Acknowledgement

This master thesis was accomplished by two master students of rehabilitation sciences and physiotherapy at the University of Hasselt. We would like to thank all individuals who contributed to this thesis.

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Research context

Non-traumatic knee pain and pes planus/foot hyperpronation are common conditions in the adult population. Because these two conditions regularly occur together, research is trying to determine whether there is a connection between these two. Research described a significantly increased prevalence of anterior knee pain in individuals with moderate to severe pes planus compared to individuals with no to mild pes planus. The idea behind this correlation is based on biomechanics. Pes planus/ foot hyperpronation could lead to abnormal joint reaction forces in the knee and hip, which in turn are related to the development and progression of lower limb injuries like non-traumatic knee pathology. However, large prospective studies couldn't confirm this correlation. Research is needed to define whether this correlation exists in order to optimize rehabilitation of non-traumatic knee pain or pathology.

This master thesis was part of the program "Rehabilitation sciences and physiotherapy", a master's degree at the University of Hasselt. The course of the thesis was supervised by promotor Prof. Dr. Johan Bellemans. The subject fits in the research domain of musculoskeletal rehabilitation of the lower extremity.

This thesis was a result of two years of research. In the first year, a literature review was made concerning the possible influence of pes planus/foot hyperpronation on knee pain or pathology. This led to the conclusion that the prevalence of anterior knee pain was higher when severity of pes planus increased. Several biomechanical differences were found in individuals with non-traumatic knee pain compared to controls. These differences were diverse and sometimes findings were contradicting across different studies. The second part of our thesis aimed to investigate whether a pes planus-based exercise program could influence knee pain or symptoms in individuals who suffer from non-traumatic knee pain or symptoms in combination with pes planus/foot hyperpronation. This resulted in the following research question: "What is the effect of a pes planus-based corrective exercise program on knee symptomatology or knee pain?".

This master thesis was a start-up study and wasn't part of a running-project. The master students designed the research protocol and method with some advice from the promotor and submitted the research for approval by the committee for medical ethics of the University of Hasselt. After receiving a positive advice, possible participants were searched and tested by the master students. Participants who met the inclusion and exclusion criteria were recruited and participated in an eight-week program. After eight weeks, participants were re-tested and data was statistically analyzed. Afterwards, this thesis was written by the use of academic writing. The research method and design, recruitment of participants, data acquisition and data processing of this thesis were produced independently by the master students under the supervision of the promotor. Academic writing was performed completely independent by the master students. References were processed conform to the APA 6th style.

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1. Abstract

Background: According to research, malalignments of the lower extremity, like pes planus, can lead to altered biomechanics in the lower limbs. These altered biomechanics may cause increased joint reaction forces in the knees and hips which are known to be associated with the development and progression of lower limb syndromes, like non-traumatic knee pain.

Objectives: The primary aim of our study was to investigate the effect of a pes planus-based corrective exercise program on knee symptomatology or pain in individuals suffering from pes planus/foot hyperpronation in combination with non-traumatic knee pain. Secondary outcomes were the influence of age, gender, amount of knee pain, degree of foot pronation and therapy loyalty on the results of the primary outcome.

Trail design: Randomized controlled trail

Method: Twenty-eight volunteers met the inclusion- and exclusion criteria. These participants were randomly allocated to either exercise group or control group. Each group was equally sized and consisted of 14 participants. Pre- and posttests were conducted to measure pre-posttest and between-group changes. The posttest took place after an eight-week pes planus-based corrective exercise program. Primary outcome measures were changes in foot posture and knee pain. The FPI-6 was used to assess foot posture. Knee pain and symptoms were assessed by using the KOOS and the Kujala.

Results: Significant between-group differences were found for the Kujala ($p = 0.0403$), KoosPain ($p = 0.0358$), koosADL ($p = 0.0066$) and KoosSport/Rec ($p = 0.0159$) in favor of the exercise group. The FPI-6 didn't show any significant changes.

Conclusion: A pes planus-based corrective exercise program could improve knee pain and functioning in individuals suffering from pes planus/hyperpronation in combination with non-traumatic knee pain. This kind of exercise program does not improve the static foot posture. Further research is needed.

Trail registration: B9115201834828

2. Introduction

The foot forms the basis of interactional forces applied on the human body. During locomotion, those forces act upon the skeletal system. Evidence suggests that an abnormal foot structure or biomechanics may lead to a higher chance of developing overuse injuries (Cowan, Jones, & Robinson, 1993).

Pes planus is present in most infants, many children and about 15% of adults. The most common form of pes planus is flexible pes planus. In only one percent of all cases, rigid pes planus is observed. The clinical relevance of flexible pes planus is controversial, though the clinical significance of the rigid form is clear in most cases (Stormont & Peterson, 1983). According to some studies, pes planus is more common in males (Kosashvili, Fridman, Backstein, Safir, & Bar Ziv, 2008; Lakstein, Fridman, Ziv, & Kosashvili, 2010).

Non-traumatic knee pain is a very common condition. It is reported to be the second most prevalent musculoskeletal disorder in the United States. Within this condition, patellofemoral pain (PFP)/anterior knee pain is considered to be one of the most frequent occurring forms (Smith et al., 2018). A recent study by Smith et al. (2018) reported an annual prevalence of PFPS of 22.7% in the general population.

PFPS is described as diffuse anterior knee pain in the retropatellar or peripatellar region without other specific pathology whereby worsening of symptoms occurs whenever tasks are performed which result in increased patellofemoral joint (PFJ) loading (Powers, 2003; Tiberio, 1987). It is assumed that this pathology is related to abnormal movement and joint reaction forces between femur and patella. Pathological mechanics of the patella could arise from two possible causes: abnormal neuromuscular control of muscles which exert forces on the femur and patella or abnormal mechanics of the lower-extremity. Patellofemoral pain can lead to osteoarthritis and individuals with patellofemoral pain often decrease their physical activity (Gross et al., 2011). Many athletes are forced to limit their sportive activities because of PFPS symptoms (Blond & Hansen, 1998).

PFPS, patellar tendinopathy, jumpers knee, plica syndrome, chondromalacia and pes anserinus tendinitis are all conditions that belong to the category of non-traumatic knee injuries and cause anterior knee pain. The etiology of these injuries is multifactorial and not well understood. Patella abnormalities or extensor mechanism disorders lead to patellar malalignment during activities and can cause abnormal loading in the PFJ. Symptoms consist of non-specific knee pain or patellar instability. Both extrinsic and intrinsic factors contribute to the development of these conditions (Barton, Levinger, Menz, & Webster, 2009).

Excessive or prolonged foot pronation is expected to contribute to the development of non-traumatic knee pain complaints. The idea behind this possible causal relationship is based on biomechanics. According to several studies, hyperpronation of the foot or excessive rearfoot eversion are associated with an excessive internal rotation and delayed external rotation of the tibia during gait due to joint coupling. Consequently, an increased internal rotation of the femur will occur to conserve normal sagittal plane mechanics of the knee and to make knee extension possible throughout midstance. This is thought to increase the lateral tracking of the patella on the femur which will cause abnormal joint reaction forces (JRF) on the retropatellar surface (Powers, 2003; Tiberio, 1987). Although the correlation between foot posture and knee injury seems biomechanically likely, large prospective studies couldn't confirm the existence of such a correlation (Lun, Meeuwisse, Stergiou, & Stefanyshyn, 2004; Michelson, Durant, & McFarland, 2002; Witvrouw, Bellemans, Lysens, Danneels, & Cambier, 2001). On the other hand, research described a significantly higher prevalence of anterior knee pain in individuals with moderate to severe pes planus compared to individuals with no to mild pes planus (Kosashvili et al., 2008). One case control study reported an increased pronated foot posture in individuals with PFPS compared with controls (Barton, Bonanno, Levinger, & Menz, 2010).

Knowledge of the relationship between foot deformities (hyperpronation/pes planus) and knee symptoms or pain is important for researchers and health care professionals. Research is needed to understand biomechanical changes in the lower limb caused by pes planus and to improve treatment for pes planus or non-traumatic knee pathologies which could be related to pes planus. The aim of our study is to investigate the effect of a pes planus-based corrective exercise program on knee symptomatology or pain in individuals with pes planus/foot hyperpronation in combination with knee pain.

3. Method

3.1 Trail design

The trail design was a prospective randomized controlled trial with baseline and post-intervention tests. The study consisted of two groups: (I) an exercise group and (II) a control group. The allocation ratio to both groups was equal. The research was approved by the Committee of Medical Ethics of Uhasselt on 09/01/2018 (Appendix 1). The registration number B9115201834828 was assigned to this research. All participants agreed the informed consent. The randomized controlled trail was written conform to the Consort (Consolidated Standards of Reporting Trials) 2010 guideline.

3.2 Participants

Individuals with diagnosis or suspected pes planus in combination with knee pain were recruited using flyers and the social media of the master students (Appendix 2). All individuals with diagnosis or suspected pes planus in combination with knee pain could apply for this research.

Potential participants were screened using the following inclusion criteria: (I) Age between 18 and 60 years, (II) Foot hyperpronation/pes planus and (III) non-traumatic knee pain. Participants were excluded in case of (I) Traumatic origin of knee pain, (II) Neurological disorders or (III) if they participated in a pes planus-based intervention in the last six months. Interested individuals who thought to meet the criteria were invited for a screening true social media and/or mail. The screening took place in a practice room for physiotherapy students at the University of Hasselt or at the participant's home.

3.3 Procedure

As part of screening for eligibility, the Foot posture was assessed by means of the Foot Posture Index (FPI-6). Pes planus/foot hyperpronation was concluded if participants scored six or higher on the FPI-6. Knee pain was assessed with the Knee injury and Osteoarthritis Outcome Score (KOOS) and the Kujala Patellofemoral Score Questionnaire (Kujala). Age, origin of symptoms, neurological disorders and recent interventions were questioned during the screening. Test days were organized by the researchers to test as many participants as possible on the same day. Pre-tests were performed on January 20th, 2018. Post-test were performed on the 3th and 4th of April 2018. The website www.doodle.com was used to plan these days in an efficient way. When participants weren't available during these days, they were contacted individually to make an appointment. These appointments were planned as close as possible to the test days and took place at the home of the participant. Measurements were executed by two second master students "Rehabilitation sciences and Physiotherapy" of the University of Hasselt. To perform the FPI-6 correctly and to make sure their test result scores were calibrated, the researchers watched videos on YouTube and the execution of the test was practiced together, before testing the participants. The FPI-6 user guide and manual of the University of Leeds was used to measure the participants (A. Redmond, 2005). Participants were assigned to one of the two researchers who performed pre- and posttests on the same individuals. After screening, 28 individuals were included in the study.

3.4 Interventions

Participants were randomly allocated to two study groups: an exercise group and a control group. Individuals who were assigned to the exercise group received an email containing a home-based exercise program. The exercise program instruction consisted of a document with different pes planus-based corrective exercises accompanied by an explanation and an exercise schedule. The program included stretching exercises of the foot pronators and strengthening exercises of the intrinsic foot musculature and supinator's. The following exercises were used: Toe clawing, raising the medial border of the foot, making a fist with the foot, supinating the foot in stance, picking up objects with the toes, stretching of the dorsal side of the foot, forward/backward swaying in stance and heel raises. The exercise instruction document can be found in Appendix 4.

Participants in the exercise group were asked to preform three exercises a day for eight weeks. The different exercises that had to be performed on each day were described in the exercise schedule (Appendix 5).

The participants were instructed to start the exercise program on the 5th of February 2018. Participants were contacted after one and a half, tree, five and six and a half weeks and were questioned about the progress of the exercises and whether any questions on the exercise program did arise. The other group served as a control group. Participants in this group didn't receive any intervention and were asked to continue their normal daily activities for eight weeks.

3.5 Outcome measures

The research question of our study was "The effect of a pes planus-based corrective exercise program on the severity of pes planus/hyperpronation and non-traumatic knee pain or symptoms." Pes planus/hyperpronation was measured by using the FPI-6. The Kujala and Koos were used to assess knee pain levels. The FPI-6, Kujala, Koos, age and gender were assessed at the pretest, prior to randomization, and posttest. Therapy loyalty was assessed at the posttest.

3.5.1 Primary outcome measures

The primary goal of our study was to measure possible differences in pre-post tests and possible differences in changes between the exercise and the control group after eight weeks. The following outcome measures were used to detect these changes.

3.5.1.1 Pes planus/hyperpronation (FPI-6)

The foot posture index (FPI-6) is a diagnostic and clinical tool to measure overall foot posture. It is used to quantify the extent of pronation or supination the foot is in. It's a form of static assessment which is frequently used in clinical practice to evaluate individuals with lower limb overuse injuries, like PFPS. Especially when considering the prescription of foot orthotics. The FPI-6 consists of a multi-segmental assessment of the foot posture in the three different planes. No specialized equipment is needed for this test. It has a good face validity and high inter-rater (0.62-0.91 depending on population) and intra-rater (0.81-0.93) reliability in individuals with PFPS (Barton, Levinger, Crossley, Webster, & Menz, 2011; Langley, Cramp, & Morrison, 2016).

The FPI-6 consists of six items: talar head palpation, supra and infra lateral malleolar curvature, calcaneal frontal plane motion, prominence in the region of the talonavicular joint, congruence of the medial longitudinal arch and abduction/adduction of the forefoot on the rearfoot (A. Redmond, 2005).

3.5.1.2 Knee pain (Kujala & Koos)

To assess knee pain levels (non-traumatic knee pain) and functioning of the knee, the Kujala patellofemoral score and the KOOS were used. The Kujala score evaluates the functioning and the subjective symptoms of the knee. It consists of 13 items and evaluates the knee on activity level. It has a good test-retest reliability and good internal consistency. We used the Dutch translation of the Kujala Patellofemoral Score in our study. This questionnaire has a reported internal consistency of 0.78 to 0.80 and an interclass correlation coefficient (ICC) of 0.98 (Ummels, Lenssen, Barendrecht, & Beurskens, 2017)(Appendix 6).

The Knee injury and osteoarthritis outcome score (KOOS) is a questionnaire containing five main items: Pain, other Symptoms, Function in daily living (ADL), Function in sport and recreation (Sport/Rec) and knee related Quality of life (QOL). It questions the opinion of the patient towards pain and functioning of the knee. A big advantage of this questionnaire is the fact that it measures the functionality of the knee both during sports and recreation as well as during daily activities. It has a high test-retest reliability and an adequate internal consistency and construct validity (Collins et al., 2016). We used the Dutch version of the KOOS in our study (Appendix 7).

3.5.2 Secondary outcome measures

Secondary outcome measures were the influence of age, gender, therapy loyalty, severity of pes planus and severity of knee pain on severity of knee pain or pes planus at baseline (if possible) and on pre-post changes in the exercise group. All these factors were categorized. For therapy loyalty, the median (83.96) of the exercise group was used to divide the exercise group into two groups. For age and severity of knee pain (Kujala), the medians of all participants (29 and 83.5 respectively) were used to divide the participants into two groups. The median of the Kujala was used to categorize knee pain severity. The cutoff value of +10 (hyper pronation) on the FPI-6 was used to sort participants into the pronated or hyper pronated group.

Therapy loyalty was measured by the percentage of performed exercise days and a self-reported exercise adherence scale. In the exercise schedule, a column named “done my exercises” was provided as shown in appendix 5. The participants were instructed to put a check mark in this column behind the right date, each time they completed their scheduled exercises. The exercise schedules were collected at the posttests and the percentage of performed exercises was calculated.

The self-reported exercise adherence scale was also used at the posttests. Participants in the exercise group had to score to what extent they thought they had adhered to the prescribed exercise program. It is a numerical scale where the participant gives a score from 0 ("I have never done my exercises") to 10 ("I have done my exercises every day"). Similar scales have been used to measure adherence in studies of musculoskeletal therapy. This type of scale is often used in studies that do research on medication adherence and it has good validity and reliability.

The results of the self-reported exercise adherence scale were conform to the percentage of performed exercise days in almost all cases. The median of the percentage of performed exercise days was decided to be used to categorize therapy loyalty.

3.6 Sample size

To determine the sample size, the G*Power application was used. For non-parametric T-test with matched/unmatched pairs and a power of 0.80, effect size of 0.5 and α of 0.05, a total sample size of at least 28 and 106 individuals were required for matched pairs and two groups respectively. We tried to include as much participants as possible. Finally, 28 participants met the inclusion and exclusion criteria and were included in the study. These were randomly divided in to two groups of 14 participants. Because of the low number of included participants, our research did not provide enough statistical power.

3.7 Randomization

Before randomization, each included participant was given an individual number between one and 28. The website www.randomizer.org was used to generate a list of 28 random numbers. The 14 participants matching the first 14 random numbers generated by the randomizer were allocated to the exercise group. The 14 remaining participants were assigned to the control group (Appendix 8).

3.8 Blinding

Participants and researchers were not blinded. When retesting, researchers used a new FPI-6 scoring form instead of the form with the results of the first test. This was done to minimize observer bias.

3.9 Statistical methods

Data was analyzed using JMP pro 13.2.0 (64-bit). The Shapiro-Wilk test was used to assess normality of the data. Homoscedasticity was analyzed by using the Brown-Forsythe test. Nonparametric testing was performed because of the small sample sizes ($n<20$). Mann-Whitney U/Wilcoxon rank-sum tests were used to detect significant between-group differences. The Wilcoxon signed-rank test was used to detect significant pre-post changes in each group. Statistical significance was set at $p <0.05$.

4. Results

4.1 Participant flow

Participants were recruited between December 2017 and January 2018. After an intensive search, 38 potential participants were found who volunteered to participate in the study. Eight of those were excluded because they didn't meet the inclusion or exclusion criteria. The other 30 potential participants were tested in January 2018. Two of those scored lower than a +6 on the FPI-6, which indicated a normally aligned or supinated foot. Consequently, they were excluded from the study. The 28 participants who met the inclusion and exclusion criteria were random allocated to two groups of 14 participants. The posttest took place in the first week of April 2018. There weren't any dropouts during the study. The flowchart of the participant recruitment is shown in figure 1.

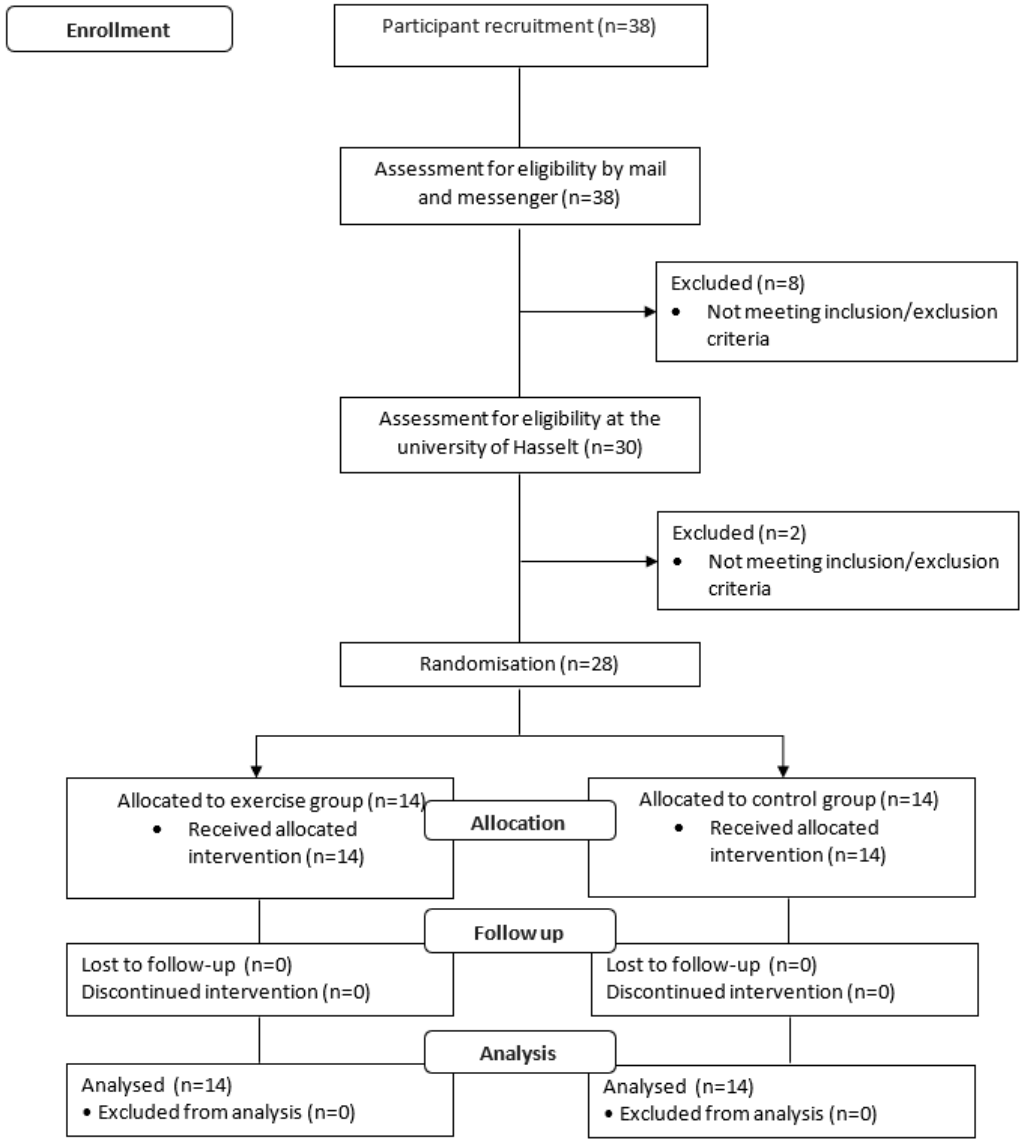

Fig. 1 Participant flow throughout the randomised control trail (RCT) (based on CONSORT 2010 statement)

4.2 Baseline data

Baseline demographic, clinical characteristics and outcome scores of each group are presented in Table 1. There were no significant between-group differences for any variable at baseline.

Table 1 | Baseline demographics, clinical characteristics and outcome scores

	Exercise group (n=14)		Control group (n=14)	
	Mean (SD)	**Median**	**Mean (SD)**	**Median**
Age (Years)	35.93 (11.16)	35.5	31.5 (11.37)	25
Gender, n (Male %)	9 (64%)	/	6 (43%)	/
FPI-6	7.93 (2.02)	7	7.61 (1.10)	7.5
Kujala	81.21 (9.74)	81.5	82.5 (10.38)	85.5
Koos				
- Pain	75.43 (3.13)	74	75.64 (3.13)	72
- Symptoms	75.64 (11.65)	73	74.14 (10.27)	75
- ADL	77.79 (14.87)	82	82.64 (10.19)	84
- Sport & rec	58.57 (19.36)	63	59.29 (19.99)	65
- QOL	64.71 (13.28)	69	66.57 (14.59)	69

** Significant between-group difference (p<0.05)*
Abbreviations: SD, standard deviation; ADL, Activities of daily living; Rec, recreation; QOL, Quality of life

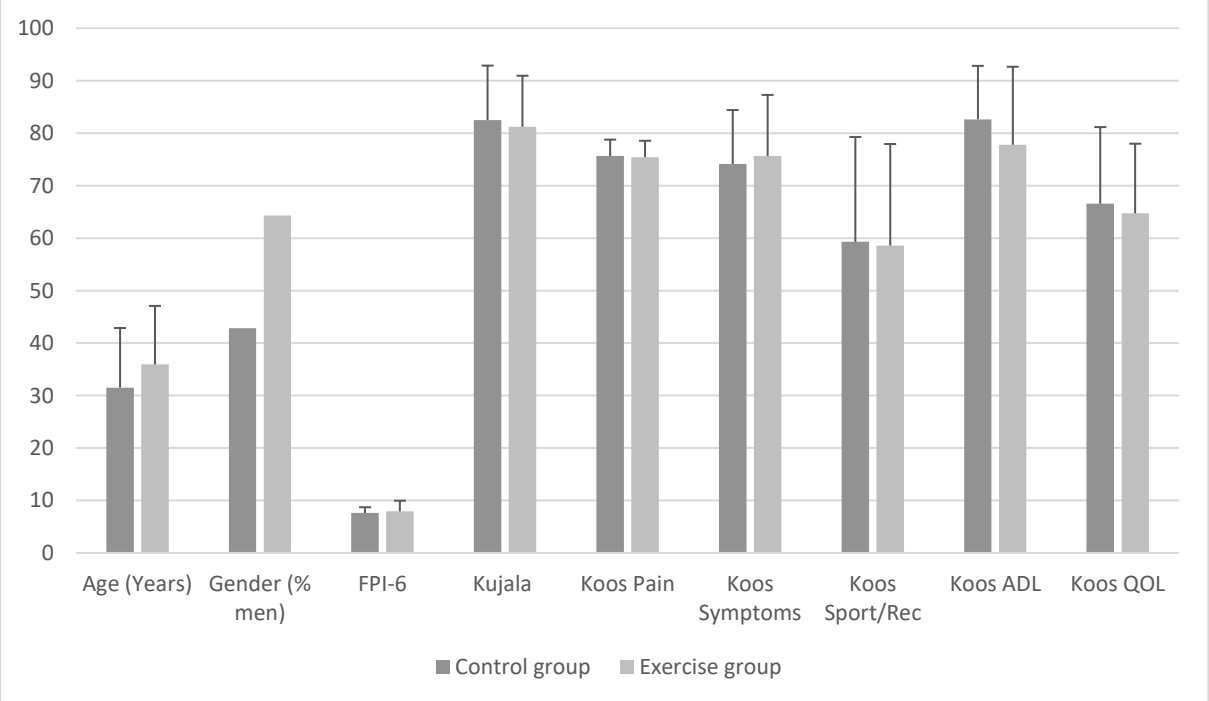

Fig 2: Baseline demographics (means)
* Significant between-group difference (p<0.05)
Abbreviations: ADL, Activities of daily living; Rec, recreation; QOL, Quality of life

4.3 Outcome measures

The mean, standard deviation (SD) and median of the posttest at the end of the intervention period are presented in table 2. Every participant was re-tested conform to the intention to treat principle.

Table 2 | Measurement values after the intervention period

	Exercise group (n=14)		Control group (n=14)	
	Mean (SD)	**Median**	**Mean (SD)**	**Median**
Pronation of the foot				
FPI-6	7.57 (1.83)	7	7.43 (1.35)	7.25
Knee pain				
Kujala	88.57 (7.02)	88.5	85 (7.96)	85.5
Koos				
- Pain	87.79 (6.39)	89	75.14 (13.13)	71
- Symptoms	87 (9.58)	89	80.79 (11.64)	81
- ADL	88.43 (9.10)	91	79.21 (12.67)	77
- Sport/Rec	78.21 (15.39)	78	61.43 (22.74)	60
- QOL	75.64 (10.99)	75	66.93 (16.26)	69
Therapy loyalty				
Self-reported EA	7.14 (0.86)	7		
% Performed exercise days	81.70 (9.62)	83.96		

** Significant pre-post difference*

Abbreviations: SD, standard deviation; ADL, Activities of daily living; Rec, recreation; QOL, Quality of life; EA, exercise adherence

4.3.1 Primary outcome measures

4.3.1.1 Pre-post changes

Pre-post changes in both the exercise and the control group were statistically analyzed and are shown in Table 3. Both groups showed a slight decrease on the FPI-6 after eight weeks but no significant changes were found compared to the pre-test. Participants in the exercise group showed a significant improvement regarding knee pain and functioning after eight weeks. A significant increase was found on the Kujala (p = 0.0024), KoosPain (p = 0.0078), KoosSymptoms (p = 0.0022), KoosAdl (p = 0.0052), KoosSport/Rec (p = 0.0105) and KoosQOL (p = 0.0332). In the control group, the KoosSymptoms (p = 0.0137) significantly increased. Other changes regarding knee pain or functioning were not found in the control group. Participants in the control group scored worse on the KoosPain and KoosADL at the posttest, but these changes weren't significant.

Table 3 | Pre-posttest changes

	Exercise group (n=14)		**Control group (n=14)**	
	Mean improvement (SD)	**P-Value**	**Mean improvement (SD)**	**P-Value**
Pronation of the foot				
FPI-6	-0.36 (0.95)	0.0821	-0.18 (0.67)	0.1696
Knee pain				
Kujala	7.36 (6.17)	0.0024*	2.5 (6.53)	0.1981
Koos				
- Pain	12.29 (14.98)	0.0078*	-0.5 (10.78)	0.7467
- Symptoms	11.36 (10.71)	0.0022*	6.14 (8.07)	0.0137*
- ADL	10.64 (14.00)	0.0052*	-3.43 (9.03)	0.5090
- Sport/Rec	19.64 (25.07)	0.0105*	2.14 (14.51)	0.4990
- QOL	10.93 (17.09)	0.0332*	0.5 (12.86)	0.8145

** Significant pre-post difference*

Abbreviations: SD, standard deviation; ADL, Activities of daily living; Rec, recreation; QOL, Quality of life

4.3.1.2 Between group differences

Between-group pre-post change differences were calculated. These are shown in Table 4. No significant differences between exercise group and control group were found on the FPI-6. The FPI-6 did improve more in the exercise group but these changes were small. A significant greater improvement on the Kujala was found in the exercise group compared to the control group (p=0.0403). Participants in the exercise group showed a significant greater improvement on the KoosPain (p=0.0358), KoosADL (p=0.0066) and KoosSport (p=0.0159). No significant between group differences were found regarding the KoosSymptoms or KoosQOL, although more clear improvements were measured in the exercise group.

Table 4 | Between-group differences

	Exercise group (n=14)	Control group (n=14)		
	Mean improvement (95% confidence interval)		Difference	P-value
Pronation of the foot				
FPI-6	-0.36 (0.01, -0.73)	-0.18 (0.08, -0.44)	-0.18	0.6539
Knee pain				
Kujala	7.36 (10.92, 3.79)	2.5 (6.27, -1.27)	4.86	0.0403*
Koos				
- Pain	12.29 (21.00, 3.72)	-0.5 (5.69, -6.69)	12.79	0.0358*
- Symptoms	11.36 (17.54, 5.17)	6.14 (10.74, 1.40)	5.21	0.2385
- ADL	10.64 (18.72, 2.56)	-3.43 (1.78, -8.64)	14.07	0.0066*
- Sport/Rec	19.64 (34.12, 5.17)	2.14 (10.52, -6.23)	17.50	0.0159*
- QOL	10.93 (20.80, 1.06)	0.5 (7.72, -7.00)	10.43	0.0721

** Significant between-group difference. Abbreviations: SD, standard deviation; ADL, Activities of daily living; Rec, recreation; QOL, Quality of life*

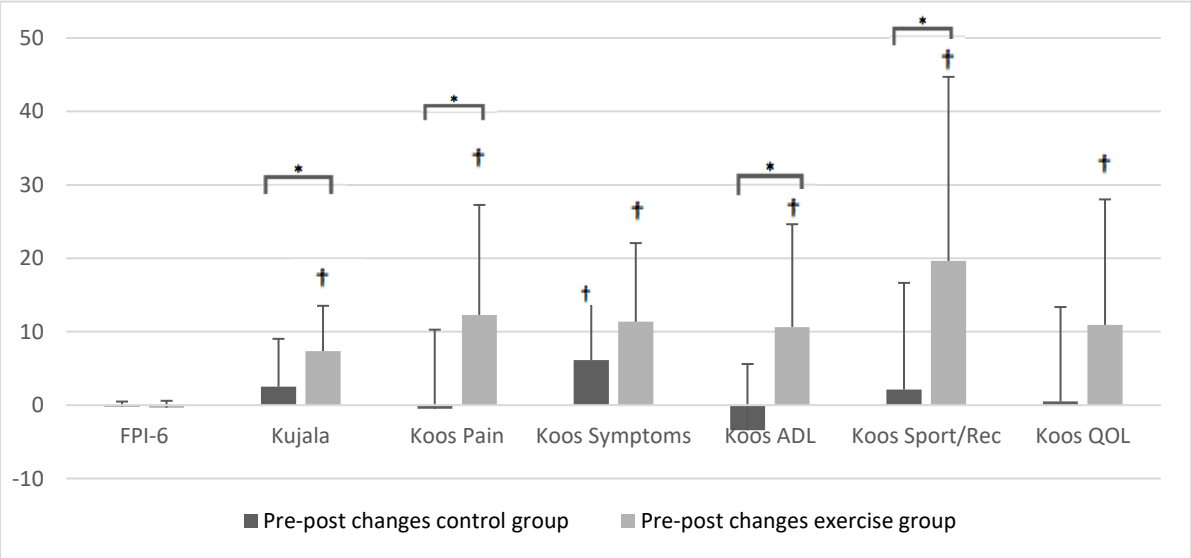

Fig 3: pre-post and between-group differences after intervention (means)

† *Significant pre-post difference* * *Significant between groups difference*

4.3.2 Secondary outcome measurements

4.3.2.1 Baseline outcomes

Pre-test outcomes were used to determine if a correlation between age, gender, degree of pes planus/hyperpronation or amount of knee pain could be detected. Age, gender or amount of knee pain weren't associated with a higher FPI-6. The older half of participants reported a significant lower score on the Kujala compared to the younger half (p=0.01). No significant differences regarding the Kujala were found for gender or degree of foot pronation. The Koos reported a significant difference between subgroups regarding the KoosSymptoms scale. In female participants, a significant lower score on the KoosSymptoms scale was found (p= 0.0123). The other Koos subscales didn't report any significant differences regarding age, gender or degree of foot pronation.

4.3.2.2 Pre-post changes (exercise group)

Pre-post changes in the exercise group were used to determine if a correlation between age, gender, degree of pes planus/hyperpronation, amount of knee pain or therapy loyalty and amount of improvement after an exercise program could exist. Age, gender, therapy loyalty, degree of pes planus/hyperpronation or amount of knee pain didn't influence the outcome on the FPI-6. A significant better improvement on the Kujala was found in older adults after the exercise intervention (p= 0.0093). Other factors didn't show a significant difference regarding the Kujala. No significant findings were detected in any of the Koos measurements. Therapy loyalty didn't show any significant impact regarding pre-post improvements. The results of these measurements can be found in Appendix 9.

4.4 Harms

Two participants in the exercise group reported foot or toe pain when performing the exercises. One of these participants had a diagnose of osteoarthritis in the big toe. Both participants received an explanation about the fact that the exercises were not harmful. The two participants both found the pain to be bearable and continued the exercise program.

5. Discussion

5.1 Interpretation of results

This Randomized control trail (RCT) aimed to evaluate the effect of a pes planus-based corrective exercise program on knee symptomatology or knee pain. No significant pre-post or between group changes were found regarding the FPI-6. These findings indicate that a pes planus-based corrective exercise program does not influence the static foot posture. These results are in accordance with a similar study which investigated the effectiveness of different interventions on pes planus (Taspinar et al., 2017).

The other primary outcome, knee pain or symptomatology, was tested using the Kujala and the Koos tests. When analyzing pre-post changes, significant improvements on the Kujala and all subscales of the Koos were found in the exercise group. A pes planus-based corrective exercise program seems to improve knee pain, symptoms, functioning and quality of life in patients suffering from pes planus in combination with non-traumatic knee pain. These findings should be interpreted with caution because a significant improvement was also found in the control group, where participants were instructed to continue normal activity levels. Furthermore, when assessing between group differences, the KoosSymptoms and KoosQOL did not show significant better improvements in the exercise group compared to the control group. Between group differences on the Kujala, KoosPain, KoosADL and KoosSport/Rec were found, in favor of the exercise group.

According to these results, a pes planus-based exercise program can decrease knee pain and increase functioning. Knee related quality of life does not seem to improve. The findings regarding knee symptoms are unclear. Pre-posttests showed significant improvements but between-group differences on the KoosSymptoms scale were not found. Furthermore, several questions of the KoosSymptoms were similar to those of the Kujala, which did show a significant between-groups improvement. Therefore, further research is necessary.

When examining secondary outcomes, a significant lower score on the Kujala was found in the older half of the participants, meaning older participants suffered from higher levels of knee pain and function limitation at baseline. This finding seems normal because of the occurrence of age-related degenerative processes, like osteoarthritis, in older adults.

Females had a significant lower score on the Koossymptoms, which could be explained by the fact that patellofemoral pain has a higher occurrence in females, according to several studies (Lakstein et al., 2010). However, no other significant female-related differences were found.

In the exercise group, the older participants showed a significantly greater improvement on the Kujala compared to younger participants. This could indicate that a pes planus-based corrective exercise program has a bigger clinical effect on older adults, regarding knee pain and functioning. On the other hand, these findings could also be partially explained by the fact that older adults had worse scores on the Kujala at baseline and therefore had more room for improvement. Furthermore, these significant age-related findings were not found for the Koos. When comparing the pronation with the hyper pronation group, no significant differences were found. Only five participants in this study had a hyperpronated foot posture. A bigger number of participants is needed to correctly evaluate these differences. The median of the percentage of performed exercise days was used to calculate differences between the participants with higher exercise adherence and lower exercise adherence. Although greater improvements were observed in the higher therapy loyalty group, no significant differences were found between these groups regarding improvement of symptoms. These findings could be explained by the fact that the difference between the median and lowest measured score of performed exercise days was limited (84 percent and 64 percent respectively). This means that all participants in the exercise group had a good therapy loyalty and could all have benefited from the possible advantages of the exercise program (Appendix 9-10).

5.2 Limitations

By using the FPI-6, a static test was used to measure foot posture. Static tests are often performed to measure foot structure, assuming it will provide insight into dynamic foot function. Although the FPI-6 is often used for measuring the foot posture in individuals with patellofemoral pain syndrome, there are only fair to moderate associations between this static test and dynamic foot function. The predictive ability of the FPI-6 is only weak to moderate. In depth camera's and 3D motion analyses can increase accuracy of dynamic foot posture measurements but don't have a better predictive ability. Therefore, a combination of static and dynamic measurements of foot posture should be performed to get an optimal insight into foot mechanics (Barton et al., 2011; Paterson, Clark, Mullins, Bryant, & Mentiplay, 2015).

The FPI-6 was measured by two second master students “Rehabilitation sciences and Physiotherapy” from the university of Hasselt. The students received extensive training on musculoskeletal pathologies and assessment during their training but never specifically learned how to perform the FPI-6. According to a study by McLaughlin et al. (2016), even novice examiners can produce reliable inter-rater results of the FPI-6, if they have a background in musculoskeletal assessment (McLaughlin, Vaughan, Shanahan, Martin, & Linger, 2016). Each researcher measured the FPI-6 of the same participants at pre- and posttest. This was done to increase the reliability (0.93) of these measurements. However, the therapists were not blinded. This could have caused an observer bias. The researchers used a new FPI-6 form at posttest. This way, the pretest values of the participants were not visible for the researcher at the posttest. This was done to minimize the observer bias.

Conform to the FPI-6 guide and manual, cutoff values of +6 and +10 were used to diagnose participants with a pronated foot or a highly pronated foot respectively. However, one study that examined the normative values of the FPI-6 in healthy adults, measured a slightly pronated foot in healthy individuals with a mean score of +4. A score of +10 was considered to be a potentially abnormal foot posture and a score of >10 was considered to be a pathological foot structure (A. C. Redmond, Crane, & Menz, 2008). These findings should be taken into account when interpreting the results of our study.

Only individuals between 18 and 60 years old were selected to participate in this study. This might have influenced the generalizability of the results in a negative way. This inclusion criteria was integrated because a study by Redmond et al. (2008) reported systematic differences on the FPI-6 by age group. Both minors and adults older than 60 years reported a significant higher score on the FPI-6 than the general population. These differences were caused by age-related processes. Therefore, these age groups were excluded.

The mean age of participants in our study was 29 years. This is young, considering the inclusion criteria for age was set between 18 and 60 years old. This might have influenced the results. The median of the Kujala was used to measure secondary outcomes regarding knee pain, because it seemed to be the more valid test compared to the Koos regarding our population, considering the mean age of the participants.

Therapy loyalty was measured using the percentage of performed exercise days and a self-reported exercise adherence scale. Although the self-reported exercise adherence scale has a good validity and reliability, these measurements are dependent on the honesty of the individuals participating in the exercise group. In our study, there was no certainty that the participants in the exercise group performed the exercises correctly and every day. Further research should include at least one supervised therapy session, where exercises can be explained and corrected by professionals before starting or during the exercise program. Furthermore, participants in the control group were asked at the start of the study to continue their normal daily activity level. Whether or not participants adhered to this condition was not checked during the further course of the study. This might have influenced the results and could possibly explain, in combination with other factors, the significant pre-post improvement on the KoosSymptoms in the control group.

A significant part of the population participating in the study consisted of friends and family of the researchers. Therefore, mostly students and middle-aged participants were included in this study. This could have limited the generalizability of the results.

Participants were not blinded during the study. They were informed there would be an exercise group and a control group. Furthermore, no placebo treatment was introduced in the control group. This might have caused exaggerated effect in the exercise groups (Hróbjartsson, Emanuelsson, Skou Thomsen, Hilden, & Brorson, 2014). Feature research should include a placebo treatment and a blinding of participants and, if possible, observers.

Finally, the researchers weren't able to find enough participants during their second master year to provide results with sufficient statistical power. Because of all mentioned limiting factors, the results of this study should be interpreted with caution.

5.3 Strengths

The study was a randomized controlled trail and is written conform to the CONSORT 2010 guidelines. It investigated the influence of a pes planus-based corrective exercise program on non-traumatic knee pain or symptomatology, which had never been done before. Individuals with any form of non-traumatic knee pain/injuries were included in this study, which led to a higher generalizability. Also, measurements of the FPI-6 were performed on the same individuals by one researcher, which increased reliability. Furthermore, the used measurement tools provided sufficient validity and reliability. Statistical analysis was performed separately by the researchers and results were compared afterwards to avoid errors.

5.4 Generalizability

Because the intervention was implemented for both sexes, ages between 18 and 60 and all types of non-traumatic knee pain/injuries combined with pes planus, there should be a relatively good generalizability of these results for all individuals who meet these characteristics (see also limitations).

5.5 Recommendations for the future

Firstly, future research investigating this subject should include a bigger sample size to make sure results could be provided with enough statistical power. This way, differences between age, gender, therapy loyalty, amounts of knee pain and degrees of foot pronation could also be analyzed more properly. Also, a combination of static and dynamic measurements of foot posture should be integrated in the study to get an optimal insight into foot mechanics. Implementation of the entire kinetic chain of the lower extremity would provide even more educative results. Research should include at least one supervised therapy session, where exercises could be explained and corrected by professionals before starting the home-based exercise program in the exercise group. Participant blinding and, if possible, observer blinding should be performed in combination with a placebo treatment in the control group to avoid bias. Further research regarding this subject is necessary to optimize the treatment of patients with non-traumatic knee injuries.

6. Conclusion

A pes planus-based corrective exercise program has no effect on static foot posture. However, our study indicates that such a program does seem to improve knee pain and functioning in individuals suffering from pes planus/hyperpronation in combination with non-traumatic knee pain or pathology. Therefore, measurement of the foot posture should be recommended in individuals suffering from non-traumatic knee pain or pathologies. Implementation of pes planus-based corrective exercises should be considered in the treatment of patients with pes planus/foot hyperpronation who suffer from non-traumatic knee pain to improve clinical outcomes. Further research regarding the relationship between pes planus and non-traumatic knee pain or symptoms is necessary.

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8. Appendices

- Appendix 1: Advise Committee for medical ethics of the University of Hasselt + insurance (Dutch)
- Appendix 2: Recruitment flyer (Dutch)
- Appendix 3: The FPI-Score form
- Appendix 4: Exercise instruction document (Dutch)
- Appendix 5: Exercise schedule and therapy loyalty (Dutch)
- Appendix 6: The Kujala Patellofemoral Score Questionnaire (Dutch)
- Appendix 7: The Knee injury and Osteoarthritis Outcome Score (Dutch)
- Appendix 8: Randomization program
- Appendix 9: Secondary outcomes
- Appendix 10: Graphs secondary outcomes
- Appendix 11: List of Abbreviations
- Appendix 12: Inventory form

Appendix 1: Advise Committee for medical ethics of the University of Hasselt + insurance (Dutch)

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Definitief gunstig advies

Faculteit Geneeskunde en Levenswetenschappen
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ons kenmerk	uw kenmerk	Diepenbeek
CME2017/765		09/01/2018

Titel protocol	**The effect of a pes planus-based corrective exercise program on knee symptomatology or knee pain.**
Nummer protocol	
Opdrachtgever	Universiteit Hasselt
Eudractnummer	NVT
Belgisch nummer	**B9115201834828**
Onderzoeker	*Prof. dr. Johan Bellemans*

Geachte collega,

Tijdens de vergadering van 5 december 2017 werd het hierboven vermeld dossier besproken.

Na inzage van de bijkomende informatie en/of aangepaste documenten met betrekking tot dit dossier is het Comité voor Medische Ethiek UHasselt van oordeel dat de voorgestelde studie, zoals beschreven in het protocol, wetenschappelijk relevant en ethisch verantwoord is.

Het definitief gunstig advies betreft de volgende documenten:
- Protocol versie 2
- Informatie en toestemmingsformulier versie 2
- Bewijs van 'No-fault' verzekering,
- Oefenbundel
- Kujala Patellofemoral score
- KOOS vragenlijst
- Flyer

Het Comité voor Medische Ethiek van UHasselt handelt volgens de geldende richtlijnen van de 'International Conference of Harmonization (ICH) Good Clinical Practice (GCP)' en volgens alle geldende en van toepassing zijnde wetten en reglementen.

Dit gunstig advies houdt niet in dat het Comité de verantwoordelijkheid voor de geplande studie op zich neemt. De onderzoeker blijft zelf verantwoordelijk hiervoor. Bovendien dient u er over te waken dat uw mening als betrokken onderzoeker wordt weergegeven in publicaties, rapporten voor de overheid enz., die het resultaat zijn van dit onderzoek.

Het comité vraagt aan de onderzoeker op de hoogte te worden gehouden wanneer de studie wordt gestart of wanneer ze wordt afgesloten of vroegtijdig onderbroken (met opgave van reden)

Indien de studie niet binnen het jaar beëindigd is dient de onderzoeker een jaarlijks rapport met het verloop van de studie te bezorgen aan het CME UHasselt.

Bij Serious Adverse events (SAE's) dient de onderzoeker het comité hiervan op de hoogte te brengen.

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KNOWLEDGE IN ACTION

Wijzigingen in het studieprotocol, informatie en toestemmingsformulier, onderzoeksteam) dienen te worden goedgekeurd door het Comité via een amendement.

Wanneer een studie beëindigd wordt dient de onderzoeker een studierapport op te maken met het verloop van de studie (startdatum, einddatum, aantal geïncludeerde patiënten, aantal drop-outs, aantal patiënten die de studie volledig doorlopen hebben, eventuele adverse events, ...

Met oprechte hoogachting,

Prof. dr. Ivo Lambrichts
Voorzitter Comité voor Medische Ethiek

Cc:

FAGG – Research & Development department, Victor Hortaplein 40, bus 40, 1060 Brussel

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Commissie voor Medische Ethiek UHasselt

ledenlijst per 01.05.2016

Functie	Titel	Voornaam	Naam	Discipline	Instelling
Voorz.	Prof.dr.	Ivo	Lambrichts	Histoloog	Universiteit Hasselt
	Prof.dr.	Koen	Magerman	Arts/klinisch bioloog	Jessa Ziekenhuis
	Dr.	Patrick	Noyens	Arts/cardioloog	Ziekenhuis Oost-Limburg
	Prof. dr.	Jeroen	Mebis	Arts/oncoloog	Jessa Ziekenhuis
	Prof.dr.	Geert	Robaeys	Arts/internist	Ziekenhuis Oost-Limburg
	Dr.	Wouter	Lansink	Arts/thoracovasculaire heelkunde	Ziekenhuis Oost-Limburg
	Prof.dr.	Marjan	Vandersteen	Arts/anatoom	Universiteit Hasselt
	Prof.dr.	Frank	Vandenabeele	huisarts	Universiteit Hasselt
	Mevrouw	Britt	Loos	Jurist	Universiteit Hasselt
	Prof. dr.	Wim	Pinxten	Ethicus	Universiteit Hasselt
	Mevrouw	Bojoura	Schouten	Psycholoog	Universiteit Hasselt
	Mevrouw	Kristel	Marquet	Verpleegkundige	Jessa Ziekenhuis
	Mevrouw	Anne	Bogaers	Verpleegkundige	Universiteit Hasselt
	Prof. dr.	Neree	Claes	huisarts	Universiteit Hasselt
	Prof. dr.	Elke	De Troy	Ziekenhuisapotheker	Jessa Ziekenhuis

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85 63 10

VERZEKERINGSATTEST

Ethias NV, Prins-Bisschopssingel 73 te 3500 Hasselt, bevestigt dat de waarborgen van polis nr. **45.197.381**, afgesloten door **Universiteit Hasselt**, Martelarenlaan 42 te 3500 Hasselt, binnen de grenzen der algemene en speciale voorwaarden én overeenkomstig de bepalingen van de Wet van 7 mei 2004 inzake de experimenten op de menselijke persoon, van toepassing zijn op de burgerlijke aansprakelijkheid welke, uit hoofde van schade veroorzaakt aan de deelnemers en / of hun rechthebbenden, ten laste gelegd kan worden van de opdrachtgever in het kader van de klinische studie:

"The effect of a pes planus-based corrective exercise program on knee symptomatology or knee pain."

Deze dekking wordt verleend onder voorbehoud van goedkeuring door de Commissie Medische Ethiek.

Waarborgbedragen

De waarborg wordt verleend tot beloop van 2.500.000,00 € per schadegeval inzake de lichamelijke, materiële en immateriële gevolgschade vermengd. Voornoemd bedrag maakt tevens de maximale waarborgtussenkomst uit voor de volledige duur van de studie.

Opgemaakt te Hasselt, 9 januari 2018.

Voor Ethias,
Voor het Directiecomité

Katrien Germeys
Dienstverantwoordelijke

Appendix 2: Recruitment flyer (Dutch)

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GEZOCHT!

Als 2de master studenten binnen de revalidatiewetenschappen en kinesitherapie aan de UHasselt doen we in het kader van onze Masterproef het volgende onderzoek: *"Het effect van een platvoet corrigerend oefenprogramma op kniepijn/symptomen bij mensen met platvoeten gecombineerd met kniepijn"*. Wij onderzoeken een mogelijk verband tussen platvoeten en knieproblematiek.

Wie?

- Volwassenen tussen 18 en 65 jaar &
- Vermoeden of diagnose van platvoet &
- Knieklachten bij bepaalde houdingen/bewegingen/activiteiten

Wat?

Bij deelname aan het onderzoek zal:

- *De mate van platvoeten onderzocht worden.*
- *U gevraagd worden om enkele vragenlijsten rond knieproblematiek in te vullen.*
- *u gevraagd worden al dan niet deel te nemen aan een oefenprogramma gedurende 8 weken. (oefeningen voor thuis!)*

Waar?

Het onderzoek zal 2 maal plaatsvinden in gebouw D van de universitaire campus te Diepenbeek en zal maximaal 30 minuten in beslag nemen.

Deelname aan de studie is volledig ***gratis****.*

Indien u interesse hebt om deel te nemen of meer wilt weten over dit onderzoek, gelieve ons te contacteren via onderstaande gegevens:

sander_willems@student.uhasselt.be
glenn.kelchtermans@student.uhasselt.be

Appendix 3: The FPI-6 score form

Foot Posture Index Datasheet

Patient name ***ID number***

	FACTOR	PLANE	SCORE 1 Date_____ Comment_____		SCORE 2 Date_____ Comment_____		SCORE 3 Date_____ Comment_____	
			Left -2 to +2	**Right** -2 to +2	**Left** -2 to +2	**Right** -2 to +2	**Left** -2 to +2	**Right** -2 to +2
Rearfoot	Talar head palpation	*Transverse*						
	Curves above and below the lateral malleolus	*Frontal/ transverse*						
	Inversion/eversion of the calcaneus	*Frontal*						
Forefoot	Prominence in the region of the TNJ	*Transverse*						
	Congruence of the medial longitudinal arch	*Sagittal*						
	Abd/adduction forefoot on rearfoot	*Transverse*						
	TOTAL							

Reference values
Normal = 0 to +5
Pronated = +6 to +9, Highly pronated 10+
Supinated = -1 to –4, Highly supinated –5 to -12

Foot Posture Index Datasheet

Patient name ***ID number***

	FACTOR	PLANE	SCORE 1 Date_____ Comment_____		SCORE 2 Date_____ Comment_____		SCORE 3 Date_____ Comment_____	
			Left -2 to +2	**Right** -2 to +2	**Left** -2 to +2	**Right** -2 to +2	**Left** -2 to +2	**Right** -2 to +2
Rearfoot	Talar head palpation	*Transverse*						
	Curves above and below the lateral malleolus	*Frontal/ transverse*						
	Inversion/eversion of the calcaneus	*Frontal*						
Forefoot	Prominence in the region of the TNJ	*Transverse*						
	Congruence of the medial longitudinal arch	*Sagittal*						
	Abd/adduction forefoot on rearfoot	*Transverse*						
	TOTAL							

Reference values
Normal = 0 to +5
Pronated = +6 to +9, Highly pronated 10+
Supinated = -1 to –4, Highly supinated –5 to -12

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Appendix 4: Exercise instruction document in Dutch

Oefenbundel

Algemene informatie:

- De oefeningen dienen elke dag uitgevoerd te worden.
- Indien u om een bepaalde reden de oefeningen niet meer kunt uitvoeren gelieven dan de onderzoekers te contacteren.

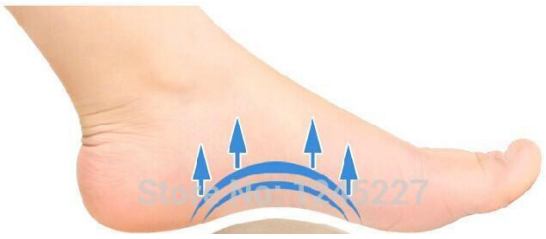
Oefeningen:

Oefening 1: Klauwen maken met de tenen

- Beginpositie: De oefening kan in lig of in zit uitgevoerd worden.
- Uitvoering: De bedoeling van deze oefening is het maximaal strekken van de tenen. Deze positie proberen ze 10 seconden vol te houden. Vervolgens worden de tenen maximaal gebogen en ook weer 10 seconden volgehouden.
- **3 x 10 herhalingen van elke houding, 30 seconden rust tussen de sets**

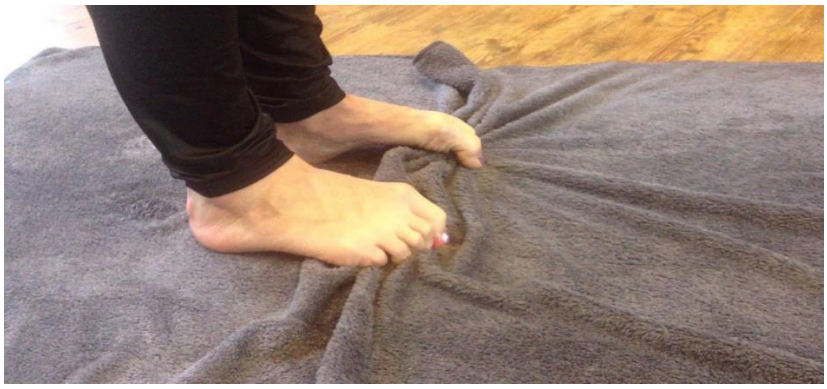
Oefening 2: Opheffen mediale voetboog

- Beginpositie: De oefening wordt in stand of in zit uitgevoerd.
- Uitvoering: Plaats de voeten plat op de grond. Probeer het midden van de binnenste rand van de voeten omhoog te tillen (maak een greep met de tenen). Hou dit 10 seconden vast.
- **3 x 10 herhalingen (10 seconden), 30 seconden rust tussen de sets**



Oefening 3: Handdoek oprollen met de voeten/ vuist maken met de voeten

- Beginpositie: De oefening wordt in zit uitgevoerd met de voeten op een handdoek.
- Uitvoering: Je trekt met de tenen de handdoek naar je toe en houdt dit voor 10 seconden vast. De handdoek ligt hierbij op de grond.
- **3 x 10 herhalingen (10 seconden), 30 seconden rust tussen de sets**



Oefening 4: klein object oppakken met de tenen

- Beginpositie: De oefening kan in stand of in zit uitgevoerd worden.
- Uitvoering: Gedurende deze oefening is het de bedoeling dat er een aantal kleine voorwerpen op de grond worden gelegd. Vervolgens probeer je deze op te rapen met de tenen door de tenen te buigen. Til het voorwerp 10cm van de grond en leg het voorwerp terug zachtjes neer op de grond. Elke dag dient gewisseld te worden van voorwerp.
- Voorwerpen:
    - Pen
    - Potlood
    - Gom
    - Dopje van een flesje
    - Sponsje
    - Knikker
    - Lego blokje

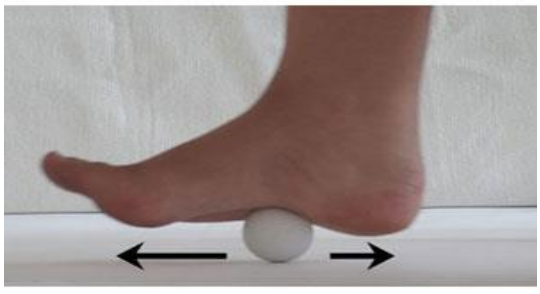
- **3 x 10 herhalingen van 1 voorwerp, 30 seconden rust**

Oefening 5: Op de buitenkant van de voeten gaan staan

- Beginpositie: Deze oefening wordt in stand uitgevoerd.
- Uitvoering: De bedoeling is om de binnenkant van de voet op te heffen, waardoor je op de buitenkant van de voet komt te staan.
- **3 x 10 herhalingen (10 seconden houden)**

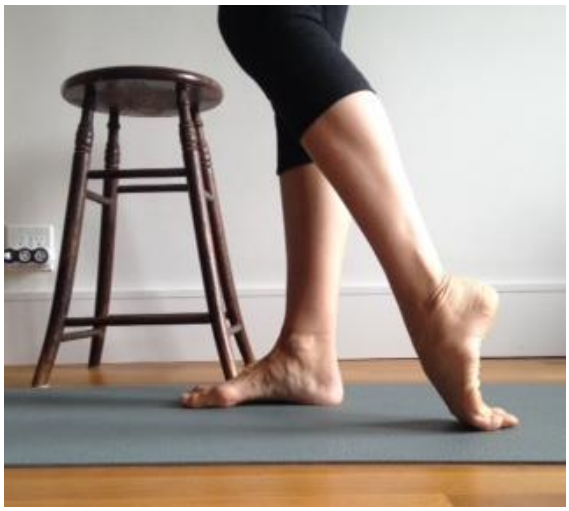
Oefening 6: tennisbal rollen onder de voet

- Beginpositie: In het begin wordt de oefening in zit uitgevoerd later kan er worden overgegaan naar stand (meer druk op de voet).
- Nut: Deze oefening is voor het strekken en flexibel maken van de peesplaat onder de voet (de 'plantar fascia').
- Uitvoering: Gebruik een tennis - of golfbal. Leg het op de grond en rol de voet erover heen van de hiel naar de tenen, heen en weer. Als het goed voelt en geen pijn doet, dan mag u rechtstaan terwijl u deze oefening doet.
- **2 x 2 minuten aan elke voet**



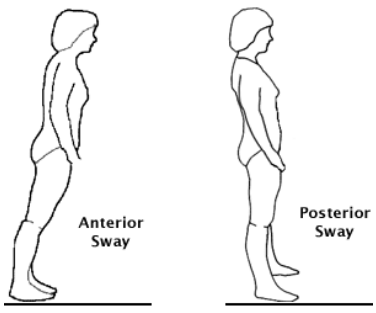
Oefening 7: Stretchen dorsale zijde van de voet

- Beginpositie: De oefening wordt uitgevoerd in zit of stand met blote voeten.
- Uitvoering: Probeer de bovenzijde van uw voet zo ver mogelijk op de grond te leggen, beginnend bij de tenen. Hou dit 30 seconden aan. Doe dit aan beide kanten.
- **3 x 30 seconden bij elke voet**



Oefening 8: voor en achterwaarts leunen

- Beginpositie: De oefening wordt in stand uitgevoerd. De voeten staan hierbij op een onstabiel oppervlakte.
- Uitvoering: Gedurende deze stabiliteitsoefening is het de bedoeling om zo ver mogelijk naar voor en achter de leunen met gestrekte knieën en heupen. Probeer enkel in de voeten te bewegen.
- **3 x 10 keer naar voor en naar achter**
- Aandachtspunten: Voer deze oefening uit in het bijzijn van iemand of langs een object dat u kan vastpakken wanneer u uw evenwicht dreigt te verliezen.



Oefening 9: Oefening kuitspieren

- Beginpositie: Ga rechtop staan.
- Uitvoering: Ga op je tenen staan. Je probeert de hielen gedurende een seconde van de grond te houden. Laat de hielen vervolgens traag zakken naar de grond.
- **3x 10 herhalingen**

Appendix 5: Exercise schedule and therapy loyalty

Dag	Oef 1	Oef 2	Oef 3	Oef 4	Oef 5	Oef 6	Oef 7	Oef 8	Oef 9	Voltooid
5/02/2018	x	x	x							
6/02/2018				x	x	x				
7/02/2018							x	x	x	
8/02/2018	x			x	x					
9/02/2018		x				x	x			
10/02/2018			x					x	x	
11/02/2018	x					x		x		
12/02/2018		x		x			x			
13/02/2018			x		x				x	
14/02/2018	x						x		x	
15/02/2018		x				x		x		
16/02/2018			x	x	x					
17/02/2018	x	x	x							
18/02/2018				x	x	x				
19/02/2018							x	x	x	
20/02/2018	x			x	x					
21/02/2018		x				x	x			
22/02/2018			x					x	x	
23/02/2018	x					x		x		
24/02/2018		x		x			x			
25/02/2018			x		x				x	
26/02/2018	x						x		x	
27/02/2018		x				x		x		
28/02/2018			x	x	x					
1/03/2018	x	x	x							
2/03/2018				x	x	x				
3/03/2018							x	x	x	
4/03/2018	x			x	x					
5/03/2018		x				x	x			
6/03/2018			x					x	x	
7/03/2018	x					x		x		
8/03/2018		x		x			x			
9/03/2018			x		x				x	
10/03/2018	x						x		x	
11/03/2018		x				x		x		
12/03/2018			x	x	x					
13/03/2018	x	x	x							
14/03/2018				x	x	x				
15/03/2018							x	x	x	
16/03/2018	x			x	x					
17/03/2018		x				x	x			
18/03/2018			x					x	x	
19/03/2018	x					x		x		
20/03/2018		x		x			x			
21/03/2018			x		x				x	
22/03/2018	x						x		x	
23/03/2018		x				x		x		
24/03/2018			x	x	x					
25/03/2018	x	x	x							
26/03/2018				x	x	x				
27/03/2018							x	x	x	
28/03/2018	x			x	x					
29/03/2018		x				x	x			
30/03/2018			x					x	x	
31/03/2018	x					x		x		
1/04/2018		x		x			x			

Appendix 6: The Kujala Patellofemoral Score Questionnaire (Dutch)

Kujala Patellofemoral Score – Dutch translated Version

Vertaling: P.E.J. Ummels

Naam: Datum:

Geboortedatum: Geslacht: Man/Vrouw

Knie: L/R

Duur van de klachten: Jaar Maanden Weken

Omcirkel bij elke vraag de keuze (letter) die het beste past bij uw knieklachten.

1. Mank lopen: a) Niet (5) b) Af en toe of een beetje (3) c) Altijd (0)	**8. Langdurig zitten met gebogen knieën:** a) Geen probleem (10) b) Pijn na langdurig zitten met gebogen knieën (8) c) Continu pijn (6) d) Ik moet nu en dan mijn knie strekken vanwege de pijn (4) e) Niet mogelijk (0)
2. Belastbaarheid: a) Staan op één been is niet pijnlijk (5) b) Staan op één been is pijnlijk (3) c) Staan op één been is niet mogelijk (0)	**9. Pijn:** a) Geen (10) b) Af en toe een beetje (8) c) Het hindert bij het slapen (6) d) Soms hevig (3) e) Altijd hevig aanwezig (0)
3. Wandelen: a) Onbeperkt (5) b) Meer dan 2 km (3) c) 1-2 km (2) d) Niet mogelijk (0)	**10. Zwelling:** a) Geen (10) b) Na forse in spanning (8) c) Na dagelijkse activiteiten (6) d) Iedere avond (4) e) Altijd (0)
4. Traplopen: a) Geen probleem (10) b) Lichte pijn bij trap aflopen (8) c) Zowel trap op als trap aflopen is pijnlijk (5) d) Niet mogelijk (0)	**11. Voelt u uw knieschijf (patella) wel eens pijnlijk wegschieten (dislocatie)?** a) Nooit (10) b) Soms tijdens het sporten (6) c) Soms bij dagelijkse activiteiten (4) d) 1 of 2 vastgestelde dislocaties (2) e) Meer dan twee vastgestelde dislocaties (0)
5. Hurken a) Geen probleem (5) b) Herhaald hurken is pijnlijk (4) c) Hurken is iedere keer pijnlijk (3) d) Alleen mogelijk indien niet volledig belast (2) e) Niet mogelijk (0)	**12. Zijn uw bovenbeenspieren dunner geworden?** a) Nee (5) b) Ja, een beetje (3) c) Ja, veel (0)
6.Hardlopen: a) Geen probleem (10) b) Pijn na meer dan 2 km hardlopen (8) c) Lichte pijn vanaf begin hardlopen(6) d) Zeer Pijnlijk (3) e) Niet mogelijk (0)	**13. Kunt u de knie volledig buigen?:** a) Ja (5) b) Een beetje beperkt (3) c) Heel erg beperkt (0)
7. Springen: a) Geen probleem (10) b) Enige moeite (7) c) Altijd pijnlijk (2) d) Niet mogelijk (0)	

Referentie: Urho M. Kujala, Laura H. Jaakkola et. al., (1993), Scoring of Patellofemoral Disorders, Arthoscopy: the Journal of Arthoscopy and Related Surgery (2):159-163

KOOS
Vragenformulier voor kniepatiënten

Datum: _____/_____/_____ **Geboortedatum:** _____/_____/_____

Naam: _____

Instructies: Deze vragenlijst vraagt naar uw mening over uw knie. Deze informatie helpt ons na te gaan hoe u zich voelt over uw knie en hoe goed u in staat bent om uw normale dagelijkse activiteiten uit te voeren. Beantwoord elke vraag door één hokje aan te kruisen. Wanneer u twijfelt over de beantwoording van een vraag, kruis dan de best mogelijke optie aan.

Symptomen

Denkt u bij het beantwoorden van deze vragen aan symptomen en problemen van uw knie gedurende de afgelopen week.

S1. Was uw knie gezwollen?

nooit	zelden	soms	vaak	voortdurend
☐	☐	☐	☐	☐

S2. Heeft u een knarsend gevoel in uw knie, klikkende of andere geluiden uit uw knie gehoord?

nooit	zelden	soms	vaak	voortdurend
☐	☐	☐	☐	☐

S3. Gebeurde het dat uw knie even vast bleef steken of helemaal op slot zat?

nooit	zelden	soms	vaak	voortdurend
☐	☐	☐	☐	☐

S4. Kon u uw knie helemaal strekken?

voortdurend	vaak	soms	zelden	nooit
☐	☐	☐	☐	☐

S5. Kon u uw knie helemaal buigen?

voortdurend	vaak	soms	zelden	nooit
☐	☐	☐	☐	☐

Stijfheid

Onderstaande vragen betreffen de gewrichtsstijfheid die u heeft ervaren in de knie gedurende de afgelopen week. Met stijfheid bedoelen we het gevoel dat uw gewricht
minder soepel beweegt.

S6. Hoe ernstig was de gewrichtsstijfheid van de knie 's morgens direct na het wakker worden?

geen	gering	matig	veel	erg veel
☐	☐	☐	☐	☐

S7. Hoe ernstig was de gewrichtsstijfheid van de knie later op de dag, na zitten liggen of rusten

geen	gering	matig	veel	erg veel
☐	☐	☐	☐	☐

Pijn

P1. Hoe vaak heeft u pijn aan uw knie?

nooit	elke maand	elke week	elke dag	altijd
☐	☐	☐	☐	☐

Welke mate van kniepijn heeft u de afgelopen week ervaren tijdens de volgende activiteiten?

P2. Draaien op een belaste knie

geen	gering	matig	veel	erg veel
☐	☐	☐	☐	☐

P3. De knie helemaal strekken

geen	gering	matig	veel	erg veel
☐	☐	☐	☐	☐

P4. De knie helemaal buigen

geen	gering	matig	veel	erg veel
☐	☐	☐	☐	☐

P5. Lopen op een vlakke ondergrond

geen	gering	matig	veel	erg veel
☐	☐	☐	☐	☐

P6. Trap oplopen of aflopen

geen	gering	matig	veel	erg veel
☐	☐	☐	☐	☐

P7. ’s Nachts in bed

geen	gering	matig	veel	erg veel
☐	☐	☐	☐	☐

P8. Zitten of liggen

geen	gering	matig	veel	erg veel
☐	☐	☐	☐	☐

P9. Rechtop staan

geen	gering	matig	veel	erg veel
☐	☐	☐	☐	☐

Functioneren in het dagelijks leven

Onderstaande vragen betreffen uw dagelijks functioneren. Wilt u voor elk van de onderstaande activiteiten aangeven hoeveel moeite u de afgelopen week heeft ervaren tijdens deze activiteiten vanwege uw knie.

A1. Trap aflopen

geen	gering	matig	veel	erg veel
☐	☐	☐	☐	☐

A2. Trap oplopen

geen	gering	matig	veel	erg veel
☐	☐	☐	☐	☐

A3. Opstaan vanuit een stoel

geen	gering	matig	veel	erg veel
☐	☐	☐	☐	☐

A4. Staan

geen	gering	matig	veel	erg veel
☐	☐	☐	☐	☐

A5. Bukken naar de grond/iets oppakken van de grond

geen	gering	matig	veel	erg veel
☐	☐	☐	☐	☐

A6. Lopen op een vlakke ondergrond

geen	gering	matig	veel	erg veel
☐	☐	☐	☐	☐

A7. Instappen / uitstappen uit een auto

geen	gering	matig	veel	erg veel
☐	☐	☐	☐	☐

A8. Winkelen

geen	gering	matig	veel	erg veel
☐	☐	☐	☐	☐

A9. Sokken / kousen aantrekken

geen	gering	matig	veel	erg veel
☐	☐	☐	☐	☐

A10. Opstaan vanuit bed

geen	gering	matig	veel	erg veel
☐	☐	☐	☐	☐

A11. Sokken / kousen uittrekken

geen	gering	matig	veel	erg veel
☐	☐	☐	☐	☐

A12. In bed liggen

geen	gering	matig	veel	erg veel
☐	☐	☐	☐	☐

A13. In / uit bad of douche gaan

geen	gering	matig	veel	erg veel
☐	☐	☐	☐	☐

A14. Zitten

geen	gering	matig	veel	erg veel
☐	☐	☐	☐	☐

A15. Gaan zitten / opstaan van het toilet

geen	gering	matig	veel	erg veel
☐	☐	☐	☐	☐

A16. Zware huishoudelijke activiteiten (zware dozen tillen, de vloer schrobben etc)

geen	gering	matig	veel	erg veel
☐	☐	☐	☐	☐

A17. Lichte huishoudelijke werkzaamheden (koken, stoffen etc)

geen	gering	matig	veel	erg veel
☐	☐	☐	☐	☐

Functioneren in vrije tijd en sport

De volgende vragen gaan over uw lichamelijke functioneren tijdens recreatieve/ sportieve activiteiten. Geef aan hoeveel moeite u heeft ervaren op grond van uw knieklachten in de afgelopen week bij de volgende activiteiten

Sp1. Op uw hurken zitten

geen	gering	matig	veel	erg veel
☐	☐	☐	☐	☐

Sp2. Hardlopen

geen	gering	matig	veel	erg veel
☐	☐	☐	☐	☐

SP3. Springen

geen	gering	matig	veel	erg veel
☐	☐	☐	☐	☐

Sp4. Draaien op een belaste knie

geen	gering	matig	veel	erg veel
☐	☐	☐	☐	☐

Sp5. Knielen

geen	gering	matig	veel	erg veel
☐	☐	☐	☐	☐

Kwaliteit van leven

Q1. Hoe vaak wordt u aan uw knie herinnerd?

nooit	elke maand	elke week	elke dag	altijd
☐	☐	☐	☐	☐

Q2. Heeft u uw manier van leven veranderd om uw knie te ontzien?

totaal niet	iets	matig	grotendeels	totaal
☐	☐	☐	☐	☐

Q3. In welke mate kunt u op uw knie vertrouwen?

totaal	grotendeels	matig	iets	totaal niet
□	□	□	□	□

Q4. Hoe groot zijn uw problemen met de knie in het algemeen?

geen	gering	matig	groot	zeer groot
☐	☐	☐	☐	☐

Appendix 8: Randomization

4-2-2018 Research Randomizer

DOWNLOAD PRINT CLOSE

RESULTS

1 Set of **28 Unique** Numbers
Range: From **1** to **28**

Set #1

5, 15, 14, 12, 24, 2, 8, 18, 1, 28, 21, 19, 27, 9, 3, 6, 20, 26, 22, 25, 7, 16, 23, 11, 17, 10, 4, 13

Appendix 9: Secondary outcome measures

	Difference at baseline	Change in the exercise group
Influence of Age		
FPI-6	0.5409	0.7827
Kujala	0.01*	0.0093*
Koos Pain	0.5625	0.3324
Koos Symptoms	0.5325	0.363
Koos ADL	0.0506	0.218
Koos Sport/Recreation	0.092	0.1363
Koos QOL	0.7971	0.8948
Influence of Gender		
FPI-6	0.3258	0.0736
Kujala	0.134	0.0602
Koos Pain	0.6094	1
Koos Symptoms	0.0123*	0.5022
Koos ADL	0.2216	1
Koos Sport/Recreation	0.1581	0.9467
Koos QOL	0.3988	0.1332
Influence of Therapy Loyalty		
FPI-6	NA	0.7849
Kujala	NA	0.847
Koos Pain	NA	0.0633
Koos Symptoms	NA	0.1984
Koos ADL	NA	0.0724
Koos Sport/Recreation	NA	0.063
Koos QOL	NA	0.4325
Influence of Degree of Foot Pronation		
FPI-6	NA	0.4258
Kujala	0.9761	0.569
Koos Pain	0.2763	0.2021
Koos Symptoms	1	1
Koos ADL	0.9044	0.8313
Koos Sport/Recreation	0.567	0.1559
Koos QOL	0.2108	0.1925

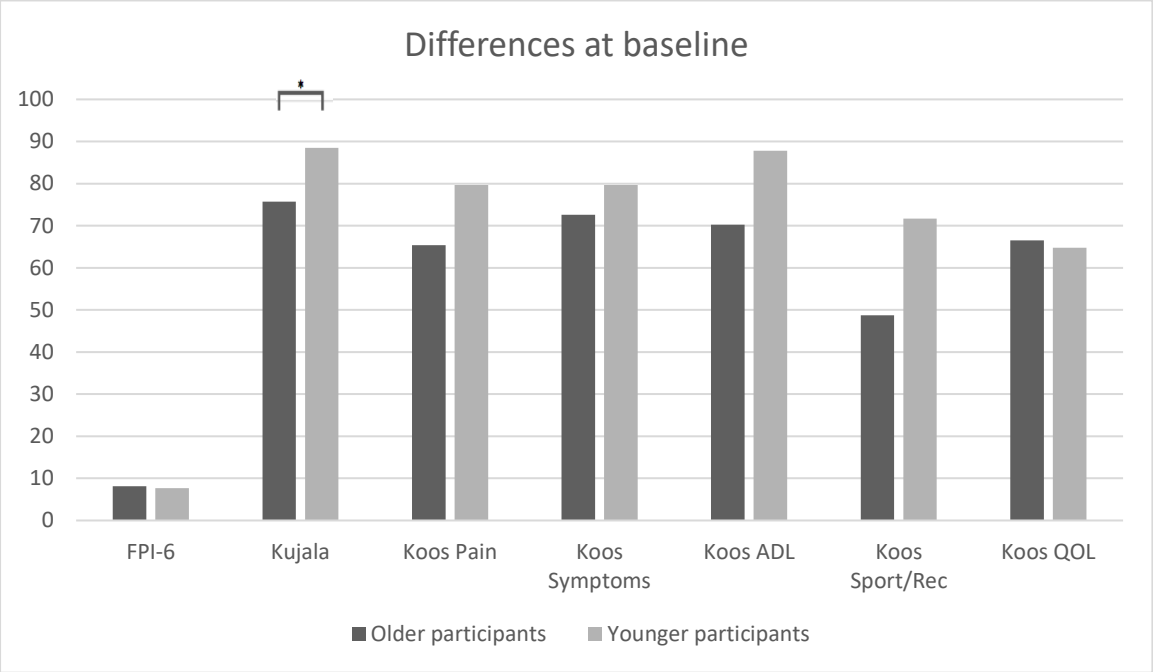
Influence of Quantity of Knee Pain		
FPI-6	0.231	0.1839
Kujala	NA	0.0794
Koos Pain	NA	0.6048
Koos Symptoms	NA	0.6032
Koos ADL	NA	0.9483
Koos Sport/Recreation	NA	1
Koos QOL	NA	0.552

** Significant difference between groups*

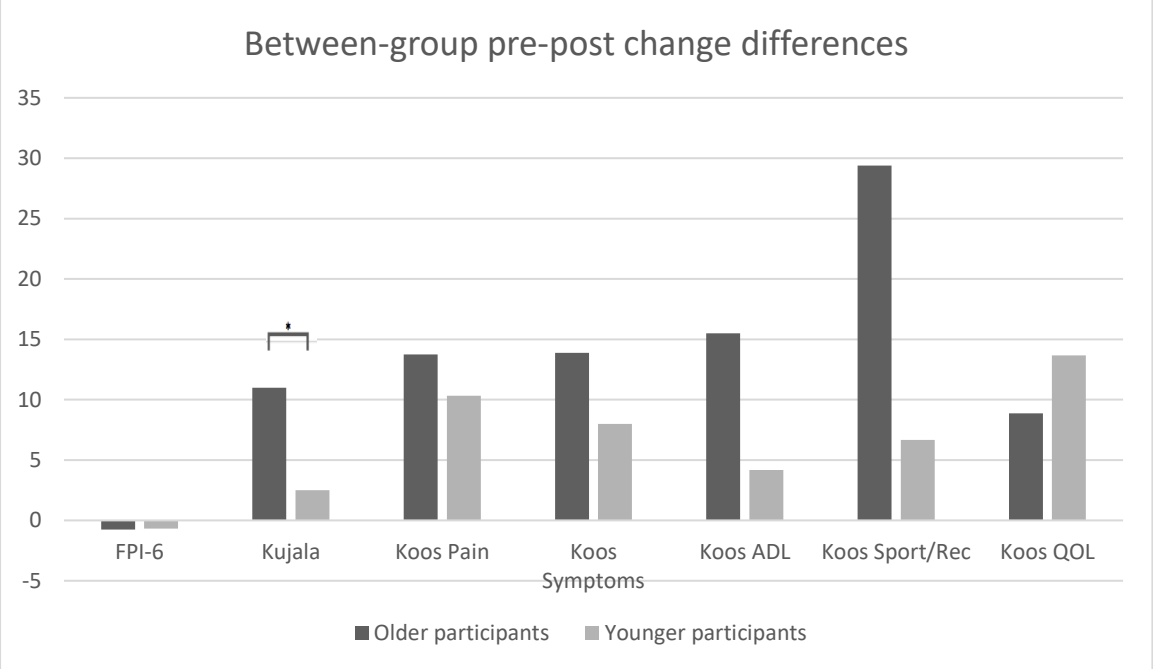
Abbreviations: NA, not applicable; QOL, Quality of life; ADL, Activities of daily living

Appendix 10: Graphs secondary outcome measurements

1. Influence of age

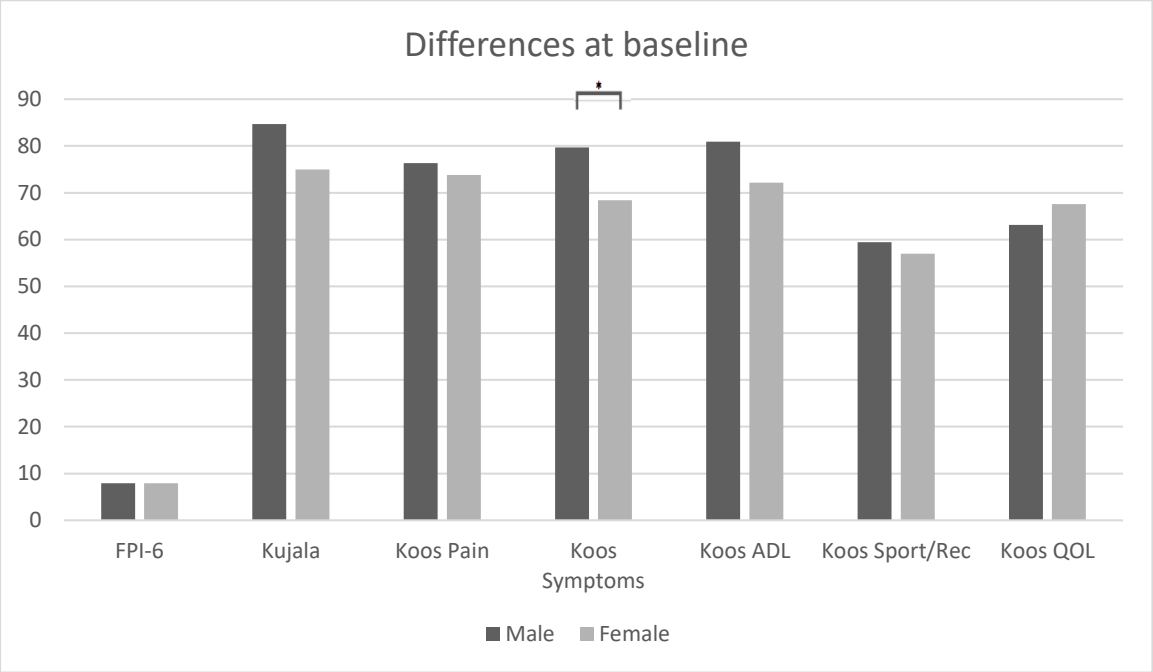


- *Significant difference*

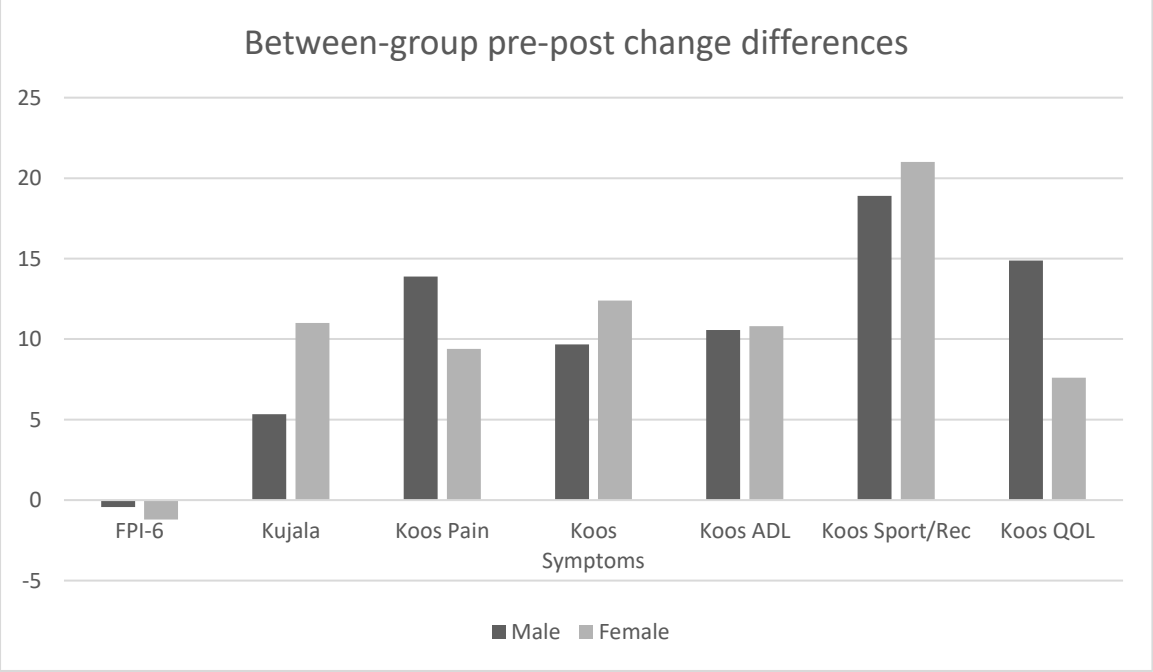


- *Significant difference*

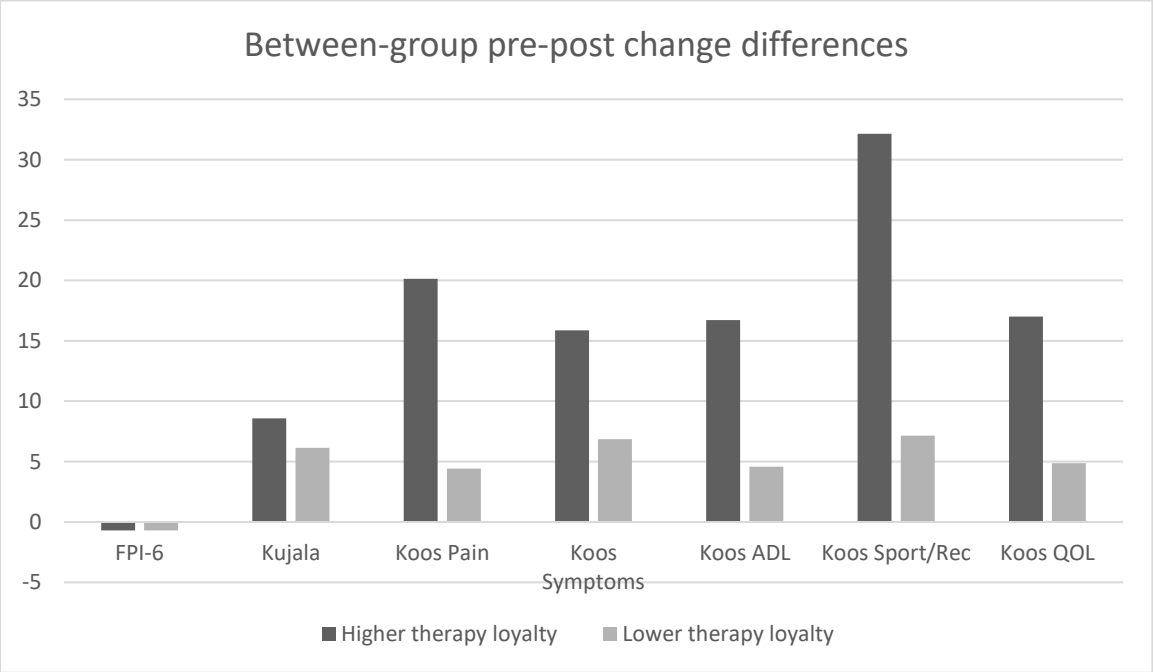
2. Influence of gender



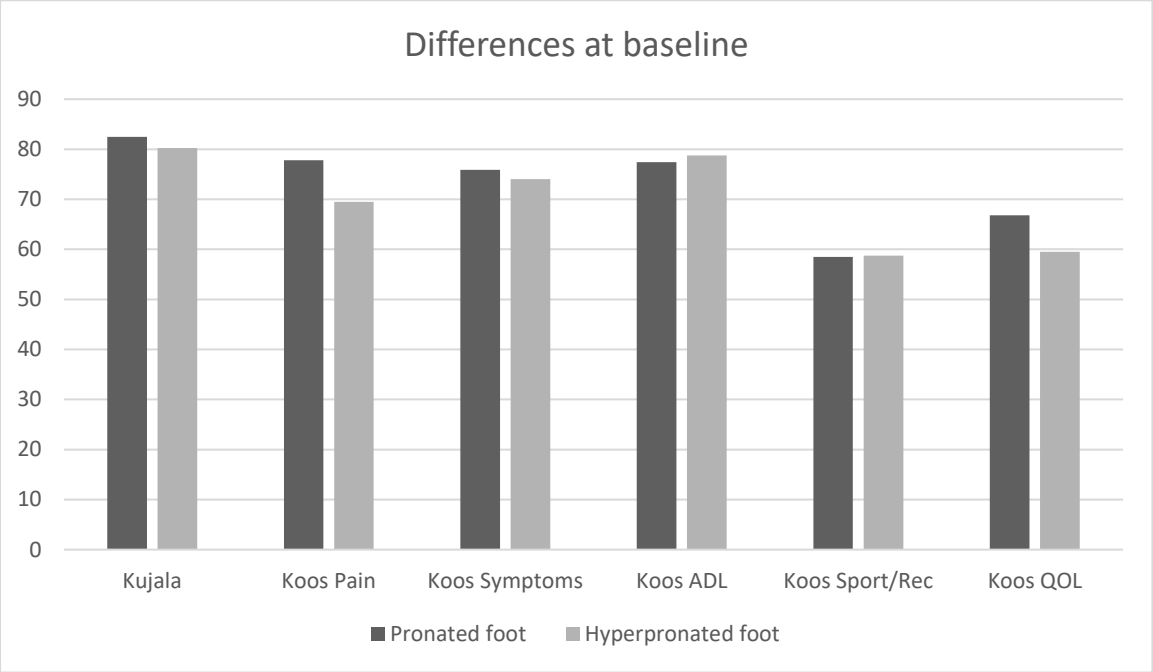
- *Significant Difference*

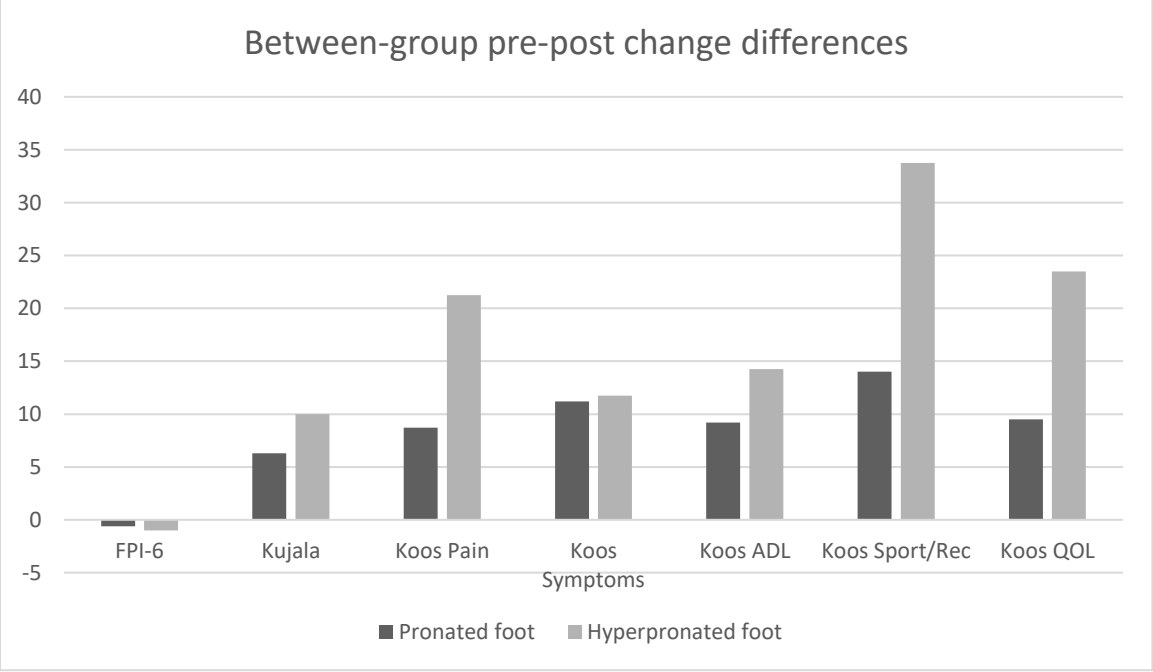


3. Influence of therapy loyalty

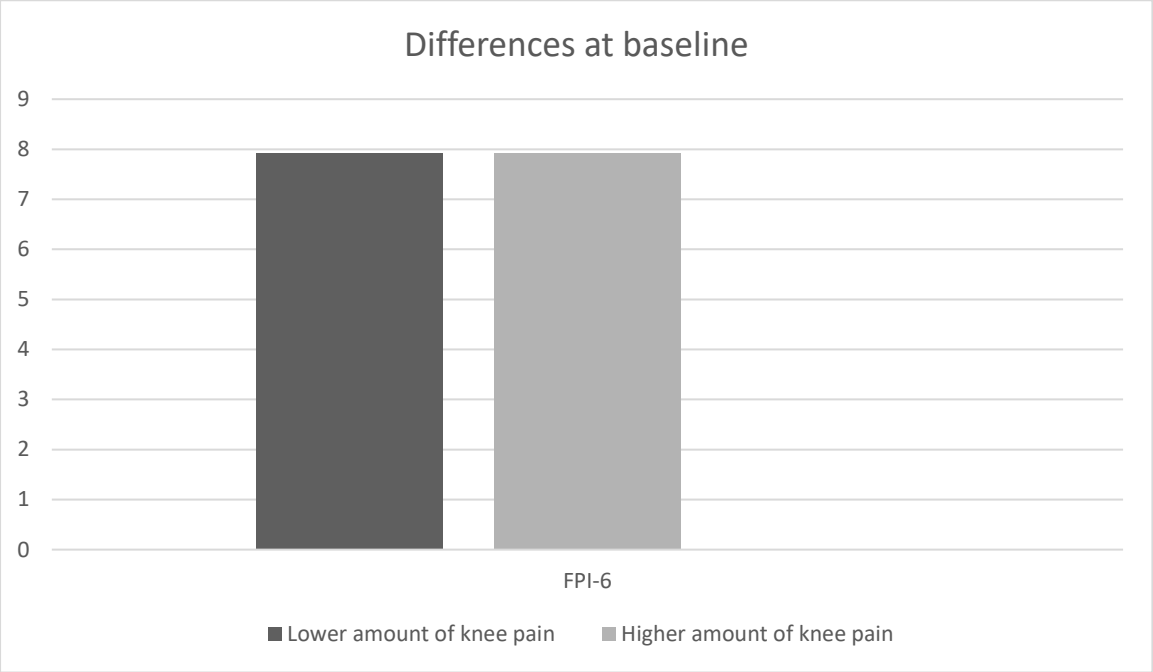


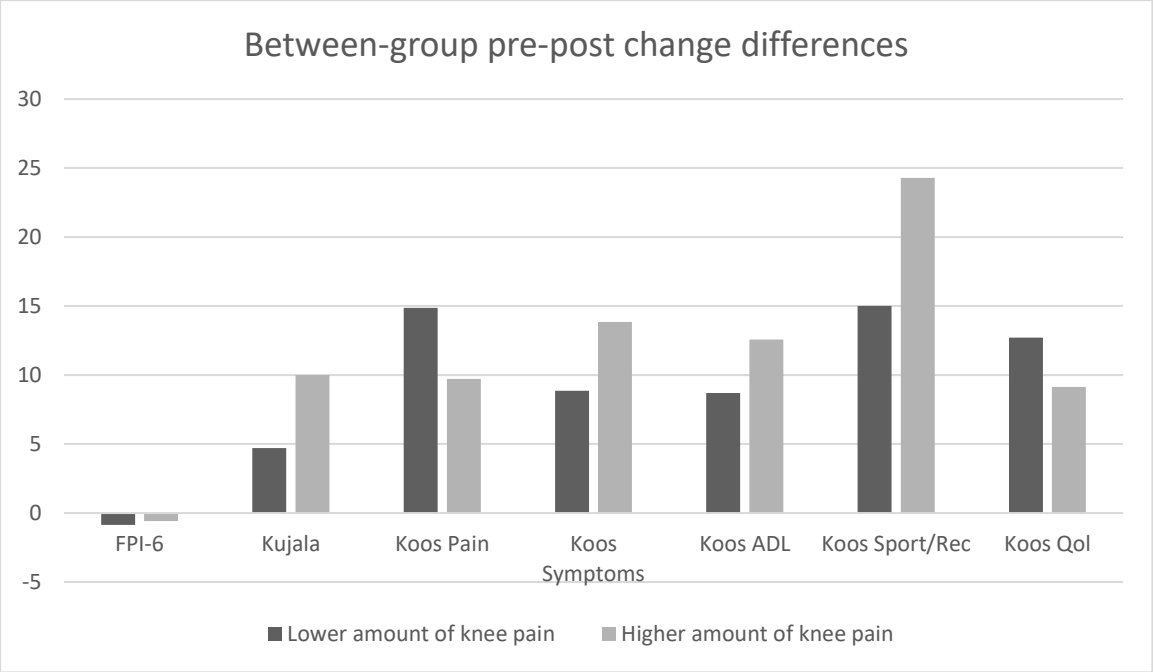
4. Influence of degree of foot pronation





5. Influence of Quantity of knee pain





Appendix 11: List of abbreviations

- PFPS = Patellofemoral pain syndrome
- PFP = Patellofemoral pain
- PFJ = Patellofemoral joint
- JRF = Joint reaction force
- Consort = Consolidated Standards of Reporting Trials
- FPI-6 = Foot posture index
- Koos = Knee injury and Osteoarthritis Outcome Score
- Kujala = The Kujala Patellofemoral Score Questionnaire
- ADL = activities of daily living
- QOL = Quality of life
- ICC = Interclass correlation coefficient
- RCT = Randomised controlled trail
- JMP = “JUMP” a Statistical software
- REC = Recreation
- SD = Standard Deviation

Appendix 12: Inventory form

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DATUM	INHOUD OVERLEG	HANDTEKENINGEN
23/08 2017	1ste afspraak protocol thesis	Promotor: Copromotor: Student(e): Student(e):
24/10 2017	Definitieve versie protocol + ethische commissie	Promotor: Copromotor: Student(e): Student(e):
28/12 2017	Advies ethische commissie + start Rekrutering	Promotor: Copromotor: Student(e): Student(e):
24/01 2018	proefpersoon gerekruteerd + start tester en onderzoek	Promotor: Copromotor: Student(e): Student(e):
27/03 2018	Einde testen + statistische berekening resultaten	Promotor: Copromotor: Student(e): Student(e):
02/05 2018	bespreken resultaten	Promotor: Copromotor: Student(e): Student(e):
22/05 2018	Controle finale versie thesis	Promotor: Copromotor: Student(e): Student(e):
		Promotor: Copromotor: Student(e): Student(e):
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Richting: **master in de revalidatiewetenschappen en de kinesitherapie-revalidatiewetenschappen en kinesitherapie bij musculoskeletale aandoeningen**
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