

reliability of ICC 0.95 and low detectable change of 1.33 points.¹⁶⁸ Frequency will also be captured using the P1 question from the KOOS 'Pain' subscale: "During the past month, how often have you experienced knee pain?" with potential responses "Never" (1), "Rarely" (2), "Sometimes" (3), "Often" (4), "All the time" (5). Finally, participants will rate their problems with Pain/Discomfort in the 3-point Likert EQ-D5-Y.

Participation in sports and physical activity

According to WHO recommendations, a daily minimum of 60 min of moderate to vigorous physical activity (MVPA, such as biking, running/exercising/high-intensity training) is needed to stay healthy for 5-17-year-olds.¹⁶⁹ Thus, being at either under or above this cutoff during a 4-week average from week 18-22 will be assessed, in addition to a continuous comparison between the two groups of minutes of MVPA during the same time period. Self-reported levels of physical activity are highly under-reported from trials-participants, and sensors increase the precision.¹⁷⁰ Minutes of MVPA will be captured using waterproof three-axis 12 Hz accelerometers (SENS®, Copenhagen, Denmark) applied once to the participant's thigh during the enrollment visit using an adhesive patch (35 cm², 8 g). The sensors have shown 92±5% discriminate agreement when distinguishing between different activities (light sleep, deep sleep, lying/sitting, standing, sporadic walking/slow biking, walking, biking, running/exercising/high-intensity training).¹⁷¹ Physical activity data will also allow posthoc analyses of exposure.

In addition to physical activity, the level of participation in sports will be captured through weekly monitoring. Participants will be asked if they have been participating in sports in the preceding week and for how many hours. Return to sport time will be defined as the first week participating in sports, followed by one more week also with sports participation. Participants will also be asked during clinical visits if their return to sport was at their pre-injury level or less/more and if they are satisfied with the current extent of their sports participation.

Morphology

Involvement of the tendon is common in patients with Osgood Schlatter,^{172,173} and associated signs of bursitis and severity have shown to be prognostic of a worse outcome.³² A series of Osgood Schlatter patients has been described for whom less hyperemia on color doppler ultrasound was associated with milder symptoms.¹⁰⁵ Hyperemia on color doppler ultrasound (ad modum modified Öhberg 1-4) will therefore be assessed for the patella tendon and tibial tubercle (yes/no) at baseline, month 3, month 5, and month 8. High inter-rater reliability of color doppler evaluations in the patella tendon has been established,¹⁷⁴ and we are currently investigating the reliability and clinical relevance of the full ultrasound protocol being

Appendix 3: Pragmatic-Exploratory indicators

Figure 6. PRagmatic-Explanatory Continuum Indicator Summary – PRECIS ‘Wheel’

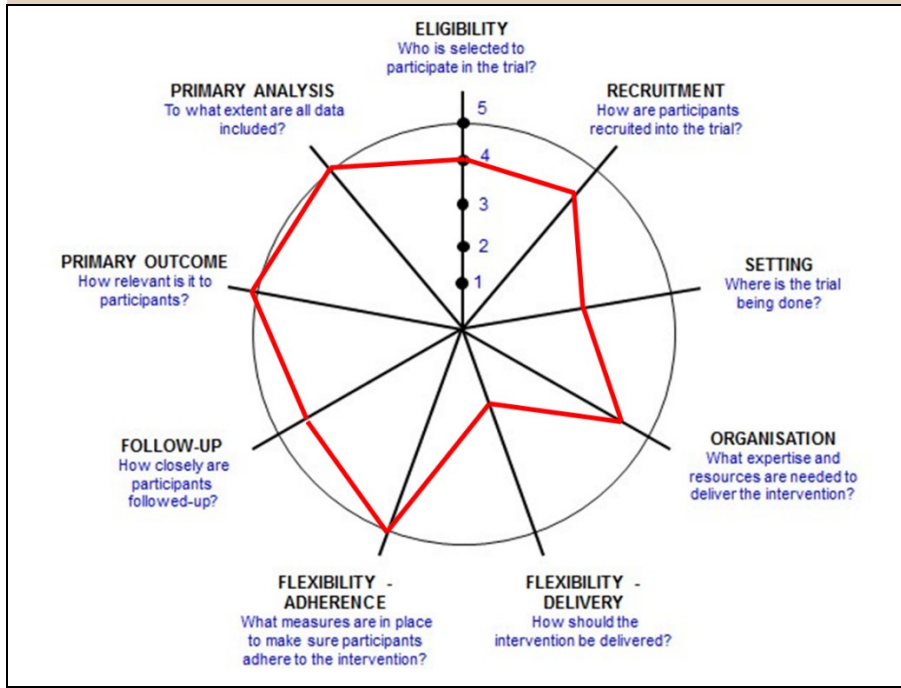


Table 9. PRECIS-2 scores for trial domains

	Domain	Score	Rationale
1	Eligibility Criteria	4	Participants included will resemble those that present in the clinic to a large degree, and concomitant complaints are also allowed to some degree.
2	Recruitment Path	4	As there are limited treatment options, participants are usually not contained in the health care system. For those that do seek treatment, we will supply nearby GP clinics and private physio clinics with contact information for potential participants. Similarly, nearby sports clubs will be provided the same material. Moreover, all patients who are referred for specialized care in the uptake area of our orthopedic department will be screened for eligibility. Finally, we will supplement the above recruitment channels with social media adverts for those that are not currently in the health care system, targeting 40-55-year-old (potential parents) in the uptake area. As such, we are attempting to potentially offer recruitment to the entirety of the local potential population.
3	Setting	3	The intervention and outcome assessments will take place at the physiotherapy department in the hospital.
4	Organization	4	The intervention is comprised by field experts, but the personnel trained to deliver the intervention will not have extensive experience with either the intervention or the target-population. Post-trial dissemination to other clinicians will consist of leaflets, intervention descriptions, and a clinician manuscript.

employed in the study.¹⁷²

Knee pain during loading

The pain evoked from loading the affected tissue will be measured in four different ways. Firstly, by rating the pain level after performing the Anterior Knee Pain Provocation test (we have recently shown this test to be associated with KOOS 'Sport/rec' and NPRS, and response over time for adolescents with knee pain).¹⁷⁵ Secondly, by a NPRS 0-10 rating from performing the maximal isometric knee extension strength test and the countermovement jump (mean of three trials). Thirdly, by manual palpation of the tibial tubercle for known pain (y/n). Finally, to evaluate local hyperalgesia, specifically at the tibial tubercle, we will use handheld algometry to detect the pressure (kPa) needed to evoke pain (going from no pain to the slightest sensation of pain) on the tibial tubercle on both knees. The intra-day and intra-tester reliability has been found to be >0.98 (ICC 3.1) for two similar sites; the center of the patella and the muscle belly of the tibialis anterior in young adults with longstanding knee pain.¹⁷⁶

Knee function

Knee pain is known to reduce muscle function.¹⁷⁷ To evaluate the capacity of the quadriceps femoris muscle inserting at the site of pain, handheld dynamometry will be used to measure maximal isometric force generation, which will be normalized to body weight and lever-length (Nm/kg). This test has shown inter-tester reliability of ICC: 0.76-0.96^{178,179} with a low standard error of measurement (5-11%)¹⁷⁹ and good validity compared to the gold standard of isokinetic strength assessment.^{178,180,181} We have recently investigated the inter-tester reliability of this test in an Osgood Schlatter cohort and found acceptable reliability.¹⁸² As a measure of power and a sports-specific skill, a countermovement jump will be performed to record jump height (cm) and power-production (watts), using high-speed video analysis via a smartphone app (My Jump 2). The test has been found feasible in adolescents,¹⁸³ been validated against the gold standard of using a force-plate,¹⁸⁴⁻¹⁸⁶ and is highly reliable.^{184,186-189} Adolescents with Osgood Schlatter have been reported to have tighter knee-extensor muscles, but it's unclear if this is thought to be a contributing cause or derived effect or if this is merely is a characteristic of increased musculoskeletal maturation.³⁸ We will compare the change in knee flexion angle, assessed by smartphone-inclinometry during a modified Thomas Test. Different apps based on the standard smartphone level-function have been investigated with near-perfect validity with other digital methods (video-analysis, digital inclinometers) and with good to excellent inter-and intra-tester reliability and low error of measurement and detectability.¹⁹⁰ However, we will utilize the built-in level app in iPhone 7 (Apple, USA) as the apps investigated in the literature are no longer available for download. We have recently investigated the inter-tester reliability of using the built-in level app in the iPhone 7 to measure the knee flexion angle in an Osgood-Schlatter cohort and found

5	Flexibility of experimental intervention – Delivery	2	Only one mode of delivery will be used in the trial (in-person visits, combined with information leaflets), but the actual contents of the visits will vary based on the progress and context of the individual participant.
6	Flexibility of experimental intervention – Adherence	5	All patients will be included in the final analyses, regardless of adherence levels.
7	Follow up	4	The number of clinical follow-up visits (4 visits) will likely be the same as in a physiotherapy clinic.
8	Outcome	5	The primary outcome is self-reported validated measured of knee-function, supplemented by level and satisfaction with sport and physical activity participation levels.
9	Analysis	5	Intention-to-treat analysis is planned for all outcomes as the standard approach