Høgskulen på Vestlandet

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Høgskulen på Vestlandet

MASTEROPPGÅVE

Funksjon, målt med fysiske testar og pasientrapporterte utfallsmål, seks månader etter operasjon for patellar instabilitet. Eit tverrsnittsstudie.

Function, measured with physical tests and patient reported outcome measures, six months after surgery for patellar instability. A cross-sectional study.

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Master i klinisk fysioterapi

Fysioterapi ved muskelskjelett-, revmatiske og ortopediske lidingar

Innleveringsdato: 15.05.2022

Eg stadfestar at arbeidet er sjølvstendig utarbeida, og at referansar/kjeldetilvisingar til alle kjelder som er brukt i arbeidet er oppgitt, jf. Forskrift om studium og eksamen ved Høgskulen på Vestlandet, § 12-1.

PREFACE

After several years in clinical practice as physiotherapists, it has been an inspirational experience to return to Bergen as students again, and especially as colleagues. This has given us motivation in further professional practice.

We want to thank those involved or helping us in the process:

The patients.

Trine Hysing-Dahl, for access to the data.

Our supervisor, Bård Erik Bogen, for his flexibility and constructive feedback.

Our colleagues at Aktiv fysio- og manuellterapi for stepping up at the clinic.

Our families for their patience and technical support.

Thank you!

Elise and Kjersti

Førde, May 2022

SAMANDRAG

Bakgrunn: Patellar instabilitet kan begrense aktivitet og deltaking for mange unge menneske og det er behov for meir kunnskap om denne komplekse tilstanden. Målet med studien er å samle fysisk og pasientrapportert informasjon om knefunksjon hos personar seks månader etter operasjon for patellar instabilitet. Føremålet er å bidra til utvikling av eit testbatteri for å rettleie trygg retur til aktivitet og sport for denne pasientgruppa. Innsamla data er del av eit større prosjekt ved UiB.

Metode: Dette er eit kvantitativt tverrsnittsstudie, og data vart samla inn frå fysiske testar (isokinetisk styrketest, Y-balansetest og hinketestar) og pasientrapporterte utfallsmål (NPI og BPII 2.0). Limb Symmetry Index (LSI) vart utrekna for dei fysiske testane. Pearson`s korrelasjonskoeffisient vart kalkulert for å vurdere samanhengane mellom pasient rapporterte utfallsmål (PROMs) og dei fysiske testane og forholdet mellom NPI og BPII 2.0. Statistisk signifikans vart definert som $p \leq 0.05$.

Resultat: Y-balansetestane viser gode resultat seks månader postoperativt (95% LSI). Isokinetisk kneekstensjon, enkelt-hink og trippel-hink testar viser lav LSI (73 til 89% LSI). Vidare viser resultata svak samanheng mellom fysiske testar og PROMs. NPI og BPII2.0 var sterkt korrelert (-.595).

Konklusjon: Det er behov for rehabilitering utover seks månader, dersom målet er å delta i idrett. I rehabilitering er det viktig å vurdere både fysiske aspekt og korleis pasientane opplever eigen situasjon.

Registrering: Prosjektet er registrert i den Regionale komitear for medisinsk og helsefagleg forskingsetikk (REK) med referansenummer 185067.

ABSTRACT

Background: Patellar instability can limit activity and participation for many young people, and more knowledge is needed to assess this complex condition. The aim of this study is to collect physical, and patient reported information about knee function in persons six months after surgery for patellar instability. The purpose is to contribute to the development of a test-battery to guide safe return to activity and sports for this group of patients. The data is collected for an ongoing project at The University in Bergen.

Methods: This study is a quantitative study with a cross-sectional design, and the data were collected from physical tests (isokinetic strength tests, Y-balance test and single-leg hop tests) and patient reported outcome measures (NPI and BPII 2.0). Limb symmetry index (LSI) was calculated at the physical tests. Pearson's *r* correlation coefficients were calculated to assess the relationships between the patient reported outcome measures (PROMs) and the physical tests and the relationship between the two PROMs. Statistical significance was defined as $p \leq 0.05$.

Results: The Y-balance tests show good results six months postoperatively (95% LSI). Isokinetic knee extension, single hop and triple hop tests show low LSI (73 to 89% LSI). Further, the results show weak correlation between physical tests and the PROMs. NPI and BPII2.0 were strongly correlated (-.595).

Conclusions: There is a need for rehabilitation beyond six months, if the aim is to participate in sports. In the rehabilitation it is important to consider both physical aspects and the patient's own experience of the situation.

Trial registration: The project is registered in the regional ethical committee (REC) with reference number: 185067.

Keywords: patellar, dislocation, instability, testing, PROM, sports.

TABLE OF CONTENT

Appendix

1. Ethics approval from REC
2. Written consent
3. Questionnaire (activity)
4. Test procedure Y-balance test
5. Test procedure Single-hop test
6. Scatterplots
7. Authors guidance (BMJ Sports, Science, Medicine and Rehabilitation)
8. NPI, Norwegian version
9. BPII 2.0, Norwegian version

Abbreviations

ACL: anterior cruciate ligament

ACL-RSI: anterior cruciate ligament –return to sport after injury scale

BPII: Banff Patellofemoral Instability Instrument

ICF: International Classification of Function, disability and health

LSI: Limb Symmetry Index

MPFL: medial patellofemoral ligament

NPI: Norwich Patellar Instability

PROM: patient reported outcome measures

REC: Reginal Committee for Medical and Health Research Ethics

RTS: return to sport

SD: standard deviation

VLO: vastus lateralis obliques

VMO: vastus medialis obliques

Figures

Tables

1.0 INTRODUCTION

1.1 Background

As physiotherapists we meet patients with patellar instability and see how this condition affects their quality of life. The typical patients are young women or girls where this condition has limited their participation in activities like sports or physical education at school, often for a long period of time. Many have had scary experiences with patellar dislocations and are finding it hard to trust their knee even in low energy activities. In a time where we are worried about children's and adolescents' activity level, rehabilitation to enable participation in sports and physical activity is very important. This is the motivation for us to carry out this project.

From the physiotherapists` perspective, physical functioning is always at the core of how we approach assessments and treatments. Physical functioning involves to which extent individuals are able to complete meaningful tasks and relies both on bodily capacity and the ability to interact with society. The International Classification of Function, disability and health (ICF) is helpful as a framework in this study and makes us approach health and function in three levels (1):

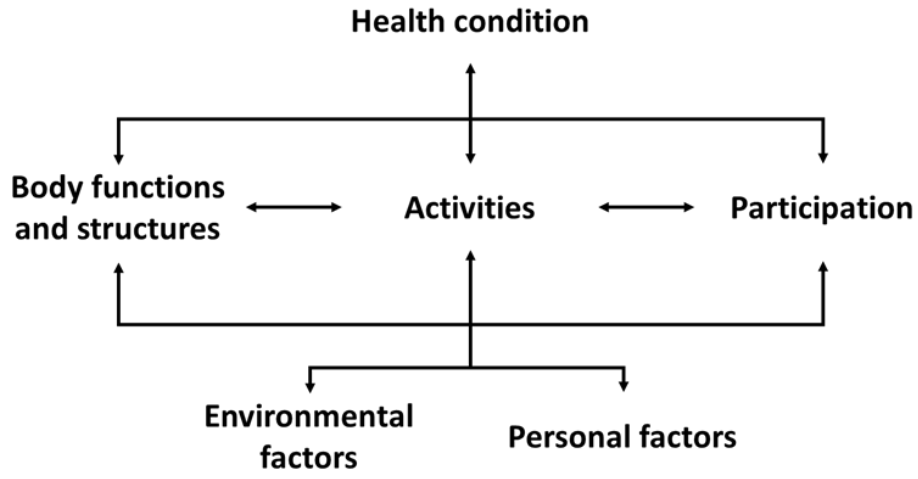

Figure 1. ICF model. World Health Organization, 2001 (1).

In this model, patellar instability is the health condition. Patellar instability is caused by structural abnormalities in the patellofemoral joint or an acute injury to the knee. The model reflects the way these structures and body functions affects activities like running or jumping and participation in meaningful tasks like work, sports or physical education. Personal factors like motivation, fear while moving and psychological readiness may also influence the process as can the environment the patient move in. A challenging physical environment, like hills and bumps on the road will pose a larger challenge for the stability of the knee than walking on a flat surface. Patellar instability is a complex health condition, but the ICF as a framework helps to capture these various aspects. The model is a reminder that these different levels of function interact and influence each other both ways.

1.2 Anatomy and biomechanics

Patella is a sesamoid bone embedded in the quadriceps tendon that helps proceed the mechanical advantage of the quadriceps during extension of the knee. It is also a centre of the forces from the contractile tissue surrounding the knee and transmits these forces through the patellar tendon. The patellofemoral joint is a complex unit and holds a great potential for joint instability without it's static and dynamic stabilizers (2). The static stabilizers of the knee consist of the ligaments, the trochlear groove, patella and the limb alignment. Medially there are three ligaments with the medial patellofemoral ligament (MPFL) considered the most important, contributing 50-60 percent of the medial force against the lateral force (3, p. 528;4). The static lateral forces consist of the epicondylopatellar ligament, the superficial oblique retinaculum, the transverse retinaculum and the iliotibial band. The dynamic stabilisers consist of the quadriceps muscle, in particular the vastus medialis obliques (VMO) and the vastus lateralis obliques (VLO) (3, p. 528). The MPFL is a continuation of the VMO and opposes the lateral force from the quadriceps muscle (2). All these factors affect patellar tracking, and the anatomy and the biomechanics of these forces can vary between individuals. Abnormalities in the anatomy of the patellofemoral joint can be risk factors for patellar dislocation and patellar instability (5).

1.3 Patellar instability and dislocation

Patellar dislocation is the term used when the patella is displaced from the trochlear groove, and account for three percent of all knee injuries (5). It can be caused by trauma with a lateral force at a healthy knee or be a result of innate abnormalities in the stabilizing structures of the knee. These abnormalities can be laxity in the MPFL, generalized joint laxity, lower extremity malalignment, patella alta or trochlea dysplasia (5). *Patellar instability* is a condition where patella tends to dislocate easily from the trochlear groove during high or low energy activities, or the patient describes a feeling that it can «pop out» any time (5). The patella dislocates laterally in most cases and causes severe stress to the medial structures (MPFL and the medial retinaculum) (5). More than 90 percent of patients with recurrent patellar dislocations have a rupture in these medial structures (6). Patellar dislocations also hold a significant risk for developing patellofemoral osteoarthritis (7). In addition, the risk of recurrence after a dislocation is high, reported up to 70 percent for children younger than 16 years in some studies (5).

1.4 Management of patellar instability

For a first-time dislocation without osteochondral damage, nonoperative treatment is the current standard of care. Those with recurrent instability or failure of nonoperative treatment, however, should be treated surgically (8). Several surgical techniques exist, both soft and bony related, as well as combinations of these. MPFL reconstruction is frequently used. Osteotomy or plastic surgery are implemented when the orthopaedic surgeon finds the abnormalities to be the reason for the instability (8). Research have been conducted to investigate the outcomes after surgery, often based on an athletic population. A systematic review from 2016 reveals that a high percentage of young patients return to sports (RTS) after isolated MPFL reconstructions. The results show low incidence of recurrent instability, postoperative apprehension, and reoperations (9). A recent systematic review from 2021 finds similar results and a high rate of RTS after MPFL reconstruction alone or with concomitant osteotomy (10). On the other hand, several studies have shown reduced knee function and muscle strength after surgical treatment for patellar instability, also in a long-term perspective (11–13). Saper et al. (11) concluded that adolescent athletes may need

prolonged rehabilitation beyond 8 months to achieve adequate recovery of muscle strength after MPFL reconstruction and claim that residual strength deficits are limiting factors in returning to preinjury level of function and activity. Forde et al. (13) found that knee extension strength deficits are observed frequently and can persist for a long time after patellar dislocation.

1.5 Return to activity and sports after surgery

Traditionally, decisions on when to return to activity after injury have relied on time-based criteria. Zaman et al.'s systematic review of guidelines after MPFL-reconstruction (14) showed that most studies included an expected timeline for return to full activity. Of these, 51 percent suggested return to play after six months, while 17 percent recommended three months of rehabilitation before full activity. Only a minority of the studies included subjective or objective criteria to determine return to activity in their rehabilitation protocol. Time does not necessarily reflect function and the individual’s readiness for sports activity after MPFL reconstruction (15) emphasizing the importance of objective and patient-centred criteria to guide safe RTS. There seems to be increasing agreement that such criteria should include both physical and psychological factors. A consensus statement from the First World Congress in Sports Physical Therapy (16) emphasizes both strength, neuromuscular control and psychological factors in RTS decision making.

1.6 Purpose and research questions

Although patellar instability affects many young people and can have detrimental effects on quality of life and the ability to participate in physical activity, there is conflicting documentation on function and lack of patient-centred criteria to guide safe return to sports or activity after surgery. Translation and validation of the Norwich Patella Instability Score (NPI) and Banff Patellofemoral Instability Instrument (BPII 2.0) is part of an ongoing PhD-project at the University of Bergen (17). The two PROMs are specific to patellar instability and are meant to support physiotherapists in capturing the patient's own experience of function.

Therefore, we will investigate function, both by commonly used physical tests and the patient reported outcome measures (PROMs) NPI and BPII 2.0 six months after surgery, a timepoint where many consider returning to sports. We will also investigate correlation between the physical tests and the PROMs, to see to which extent they measure the same constructs of function. Results from this project may facilitate evidence-based rehabilitation and support decision making regarding return to participation in activity and sports.

We have formulated the following research questions:
How is function in this group of patients, measured by physical tests and PROMs, six months after surgery for patellar instability?

How do physical function and patient reported outcome measures correlate six months after surgery for patellar instability?

2.0 METHODS

2.1 Scientific perspective

This is a quantitative study that seeks objective and measurable information about knee function in persons six months after surgery for patellar instability. The physical tests measure centimetres, seconds, Newton metres and Watt. The patients' own experience of function and quality of life is also quantified through PROMs. This reflects the post positivistic paradigm that has had a large influence on biomedical research. The post positivistic paradigm strives for objectivity and neutrality, but also recognizes the impossibility of total neutrality (18, p. 8). As researchers, we carry with us a preconception based on previous experience and knowledge, even though we seek objectivity. Therefore, we must be critical to own research and be conscious about limitations in the methods that we use.

2.2 Study design

We used a cross-sectional design in this study, as all the analysed data was collected at one timepoint. Inferences about cause and effect cannot be made, but the results provide a description of knee function and correlations between outcome measures six months postoperatively.

2.3 Ethics

The study was approved by the Regional Committee for Medical and Health Research Ethics Central (REC), id number 185067. All patients received a written invitation to participate. Signed informed consent were obtained from participants and their guardians before data collection. An internal quality assessment database was established at a secure research server provided by Helse Vest IKT. Data was coded and kept in a separate secure location with access provided to project members only. Data from the clinical examinations will be stored in the patients' medical records after the study is completed. Beyond time spent on testing, the participants were not exposed to further disadvantages.

2.4 Data collection

This study is based on data from an ongoing project at Haraldsplass Deaconess Hospital in Western Norway (CRISTIN ID 2499622) (17). Data from patients scheduled for surgery for recurrent patellar dislocation in Haraldsplass Deaconess Hospital and Haukeland University Hospital were collected in the period of January 2021 to February 2022. Inclusion criteria were patients operated with MPFL reconstruction, trochlea plastic, tibial tubercle osteotomy or concomitant procedures from thirteen years of age. Patients with other knee injuries, who did not speak Norwegian or that could not give their content were excluded. In the present study we analysed data from the 53 participants who had completed assessments six months after surgery. Demographic data at time of operation were recorded, including age, height, weight, body mass index, gender and type of surgery. The participants answered patient reported outcome measures (PROMs) and performed physical tests six months postoperatively.

2.5 Patient reported outcome measures

2.5.1 Norwich Patellar Instability Score (NPI)

This 19-item questionnaire is specialised to assess patellar instability. It consists of 12 items of low-energy activities such as “turning to look over your shoulder” and higher energy activities either uniplanar or multidirectional like “changing direction while running”. The English version of the NPI is indicated to be a valid tool to assess patellar instability for patients after patellar dislocation (19). In this study, the sum score is presented in percentage where a higher score indicates higher instability.

2.5.2 Banff Patellofemoral Instability Instrument (BPII 2.0)

This 23–item questionnaire was developed and evaluated especially for patients with patellofemoral instability. It covers five domains such as symptoms/physical complaints, work-related concerns, recreational activity and sport participation/competition. Each question is equally weighted, and the final score is calculated as an average of the scores from all answered items. A higher score indicates a higher quality of life, and the highest possible score is 100. According to the investigation of Hiemstra et al. “the BPII demonstrates content validity, strong internal consistency, excellent reliability and a statistically significant level of construct validity in the population with patellar instability” (20).

Both NPI and BPII 2.0 have been translated into Norwegian in accordance with international guidelines and are currently under validation, as part of an ongoing PhD-project at the University of Bergen (17).

2.6 Physical tests

All tests were conducted by the same experienced physiotherapist at a test lab at Haraldsplass Deaconess Hospital.

2.6.1 Y-balance test

Y-balance test was carried out with the patients barefoot, performing a single-limb stance while reaching the free limb outside their base of support in anterior, posteromedial and posterolateral direction (Figure 2). Prior to testing, the participants warmed up for five minutes on an exercise bike. After four to six test-performances, maximum reach distance was recorded in centimetres, and the average of three attempts was calculated. Results are presented as a percentage difference between the performance of the limbs (Limb Symmetry Index, LSI %), where 100% represents complete leg symmetry and < 100% indicates poorer results for the affected leg compared to the unaffected [(involved/uninvolved)*100]. Plisky et al. (2) have shown the Y-balance test to be reliable for dynamic neuromuscular control.

Figure 2. Y-balance test setup. Photo: Trine Hysing-Dahl, reprinted with permission.

2.6.2 Single-leg hop tests

Single-leg hop tests (Figure 3) were performed barefoot with one test-hop before the average of two counting hops were registered. Prior to testing, the participants warmed up for five minutes on an exercise bike. This combination of four different hop tests originally described by Noyes et al. (21) involve a single hop for distance (cm), a triple hop for distance (cm), a triple cross-over hop for distance (cm) and a six-meter timed hop (seconds). Results are presented as a percentage difference between the performance of the limbs (Leg Symmetry Index, LSI %). A 100 % leg symmetry index (LSI) represents total leg symmetry, and LSI < 100 indicates poorer results for the affected leg compared with the unaffected.

These tests provide reliable and valid outcome measures after anterior cruciate ligament reconstruction (22).

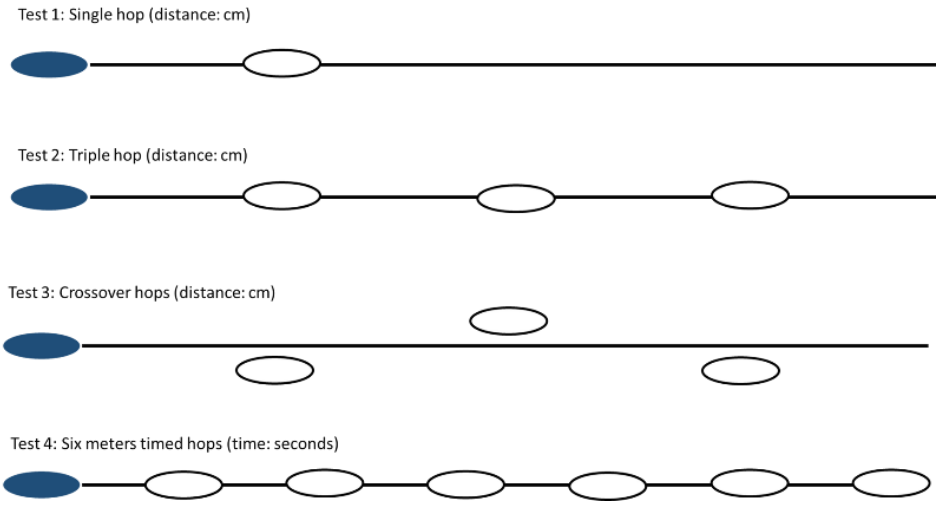

Figure 3. Single-leg hop tests.

2.6.3 Isokinetic strength test

Isokinetic strength testing of knee flexion and extension was performed with Biodex system 4 dynamometer (figure 4). Prior to testing, the participants warmed up by seven minutes on an exercise bike. Next, they were attached to the chair by straps at the chest, waist, thigh and ankle before the dynamometer was set to 0 to 90 degrees knee flexion. Testing was conducted first on the non-affected leg, followed by the operated leg, and no trial attempt was given. A standardized protocol of five repetitions at 60° per second and 30 repetitions at 240° per second was used, with a 40-seconds break between the two tests. Peak torque (Newton meters) and total work (Watt) were registered. Results are presented as a percentage difference between the performance of the limbs (Leg Symmetry Index, LSI %), where 100 % represents complete leg symmetry and < 100% indicates poorer results for the affected leg compared to the unaffected. In this study we have selected peak torque at 60° per second and total work at 240° per second for analysis. The two measurements provide complementary information: the average highest torque of each repetition and the total output of mechanical energy through all repetitions (23) Isokinetic knee extensor and flexor

strength variables have been found reliable when measured by the same examiner in asymptomatic subjects (23).

Figure 4. Isokinetic strength testing. Photo by the authors, everyone pictured gave their permission to be in the picture.

2.7 Statistical analysis

IBM SPSS Statistics 28 software was used for statistical analysis. For descriptive statistics, continuous variables are presented as means, standard deviations (SD) and minimum to maximum values, and categorical variables are presented as numbers and percentage. Pearson's r correlation coefficients were calculated to assess the relationships between the PROMs and the physical tests. Statistical significance was defined as $p \leq 0.05$. In accordance with suggested guidelines, we classified correlation coefficients (r) of 0 to 0.29 as weak, 0.3 to 0.49 as moderate and above 0.5 as strong (24). Even though this classification is based on psychological research, we find it useful for our study, since we compare quite different

outcome measures.

3.0 RESULTS

Characteristics for the participants are presented in Table 1. Of the 53 participants, 40 completed all tests. Of the remaining 13 participants, seven did not complete either of the physical tests, three did not complete all the hop-tests, two did not perform isokinetic strength testing and one did not perform neither isokinetic nor hop tests. Figure 5 shows the participants' activity level before patellar instability occurred. Most participated on a recreational level or reported no physical activity. As for surgical procedures, nine (17%) of the participants have undergone MPFL reconstruction only. 36 (67%) of the participants have undergone MPFL surgery in combination of other surgical techniques, seven (13%) have undergone other solo techniques and one (2%) have undergone other combinations.

Table 1. Participant characteristics (N=53) preoperative

	Mean*	**SD**	**Min-max**
Gender, N (%) female	37 (70)		
Age (years)	21.7	5.8	13-34
Weight (kg)	74.3	16.4	50-120
Height (m)	1.72	0.1	1.50-1.95
Body mass index (kg/m2)	25.1	5.0	19.1-39.2

* Gender is presented as number and percentage female participants

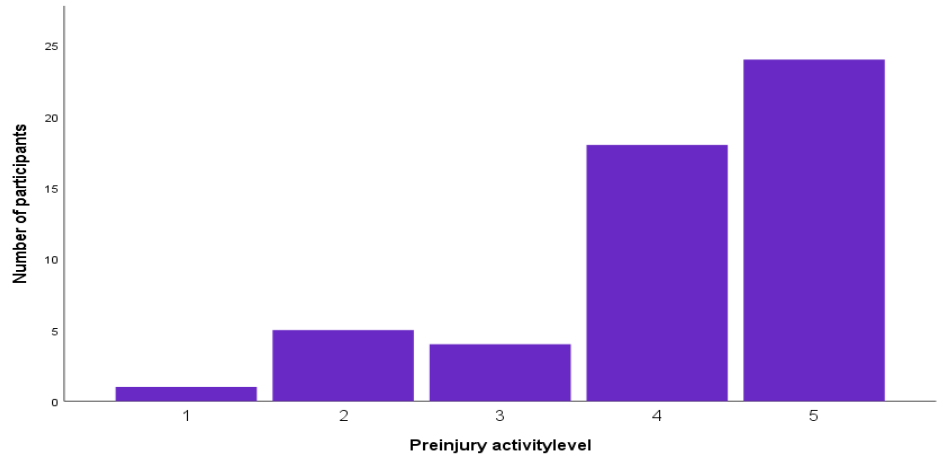

Figure 5. Preinjury activity level.
1: Elite level 2: Competition middle to high level
3: Competition lower level 4: Recreational level 5: No activity

Results from the different tests are shown in Table 2. The scores are presented for LSI, operated leg and non-operated leg. Isokinetic knee extension has the lowest LSI. Both at peak torque 60° per second and total work 240° per second, knee extension has lower LSI than the other tests, with 73.4 % and 79.7 % respectively. The single leg hop tests show LSI from 82 % (single hop) to 95 % (crossover hop). Knee flexion strength and Y-balance tests show relatively symmetrical performance between operated and non-operated leg, with 95 % LSI. Furthermore, we note that there are generally large gaps between the lowest and highest scores on the tests, i.e. total work flexion 240° per second on the operated leg (1.5-1789 W). These are legitimate values that represents correct measurements and have therefore been included in the data analyses.

Table 2. Results on PROMs and functional tests

	Leg symmetry index (LSI)			Operated leg			Non-operated leg		
	Mean	**SD**	**Min-max**	**Mean**	**SD**	**Min-max**	**Mean**	**SD**	**Min-max**
BPII 2.0 (0-100)	64.7	21.4	20-97						
NPI (0-100)	11	11.5	0-39						
Peak Torque ext 60°/sec (Nm)	73.4	28.0	29-167	93.8	45.0	13-185	130.3	47.9	38-267
Peak Torque flex 60°/sec (Nm)	94.6	20.7	43-135	66.7	26.6	17-135	70.4	24.2	28-128
Total Work ext 240°/sec (W)	79.7	24.1	19-133	1257	625	183-2722	1537	625	325-3480
Total Work flex 240 °/sec (W)	89.7	33.9	0.8-159	752	415	1.5-1789	811	360	15-1638
Y-balance composite (cm)	95.4	8.7	54-109	70.9	9.3	37-86	74.4	7.5	53-88
Y-balance anterior (cm)	95.1	6.6	81-105	58.8	7.5	45-80	61.8	6.7	50-82
Single hop (cm)	82	24.9	17-114	70.7	35.0	3-143	86.3	29.6	34-147
Triple hop (cm)	89	18	41-119	280	107	87-550	310.5	97.5	153-556
6-meter hop (sec)	94.7	16.9	42-129	3.5	1.5	1.7-7.2	3.1	1.1	1.7-6.3
Crossover hop (cm)	95.0	22.2	30-144	237	104	53-562	254.6	108	88-562

Table 3 presents correlation between the different physical tests and the two questionnaires NPI and BPII 2.0. The correlation coefficient is overall low, indicating poor correlation. The NPI and BPII 2.0, on the other hand, have strong correlation (-.595) at statistically significant level (≤0.001). Correlation is also illustrated as scatterplots in appendix 6.

Table 3. Correlation between physical tests and PROMs

	NPI		**BPII 2.0**	
	Pearson's r	p-value	Pearson's r	p-value
Peak Torque ext 60°/sec	-.100	0.522	.284	0.065
Peak Torque flex 60°/sec	.280	0.069	-.031	0.842
Total Work ext 240°/sec	-.091	0.562	.264	0.087
Total Work flex 240°/sec	-.005	0.975	.076	0.630
Y-balance composite	-.055	0.714	.177	0.239
Y-balance anterior	.019	0.900	.171	0.257
Single hop	-.108	0.486	.173	0.261
Triple hop	-.202	0.200	.111	0.486
6-meter timed hop	.121	0.450	-.055	0.732
Crossover hop	-.047	0.766	-.100	0.528
BPII 2.0	-.595	≤0.001		

4.0 DISCUSSION

4.1 Main findings

Results from the physical tests six months after surgery for patellar instability are inconsistent. Y-balance tests, 6-meter timed hop and crossover hop show good results with 95 percent limb symmetry index (LSI). Isokinetic knee flexion also presents good results with LSI 90 and 95 percent. Isokinetic knee extension, single hop and triple hop tests, however, show poorer results with values ranging from 73 to 89 percent LSI. Further, the results show weak correlation between physical tests and patient reported outcome measures (NPI and BPII 2.0) six months postoperatively. NPI and BPII 2.0, on the other hand, were strongly correlated (-.595, $p \leq 0.001$).

4.2 Y-balance and hop-tests

The high LSI from the Y-balance tests, at both composite and anterior reach, suggest that the dynamic neuromuscular control is nearly equal in the two limbs. The results may also reflect that the tests are not very demanding, allowing the foot to stay stable on the ground. For the single leg hop tests, results are inconsistent. 6-meter timed hop and crossover hop have high scores with 95 percent LSI. Single hop and triple hop, on the other hand, show poorer results, with LSI 82 and 89 percent respectively. In this study, the hop tests are

performed with the single hop first, followed by triple hop, crossover hop and finally the six-meter timed hop. It seems to be a logical progression in difficulty level, maybe except the timed test which originally is described as test number two in the protocol (21). From this, we would expect a better result for the two first tests. A possible explanation for the good results on the two last performed tests is the learning effect and confidence the participants may achieve through the two first hop tests. Reid et al. (22) speculates similarly if the initial tests may help to improve performance on the later, more difficult tests. The tests incorporate a variety of movement principles and are intended to mimic the demands of dynamic knee stability during sporting activity (22). Still, since the tests are performed in a controlled, clinical setting, they may not be directly transferable to a real life context. Importantly, as many as eleven of our participants did not complete all hop tests because of disability or unwillingness to perform. These participants would most likely have affected the mean results from the hop tests negatively if they had been counted in the analyses.

4.3 Strength tests

Isokinetic knee flexion showed good performance with 95 and 90 percent LSI at peak torque and total work. Knee extension, on the other hand, has the lowest LSI of all physical tests, both at peak torque and total work, with 73 percent and 78 percent respectively. These findings correlate well with several studies that point out reduced knee extension strength in this patient group, also in a long-term perspective (11,13). Given the quadriceps' direct impact on the patella and the fact that knee injuries are associated with inhibition of quadriceps (25), the reduced knee extension strength makes sense from a clinical perspective. Higher quadriceps strength has been found to protect against patellofemoral cartilage loss (26), and with this patient group's increased risk of patellofemoral osteoarthritis (7), restoring knee extension strength is of extra importance.

4.4 Return to activity and sport

Looking to anterior cruciate ligament (ACL) rehabilitation, current guidelines recommend 90 percent LSI for return to sport, and ≥100 percent for pivoting or contact sports measured by strength- and hop tests as well as quality of movement (27). From these guidelines, the

participants are not ready for resuming sport activity six months postoperatively. Hence, our findings challenge the time aspect of three to six months for return to full activity from Zaman et al.'s systematic review (14). Our measurements at six months after surgery indicate that the participants need a longer period of rehabilitation. This agrees with Saper et al.'s (11) conclusion that prolonged rehabilitation programs beyond eight months is needed for this patient group. Particularly knee extension strength and hop performance seem to need further progress before the participants should be recommended return to sport.

In clinical practice, however, we have noticed that lower cut-off values than addressed here often are used in RTS decisions. Avoiding reinjury is one of the most important purposes for RTS guidelines. Unlike ACL-patients with significant reinjury rates after surgery (28), there are low complication rates in sports after MPFL reconstruction (9,10), questioning need for separate guidelines. In addition, it is an essential question what the patients are returning to. The guidelines used here are based on return to sports. Most participants in this study, however, are active at a recreational level or have reported to not be physical active at all, and they will probably not have the same demands of function as an athlete. In this context, the ICF may act as a more appropriate reference tool, as it seeks to capture the various aspects and levels of health and function, not only the sport-aspect.

4.5 Limb symmetry index

The limb symmetry index (LSI) is the most frequently used criterion for assessing whether strength and hop performance are normal (29). By comparing the involved limb to a healthy control limb, the LSI is used both for evaluating progress during rehabilitation and as part of return to sport decision. Likewise, the results from this study are based on calculation of the LSI. However, it is not clear whether the LSI provides an appropriate assessment of normal function. The LSI assumes the uninvolved limb to be the gold standard, which may not necessarily be the case. Commonly, patients with patellar instability struggle with their knee injury for many years before surgery is attempted (30). It may therefore be reasonable to speculate that strength and function in the non-injured leg may decrease over a period of

time, as has been reported in ACL patients (31,32). Looking at Table 2, we see that peak torque extension at 60 degrees per second is 94 Nm in the operated leg and 130 Nm in the non-operated leg. For comparison, reference values for non-athletic persons are around 172 Nm for men and 109 Nm for women (33), and around 166 Nm for female athletes (34). From these values, it seems like strength is bilaterally lower in our participants than in comparable groups. Without a healthy and strong control limb, the LSI values may overestimate the function of the affected limb. This can in turn lead to premature return to high-level activity and increased risk of reinjury which clinicians should be aware of when giving advice about returning to sports.

4.6 Psychological factors

Knee function deficits may be due not only to weak muscles, but also to emotions and cognitive factors such as fear of reinjury and self-confidence. In this study we used the NPI and the BPII 2.0 to address the psychological readiness / aspects of the patient's undergone surgery for patellar instability. NPI covers the challenges the patients meet during different activities and BPII 2.0 covers the quality-of-life aspect. From our results, it appears like the patients experience a relatively high level of safety in performing different activities at this timepoint, with a mean NPI score at 11 (scale 0-100 with 0 as best result). The quality of life is reported at a somewhat more modest level, with a mean BPII 2.0 score at 65 (scale 0-100 with 100 as best result). The results from both questionaries show a wide range, which indicate a large variation among the participants. Further inspection of the data shows those high and low scores distributed fairly evenly between participants at all levels of preinjury activity.

Since conservatively treated patellar dislocations often recure, the fear of reinjury can affect the patients' quality of life and keep them from being as active as they want. Resent analyses of patients following MPFL reconstruction, show poor psychological readiness among those not returning to sports, with fear of re-injury being the most common reason for not returning (35). Those returning to a lower level of performance, also report fear of re-injury to be the most important reason(10). This is also in accordance with research done

in ACL patients (36). Faleide et al. (37) looked at the predictors of RTS after 2-years and found that the ACL-return to sport after injury scale (ACL-RSI), which evaluates the psychological readiness to RTS, is a predictor of the patient returning to sports. They concluded that the physical tests where not predictive in the same way. This shows the importance of valid tools to address the psychological aspect in assessment of function and return to activity or sports.

4.7 Correlation between PROMs and physical tests

Correlations between the PROMs and the physical tests in our study are overall weak, with correlation coefficients ranging from -0.005 to 0.284. This finding emphasizes the importance of using both performance-based measures and self-reported measures to fully capture the knee function after surgery for patellar instability. Biesert et al. (12) point out the difficulties for patients to define the sensation of instability and claim that physical tests can reveal challenges that cannot be discovered with questionnaires. Physical and psychological tests complement each other, and together they provide a more accurate picture of knee function after MPFL reconstruction. This is also taken into account in the consensus statement for RTS (16) that recommends incorporation of both physical and psychological readiness for optimal RTS decisions.

4.8 Correlation between NPI and BPII 2.0

There is strong correlation (-.595) between NPI and BPII 2.0 at a statistically significant level (≤0.001). The questionaries are intended to measure different aspects of function, and as such the high correlation may be unexpected. The strong correlation supports a certain degree of convergent validity, which means that the instruments measure related constructs (18, p. 328). Still, we claim that the PROMs do not overlap to the extent that one is redundant. We suggest that the instruments complement one another, and that both may be important for a comprehensive assessment of function in persons with patellar instability. As an explanation for the strong correlation between the two PROMs, it is tempting to assume an interaction between the ability to perform various activities and the experienced quality of life.

4.9 Participation

As we can see from our data analyses, the results in this study vary a lot and there is a large distance between the highest and lowest values in several variables. These variations, both in physical tests and PROMs, reflect the heterogeneity in this group of patients. From the descriptive data presented in Table 1, we notice a wide range at the body mass index (19,4-39,2), with 38 percent of the participants in the category of overweight (BMI 25-29,9) or obese (BMI > 30) (38)[1]. Further, we see that some of the patients have participated in sports, but most have participated on a recreational level or not stated any sports or activity at all (Figure 5). We speculate if this rather low level of activity can be a result of the anatomical challenges that many of these patients are born with, and a fear of luxation based in their innate laxity. Patients with patellar instability can be traumatised after one, maybe several injuries, often combined with swelling, pain and the sight of a luxated knee. They are often at young age when this occurs and live with the fear of luxation over a long period of time. In a long perspective these injuries cause soft tissue damage and often patellofemoral arthritis (7). When even low energy activities are a challenge, it is natural that sport is not a priority of these patients. Instability will most likely limit their participation in activities with friends and peers, and by that potentially limit interaction in life and society. This interaction between bodily structures, activities and participation leads to the ICF model (Figure 1), which demonstrates how the different levels interact in several directions. Less participation and physical activity caused by fear of luxation, can lead to muscle weakness and again reinforce the instability. Schneider et al. describe the challenge with this group of patients and thereby stress our point:

“These injuries are associated with significant morbidity such as recurrent instability and patellofemoral osteoarthritis and can lead to physical activity modifications and declines in physical capacity” (9, p. 2993)

[1] Reference values are based on adult population

4.10 Study strengths and limitations

A strength of this project is that all the tests were carried out by the same, experienced physiotherapist. This strengthens internal validity, as we can assume that the participants were exposed to the tests in the same way. The tests used are validated, but the physical ones are not validated specific to patellar instability. The lack of a "gold standard" test-battery for evaluating knee function in this patient group may affect internal validity negatively as different choice of tests could have resulted in different findings. This study is based on 53 participants. The larger group of subjects, the better a study can detect relationships among variables (18). However, as correlation was low in our study, we believe that the sample size was sufficient to achieve reliable results.

All patients scheduled for surgery in the selected hospitals, that met the inclusion criteria were invited to participate in the study. This suggests that the sample is representative of the target population and may be generalized to other patients who have undergone surgery for patellar instability in these hospitals. Still, participation involved rather extensive testing, which may have favoured the most resourceful and motivated patients to volunteer, resulting in a selection bias. In addition, we do not have information about number patients that declined invitation to participate, nor dropouts during the study. Further, some of the participants did not complete all tests. We know that some of this is due to functional disability, and this may also pose a risk of bias. The wide range in results from several of the tests indicate that the participants make up a heterogeny group. Outliers, values that lie outside the normal range of values on a measure (18), may have affected the magnitude of the correlation coefficient. Given the low correlation, though, we believe that the outliers, which actually represent correct measurements, have not made a significantly impact on the results. We lack information about some potentially confounding factors like quality and extent of rehabilitation that the patients have undergone. These variables may influence the test results and findings in our study.

Finally, the cross-sectional design used in this study does not allow us to make inferences about cause and effect, but this was also not the intention. It is an appropriate design for

describing the status of phenomena or relationships at a fixed timepoint (18), and in our opinion a suitably choice to the purpose of this study. The quantitative approach is useful to get objective measurements that can be reproduced and compared to each other, but it does not capture all the aspects of knee function. We lose depth information and the patients' own description of how the condition influence their lives. In our interpretation of results, we must bear this limitation in mind.

5.0 CONCLUSION

5.1 Main conclusion

Patients undergone surgery for patellar instability form a heterogeny group, and provide wide variation in test results, both at physical tests and PROMs. From physical tests, patients have not regained knee function equal to the non-affected leg six months after surgery, most striking in knee extension strength with 73 percent LSI at peak torque 60^{o} per second and 78 percent LSI at total work 240^{o} per second. According to current RTS guidelines based on ACL research, the patients are not ready for resuming sports activity. Correlations between physical tests and PROMs are weak, emphasizing the importance of considering both physical and psychological aspects. There is strong correlation between NPI and BPII 2.0, but the two questionaries do not overlap to the extent that one is redundant.

5.2 Implications for physiotherapy practice

The heterogeneity in this group of patients tell the physiotherapist to consider each individual, their function and demands in their life. The study shows that both physical and psychological factors in the assessment and rehabilitation of this group is important. Therefore, the physiotherapist depends on a detailed anamnesis to charter this and ask the patients about their thoughts and fears. NPI and BPII 2.0 may in this setting be useful tools to capture the patient's own experience of function and quality of life. It is also important that the physiotherapist asks the patients what his or her goal for rehabilitation is. Do they plan to return to sports, in what level do they plan to return to, do they have work or other

demands in their life that require a stable knee. The patients' goal should be a continuum throughout the period of rehabilitation. If the goal is to return to sports, the results from this study imply the need to focus on strengthening the quadriceps muscle. Different sports have different demands and that should be considered as well. Pivoting and contact sports have another context while performing than running the marathon or swimming. The results from the single leg hop tests imply that neuromuscular stability should be focused on. We recommend that the physiotherapist emphasises rehabilitation beyond six months. If the goal is to return to sport, the patient should not attend before the demands in the guidelines are fulfilled.

5.3 Further research

Physical tests and guidelines used in this study are based on ACL patients. We recommend further studies to develop valid physical tests and guidelines for safe return to activity and sport specific for patients after surgery for patellar instability. Given the varied activity level we found in our group of participants, it is of interest to provide guidelines for returning to a recreational activity level as well.

Declarations:

Availability of data and materials: The datasets are not available.

Competing interests: The authors declare no conflict of interest

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REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Vedlegg 1, 1/3

Region:	Saksbehandler:	Telefon:	Vår dato:	Vår referanse:
REK midt	Magnus Alm	73559949	09.02.2022	185067

Eivind Inderhaug
Prosjektsøknad: Utvikling av et testbatteri for å måle knefunksjon hos pasienter med patellar instabilitet.
Søknadsnummer: 185067 **Forskningsansvarlig institusjon**: Haraldsplass Diakonale sykehus **Samarbeidende forskningsansvarlige institusjoner:** Helse Vest RHF

Prosjektsøknad: Endring godkjennes med vilkår

Søkers beskrivelse

Patella instabilitet er et utbredt problem hos ungdommer og unge voksne og første gangs dislokasjon utgjør omkring 3% av alle kneskader. Etter første gangs dislokasjon er det en stor risiko for å utvikle kornisk ustabilt kneskjell. Det er i dag stor behandlingsvariasjonen hos pasientgruppen og et behov for mer kunnskap om behandlingseffekt for å kunne bygge evidens-baserte behandlingsalgoritmer. Dermed trenger vi gode utfallsmål for å vurdere knefunksjon hos pasientgruppen. Per i dag er avgjørelser vedrørende sikker gjenopptagelse av aktivitet/idrett i stor grad basert på den enkelte fysioterapeut/kirurgs subjektive vurderinger. Vi ønsker å utvikle et testbatteri bestående av pasientrapporterte utfallsmål (PROM) og fysiske tester i post operativ oppfølging. Pasientenes funksjon vil undersøkes ved fysiske tester og spørreskjema. Banff Patellofemoral Instability Instrument 2.0 (BPII2.0) og Norwich Patellar Instability Score (NPI) vil, som en del av prosjektet, oversetters og valideres på norsk for å kunne brukes i studien. Videre vil pasientenes aktiviteter og nivå pre- og post operativt registreres slik at vår kunnskap vedrørende hvilke idrett/aktiviteter og nivå pasientene gjenopptar etter kirurgi.
På første konsultasjon, 6, 12 og 24 måneder postoperativt vil vi samle inn opplysninger om aktivitetstype, nivå og motivasjon for gjenopptagelse av aktivitet/idrett (egenutviklet aktivitetsskår). Ved baseline og 6 måneder postoperativt gjennomgår også pasientene fysiske tester (hinke tester, Y-balanse test, steg ned og isokinetiske stryketester). I tillegg fylles 5 ulike selvrapporterte spørreskjema, BPII, NPI, 2000IKDC, KOOS og Tampa Scale for Kinesiophobia ut ved baseline og kun BPII og NPI på 6 måneders kontrollen. Tre uker før kontrollen vil vi ringe pasientene og deretter sende deltagerne disse to spørreskjemaene pr post i konvolutt uten andre kjennetegn enn HDS sin logo. Vedlagt vil de finne en ferdig adressert og frankert konvolutt til å returnere spørreskjemaene i.
Økt kunnskap om behandlings effekt hos pasientgruppen vil kunne bidra til å bygge evidens-baserte behandlings algoritmer. Videre vil evidensbaserte avgjørelser vedrørende retur til aktivitet/idrett bidra til sikker retur og dermed redusere risiko for re-skader.

REK midt **Telefon**:73 59 75 11 | **E-post**:rek-midt@mh.ntnu.no
Besøksadresse: Øya Helsehus, 3. etasje, Mauritz Hansens gate 2, Trondheim **Web**:https://rekportalen.no

Vedlegg 1, 2/3

Vi viser til søknad om prosjektendring mottatt 31.01.2022 for ovennevnte forskningsprosjekt. Søknaden er behandlet av sekretariatet i REK midt på delegert fullmakt fra komiteen, med hjemmel i forskningsetikkforskriften § 7, første ledd, tredje punktum. Søknaden er vurdert med hjemmel i helseforskningsloven § 11.

REKs vurdering

Du søker om følgende prosjektendringer:

- Inklusjon av Kjersti Østerbø Bell og Elise Astad Sygna ved Høgskulen på Vestlandet som nye prosjektmedarbeidere.
- Utsendelse av et spørreskjema hvor pasientene skal vurdere hvor fornøyd de er med operasjonen på en syvpunktsskala.
- Utsendelse av spørreskjemaene BPII og NPI 12 og 24 måneder etter operasjon.

Vi har ingen forskningsetiske innvendinger til prosjektendringene. De nye prosjektmedarbeiderne er masterstudenter som skal skrive oppgave på allerede innsamlede data. Vi vurder at problemstillingene i masteroppgaven er innenfor de tematiske rammene til hovedprosjektet. Ettersom masterstudentene er tilknyttet Høgskulen på Vestlandet ber vi om at denne institusjonen oppføres som forskningsansvarlig institusjon i tillegg til Haraldsplass Diakonale sykehus og Helse Vest RHF. Vi har tidligere godkjent utsending av spørreskjemaene BPII 2.0 og NPI før og seks måneder etter operasjon, og vi har ingen innvendinger til at disse også sendes ut etter 12 og 24 måneder. Vi vurderer at hensynet til deltakernes velferd og integritet fremdeles er godt ivaretatt.

Vilkår for godkjenning

1. Vi forutsetter at Høgskulen på Vestlandet registreres som forskningsansvarlige institusjonene i prosjektet. Vennligst benytt søknadsskjemaet «endringsmelding og/eller henvendelse» i REK-portalen for dette.

Vedtak

Godkjent på vilkår

Sluttmelding

Prosjektleder skal sende sluttmelding til REK på eget skjema via REK-portalen senest 6 måneder etter sluttdato 01.01.2028, jf. helseforskningsloven § 12. Dersom prosjektet ikke starter opp eller gjennomføres meldes dette også via skjemaet for sluttmelding.

Søknad om endring

Dersom man ønsker å foreta vesentlige endringer i formål, metode, tidsløp eller organisering må prosjektleder sende søknad om endring via portalen på eget skjema til REK, jf. helseforskningsloven § 11.

Vedlegg 1, 3/3

Klageadgang
Du kan klage på REKs vedtak, jf. forvaltningsloven § 28 flg. Klagen sendes på eget skjema via REK portalen. Klagefristen er tre uker fra du mottar dette brevet. Dersom REK opprettholder vedtaket, sender REK klagen videre til Den nasjonale forskningsetiske komité for medisin og helsefag (NEM) for endelig vurdering, jf. forskningsetikkloven § 10 og helseforskningsloven § 10.

Med vennlig hilsen
Hilde Eikemo
Sekretariatsleder, REK midt
Magnus Alm rådgiver,
REK midt
Kopi til:
Haraldsplass Diakonale sykehus
Helse Vest RHF
Trine Hysing-Dahl

INFORMASJONSSKRIV TIL BARN/UNGDOM 12-16 (- 18) ÅR: **Appendix 2, 1/10**

USTABILT KNESKJELL - UTVIKLING AV ET TESTBATTERI OG AKTIVITETSREGISTRERING

BAKGRUNN OG HENSIKT

Dette er et spørsmål til deg om å delta i en forskningsstudie for å undersøke nytten av ulike tester og spørreskjema etter stabiliserende kirurgi for ustabilt kneskjellet.
Du er operert eller skal gjennomgå stabiliserende kirurgi ved Haraldsplass Diakonale Sykehus eller et av sykehusene i Helse Vest og vi inviterer deg derfor til å delta i studien. Haraldsplass Diakonale Sykehus er ansvarlig for prosjektet. Prosjektet gjennomføres i samarbeid med de andre sykehusene i Helse Vest.

HVA INNEBÆRER STUDIEN?

Deltakelse innebærer at du ved første undersøkelse på sykehuset gjennomgår 4 fysiske tester og 6 spørreskjema i etterkant av undersøkelse hos legen. Spørreskjemaene omhandler plager fra kneet, hvor ustabilt kneet oppleves og bekymringer vedrørende kne plagene. I tillegg til hvilke aktiviteter/idrett du deltok i før kneproblemene oppstod, dagens deltakelse og motivasjon for å gjenoppta samme nivå som tidligere.
Denne undersøkelsen vil ta omtrent 60 minutter. Omkring seks måneder etter operasjonen vil du bli innkalt til en ekstra kontroll. Vi vil da be deg gjenta de fysiske testene samt fylle ut 3 av spørreskjemaene. Du vil også bli spurt om å fylle ut 3 av spørreskjemaene 2 uker før seks måneders kontrollen. Når det er gått 1 og 2 år siden operasjonen vil vi sende ut spørreskjemaet som omhandler aktivitet og idrett i posten for utfylling, med vedlagt frankert returkonvolutt. Fra journalen din vil vi hent følgende opplysninger om deg: fødselsnummer, operasjonsmetode, tidligere skader kneet, vekt og høyde. Skulle du ikke ønske å delta i studien vil du følge våre standard kontrollrutiner.

MULIGE FORDELER OG ULEMPER

Ved å delta i studien vil du få mulighet til å belyse viktige sider ved vår evaluering om du er klar for retur til fritidsaktiviteter og/eller idrett. Videre vil du få tettere oppfølging enn vanlig. Undersøkelsen på sykehuset tar litt lengre tid enn vanlig. Testene du skal gjennomføre gjør ikke vondt eller er ubehagelige.
Du vil ikke bli utsatt for noen andre undersøkelser eller behandlinger enn det som er beskrevet over.

HVA SKJER MED PRØVENE OG INFORMASJONEN OM DEG?

Alle personopplysninger vil bli behandlet konfidensielt. Informasjonen som registreres om deg skal kun brukes slik som beskrevet over studien. Alle opplysningene vil bli behandlet uten navn og fødselsnummer eller andre direkte gjenkjennende opplysninger. En kode knytter deg til dine opplysninger gjennom en navneliste. Det betyr at opplysningene er avidentifisert.
Det er kun autorisert personell i prosjektgruppen som har adgang til navnelisten og som kan finne tilbake til deg. Opplysningene vi har samlet om deg vil bli slettet innen 01.01.2033.
Det vil ikke være mulig å identifisere deg i resultatene av studien når disse publiseres.

Appendix 2, 2/10

DELTAKELSE

Det er frivillig å delta i studien. Du kan når som helst og uten å oppgi noen grunn trekke deg fra deltagelse i studien. Alle opplysninger om deg vil da bli anonymisert. Dette vil ikke få konsekvenser for din videre behandling.

KONTAKTOPPLYSNINGER

Dersom du har spørsmål til prosjektet eller ønsker å trekke deg fra deltakelse, kan du kontakte:
Prosjektleder: Trine Hysing-Dahl, tlf. 469 03 740,
trine.hysingdahl@haraldsplass.no
Forskningskoordinator: Ingun Fleten Mo, tlf. 469 03 961, ingunn.fleten.mo@haraldsplass.no.

Appendix 2, 3/10

Forespørsel om deltakelse i forskningsprosjektet *Ustabilt kneskjell - utvikling av et testbatteri og aktivitetsregistrering*

FORMÅLET MED PROSJEKTET OG HVORFOR DU BLIR SPURT

Dette er et spørsmål til deg om å delta i en forskningsstudie for å undersøke nytten av ulike tester og spørreskjema etter stabiliserende kirurgi for ustabilt kneskjellet.
Du er operert eller skal gjennomgå stabiliserende kirurgi ved Haraldsplass Diakonale Sykehus eller et av sykehusene i Helse Vest og vi inviterer deg derfor til å delta i studien. Haraldsplass Diakonale Sykehus er ansvarlig for prosjektet. Prosjektet gjennomføres i samarbeid med de andre sykehusene i Helse Vest.

HVA INNEBÆRER DELTAKELSE I PROSJEKTET?

Deltakelse innebærer at du ved første undersøkelse på sykehuset gjennomgår 4 fysiske tester og 6 spørreskjema i etterkant av undersøkelse hos legen. Spørreskjemaene omhandler plager fra kneet, hvor ustabilt kneet oppleves og bekymringer vedrørende kne plagene. I tillegg til hvilke aktiviteter/idrett du deltok i før kneproblemene oppstod, dagens deltakelse og motivasjon for å gjenoppta samme nivå som tidligere. Denne undersøkelsen vil ta omtrent 60 minutter. Omkring seks måneder etter operasjonen vil du bli innkalt til en ekstra kontroll. Vi vil da be deg gjenta de fysiske testene samt fylle ut 3 av spørreskjemaene. Du vil også bli spurt om å fylle ut 3 av spørreskjemaene 2 uker før seks måneders kontrollen. Når det er gått 1 og 2 år siden operasjonen vil vi sende ut spørreskjemaet som omhandler aktivitet og idrett i posten for utfylling, med vedlagt frankert returkonvolutt. Vi vil i tillegg registrere følgende opplysninger om deg, fødselsnummer, operasjonsmetode, tidligere skader kneet, vekt og høyde. Skulle du ikke ønske å delta i studien vil du følge våre standard kontrollrutiner.

MULIGE FORDELER OG ULEMPER

Ved å delta i studien vil du få mulighet til å belyse viktige sider ved vår evaluering om du er klar for retur til fritidsaktiviteter og/eller idrett. Videre vil du få tettere poliklinisk oppfølging enn vanlig.
Du vil ikke bli utsatt for noen andre undersøkelser eller behandlinger enn det som er beskrevet over.

FRIVILLIG DELTAKELSE OG MULIGHET FOR Å TREKKE DITT SAMTYKKE

Appendix 2, 4/10

Det er frivillig å delta i prosjektet. Dersom du ønsker å delta, undertegner du samtykkeerklæringen på siste side. Du kan når som helst og uten å oppgi noen grunn trekke ditt samtykke. Det vil ikke ha noen negative konsekvenser for deg eller din behandling hvis du ikke vil delta eller senere velger å trekke deg. Dersom du trekker tilbake samtykket, vil det ikke forskes videre på dine helseopplysninger. Du kan også kreve at dine helseopplysninger i prosjektet slettes eller utleveres innen 30 dager, og at det biologiske materialet destrueres. Adgangen til å kreve destruksjon, sletting eller utlevering gjelder ikke dersom materialet eller opplysningene er anonymisert eller publisert. Denne adgangen kan også begrenses dersom opplysningene er inngått i utførte analyser. Dersom du senere ønsker å trekke deg eller har spørsmål til prosjektet, kan du kontakte prosjektleder (se kontaktinformasjon på siste side). Dette vil ikke få konsekvenser for din videre behandling.

HVA SKJER MED OPPLYSNINGENE OM DEG?

Alle personopplysninger vil bli behandlet konfidensielt. Informasjonen som registreres om deg skal kun brukes slik som beskrevet i hensikten med studien. Alle opplysningene vil bli behandlet uten navn og fødselsnummer eller andre direkte gjenkjennende opplysninger. En kode knytter deg til dine opplysninger gjennom en navneliste. Det betyr at opplysningene er avidentifisert. Det er kun autorisert personell i prosjektgruppen som har adgang til navnelisten og som kan finne tilbake til deg. Opplysningene vi har samlet om deg vil bli slettet innen 01.01.2033. Det vil ikke være mulig å identifisere deg i resultatene av studien når disse publiseres.

Opplysningene som registreres om deg skal kun brukes slik som beskrevet under formålet med prosjektet, og planlegges brukt til 01.01.2028. Eventuelle utvidelser i bruk og oppbevaringstid kan kun skje etter godkjenning fra REK og andre relevante myndigheter. Du har rett til innsyn i hvilke opplysninger som er registrert om deg og rett til å få korrigert eventuelle feil i de opplysningene som er registrert. Du har også rett til å få innsyn i sikkerhetstiltakene ved behandling av opplysningene. Du kan klage på behandlingen av dine opplysninger til Datatilsynet og institusjonen sitt personvernombud. Alle opplysningene vil bli behandlet uten navn og fødselsnummer eller andre direkte gjenkjennende opplysninger (=kodede opplysninger). En kode knytter deg til dine opplysninger gjennom en navneliste. Det er kun prosjektleder, Trine Hysing-Dahl og forskningskoordinator, Ingun Fleten Mo, som har tilgang til denne listen.
Opplysningene om deg vil bli oppbevart i fem år etter prosjektslutt av kontrollhensyn.

FORSIKRING

Ved deltakelse i prosjektet vil du være dekket av pasientskadeloven.

ØKONOMI

Prosjektet er finansiert av forskningsmidler fra Helse Vest. Du vil ikke motta økonomisk kompensasjon for deltakelse. Egenandel ved tilleggs kontrollen vil dekkes av prosjektet.

Appendix 2, 5/10

GODKJENNINGER

Regional komité for medisinsk og helsefaglig forskningsetikk har gjort en forskningsetisk vurdering og godkjent prosjektet (ID:185067). Haraldsplass Diakonale Sykehus og prosjektleder Trine Hysing-Dahl er ansvarlig for personvernet i prosjektet.
Vi behandler opplysningene basert på ditt samtykke.

KONTAKTOPPLYSNINGER

Dersom du har spørsmål til prosjektet eller ønsker å trekke deg fra deltakelse, kan du kontakte:
Prosjektleder: Trine Hysing-Dahl, tlf. 469 03 740, e-post trine.hysing-dahl@haraldsplass.no
Forskningskoordinator: Ingun Fleten Mo, tlf. 469 03 961, e-post ingunn.fleten.mo@haraldsplass.no.
Dersom du har spørsmål om personvernet i prosjektet, kan du kontakte personvernombudet ved institusjonen: Personvern@haraldsplass.no
Datatilsynets e-postadresse er: Postkasse@datatilsynet.no

Appendix 2, 6/10

JEG SAMTYKKER TIL Å DELTA I PROSJEKTET OG TIL AT MINE PERSONOPPLYSNINGER OG MITT BIOLOGISKE MATERIALE BRUKES SLIK DET ER BESKREVET

Sted og dato

Deltakers signatur

Deltakers navn med trykte bokstaver

Appendix 2, 7/10

Forespørsel om deltakelse i forskningsprosjektet *Ustabilt kneskjell - utvikling av et testbatteri og aktivitetsregistrering*

FORMÅLET MED PROSJEKTET OG HVORFOR DU BLIR SPURT PÅ VEGNET AV DITT BARN

Dette er et spørsmål til deg om deltagelse for ditt barn i en forskningsstudie for å undersøke gjennomførbarheten til et testbatteri til bruk etter stabiliserende kirurgi for ustabilt kneskjell.
Ditt barn er operert eller skal gjennomgå stabiliserende kirurgi ved Haraldsplass Diakonale Sykehus eller et av sykehusene i Helse Vest og vi inviterer derfor han/henne til å delta i studien. Haraldsplass Diakonale Sykehus er ansvarlig for prosjektet. Prosjektet gjennomføres i samarbeid med de andre sykehusene i Helse Vest.

HVA INNEBÆRER DELTAKELSE I PROSJEKTET FOR DITT BARN?

Deltakelse innebærer at barnet ved første undersøkelse på sykehuset gjennomgår 4 fysiske tester og 6 spørreskjema i etterkant av undersøkelse hos legen. Spørreskjemaene omhandler plager fra kneet, hvor ustabilt kneet oppleves og bekymringer vedrørende kne plagene. I tillegg til hvilke aktiviteter/idrett barnet deltok i før kneproblemene oppstod, dagens deltakelse og motivasjon for å gjenoppta samme nivå som tidligere. Denne undersøkelsen vil ta omtrent 60 minutter. Omkring seks måneder etter operasjonen vil barnet bli innkalt til en ekstra kontroll. Vi vil da be barnet gjenta de fysiske testene samt fylle 3 av spørreskjemaene. Barnet vil også bli spurt om å fylle ut 3 av spørreskjemaene 2 uker før seks måneders kontrollen. Når det er gått 1 og 2 år siden operasjonen vil vi sende ut spørreskjemaet som omhandler aktivitet og idrett i posten for utfylling, med vedlagt frankert returkonvolutt. Vi vil i tillegg registrere følgende opplysninger om barnet, fødselsnummer, operasjonsmetode, tidligere skader kneet, vekt og høyde. Skulle ditt barn ikke ønske å delta i studien vil han/henne følge våre standard kontrollrutiner.

Foreldre som samtykker på vegne av barn kan på forespørsel få se spørreskjemaene og beskrivelse av de fysiske testene før samtykke gis.

Appendix 2, 8/10

MULIGE FORDELER OG ULEMPER

Ved å delta i studien vil deltakeren få mulighet til å belyse viktige sider ved vår evaluering om han/hun er klar for retur til fritidsaktiviteter og/eller idrett. Barnet vil få tettere poliklinisk oppfølging enn vanlig. Vi vil ikke gjennomføre noen andre undersøkelser eller behandlinger enn det som er beskrevet over.

FRIVILLIG DELTAKELSE OG MULIGHET FOR Å TREKKE DITT SAMTYKKE

Det er frivillig å delta i prosjektet. Dersom barnet ønsker å delta, undertegner du samtykkeerklæringen på siste side. Du kan når som helst og uten å oppgi noen grunn trekke ditt samtykke. Det vil ikke ha noen negative konsekvenser for barnet eller han/hennes behandling hvis dere ikke vil delta eller senere velger å trekke samtykket. Dersom du trekker tilbake samtykket, vil det ikke forskes videre på barnets helseopplysninger. Du kan også kreve at barnets helseopplysninger i prosjektet slettes eller utleveres innen 30 dager, og at det biologiske materialet destrueres. Adgangen til å kreve destruksjon, sletting eller utlevering gjelder ikke dersom materialet eller opplysningene er anonymisert eller publisert. Denne adgangen kan også begrenses dersom opplysningene er inngått i utførte analyser. Dersom du senere ønsker å trekke samtykket eller har spørsmål til prosjektet, kan du kontakte prosjektleder (se kontaktinformasjon på siste side). Dette vil ikke få konsekvenser for barnets videre behandling.

HVA SKJER MED OPPLYSNINGENE OM BARNET?

Alle personopplysninger vil bli behandlet konfidensielt. Informasjonen som registreres om barnet skal kun brukes slik som beskrevet i hensikten med studien. Alle opplysningene vil bli behandlet uten navn og fødselsnummer eller andre direkte gjenkjennende opplysninger. En kode knytter barnet og barnets opplysninger gjennom en navneliste. Det betyr at opplysningene er avidentifisert. Det er kun autorisert personell i prosjektgruppen som har adgang til navnelisten og som kan finne tilbake til barnet. Opplysningene vi har samlet om barnet vil bli slettet innen 01.01.2033. Det vil ikke være mulig å identifisere barnet i resultatene av studien når disse publiseres.

Opplysningene som registreres om barnet skal kun brukes slik som beskrevet under formålet med prosjektet, og planlegges brukt til 01.01.2028. Eventuelle utvidelser i bruk og oppbevaringstid kan kun skje etter godkjenning fra REK og andre relevante myndigheter. Du har rett til innsyn i hvilke opplysninger som er registrert om barnet og rett til å få korrigert eventuelle feil i de opplysningene som er registrert. Du har også rett til å få innsyn i sikkerhetstiltakene ved behandling av opplysningene. Du kan klage på behandlingen av barnets opplysninger til Datatilsynet og institusjonen sitt personvernombud. Alle opplysningene vil bli behandlet uten navn og fødselsnummer eller andre direkte gjenkjennende opplysninger (=kodede opplysninger). En kode knytter barnet og barnets opplysninger gjennom en navneliste. Det er kun prosjektleder, Trine Hysing-Dahl og forskningskoordinator, Ingun Fleten Mo, som har tilgang til denne listen. Opplysningene om ditt barn vil bli oppbevart i fem år etter prosjektslutt av kontrollhensyn.

Appendix 2, 9/10

FORSIKRING
Ved deltakelse i prosjektet vil barnet være dekket av pasientskadeloven.

ØKONOMI
Prosjektet er finansiert av forskningsmidler fra Helse Vest. Barnet vil ikke motta økonomisk kompensasjon for deltakelse. Egenandel ved tilleggs kontrollen vil dekkes av prosjektet.

GODKJENNINGER
Regional komité for medisinsk og helsefaglig forskningsetikk har gjort en forskningsetisk vurdering og godkjent prosjektet (ID:185067). Haraldsplass Diakonale Sykehus og prosjektleder Trine Hysing-Dahl er ansvarlig for personvernet i prosjektet.
Vi behandler opplysningene basert på ditt samtykke.

KONTAKTOPPLYSNINGER
Dersom du har spørsmål til prosjektet eller ønsker å trekke ditt samtykke, kan du kontakte:
Prosjektleder: Trine Hysing-Dahl, tlf. 469 03 740, e-post trine.hysing-dahl@haraldsplass.no
Forskningskoordinator: Ingun Fleten Mo, tlf. 469 03 961, e-post ingunn.fleten.mo@haraldsplass.no.
Dersom du har spørsmål om personvernet i prosjektet, kan du kontakte personvernombudet ved institusjonen: Personvern@haraldsplass.no
Datatilsynets e-postadresse er: Postkasse@datatilsynet.no

Appendix 2, 10/10

Som foresatte til_ (Fullt navn) samtykker vi til at hun/han kan delta i prosjektet

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Sted og dato

Foresattes signatur

Foresattes navn med trykte bokstaver

Sted og dato

Foresattes signatur

Foresattes navn med trykte bokstaver

Appendix 3

Navn:	*Fødselsnr:*	*Dato for utfylling:*

1. Hva regner du som din hoved-idrett/aktivitet? Sett et kryss bak din idrett/aktivitet.

1 Fotball	8 Aerobic	15 Svømme
2 Håndball	9 Styrketrening	16 Turn/Rytmisk gymnastikk
3 Basketball	10 Alpint/Telemark	17 Sykle
4 Volleyball	11 Langrenn	18 Gange i terreng
5 Tennis/badminton	12 Dans	19 Gange jevnt underlag
6 Kampsport	13 Løp i terreng	20 Annet
7 Trampoline	14 Løp jevnt underlag	Beskriv annen idrett:

2. På hvilket nivå utførte du din idrett/aktivitet før plagene oppstod? Sett kun ett kryss.

1 Elitenivå	☐	2 Konkurranse middels til høyt nivå	☐
3 Konkurranse lavere nivå	☐	4 Mosjonsnivå	☐

3. På hvilket nivå utfører du idrett/aktivitet nå? Sett kun ett kryss.

1 Elitenivå	☐	2 Konkurranse middels til høyt nivå	☐
3 Konkurranse lavere nivå	☐	4 Mosjonsnivå	☐
5 Sluttet/driver ikke lenger med	☐	6 Ikke prøvd ennå	☐

4. Hvordan fungerer kneet ditt nå ved din idrett/aktivitet?

1 Som før plagene oppstod/uten plager	☐	2 Med små plager eller begrensninger	☐
3 Betydelige plager eller begrensninger	☐	4 Forsøkt, men gitt opp grunnet kneplagene	☐
5 Ikke forsøkt pga frykt for nye plager	☐	6 Ikke gjenopptatt, annen årsak	☐

5. Hvor stor er din motivasjon for å gjenoppta din idrett/aktiviteter på samme nivå som før plagene oppstod?

(Sett skråstrek helt til venstre (ved 0) dersom du ikke er motivert for å gjenoppta din idrett/aktivitet på samme nivå som før plagene oppstod).

0	100
Ikke motivert	Ekstremt motivert

Appendix 4, 1/2

Test Prosedyre Y-balanse test (YBT)

Utstyr: YBT tapet/tegnet opp på gulv.

Oppvarming

1. Deltageren skal varme opp på ergometersykkel i 7 min før testen.

Gjennomføring av testen:

1. Testen gjennomføres i behagelige klær og barbeint.
1. 3 gjennomføringer: 4-6 oppvarmingsforsøk, opptil 5 min pause (hvis behov) før 3 tester (opptil 6 forsøk tillates for å klare 3 godkjente forsøk).
1. Etter 3 gjennomføringer går en videre til neste testretning (posteromedial).
1. Registrer hvert forsøk før neste retning. Distansen registreres som nærmeste 0.5 cm.
1. Testing i følgende rekkefølge:
    1. Ikke opr. Anterior
    1. Opr. Anterior
    1. Ikke opr. Posteromedial
    1. Opr. Posteromedial
    1. Ikke opr. Posterolateral
    1. Opr. Posterolateral
1. *Startposisjon:* anterior retning tå i kant av sort linje, posterior retning hæl i kant av sort linje.
1. *Instruksjon:* hendene i hoftefeste, før affisert bein fremover så langt du klarer og tapp i gulvet (tester markerer med kritt på linjen foran tå nr 1), løft beinet rolig tilbake til startposisjonen og gjenta uten å sette foten i bakken. NB! uaffisert bein testes først.

NB: Ikke godkjente forsøk innebærer:

- Berøring av gulvet før maksimal lengde.
    - Unilateral undereks skal ikke berøre gulvet annet enn ved maksimal distanse.
- Setter foten tungt ned.
- Pause ved startpunktet mellom de 3 forsøkene.
- Mister balanse.
- Hælen på standfoten løftes fra underlaget.

Skåring

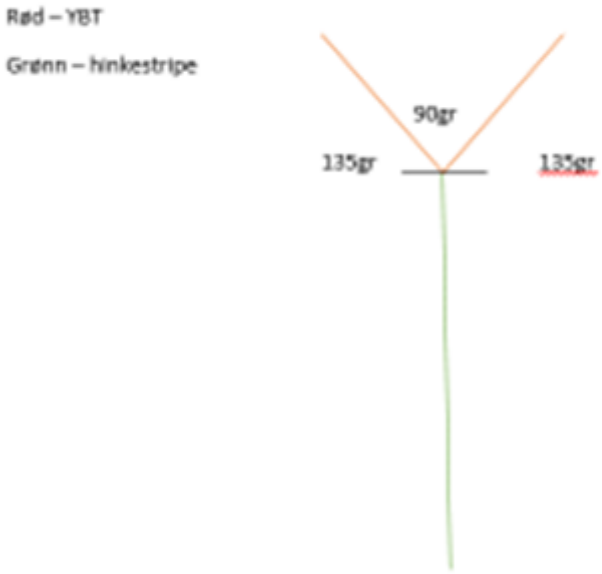
Retning - lengde i cm	**Måling aktuell side:**				**Måling kontroll (frisk) side:**			
Beinlengde (cm):	(SIAS hø side til distale del av mediale malleol i ryggliggende)							
	1.gang:	2.gang:	3.gang:	Snitt:	1.gang:	2.gang:	3.gang:	Snitt:
Anterior								
Postero- medial								
Postero- lateral								
Merknader til Y-balanse test:								

Appendix 4, 2/2

Skåres på 3 ulike måter:

1. Absolute reach distance (snitt) (cm) = (Reach 1 + Reach 2 + Reach 3) / 3.
1. Relative (normalised) reach distance (%) = Absolute reach distance / limb length * 100.
1. Composite reach distance (%) = Sum of the 3 reach directions / 3 times the limb length * 100.

Sideforskjell < 4cm er godkjent RTS kriteriet.



Appendix 5

Testprosedyre hinketest:
Utstyr: Hinkestripe tapet/tegnet opp på gulv.
Oppvarming

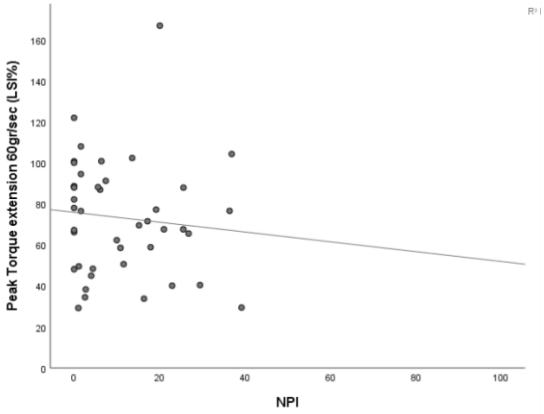
1. Deltageren skal varme opp på ergometersykkel i 5 min før testen.

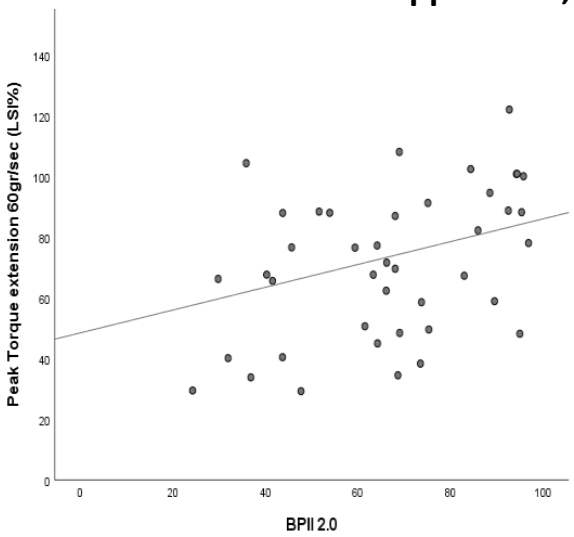
Gjennomføring av testen:

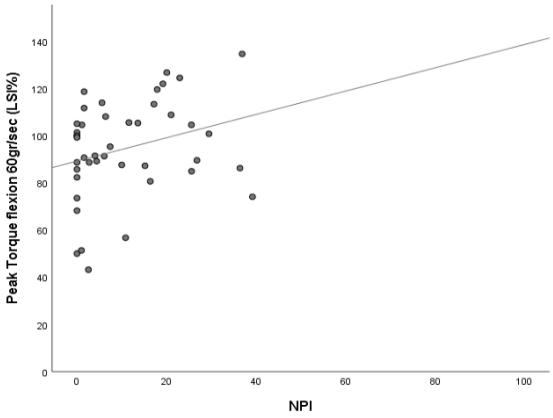
1. Testen gjennomføres i behagelige klær og barbeint.
1. Gjennomfør 1 øvings-hopp før 2 test-hopp registreres.
1. Etter 2 registrerte gjennomføringer går en videre til neste hoppe-øvelse.
1. Alle målinger registreres ved hæl.
1. Distansen registreres som nærmeste 0.5 cm.

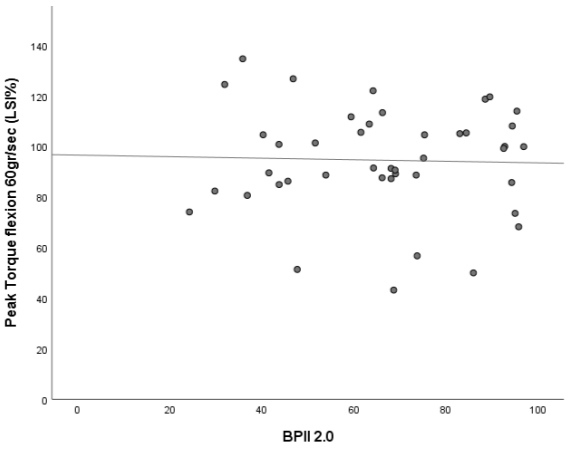
Hinketest						
	Uoperert			Operert		
	1 gang	2 gang	Gjsnitt	1 gang	2 gang	Gjsnitt
1 hink						
3 hink						
6 m på tid						
3 x-hink						
Merknader hinktestes:						

Appendix 6, 1/7

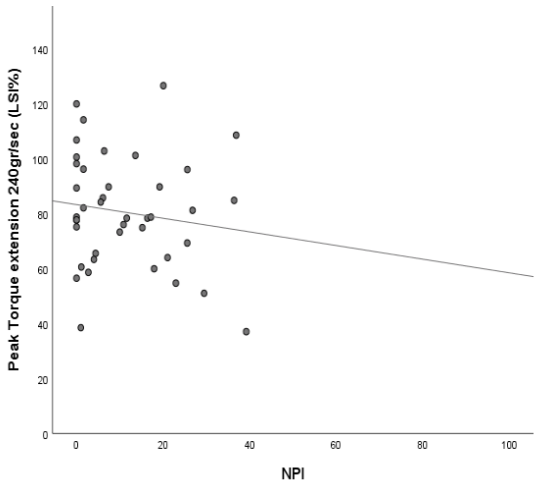


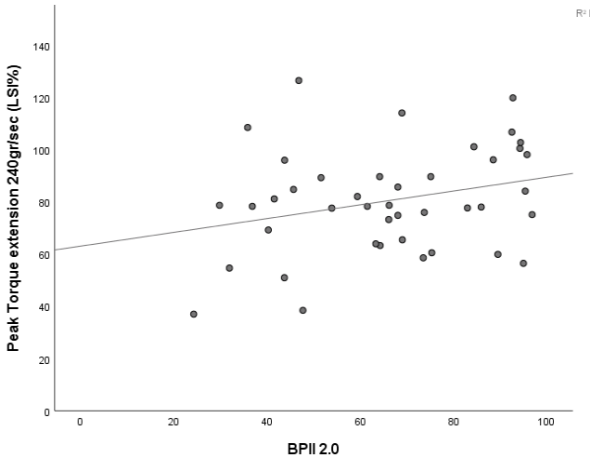


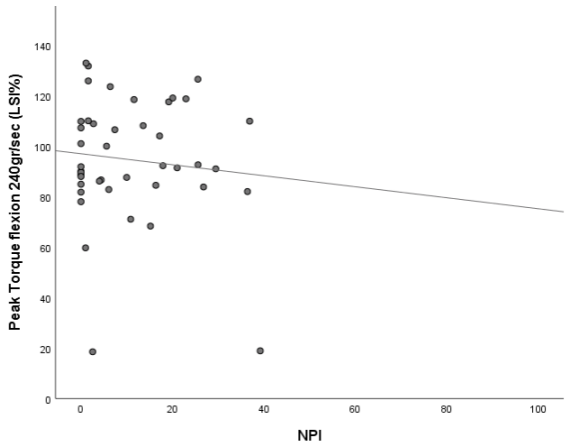


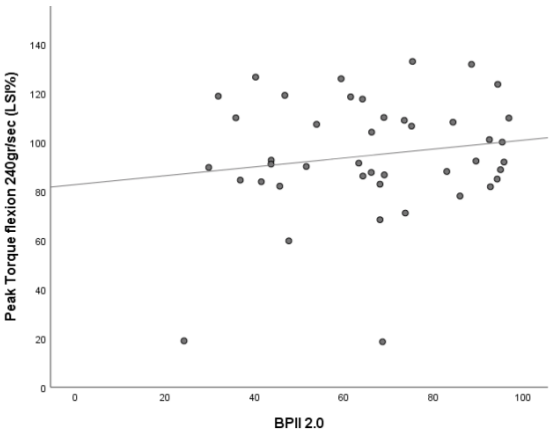


Appendix 6, 2/7

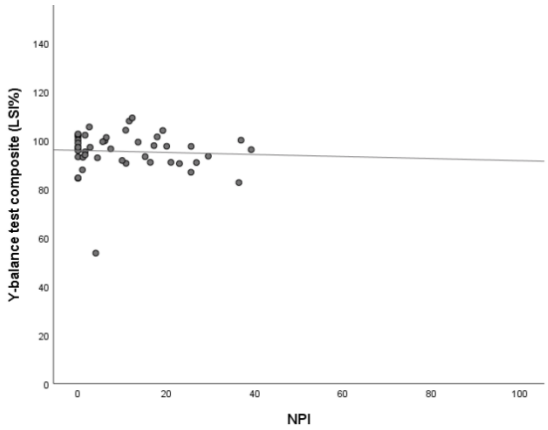


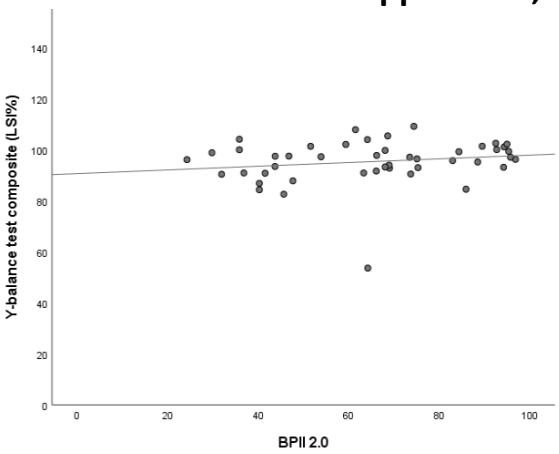


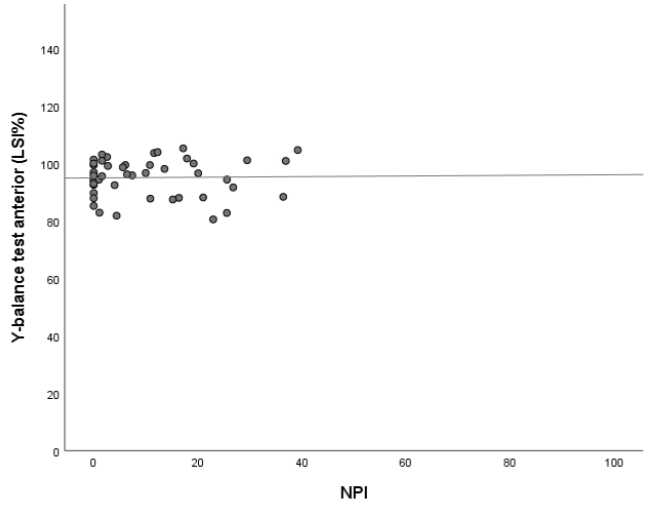


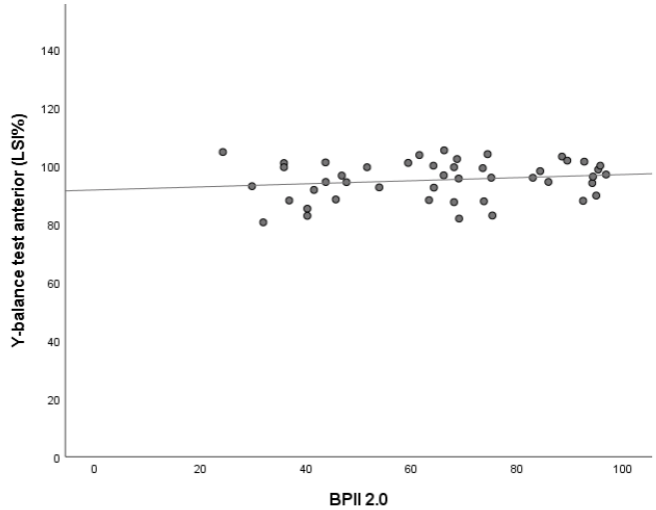


Appendix 6, 3/7

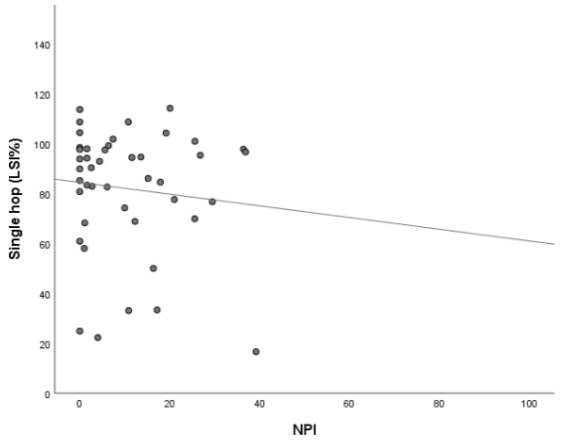


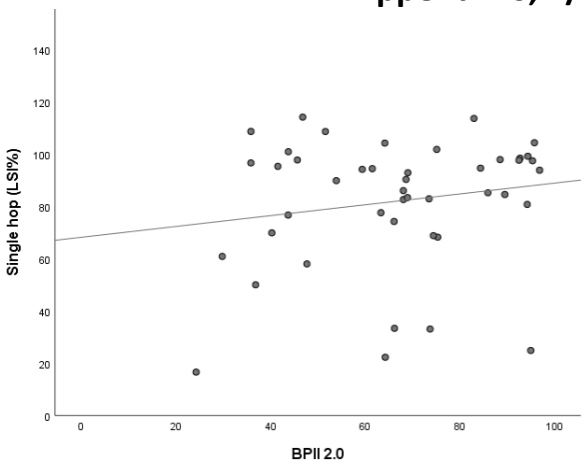


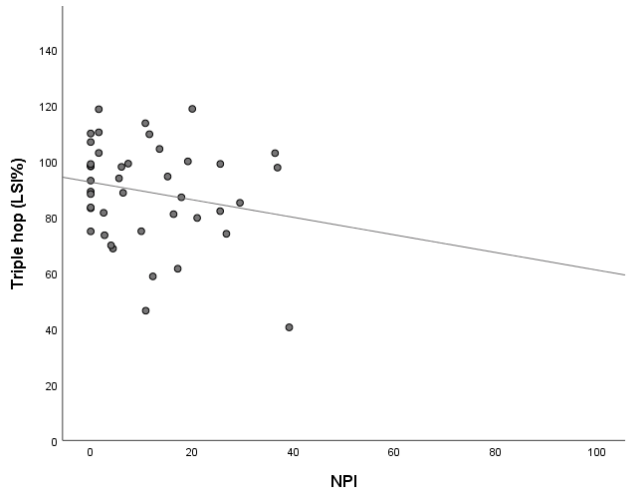


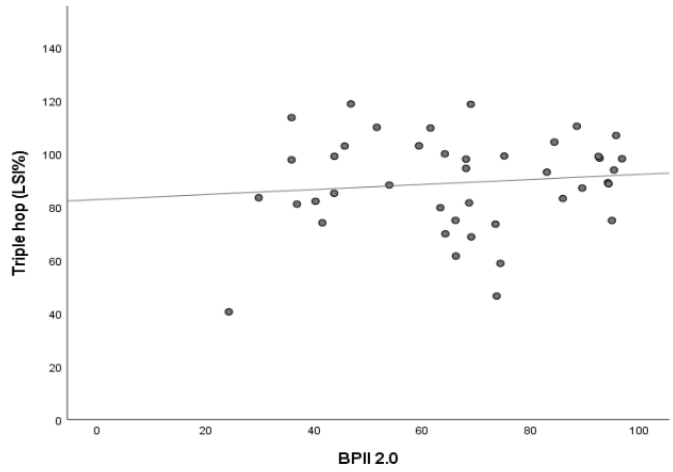


Appendix 6, 4/7

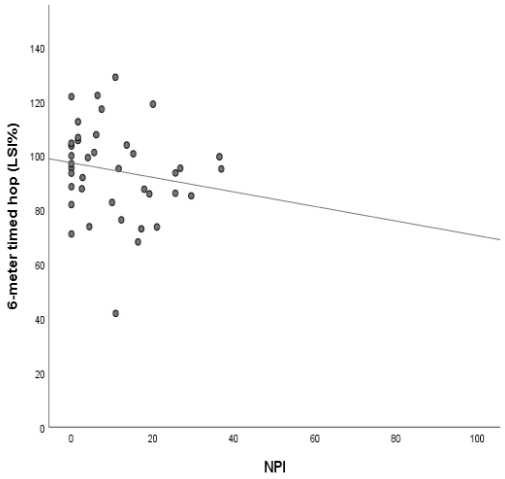


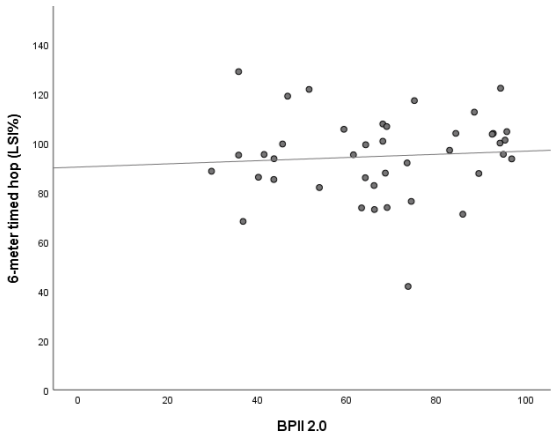


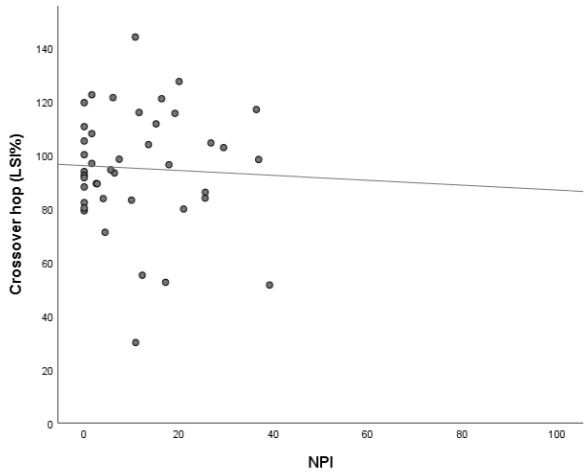


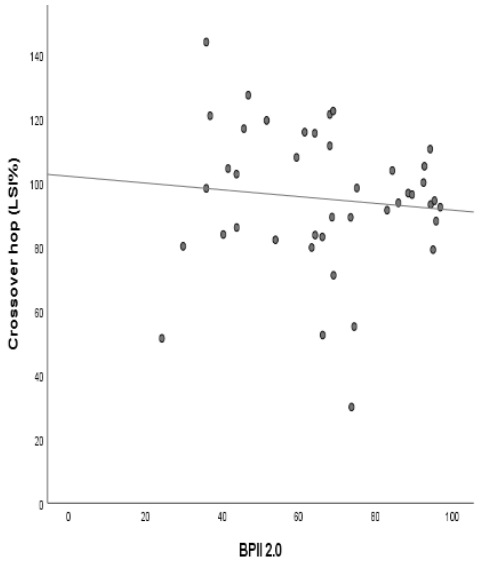


Appendix 6, 5/7

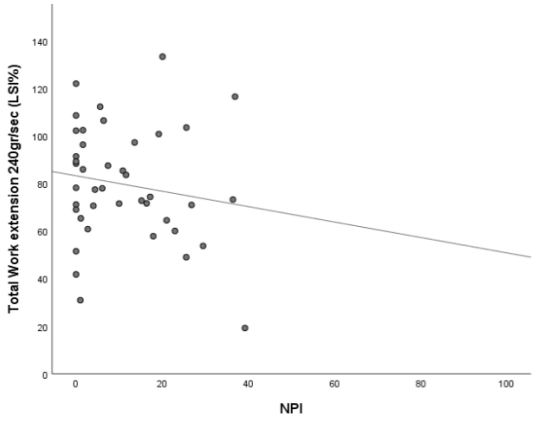


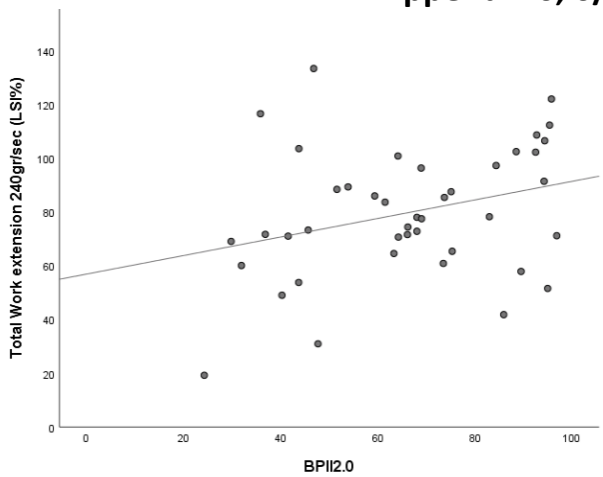


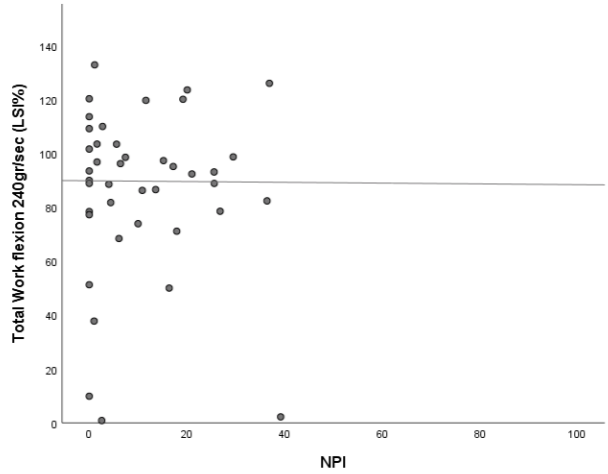


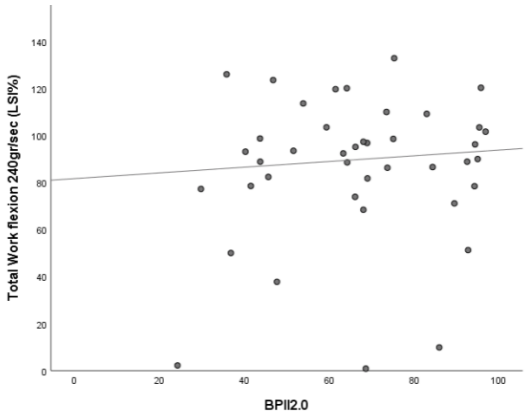


Appendix 6, 6/7

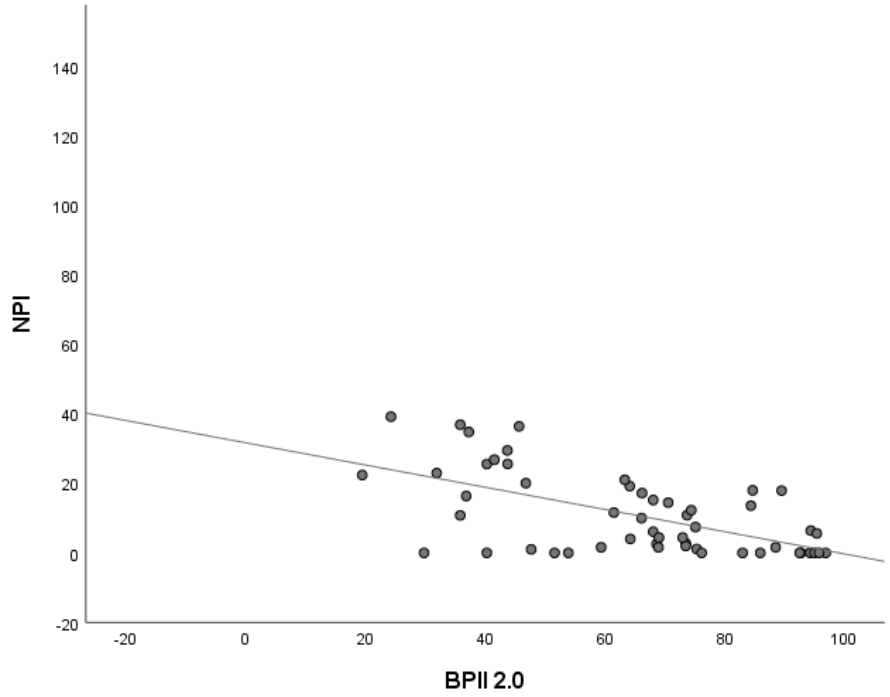








Appendix 6, 7/7



Appendix 7, 1/9

BMJ Sports Science, Medicine and Rehabilitation

Research article

Criteria

Research articles should report on original primary research or a new experimental or computational method, test or procedure. Manuscripts reporting results of a clinical trial must conform to CONSORT 2010 guidelines. Authors of randomized controlled trials should submit a completed CONSORT checklist alongside their manuscript, available at www.consort-statement.org. Research articles may also report on systematic reviews of published research provided they adhere to the appropriate reporting guidelines which are detailed in our editorial policies. Please note that non-commissioned pooled analyses of selected published research and bibliometric analyses will not be considered. Studies reporting descriptive results from a single institution or region will only be considered if analogous data have not been previously published in a peer reviewed journal and the conclusions provide distinct insights that are of relevance to a regional or international audience.

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Appendix 7, 2/9

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Preparing your manuscript

The information below details the section headings that you should include in your manuscript and what information should be within each section.
Please note that your manuscript must include a Declarations' section including all of the subheadings (please see below for more information).

Title page

The title page should:

- present a title that includes, if appropriate, the study design e.g.:
- "A versus B in the treatment of C: a randomized controlled trial", "X is a risk factor for Y: a case control study", "What is the impact of factor X on subject Y:
  A systematic review"
- or for non-clinical or non-research studies a description of what the article reports
- list the full names and institutional addresses for all authors o if a collaboration group should be listed as an author, please list the Group name as an author. If you would like the names of the individual members of the Group to be searchable through their individual PubMed records, please include this information in the "Acknowledgements" section in accordance with the instructions below

Appendix 7, 3/9

- indicate the corresponding author

Abstract

The Abstract should not exceed 350 words. Please minimize the use of abbreviations and do not cite references in the abstract. Reports of randomized controlled trials should follow the CONSORT extension for abstracts. The abstract must include the following separate sections:

- Background: the context and purpose of the study
- Methods: how the study was performed and statistical tests used ●Results: the main findings
- Conclusions: brief summary and potential implications
- Trial registration: If your article reports the results of a health care intervention on human participants, it must be registered in an appropriate registry and the registration number and date of registration should be in stated in this section. If it was not registered prospectively (before enrollment of the first participant), you should include the words 'retrospectively registered'. See our editorial policies for more information on trial registration

Keywords

Three to ten keywords representing the main content of the article.

Background

The Background section should explain the background to the study, its aims, a summary of the existing literature and why this study was necessary or its contribution to the field.

Methods

The methods section should include:

- the aim, design and setting of the study
- the characteristics of participants or description of materials
- a clear description of all processes, interventions and comparisons. Generic drug names should generally be used. When proprietary brands are used in research, include the brand names in parentheses
- the type of statistical analysis used, including a power calculation if appropriate

Results
This should include the findings of the study including, if appropriate, results of statistical analysis which must be included either in the text or as tables and figures.

Discussion
This section should discuss the implications of the findings in context of existing research and highlight limitations of the study.

Conclusions
This should state clearly the main conclusions and provide an explanation of the importance and relevance of the study reported.

List of abbreviations
If abbreviations are used in the text they should be defined in the text at first use, and a list of abbreviations should be provided.

Declarations
All manuscripts must contain the following sections under the heading 'Declarations':

- Ethics approval and consent to participate
- Consent for publication
- Availability of data and materials
- Competing interests
- Funding
- Authors' contributions
- Acknowledgements
- Authors' information (optional)

Please see below for details on the information to be included in these sections.

If any of the sections are not relevant to your manuscript, please include the heading and write 'Not applicable' for that section.

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Manuscripts reporting studies involving human participants, human data or human tissue must:

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- include the name of the ethics committee that approved the study and the committee's reference number if appropriate

Appendix 7, 5/9

Studies involving animals must include a statement on ethics approval and for experimental studies involving client-owned animals, authors must also include a statement on informed consent from the client or owner.
See our editor-iaLpglicjes for more information.
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If your manuscript contains any individual person's data in any form (including any individual details, images or videos), consent for publication must be obtained from that person, or in the case of children, their parent or legal guardian. All presentations of case reports must have consent for publication.
You can use your institutional consent form or our consent form if you prefer. You should not send the form to us on submission, but we may request to see a copy at any stage (including after publication).
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All manuscripts must include an 'Availability of data and materials' statement. Data availability statements should include information on where data supporting the results reported in the article can be found including, where applicable, hyperlinks to publicly archived datasets analysed or generated during the study. By data we mean the minimal dataset that would be necessary to interpret, replicate and build upon the findings reported in the article. We recognise it is not always possible to share research data publicly, for instance when individual privacy could be compromised, and in such instances data availability should still be stated in the manuscript along with any conditions for access.

Data availability statements can take one of the following forms (or a combination of more than one if required for multiple datasets):

- The datasets generated and/or analysed during the current study are available in the [NAME] repository, [PERSISTENT WEB LINK TO DATASETS]

Appendix 7, 6/9

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Hao Z, AghaKouchak A, Nakhjiri N, Farahmand A. Global integrated drought monitoring and prediction system (GIDMaPS) data sets. figshare. 2014.
http://dx.doi.org/10.6084/m9.figshare.853801

Appendix 7, 7/9

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Appendix 7, 8/9

Acknowledgements

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Appendix 7, 9/9

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Always use footnotes instead of endnotes.

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Web links and URLs: All web links and URLs, including links to the authors' own websites, should be given a reference number and included in the reference list rather than within the text of the manuscript. They should be provided in full, including both the title of the site and the URL, as well as the date the site was accessed, in the following format: The Mouse Tumor Biology Database. http://tumor.informatics.jax.org/mtbwi/index.do. Accessed 20 May 2013. If an author or group of authors can clearly be associated with a web link, such as for weblogs, then they should be included in the reference.

Appendix 8

Norwich Patellar Instabilitets Skår

For- og etternavn:			
Fødselsnummer: (11 siffer)			
Dato for undersøkelse:		Undersøkelse:	☐Første ☐3mnd ☐6mnd ☐1år ☐2år
Kne:	☐Høyre ☐Venstre		

Under følger en liste med aktiviteter som kan gi følelsen av at kneskjellet vil «hoppe ut» av ledd eller føles ustabilt.

Vennligst les igjennom hver påstand og kryss av i den boksen som best beskriver hvor ofte du opplever at kneskjellet vil «hoppe ut» av ledd eller føles ustabilt når du gjør følgende aktiviteter. Hvis du ikke gjør aktiviteten på grunn av ditt kneproblem kryss av i gjør ikke ruten.

#	Spørsmål	Alltid	Ofte	Noen ganger	Sjelden	Aldri	Gjør ikke
1.	Vridning/retningsendring under idrett/aktivitet						
2.	Retningsendring ved løping						
3.	Løpe rett frem på *ujevnt* underlag						
4.	Gå på glatt, vått eller isete underlag						
5.	Løpe sideveis						
6.	Hinke						
7.	Hoppe						
8.	Løpe rett frem på *jevnt* underlag						
9.	Gå ned trapper						
10.	Sette deg på huk og opp igjen						
11.	Knele/sitte på kne						
12.	Gå rett frem på *ujevnt* underlag						
13.	Gå opp trapper						
14.	Gå opp på eller over et høyt trinn						
15.	Krysse beina når du sitter						
16.	Gå rett frem på *jevnt* underlag						
17.	Gå inn eller ut av en bil						
18.	Snu en tung handlevogn rundt en butikkhylle						
19.	Snu deg for å se over skulderen						

Appendix 9, 1/5

BANFF PATELLOFEMORAL INSTABILITETSINSTRUMENT 2.0

Et mål på livskvalitet hos pasienter med ustabilt kneskjell

Pasientens navn (for-/etternavn): _____

Fødselsnummer (11 siffer): _____

Undersøkelsesdato (dd/mm/åå): _____

Hvilket kne blir du undersøkt for i dag?	**Denne undersøkelsen gjelder:**
o Venstre kne	o Første undersøkelse hos spesialist
o Høyre kne	o Operasjonsdag
	o 3 måneder etter operasjon
o Begge knær	o 6 måneder etter operasjon
	o 12 måneder etter operasjon
	o 24 måneder etter operasjon

Veiledning

Vennligst besvar hvert spørsmål med hensyn til din aktuelle status, funksjon, omstendigheter og oppfattelse vedrørende ditt kne som har et ustabilt kneskjell. Ta de siste 3 måneder i betraktning.

Marker med en skråstrek (/) det punktet på linjen mellom 0 og 100, som nærmest beskriver din situasjon. For eksempel følgende spørsmål:

Er dette et godt spørreskjema?

0 ——————————————————————— **100**
Ubrukelig **Fantastisk**

Dersom skråstreken plasseres midt på linjen, betyr det at spørreskjemaet er av middels kvalitet, eller med andre ord mellom ytterpunktene "ubrukelig" og "fantastisk". Det er viktig å sette skråstreken ved endene av linjen hvis ytterpunktene best beskriver din situasjon.

SEKSJON A: SYMPTOMER OG FYSISKE PLAGER

Appendix 9, 2/5

1. Hvor plaget er du av at kneskjellet ditt "hopper ut" eller er ustabilt?

0 ——————————————— 100
Ekstremt plaget Ikke noe plaget

2. Hvor mye smerte eller ubehag får du i kneet ditt ved langvarig aktivitet (over 30 minutter)? For eksempel: ståing, gåing, idrett og lignende.

0 ——————————————— 100
Ekstremt mye smerte Ingen smerte i det hele tatt

3. Hvor mye smerte eller ubehag får du i kneet ditt ved langvarig sitting (over 30 minutter)? For eksempel: kino, bilkjøring, eller lignende.

0 ——————————————— 100
Ekstremt mye smerte Ingen smerte i det hele tatt

4. Har du nedsatt bevegelse i kneet ditt?

0 ——————————————— 100
Svært redusert bevegelse Ingen tap av bevegelse

5. Hvor svakt føles kneet ditt?

0 ——————————————— 100
Ekstremt svakt Ikke svakt i det hele tatt

SEKSJON B: JOBB OG/ELLER SKOLERELATERTE BEKYMRINGER:

***Hvis du ikke er i jobb/skole på grunn av kneet ditt, sett en skråstrek helt til venstre (ved 0) for hvert spørsmål.*

6. Hvor store vanskeligheter opplever du med kneet ditt ved vendinger og vridninger på jobb og/eller skole?

0 ——————————————— 100
Store vanskeligheter Ingen vanskeligheter i det hele tatt

7. Hvor store vanskeligheter har du med å sette deg på huk på jobb og/eller skole?

0 ——————————————————— 100
Store vanskeligheter Ingen vanskeligheter i det hele tatt

8. Er du bekymret for å måtte være vekke fra jobb og/eller skole på grunn av ditt kneproblem?

0 ——————————————————— 100
Ekstremt bekymret Ikke bekymret i det hele tatt

9. Har ditt kneproblem forårsaket økonomiske problemer for deg eller din familie?

0 ——————————————————— 100
Store økonomiske problemer Ingen økonomiske problemer

SEKSJON C: FRITID / IDRETT / AKTIVITET

10. Hvor bekymret er du for at dine idretts- og/eller fritidsaktiviteter kan forverre ditt kneproblem?

0 ——————————————————— 100
Ekstremt bekymret Ikke bekymret i det hele tatt

11. Må du være forsiktig ved deltakelse i idrett og/eller fritidsaktiviteter?
(Sett skråstrek helt til venstre (ved 0) dersom du ikke kan delta i idrett og/eller fritidsaktiviteter på grunn av kneet ditt).

0 ——————————————————— 100
Alltid forsiktig Aldri forsiktig

12. Hvor engstelig er du for at kneskjellet skal «hoppe ut» når du deltar i idrett og/eller fritidsaktiviteter?
(Sett skråstrek helt til venstre (ved 0) dersom du ikke kan delta i idrett og/eller fritidsaktiviteter på grunn av kneet ditt).

0 ——————————————————— 100
Ekstremt engstelig Ikke engstelig i det hele tatt

13.Hvor bekymret er du for å gå på isete, vått eller ujevnt underlag? **Appendix 9, 4/5**

0 ——————————————————— 100
Ekstremt bekymret Ikke bekymret i det hele tatt

14.Kan du gi full innsats i dine idrett og/eller fritidsaktiviteter?
(Sett skråstrek helt til venstre (ved 0) dersom du ikke kan delta i idrett og/eller fritidsaktiviteter på grunn av kneet ditt).

0 ——————————————————— 100
Aldri i stand til Alltid i stand til

SEKSJON D: LIVSSTIL

15.Er generell sikkerhet en bekymring for deg på grunn av kneet ditt? For eksempel: gå opp eller ned trapper, bilkjøring, eller bæring av små barn og lignende.

0 ——————————————————— 100
Ekstrem bekymring Ingen bekymring i det hele tatt

16.Hvor mye har din evne til å trene og opprettholde fysisk form blitt begrenset av ditt kneproblem?

0 ——————————————————— 100
Fullstendig begrenset Ikke begrenset i det hele tatt

17.Hvor mye har din livsglede blitt begrenset av ditt kneproblem?

0 ——————————————————— 100
Fullstendig begrenset Ikke begrenset i det hele tatt

18.Unngår du fritidsaktiviteter med familie og/eller venner på grunn av ditt kneproblem?

0 ——————————————————— 100
Unngår alltid Unngår aldri

19.Fører ditt kneproblem til at du må planlegge sosiale- og fritidsaktiviteter mer enn familie og/eller venner?

0
——————————————————— 100

Må alltid planlegge Må ikke planlegge

SEKSJON E: SOSIALT OG FØLELSESMESSIG

Appendix 9, 5/5

20.Er du frustrert over at dine behov for fritidsaktiviteter eller konkurranse ikke lengre kan oppfylles på grunn av ditt kneproblem?

(Sett en skråstrek helt til høyre (ved 100) hvis du oppfyller dine behov. Sett en skråstrek helt til venstre (ved 0) hvis du ikke har konkurransemessige behov).

0 ——————————————————— 100
Ekstremt frustrert — Ikke frustrert i det hele tatt

21.Har du hatt problemer med å håndtere ditt kneproblem følelsesmessig?

0 ——————————————————— 100
Ekstreme problemer — Ingen problemer i det hele tatt

22.Hvor ofte er du nervøs for kneet ditt?

0 ——————————————————— 100
Alltid nervøs — Aldri nervøs

23.Hvor engstelig er du for å skade kneet igjen?

0 ——————————————————— 100
Ekstremt engstelig — Ikke engstelig i det hele tatt

Takk for at du fylte ut dette spørreskjemaet.