kg flywheel (moment inertia 0.05 kg/m^2) from week 1–6 and 4 kg flywheel (moment inertia 0.10 kg/m^2) from week 6–12.

4. Outcome measures

Outcome measures were collected at baseline and 12 weeks unless stated otherwise.

(I) Primary outcome

The Spanish VISA-P pain and function assessment was the primary outcome. This disease-specific instrument assesses symptoms, function and ability to participate in sports and has demonstrated acceptable test re-test reliability and validity (Hernandez-Sanchez et al., 2011; Visentini et al., 1998). Participants completed the VISA-P questionnaire at baseline, 6 week and 12 weeks with no assistance. The minimum clinical important difference (MCID) of VISA-P was considered to be 13 points (Hernandez-Sanchez et al., 2014).

(II) Secondary outcomes

Secondary outcomes included: (a) Functional status using Patient Specific Functional Scale (Stratford et al., 1995). The MCID was established between 2.3 and 2.7 in patients with musculoskeletal disorders of the lower limb extremity (Abbott & Schmitt, 2014); (b) Health status (using EuroQol 5D) (Badia et al., 1999); (c) Self-reported treatment effectiveness for pain and function (using the Patient Global Impression of Change questionnaire) (Dworkin et al., 2005). This variable was dichotomised for analysis purposes into the categories of 'Satisfied' ("much improved" or "very much improved") and 'Not Satisfied' ("minimally improved to very much worse") (Collins et al., 2009); (d) Provocative load test rated via a 100-mm visual analogue scale using single-leg decline squat test (SLDS) (Purdam et al., 2003; Zwerver et al., 2007) and six reps in leg extension (EXT) machine with 50% load of the participant's body weight. Given tendon pain may improve with repeated loading, these tests were performed in a randomised order and not after any periods of exercise or rehabilitation; (e) Exercise adherence (recorded every training session in the gym by fingerprint identifier). Adherence was defined as the proportion of prescribed sessions undertaken; (f) Patellar tendon thickness and Doppler (Sunding et al., 2016) assessed by ultrasound imaging. Given Doppler signal may be influenced by prior activity (Boesen et al., 2006), participants were asked not to undertake strenuous activity for 2 h before ultrasound examination and all images were taken before load tests or practising the prescribed exercises; (g) Physical testing (ankle dorsiflexión (Calatayud et al., 2015)), vertical countermovement jump test (Markovic et al., 2004) (CMJ), triple hop for distance (Hamilton et al., 2008), strength test (assessed by six rep maximum test (6RM) in leg extension and horizontal leg press machine).

4.1. Adverse events

Participants reported any changes or symptoms using an open-response questionnaire. An adverse event was defined as any unfavourable symptom or disease occurring during the study which may be related to the intervention. Participants were advised that muscle soreness by strength training was to be expected. This variable was categorized into the categories of 'Severe' (e.g. tendon rupture, fall, injury, persistent and significant disability or incapacity) and 'Non-severe' (e.g. patellar tendon discomfort, muscle soreness, fatigue).

5. Data analysis

Descriptive data are presented as means, standard deviations, and 95% confidence levels. Statistical analyzes were carried out using the InfoStat software (Version 2017, National University of Córdoba, Argentina). Categorical variables were summarized using absolute and relative frequencies, quantitative data were expressed using measures of central tendency and variability, prior to the normality test using the Shapiro-Wilk test, point estimates were completed with 95% confidence intervals.

Differences between primary and secondary outcome groups were compared at baseline and 12 weeks using analysis of covariance with baseline values as covariate. Treatment adherence was analyzed using a difference in proportion test at 12 weeks. For outcome measures with dichotomous scales, relative risk, risk difference and number needed to treat were used. The differences were considered statistically significant with a value of $p < 0.05$.

6. Results

6.1. Participants

Demographic data and clinical characteristics of participants are shown in Table 1. A total of 42 recreational athletes diagnosed with unilateral PT were recruited from January 2018 to March 2020. Twenty-one participants were allocated to each group. Baseline

Table 1
Participant characteristics at baseline: demographics and anthropometrics.

	Inertial Flywheel (N = 20)	Heavy Slow Resistance (N = 21)	P-value
	Mean (±SD)	Mean (±SD)	
Sex (female/male)	0/21	1/20	–
Age (years)	27.5 ± 5.4	31.7 ± 8.7	0.070
Height (cm)	179.2 ± 8	177.8 ± 7	0.552
Weight (kg/m^2)	80.2 ± 14.7	81.3 ± 14.1	0.806
BMI (kg/m^2)	25 ± 2.6	25.6 ± 3.6	0.568
Symptom duration (months)	9.5 ± 5.2	17.2 ± 16.4	0.052
Activity level before injury (h/week)	5.7 ± 2.2	5.1 ± 3	0.422

Abbreviations: BMI, body mass index.
Values are reported as mean ± SD. There were no differences between groups for any parameter at baseline.

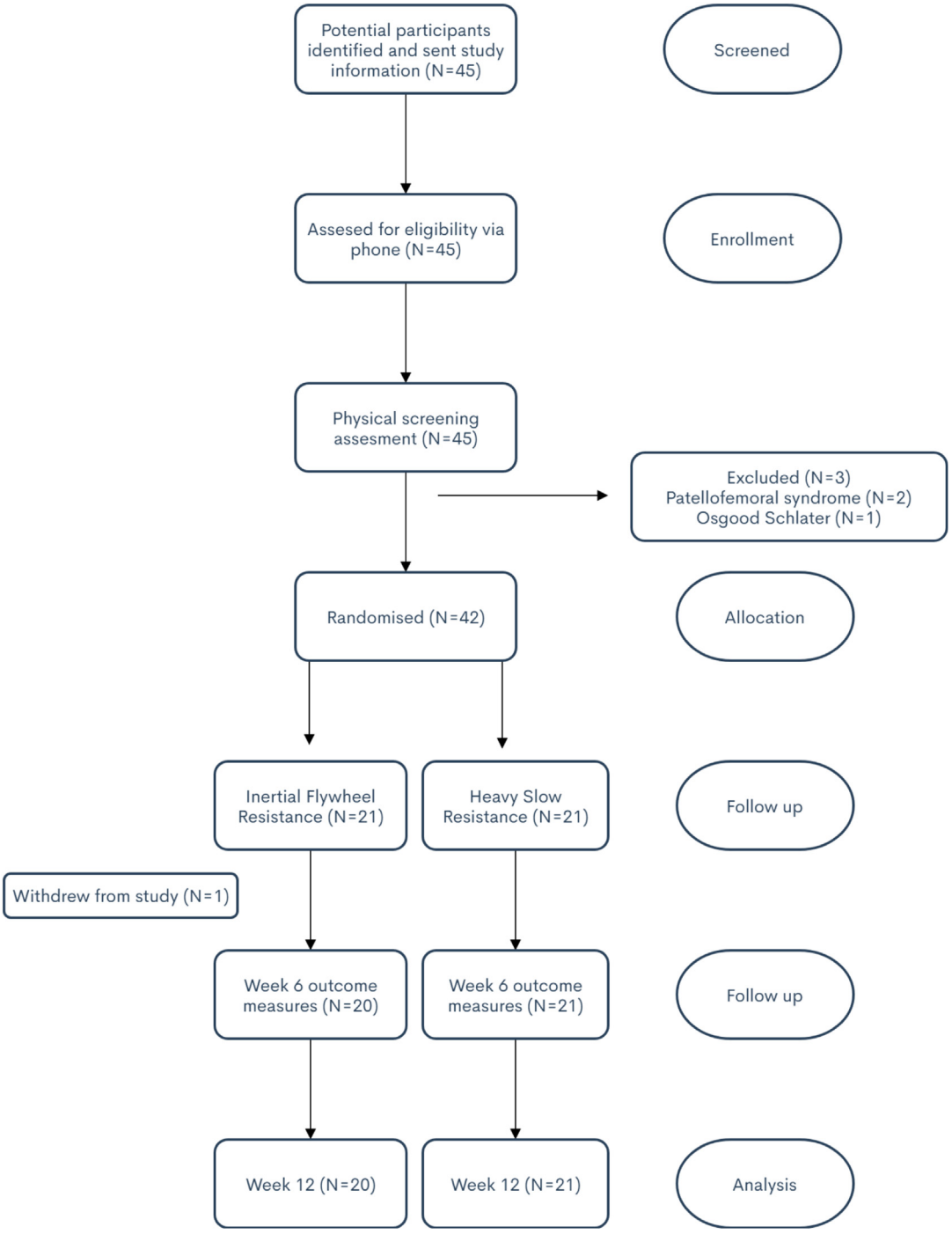

Fig. 1. Flow diagram of participants through study.

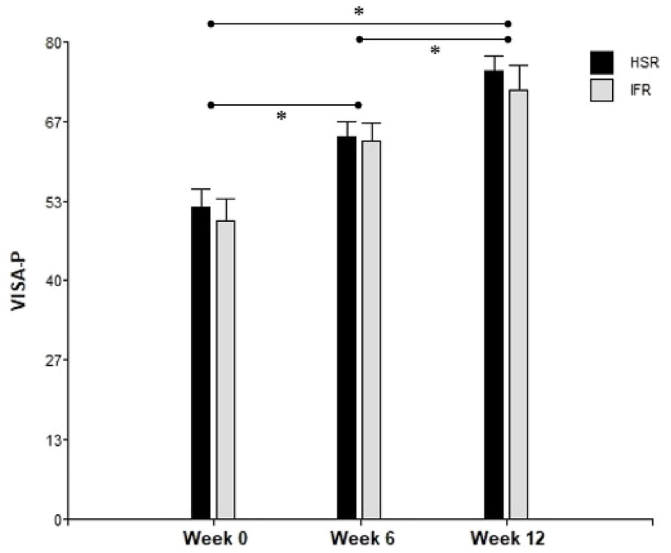

Fig. 2. Victorian Institute of Sport Assessment for Patella (VISA-P) scores at 0 (baseline), 6 and 12 weeks following treatment.
Abbreviations: HSR, Heavy slow Resistance; IFR, Inertial Flywheel Resistance.
Values are means ± SD. * P<0.05.

characteristics were similar in the two groups. Among the cohort, twenty two participants (52%) played soccer, seven (17%) volleyball, seven (17%) running and six (14%) basketball.

One participant in the inertial flywheel group withdrew due to family issues 3 weeks after starting the trial. The CONSORT flow diagram is shown in Fig. 1.

6.2. Primary self-reported outcome

There was significant within-group improvement in VISA-P scores at each time point for both groups (Fig. 2). There was no statistically significant between-group difference in VISA-P scores at 6 or 12 weeks (Fig. 2).

6.3. Secondary self-reported and imaging outcomes

Secondary outcomes data is shown in Table 2 and Table 3. At 12 weeks there were no statistically significant between-group differences in patient-specific functional scale scores (p = 0.143). There were no statistically significant differences between-groups for EQ-5D (p = 0.381) and EQ-5D-VAS (p = 0.476) neither between-groups on the SLDS (p = 0.286) and EXT (p = 0.697) for provocative loading tests. Nor were there statistically significant differences between-groups in patient impression of change on pain (relative risk [RR] 0.15, 95% CI -0.068 to 0.324, NNT 7, p = 0.341) and function (RR 0.001, 95% CI -0.28 to 0.219, p = 0.659). At 12 weeks there were no significant differences between groups in tendon AP diameter (p = 0.786).

6.4. Adverse events

At no session occasion, in either group, was the session strength training at the fitness centre stopped due to unacceptable pain (VAS >3–4) or worsened injury. Also, there were no severe adverse events in any of the groups during the intervention period.

6.5. Secondary physical test outcomes

There were no significant differences between groups in ankle dorsiflexion, CMJ, triple hop for distance and strength test (Table 3).

Table 2
Secondary outcome measures at baseline and 12 weeks.

	Inertial Flywheel (n = 20) Mean (95% IC)	Heavy Slow Resistance (n = 21) Mean (95% IC)	Adjusted mean between group difference	P-value
PSFS average score, 0-10				
Baseline	6.3 (5.69–6.91)	6.2 (5.56–6.84)	0.41 (−0.54 − 1.37)	0.710
12 Weeks	2.7 (1.62–3.78)	1.9 (1.31–2.49)	1.05 (−0.19 − 2.30)	0.143
EQ-5D, Index 0-1				
Baseline	0.84 (0.81–0.87)	0.85 (0.81–0.89)	- 0.02 (−0.07 - 0.02)	0.707
12 Weeks	0.92 (0.88–0.96)	0.94 (0.91–0.97)	−0.03 (−0.09 − 0.01)	0.381
EQ-5D, VAS				
Baseline	78.6 (74.8–82.3)	78.2 (73.1–83.2)	0.15 (−6.87 − 7.12)	0.799
12 Weeks	81.6 (75.3–87.8)	83.8 (78.7–88.9)	−0.88 (−9.63 − 7.86)	0.476
Provocative load test - Single leg decline squat (VAS)				
Baseline	7.2 (6.40–8)	6.2 (5.34–7.06)	1.03 (−0.28 − 2.35)	0.739
12 Weeks	3.7 (2.44–4.96)	2.9 (2.04–3.76)	1.22 (−0.41 − 2.86)	0.286
Provocative load test - Knee extension (VAS)				
Baseline	4.9 (3.59–6.21)	4.7 (3.70–5.70)	−0.03 (−1.73 − 1.72)	0.400
12 Weeks	2.7 (1.34–4.06)	2.1 (1.24–2.96)	1.06 (−0.72 − 2.85)	0.697
Patellar tendon AP diameter (mm)				
Baseline	6.9 (6.48–7.32)	7.1 (6.69–7.51)	0.03 (−0.68 - 0.74)	0.813
12 weeks	7.1 (6.77–7.43)	7.0 (6.59–7.41)	0.34 (−0.26 − 0.95)	0.786
Neovascularization (score 0–3)				
Baseline				
0	5 (25%)	12 (57%)	−0.32 (−0.60 -0.03)	0.037
1	10 (50%)	1 (5%)	0.45 (0.21–0.68)	0.001
2	4 (20%)	4 (19%)	0.01 (−0.23 - 0.25)	0.935
3	1 (5%)	4 (19%)	−0.14 (−0.33 -0.05)	0.170
12 Weeks				
0	9 (45%)	10 (52%)	(-0.37 − 0.23)	0.649
1	7 (35%)	4 (19%)	(-0.10 − 0.42)	0.242
2	3 (15%)	4 (19%)	(-0.26 − 0.18)	0.730
3	1 (5%)	3 (10%)	(-0.20 − 0.10)	0.538

Values are reported as mean (95% CI). For categorical variables, data are given as numbers (percentages). Adjustments were made for predefined baseline variables of age, height, weight, body mass index, activity level and duration of symptoms.
Abbreviations: PSFS, Patient specific functional scale; EQ-5D, Euroqol 5 Dimensions; EQ-VAS, EuroQol Visual Analogue Scale.

Table 3
Physical test.

	Inertial Flywheel (n = 20)Mean (±SD)		Heavy Slow Resistance (n = 21) Mean (±SD)		Mean difference between groups at 12 weeks	P-value
	Baseline	12 Weeks	Baseline	12 Weeks		
Ankle dorsiflexion						
Uninjured knee	12.5 ± 3.4	13.7 ± 2.9	13 ± 2.6	13.4 ± 2.8	0.2 (−1.6- 2)	0.809
Injured knee	13 ± 2.8	13.9 ± 2.4	12.8 ± 3	13.5 ± 2.5	0.4 (−1.1−2)	0.585
CMJ (cm)	45.1 ± 11.6	50 ± 11.2	44 ± 13.7	49.9 ± 14.9	0.1 (−8.1 − 8.5)	0.963
THD (mts)						
Uninjured knee	4.20 ± 0.69	4.60 ± 0.68	3.91 ± 0.85	4.18 ± 0.90	0.42 (−0.08 − 0.92)	0.101
Injured knee	4.04 ± 0.71	4.44 ± 0.79	3.91 ± 0.77	4.28 ± 0.94	0.16 (−0.38 − 0.70)	0.559
Strength test						
Leg extension						
Uninjured knee	76.19 ± 12.03	85 ± 14.96	69.76 ± 16.69	76.19 ± 18.57	8.81 (−1.87 − 19.4)	0.103
Injured knee	64.52 ± 20.24	78.25 ± 21.78	63.33 ± 15.68	75.24 ± 13.55	3.01 (−8.38 − 14.4)	0.596
Leg press						
Uninjured knee	70.95 ± 13.84	80.25 ± 14.37	65.24 ± 11.45	76.43 ± 10.97	3.82 (−4.23 − 11.8)	0.343
Injured knee	63.57 ± 16.06	76.00 ± 15.78	61.43 ± 9.24	76.19 ± 11.61	−0.19 (−8.91−8.53)	0.965

Values are reported as mean ± SD, unless otherwise noted.
Abbreviations: CMJ, counter movement jump, THD, triple hop for distance.

6.6. Self-reported exercise adherence

The mean training session adherence rate for inertial flywheel and heavy slow resistance groups was 88.4% and 89.9% respectively, with no significant difference between groups (P = 0.594).

7. Discussion

7.1. Principal findings

The main finding of the present study demonstrates that there were no statistical differences in the short-term between inertial flywheel and heavy slow resistance training in reducing pain and improving function in individuals with PT. There were also no differences between groups for secondary outcomes including self-reported pain and function, pain with provocative loading tests, imaging, physical testing, global pain and function improvement. These findings suggest that 12-weeks of either exercise results in within-group improvements in these outcomes over time. There were no severe adverse events with either intervention, and no differences in adverse events reported between the groups. Heavy slow resistance is an established intervention for PT (Kongsgaard et al., 2009). Our data suggest that clinicians could consider inertial flywheel training as an alternative exercise intervention. It is important to note that our superiority trial has not demonstrated that the interventions tested are equivalent, but rather that there was no evidence of a significant difference between them.

Our findings are unlikely to be explained by a type II error. The sample size calculation was based on a high-quality study that investigated heavy slow resistance training among people with PT (Kongsgaard et al., 2009). The estimated standard deviation in the heavy slow resistance group from the Kongsgaard study was 13, which is comparable to the heavy slow resistance in our study, but at some time points lower than the standard deviation in the inertial flywheel resistance group. The absolute difference in VISA-P scores, however, was only 0.7 (6 weeks) to 3.2 (12 weeks) which is much lower than the MCID of 13 points (Hernandez-Sanchez et al., 2014). The greater standard deviation of VISA-P scores at 12 weeks for the inertial flywheel resistance group (19) suggests greater variability in outcome in this group. A potential issue with flywheel training is that it involves faster quadriceps contraction and can increase patellar tendon loads (Martinez-Aranda and Fernandez-Gonzalo, 2017; Sabido et al., 2018), potentially leading to pain provocation. Nevertheless, adverse events, including reporting increased patellar tendon symptoms, were similar in both groups. This may be because we advised that participants did not undertake inertial flywheel training if pain was beyond a predefined threshold. This pain monitoring approach has been used successfully to implement exercise for lower limb tendinopathy (Kongsgaard et al., 2009; Silbernagel et al., 2007; Sprague et al., 2021) including a recent hopping program for Achilles tendinopathy (Sancho et al., 2019). We are unable to say whether a larger between-group difference in VISA-P scores may have emerged with a longer follow up period. A longer follow-up period should be considered in future studies investigating inertial flywheel resistance among this population.

We hypothesized that inertial flywheel resistance may offer benefits over heavy slow resistance to 'power outcomes' such as CMJ and triple hop because of a combination of progressive power training and concentric-eccentric overload. (Maroto-Izquierdo et al., 2017)' (Naczk et al., 2016b)' (de Hoyo et al., 2015) We did not, however, observe any advantages from these outcomes, or any functional outcomes, for the inertial flywheel resistance training. Given that mechanisms for self-reported pain and function improvement are not known (Drew et al., 2014; Macdermid and Silbernagel, 2015), it would not have been surprising to observe improved power without parallel improvements in VISA-P. What is more surprising is the lack of distinct power gains between the groups given the principle of training specificity. (Morán-Navarro et al., 2019)' (Schoenfeld et al., 2017)' (Coyle et al., 1981) However, it is important to remember that power is strongly predicted by strength which improved significantly in both groups (e.g. leg extension improved 21% in the inertial flywheel group and 19% in injured leg in the heavy slow resistance group). This is consistent with previous reports that progressive heavy slow resistance style training produces strength adaptation among people with PT (Crossley et al., 2007; Frohm et al., 2007; Kongsgaard et al., 2009).

7.2. Comparison of findings with previous research

This is the first randomised trial we are aware of that compares the efficacy of inertial flywheel resistance to heavy slow resistance training for PT. Romero-Rodriguez et al. reported improvement in pain and muscle function in professional athletes with PT using a 6-week training program, which included inertial flywheel training on a leg press machine two times per week (Romero-Rodriguez et al., 2011). More recently, Gual et al. reported that performing a single weekly in-season session of single inertial flywheel squat among

basketball and volleyball players increased functional performance, and none of the athletes included in this study developed patellar tendon pain during the season.[58] We can infer from these single cohort studies that it is safe to include flywheel training in the management of PT, or even during the season for strength and conditioning purposes, but natural history and other non-specific effects may partly explain the positive findings. Our trial enhances the current literature by demonstrating that there is no evidence of a significant difference between the heavy slow resistance and inertial flywheel resistance interventions.

In our study, within-group improvement in VISA-P was between 22.2 and 22.8 points. This was comparable to the Kongsgaard study where VISA-P improvement ranged from 18 to 22 points (higher change in the heavy slow resistance group) (Kongsgaard et al., 2009). This indicates that within-group improvement is (on a group level) clinically meaningful and in line with similar studies in the literature. However, since a control group was not included, we are unable to determine the extent to which this improvement is explained by non-specific effects such as placebo and natural history.

7.3. Strength and limitations

The strengths of this trial include rigorous allocation concealment and excellent participant retention. We also achieved very high adherence despite participants needing to attend a gym to exercise three times per week. This may be explained by supervision they received during these sessions. There are several limitations important to mention; The outcome assessor and participants were not blind to the treatment group they had been assigned. However, to minimize the potential bias, we highlighted to the participants' uncertainty about the comparative efficacy of the interventions in the explanatory and verbal statement. Furthermore, questionnaires used to collect outcomes data were completed remotely by participants without investigator assistance and strength testing was undertaken by a physical therapist unaware of group allocation. There is still the possibility that participants perceived that the inertial flywheel resistance was superior because it involves a more unusual form of training and this may have introduced performance bias. A further limitation was that we only followed participants for 12 weeks. This time frame is not sufficient to observe longer-term effects of exercise interventions and we suggest that this knowledge gap is addressed in future studies. Our sample only including one female so we urge caution in relation to generalising our findings to females with patellar tendinopathy. Another important aspect regarding the use of flywheel inertial devices is the movement velocity during exercises execution, in our case, we couldn't access a rotational encoder for measuring training characteristics, leading to difficulties to determine actual load intensity. Finally, we did not assess sport activity level during the 12-week intervention period, so we are unable to determine whether this changed or not.

8. Conclusions

There were no between-group differences in pain and function outcomes for inertial flywheel and heavy slow resistance training at 12-weeks among people with PT. Flywheel training appears safe in this population and may be considered as an alternative exercise option for this population, although studies with longer-term outcomes are needed.

Ethical approval

The study was approved by the National Clinical Hospital Córdoba Ethics Committee (N° 3365).

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

References

Abbott, J. H., & Schmitt, J. (2014 Aug). Minimum important differences for the patient-specific functional scale, 4 region-specific outcome measures, and the numeric pain rating scale. *Journal of Orthopaedic & Sports Physical Therapy, 44*(8), 560–564. https://doi.org/10.2519/jospt.2014.5248

Badia, X., Roset, M., Montserrat, S., Herdman, M., & Segura, A. (1999). La versión española del EuroQol: Descripción y aplicaciones [the Spanish version of EuroQol: A description and its applications. European quality of life scale]. *Medical Clinics of North America, 112*(Suppl 1), 79–85. Spanish.

Beato, M., & Dello Iacono, A. (2020 Jun 3). Implementing flywheel (isoinertial) exercise in strength training: Current evidence, practical recommendations, and future directions. *Frontiers in Physiology, 11*, 569. https://doi.org/10.3389/fphys.2020.00569

Beato, M., Maroto-Izquierdo, S., Turner, A. N., & Bishop, C. (2021 Jan 27). Implementing strength training strategies for injury prevention in soccer: Scientific rationale and methodological recommendations. *International Journal of Sports Physiology and Performance, 16*(3), 456–461. https://doi.org/10.1123/ijspp.2020-0862

Boesen, M. I., Koenig, M. J., Torp-Pedersen, S., Bliddal, H., & Langberg, H. (2006 Dec). Tendinopathy and Doppler activity: The vascular response of the Achilles tendon to exercise. *Scandinavian Journal of Medicine & Science in Sports, 16*(6), 463–469. https://doi.org/10.1111/j.1600-0838.2005.00512.x

Calatayud, J., Martin, F., Gargallo, P., García-Redondo, J., Colado, J. C., & Marín, P. J. (2015 Apr). The validity and reliability of a new instrumented device for measuring ankle dorsiflexion range of motion. *Int J Sports Phys Ther, 10*(2), 197–202.

Carroll, K. M., Wagle, J. P., Sato, K., Taber, C. B., Yoshida, N., Bingham, G. E., & Stone, M. H. (2019 Aug). Characterising overload in inertial flywheel devices for use in exercise training. *Sports Biomechanics, 18*(4), 390–401. https://doi.org/10.1080/14763141.2018.1433715

Collins, N., Crossley, K., Beller, E., Darnell, R., McPoil, T., & Vicenzino, B. (2009 Mar). Foot orthoses and physiotherapy in the treatment of patellofemoral pain syndrome: Randomised clinical trial. *British Journal of Sports Medicine, 43*(3), 169–171. https://doi.org/10.1136/bmj.a1735

Coyle, E. F., Feiring, D. C., Rotkis, T. C., Cote, R. W., 3rd, Roby, F. B., Lee, W., & Wilmore, J. H. (1981 Dec). Specificity of power improvements through slow and fast isokinetic training. *Journal of Applied Physiology: Respiratory, Environmental & Exercise Physiology, 51*(6), 1437–1442. https://doi.org/10.1152/jappl.1981.51.6.1437

Crossley, K. M., Thancanamootoo, K., Metcalf, B. R., Cook, J. L., Purdam, C. R., & Warden, S. J. (2007 Sep). Clinical features of patellar tendinopathy and their implications for rehabilitation. *Journal of Orthopaedic Research, 25*(9), 1164–1175. https://doi.org/10.1002/jor.20415

De Vries, A. J., Koolhaas, W., Zwerver, J., Diercks, R. L., Nieuwenhuis, K., Van Der Worp, H., Brouwer, S., & Van Den Akker-Scheek, I. (2017 Jul-Sep). The impact of patellar tendinopathy on sports and work performance in active athletes. *Research in Sports Medicine, 25*(3), 253–265. https://doi.org/10.1080/15438627.2017.1314292

Docking, S. I., Rio, E., Cook, J., Orchard, J. W., & Fortington, L. V. (2018 Sep). The prevalence of Achilles and patellar tendon injuries in Australian football players beyond a time-loss definition. *Scandinavian Journal of Medicine & Science in Sports, 28*(9), 2016–2022. https://doi.org/10.1111/sms.13086

Drew, B. T., Smith, T. O., Littlewood, C., & Sturrock, B. (2014 Jun). Do structural changes (eg, collagen/matrix) explain the response to therapeutic exercises in tendinopathy: A systematic review. *British Journal of Sports Medicine, 48*(12), 966–972. https://doi.org/10.1136/bjsports-2012-091285

Dworkin, R. H., Turk, D. C., Farrar, J. T., Haythornthwaite, J. A., Jensen, M. P., Katz, N. P., Kerns, R. D., Stucki, G., Allen, R. R., Bellamy, N., Carr, D. B., Chandler, J., Cowan, P., Dionne, R., Galer, B. S., Hertz, S., Jadad, A. R., Kramer, L. D., Manning, D. C., … Immpact. (2005 Jan). Core outcome measures for chronic pain clinical trials: IMMPACT recommendations. *Pain, 113*(1–2), 9–19. https://doi.org/10.1016/j.pain.2004.09.012

Effects of flywheel training on strength-related variables in female populations. A systematic review. Raya-González J, de Keijzer KL, Bishop C, Beato M. *Research in Sports Medicine*, , (2021 Jan 5)1–18. https://doi.org/10.1080/15438627.2020.1870977

Ferretti, A., Ippolito, E., Mariani, P., & Puddu, G. (1983 Mar-Apr). Jumper's knee. *The American Journal of Sports Medicine, 11*(2), 58–62. https://doi.org/10.1177/036354658301100202

Fredberg, U., Bolvig, L., Andersen, N. T., & Stengaard-Pedersen, K. (2008 Feb). Ultrasonography in evaluation of Achilles and patella tendon thickness. *Ultraschall in der Medizin, 29*(1), 60–65. https://doi.org/10.1055/s-2007-963027

Frohm, A., Saartok, T., Halvorsen, K., & Renström, P. (2007 Jul). Eccentric treatment for patellar tendinopathy: A prospective randomised short-term pilot study of two rehabilitation protocols. *British Journal of Sports Medicine, 41*(7), e7. https://

doi.org/10.1136/bjsm.2006.032599
Gual, G., Fort-Vanmeerhaeghe, A., Romero-Rodríguez, D., & Tesch, P. A. (2016 Jul). Effects of in season inertial resistance training with eccentric overload in a sports population at risk for patellar tendinopathy. *The Journal of Strength & Conditioning Research, 30*(7), 1834–1842. https://doi.org/10.1519/JSC.0000000000001286
Hamilton, R. T., Shultz, S. J., Schmitz, R. J., & Perrin, D. H. (2008 Apr-Jun). Triple-hop distance as a valid predictor of lower limb strength and power. *Journal of Athletic Training, 43*(2), 144–151. https://doi.org/10.4085/1062-6050-43.2.144
Harris, M., Schultz, A., Drew, M. K., Rio, E., Adams, S., & Edwards, S. (2020 Sep). Thirty-seven jump-landing biomechanical variables are associated with asymptomatic patellar tendon abnormality and patellar tendinopathy: A systematic review. *Physical Therapy in Sport, 45*, 38–55. https://doi.org/10.1016/j.ptsp.2020.03.011
Hernandez-Sanchez, S., Hidalgo, M. D., & Gomez, A. (2011 Aug). Cross-cultural adaptation of VISA-P score for patellar tendinopathy in Spanish population. *Journal of Orthopaedic & Sports Physical Therapy, 41*(8), 581–591. https://doi.org/10.2519/jospt.2011.3613
Hernandez-Sanchez, S., Hidalgo, M. D., & Gomez, A. (2014 Mar). Responsiveness of the VISA-P scale for patellar tendinopathy in athletes. *British Journal of Sports Medicine, 48*(6), 453–457. https://doi.org/10.1136/bjsports-2012-091163
Hoffmann, T. C., Glasziou, P. P., Boutron, I., Milne, R., Perera, R., Moher, D., Altman, D. G., Barbour, V., Macdonald, H., Johnston, M., Lamb, S. E., Dixon-Woods, M., McCulloch, P., Wyatt, J. C., Chan, A. W., & Michie, S. (2014 Mar 7). Better reporting of interventions: Template for intervention description and replication (TIDieR) checklist and guide. *BMJ, 348*, g1687. https://doi.org/10.1136/bmj.g1687
de Hoyo, M., Pozzo, M., Sañudo, B., Carrasco, L., Gonzalo-Skok, O., Domínguez-Cobo, S., & Morán-Camacho, E. (2015 Jan). Effects of a 10-week in-season eccentric-overload training program on muscle-injury prevention and performance in junior elite soccer players. *International Journal of Sports Physiology and Performance, 10*(1), 46–52. https://doi.org/10.1123/ijspp.2013-0547
Jonsson, P., & Alfredson, H. (2005 Nov). Superior results with eccentric compared to concentric quadriceps training in patients with jumper's knee: A prospective randomised study. *British Journal of Sports Medicine, 39*(11), 847–850. https://doi.org/10.1136/bjsm.2005.018630
Kongsgaard, M., Kovanen, V., Aagaard, P., Doessing, S., Hansen, P., Laursen, A. H., Kaldau, N. C., Kjaer, M., & Magnusson, S. P. (2009 Dec). Corticosteroid injections, eccentric decline squat training and heavy slow resistance training in patellar tendinopathy. *Scandinavian Journal of Medicine & Science in Sports, 19*(6), 790–802. https://doi.org/10.1111/j.1600-0838.2009.00949.x
Lian, O. B., Engebretsen, L., & Bahr, R. (2005 Apr). Prevalence of jumper's knee among elite athletes from different sports: A cross-sectional study. *The American Journal of Sports Medicine, 33*(4), 561–567. https://doi.org/10.1177/0363546504270454
Macdermid, J. C., & Silbernagel, K. G. (2015 Nov). Outcome evaluation in tendinopathy: Foundations of assessment and a summary of selected measures. *Journal of Orthopaedic & Sports Physical Therapy, 45*(11), 950–964. https://doi.org/10.2519/jospt.2015.6054
Malliaras, P., Barton, C. J., Reeves, N. D., & Langberg, H. (2013 Apr). Achilles and patellar tendinopathy loading programmes : A systematic review comparing clinical outcomes and identifying potential mechanisms for effectiveness. *Sports Medicine, 43*(4), 267–286. https://doi.org/10.1007/s40279-013-0019-z
Malliaras, P., Cook, J., Purdam, C., & Rio, E. (2015 Nov). Patellar tendinopathy: Clinical diagnosis, load management, and advice for challenging case presentations. *Journal of Orthopaedic & Sports Physical Therapy, 45*(11), 887–898. https://doi.org/10.2519/jospt.2015.5987
Markovic, G., Dizdar, D., Jukic, I., & Cardinale, M. (2004 Aug). Reliability and factorial validity of squat and countermovement jump tests. *The Journal of Strength & Conditioning Research, 18*(3), 551–555. https://doi.org/10.1519/1533-4287(2004)18<551:RAFVOS>2.0.CO;2
Maroto-Izquierdo, S., García-López, D., & de Paz, J. A. (2017 Dec 28). Functional and muscle-size effects of flywheel resistance training with eccentric-overload in professional handball players. *Journal of Human Kinetics, 60*, 133–143. https://doi.org/10.1515/hukin-2017-0096
Martinez-Aranda, L. M., & Fernandez-Gonzalo, R. (2017 Jun). Effects of inertial setting on power, force, work, and eccentric overload during flywheel resistance exercise in women and men. *The Journal of Strength & Conditioning Research, 31*(6), 1653–1661. https://doi.org/10.1519/JSC.0000000000001635
McAuliffe, S., Tabuena, A., McCreesh, K., O'Keeffe, M., Hurley, J., Comyns, T., Purtill, H., O'Neill, S., & O'Sullivan, K. (2019 Aug). Altered strength profile in Achilles tendinopathy: A systematic review and meta-analysis. *Journal of Athletic Training, 54*(8), 889–900. https://doi.org/10.4085/1062-6050-43-18
Morán-Navarro, R., Martínez-Cava, A., Sánchez-Medina, L., Mora-Rodríguez, R., González-Badillo, J. J., & Pallarés, J. G. (2019 Jun). Movement velocity as a measure of level of effort during resistance exercise. *The Journal of Strength & Conditioning Research, 33*(6), 1496–1504. https://doi.org/10.1519/JSC.0000000000002017
Naczk, M., Naczk, A., Brzenczek-Owczarzak, W., Arlet, J., & Adach, Z. (2016 Aug). Impact of inertial training on strength and power performance in young active men. *The Journal of Strength & Conditioning Research, 30*(8), 2107–2113. https://doi.org/10.1097/JSC.0000000000000217
Naczk, M., Naczk, A., Brzenczek-Owczarzak, W., Arlet, J., & Adach, Z. (2016 Aug). Impact of inertial training on strength and power performance in young active men. *The Journal of Strength & Conditioning Research, 30*(8), 2107–2113. https://doi.org/10.1097/JSC.0000000000000217
Norrbrand, L., Fluckey, J. D., Pozzo, M., & Tesch, P. A. (2008 Feb). Resistance training using eccentric overload induces early adaptations in skeletal muscle size. *European Journal of Applied Physiology, 102*(3), 271–281. https://doi.org/10.1007/s00421-007-0583-8
Purdam, C. R., Cook, J. L., Hopper, D. M., Khan, K. M., & VIS Tendon Study Group. (2003). Discriminative ability of functional loading tests for adolescent jumper's knee. *Physical Therapy in Sport, 4*, 3–9. https://doi.org/10.1016/S1466-853X(02)00069-X
Purdam, C. R., Jonsson, P., Alfredson, H., Lorentzon, R., Cook, J. L., & Khan, K. M. (2004 Aug). A pilot study of the eccentric decline squat in the management of painful chronic patellar tendinopathy. *British Journal of Sports Medicine, 38*(4), 395–397. https://doi.org/10.1136/bjsm.2003.000053
Romero-Rodriguez, D., Gual, G., & Tesch, P. A. (2011 Feb). Efficacy of an inertial resistance training paradigm in the treatment of patellar tendinopathy in athletes: A case-series study. *Physical Therapy in Sport, 12*(1), 43–48. https://doi.org/10.1016/j.ptsp.2010.10.003
Sabido, R., Hernández-Davó, J. L., & Pereyra-Gerber, G. T. (2018 Apr 1). Influence of different inertial loads on basic training variables during the flywheel squat exercise. *International Journal of Sports Physiology and Performance, 13*(4), 482–489. https://doi.org/10.1123/ijspp.2017-0282
Sancho, I., Morrissey, D., Willy, R. W., Barton, C., & Malliaras, P. (2019 Nov). Education and exercise supplemented by a pain-guided hopping intervention for male recreational runners with midportion Achilles tendinopathy: A single cohort feasibility study. *Physical Therapy in Sport, 40*, 107–116. https://doi.org/10.1016/j.ptsp.2019.08.007
Schoenfeld, B. J., Grgic, J., Ogborn, D., & Krieger, J. W. (2017 Dec). Strength and hypertrophy adaptations between low- vs. High-load resistance training: A systematic review and meta-analysis. *The Journal of Strength & Conditioning Research, 31*(12), 3508–3523. https://doi.org/10.1519/JSC.0000000000002200
Schulz, K. F., Altman, D. G., Moher, D., & CONSORT Group. (2010 Mar 24). CONSORT 2010 statement: Updated guidelines for reporting parallel group randomised trials. *BMC Medicine, 8*, 18. https://doi.org/10.1186/1741-7015-8-18
Silbernagel, K. G., Thomeé, R., Eriksson, B. I., & Karlsson, J. (2007 Jun). Continued sports activity, using a pain- monitoring model, during rehabilitation in patients with Achilles tendinopathy: A randomized controlled study. *The American Journal of Sports Medicine, 35*(6), 897–906, 10.1177/0363546506298279.Epub 2007 Feb 16.
Slade, S. C., Dionne, C. E., Underwood, M., & Buchbinder, R. (2016 Dec). Consensus on exercise reporting template (CERT): Explanation and elaboration statement. *British Journal of Sports Medicine, 50*(23), 1428–1437. https://doi.org/10.1136/bjsports-2016-096651
Sprague, A. L., Couppé, C., Pohlig, R. T., Snyder-Mackler, L., & Silbernagel, K. G. (2021 Feb 25). Pain-guided activity modification during treatment for patellar tendinopathy: A feasibility and pilot randomized clinical trial. *Pilot Feasibility Stud, 7*(1), 58. https://doi.org/10.1186/s40814-021-00792-5
Sprague, A. L., Smith, A. H., Knox, P., Pohlig, R. T., & Grävare Silbernagel, K. (2018 Dec). Modifiable risk factors for patellar tendinopathy in athletes: A systematic review and meta-analysis. *British Journal of Sports Medicine, 52*(24), 1575–1585. https://doi.org/10.1136/bjsports-2017-099000
Stratford, P., Gill, C., Westaway, M., & Binkley, J. (1995). Assessing disability and change on individual patients: A report of a patient specific measure. *Physiotherapie Canada, 47*, 258–263. https://doi.org/10.3138/ptc.47.4.258
Sunding, K., Fahlström, M., Werner, S., Forssblad, M., & Willberg, L. (2016 Jun). Evaluation of Achilles and patellar tendinopathy with greyscale ultrasound and colour Doppler: Using a four-grade scale. *Knee Surgery, Sports Traumatology, Arthroscopy, 24*(6), 1988–1996. https://doi.org/10.1007/s00167-014-3270-4
Tesch, P. A., Ekberg, A., Lindquist, D. M., & Trieschmann, J. T. (2004 Jan). Muscle hypertrophy following 5-week resistance training using a non-gravity-dependent exercise system. *Acta Physiologica Scandinavica, 180*(1), 89–98. https://doi.org/10.1046/j.0001-6772.2003.01225.x
Thomeé, R. (1997 Dec). A comprehensive treatment approach for patellofemoral pain syndrome in young women. *Physical Therapy, 77*(12). https://doi.org/10.1093/ptj/77.12.1690, 1690-703.
Visentini, P. J., Khan, K. M., Cook, J. L., Kiss, Z. S., Harcourt, P. R., & Wark, J. D. (1998 Jan). The VISA score: An index of severity of symptoms in patients with jumper's knee (patellar tendinosis). Victorian Institute of sport tendon study group. *Journal of Science and Medicine in Sport, 1*(1), 22–28. https://doi.org/10.1016/s1440-2440(98)80005-4
Visnes, H., & Bahr, R. (2007 Apr). The evolution of eccentric training as treatment for patellar tendinopathy (jumper's knee): A critical review of exercise programmes. *British Journal of Sports Medicine, 41*(4), 217–223. https://doi.org/10.1136/bjsm.2006.032417
Young, M. A., Cook, J. L., Purdam, C. R., Kiss, Z. S., & Alfredson, H. (2005 Feb). Eccentric decline squat protocol offers superior results at 12 months compared with traditional eccentric protocol for patellar tendinopathy in volleyball players. *British Journal of Sports Medicine, 39*(2), 102–105. https://doi.org/10.1136/bjsm.2003.010587
Zwerver, J., Bredeweg, S. W., & Hof, A. L. (2007 Apr). Biomechanical analysis of the single-leg decline squat. *British Journal of Sports Medicine, 41*(4), 264–268. https://doi.org/10.1136/bjsm.2006.032482. discussion 268.