NORWEGIAN SCHOOL OF SPORT SCIENCES

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Knee function and psychological readiness 6 to 12 months after ACLR

A comparison between nonprofessional pivoting sport athletes who followed a rehabilitation and RTS decision tool and usual care

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Abstract

Background: The better and safer return to sports (BEAST) - a rehabilitation and return to sports (RTS) decision tool has been designed to facilitate athletes returning safely to sports after anterior cruciate ligament reconstruction (ACLR). There is a need to investigate and compare knee function and psychological readiness during the return to sport phase in athletes following the BEAST tool and usual care.

Objective: To compare change in knee function and psychological readiness to RTS 6 to 12 months after ACLR between nonprofessional pivoting sport athletes who followed the BEAST tool versus usual care.

Design: A comparison between two prospective cohort studies
Method: Nonprofessional pivoting sport athletes aged 15-40 years with a primary unilateral ACLR were included. Out of 247 athletes, 77 followed the BEAST tool, and 170 received usual care (SPARX cohort). The International Knee Documentation Committee subjective knee form (IKDC-SKF) and ACL- Return to Sport after Injury (RSI) was answered electronically 6 and 12 months postoperative. The 6 to 12 months change between the groups was analyzed, adjusted for age, sex, preinjury sport, family history of ACL injury, time from injury to surgery, ACL graft type, concomitant meniscus and/or cartilage injury yes/no, and meniscal repair yes/no.

Results: No difference in change in knee function ($p=0.722$) or psychological readiness ($p=0.518$) was found between the groups. At 6 and 12 months postoperative, the IKDC-SKF scores in BEAST athletes increased from 72.3 to 85.3, and usual care from 67.3 to 79.9. The ACL-RSI scores in BEAST athletes increased from 60.3 to 71.6, and usual care from 48.4 to 56.3. At 12 months postoperative, 48% and 35% of the BEAST athletes had not achieved symmetrical quadriceps strength and hop performance, respectively.

Conclusion: Nonprofessional pivoting sport athletes with ACLR who followed the BEAST tool have comparable 6 to 12 months change in knee function and psychological readiness to RTS when compared to usual care. Few athletes following the BEAST tool achieved the functional goals within 12 months postoperative.

Content

Preface

This master thesis is written as a part of my two-year master's degree in Sports Physical Therapy at the Norwegian School of Sports Sciences (NIH). I have learned a lot the past couple of years as a student at NIH being surrounded by engaged students and dedicated lecturers. I will make use of my acquired knowledge and expanded collegial network further in my clinical career.

First and foremost, I want to thank my supervisor, Hege Grindem, for including me in the BEAST study. Her high level of knowledge is admirable, and I appreciate her solid feedbacks throughout the work on my master thesis. I also want to thank the scientific group in Better and Safer Return to Sports (BEAST) for giving me the possibility for doing my master thesis as a part of their project. I would like to thank Morten Wang Fagerland for doing the main analysis in this study. Thank you, Joanna Kvist, for helping us with the SPARX data, and helping me with all my questions.

I want to thank all my fellow students I have gotten to know the last couple of years during my master´s degree. I am looking forward to having them as good friends and colleagues throughout my working career.

Writing a master thesis has been a comprehensive and time-consuming process. I want to thank my girlfriend, friends, and family for the acceptance of seeing me less the last couple of months. I promise you will see more of me during the summer vacation. Thank you!

Oslo, May 2023.

1. Theory

This first section of my master's thesis will provide the necessary theoretical background for the scientific article. It will commence with the elaboration of anterior cruciate ligament (ACL) injuries and its associated consequences. Subsequently, I will limit my focus towards athletes who have undergone ACL reconstruction (ACLR). I will describe the criteria for ACLR eligibility among athletes, followed by a presentation of evidence-based rehabilitation and return to sport (RTS) criteria. Lastly, I will present details of my systematic literature search and the generated studies investigating knee function and psychological readiness in athletes who have undergone ACLR.

1.1 Anterior Cruciate Ligament Injury

The anterior cruciate ligament (ACL) is the most frequently injured ligament in the knee (Barber-Westin & Noyes, 2011). In cases where patients describe an injury mechanism involving a combination of deceleration/acceleration and knee valgus load, a "pop" is felt or heard at the time of injury, or hemarthrosis in the knee within 2 hours after injury, there should be a strong suspicion of an ACL injury (Logerstedt et al., 2010). Research has shown an annual incidence of 81 ACL injuries per 100.000 inhabitants aged 10-64 years (Frobell et al., 2007). Additionally, concomitant injuries such as meniscal tears, cartilage injuries, bone marrow lesions, fractures, or sprains of other knee ligaments commonly occur in addition to the ACL injury (Filbay & Grindem, 2019). The prevalence of meniscal and cartilage injuries in patients undergoing ACLR has been reported to be 47% and 26%, respectively (Granan et al., 2008).

Athletes participating in sports activities including pivoting, jumping, and cutting movements report the highest incidence of ACL injuries (Mountcastle et al., 2007). Football (52%) and handball (39%) are the primary sports activities reported by female adolescents as causative factors for ACL injuries, while football (60%) remains the predominant sport associated with ACL injuries in their male counterparts (Johnsen et al., 2016). A meta-analysis investigating ACL injuries found that female athletes participating in pivoting sports have an elevated risk of almost 4,5 times greater than their male counterparts (Prodromos et al., 2007). There is an increasing number of young and active individuals in sports, and the incidence of ACL injuries steady

increases along (Bram et al., 2021). A systematic review investigating ACL injury rates across various groups, has shown that nonprofessional athletes have higher incidence compared to the general population but a lower incidence compared to professional athletes (Moses et al., 2012). However, most athletes participating in sports are non-professionals, making them the largest group of athletes with ACL injuries (Ardern, Österberg, et al., 2014).

1.2 Consequences of an anterior cruciate ligament injury

An ACL injury might bring several consequences, impacting both individual and socioeconomic factors. Common individual consequences include reduced knee function and negative psychological responses (Filbay et al., 2014). There is a possibility of not returning to sports activities at all, and for the individuals who resume activities, there is an increased risk of sustaining a secondary ACL injury (Ardern, Taylor, et al., 2014; Wiggins et al., 2016). Additional common consequences are knee pain, knee symptoms, limits in recreation, impaired quality of life and the development of posttraumatic knee osteoarthritis (Filbay et al., 2014; Filbay et al., 2015).

Socioeconomical consequences include surgical expenses, absence from work, rehabilitation costs, and disability in occupations demanding high knee functionality (Myklebust, 2002). In Norway, the estimated cost associated with ACL injury ranges between 500.000 and 1.000.000 Norwegian kroner (NOK) (Myklebust, 2002). Further, I will elaborate about the primary individual consequences that the athletes might experience after ACL injury.

1.2.1 Knee function and psychological readiness

An ACL injury is associated with increased passive laxity in the knee, which is believed to contribute to instability (Snyder-Mackler et al., 1997). However, there appears to be a lack of association between passive laxity and the individuals perception of decreased functionality (Snyder-Mackler et al., 1997). Patients usually experience functional knee instabilities, resulting in impairments in strength, altered movement patterns and decreased joint proprioception (Filbay & Grindem, 2019). ACL injury, with or without ACLR, alters lower extremity functional activities and gait due to changes in kinetics and kinematics (Ingersoll et al., 2008). Additional consequences include reduced quadriceps strength, persisting pain and post-traumatic knee arthritis (Grindem et al.,

2014; Lohmander et al., 2004). Reduced quadriceps strength is likely caused by quadriceps inhibition and hamstring muscle activation (Ingersoll et al., 2008). These alterations in motor patterns are likely a protective mechanism as an result to structural damage on the mechanoreceptors in the ACL but may persist for a long time (Ingersoll et al., 2008).

Previous research has primarily focused on the physical consequences of reduced knee function following ACL injury (Forsdyke et al., 2016). However, physical and psychological readiness do not always coincide (Podlog & Eklund, 2010). Negative psychological responses are a common consequence among athletes after a physical trauma like an ACL injury and may impact their ability to rehabilitate and RTS (Liew et al., 2022). A qualitative study by Forsdyke et al. (2016) indicated that factors like thoughts, emotions and actions can be altered in injured athletes (Forsdyke et al., 2016). Morrey et al. (1999) investigated the athletes' emotional responses during their rehabilitation and found that negative emotions often occurred in the latter part of rehabilitation, around 6 months following surgery (Morrey et al., 1999). Altered athletic confidence to performance and the risk appraisal of return to sport has also been recognized as psychological consequences in other sporting contexts (Johnston & Carroll, 1998). Fear or reinjury, fear of pain and lack of confidence can ultimately stop the individual in RTS and even end the individual's sports career (Ardern et al., 2013; Ardern et al., 2011; Ardern, Österberg, et al., 2014; te Wierike et al., 2013).

1.2.2 Return to sports and reinjury

A systematic review and meta-analysis conducted by Ardern et al. (2014) investigated the existing literature on RTS rates following ACLR and found that only 42% of nonprofessional athletes returned to competitive sports (Ardern, Taylor, et al., 2014). The professional athletes had more than twice the odds of returning to preinjury level, and approximately six times the odds of returning to competitive level of sports compared to the nonprofessional athletes (Ardern, Taylor, et al., 2014). The systematic review with meta-analysis by Lai et al. (2018) found that 83% of professional athletes returned to preinjury sport, highlighting a huge gap between professional and non-professional athletes (Lai et al., 2018). The explanation of the huge gap is speculated to be due to the professional athlete's high investment and expectations in returning to sports (Ardern, Taylor, et al., 2014). These athletes also have financial benefits as well

as more hours participating in sports. Non-professional athletes don't have the same access to medical and rehabilitations professional, the same way professional athletes do.

Despite a successful ACLR, rehabilitation and return to activity, a graft rupture and contralateral ACL rupture represents a major problem and a devastating consequence for the individual. While ipsilateral reinjuries are common, rates of contralateral ACL injuries surpass those of ipsilateral graft ruptures regardless of age or activity level (Wiggins et al., 2016). The underlying reasons for the high incidence of contralateral injuries remain incompletely understood but are likely multifactorial (Wiggins et al., 2016). A systematic review and meta-analysis found that nearly one in four young athletes returning to high-risk sports including pivoting and cutting movements will sustain a secondary ACL injury, and the most vulnerable period being early in the RTS phase (Wiggins et al., 2016). In addition, family history of ACL ruptures doubles the odds for both graft ruptures and contralateral ACL injuries (Webster et al., 2014).

1.3 Anterior Cruciate Ligament reconstruction

Reconstruction of the ACL is usually recommended and performed in athletes when their goal is to return to preinjury sports activities (Barber-Westin & Noyes, 2011). Athletes returning to pivoting sports have three times higher incidence for ACLR compared to athletes returning to less pivoting activities like technical and endurance sports (Johnsen et al., 2016). The primary objective of the reconstruction is to stabilize the knee joint, preventing reinjury and enabling athletes to participate in their desired activities safely (Barber-Westin & Noyes, 2011). During ACLR, the torn ACL is being reconstructed with a tendon graft of preferred choice (Claes et al., 2011). The most common graft choices are the patellar, hamstring and quadriceps tendons (Lin et al., 2020).

The ligament registries in Scandinavia provides prospective data of cruciate ligament surgeries gathered from both surgeons and patients (Granan et al., 2008; Granan et al., 2009). Data from the Norwegian National Knee Ligament Registry (NKLR) indicate that the patellar tendon graft is the preferred choice in Norway, accounting for 73% of the reconstructions performed in 2021 (Visnes, 2021). Furthermore, the prevalence of meniscus repair during ACLR increased from approximately 20%, to 62% between

2011 and 2021, based on the NKLR data (Visnes, 2021). In Sweden, the hamstring graft, with or without the gracilis tendon, was the predominant graft choice during ACL reconstructions in 2021, accounting for 85% of the cases, while meniscus repair was performed in 24% of the cases. (Korsbandsregistret., 2021).

1.4 Rehabilitation

Although ACLR restores the static stability of the knee joint, the reconstruction does not restore the knee function itself (Augustsson et al., 2004). As previously stated by Ardern et al. (2015), ACLR is not exactly a one-way ticket back to preinjury level of sports. When the ACL has been surgically reconstructed there is still a long way to go, and the rehabilitation is a long and demanding process.

The primary objectives after ACLR are to restore knee function, address psychological barriers for RTS, the prevention of further knee injuries, reduce the risk of OA, and optimize long-term quality of life (Filbay & Grindem, 2019). To achieve these objectives, rehabilitation should involve objectives like strength training, neuromuscular training, dynamic activities, such as jumping, hopping, and cutting maneuvers, as well as sports specific training (Filbay & Grindem, 2019). A clinical practice guideline, based on systematic reviews and a multidisciplinary consensus group, suggest that progression should be guided by strength and hop test, psychological tests, and movement quality (van Melick et al., 2016).

Still, usual care after ACLR in Flemish physical therapists were in general not in line with the best available practice, despite their self-rated confidence and competence where high (Dingenen et al., 2021). In the United States, there is considerable variation in usual care among members of the American Physical Therapy Association (Greenberg et al., 2018). In both Europe and North America, the follow-up often discontinues before athletes returns to their previous sports (Dingenen et al., 2021; Greenberg et al., 2018). Insufficient attention has been given to the on-field rehabilitation, which represents the transition from gym-based rehabilitation to the on-field competitive team practices during rehabilitation. This is an important phase, but the athletes usually goes through this phase too quickly (Buckthorpe et al., 2019). Return to sports activities should not be a decision taken at the end of rehabilitation but

should be addressed as a continuum along the rehabilitation (Ardern et al., 2016).

1.5 Return to sports

Return to sports criteria is growing within studies on athletes after ACLR. However, there is a lack of scientific consensus on the criteria for RTS, with guidelines mainly based on observational studies and expert opinions (Dingenen & Gokeler, 2017; Filbay & Grindem, 2019). Filbay & Grindem (2019) states three key considerations for return to sports for athletes: is the athlete physically ready? Is the athlete mentally ready? Has there been allowed enough time for biological healing? The evaluation of a safe return to sports should include objective criteria involving performance-based testing, as well as subjective evaluation of knee function and psychological responses (Filbay & Grindem, 2019).

1.5.1 Objective measures

To identify weaknesses and determine an athlete's readiness to return to sports, it appears that individual tests alone may lack the necessary sensitivity. Therefore, the incorporation of test batteries comprising multiple tests is recommended (Moksnes & Risberg, 2009; Thomeé et al., 2011; van Melick et al., 2016). These test batteries should include strength and hop tests, as well as measuring movement quality (van Melick et al., 2016). Within test batteries, the limb symmetry index (LSI) is usually used to assess strength and hopping performance, calculating the ratio between the injured and non-injured side (Grindem et al., 2016; Thomeé et al., 2011). Cut-off values for LSI in strength and hopping performance range from ≥ 85-100% (Thomeé et al., 2011; van Grinsven et al., 2010; van Melick et al., 2016). However, Barber-Westin & Noyes. (2011) found in their systematic review that more than 70% of the published literature excluded functional measures when making decisions about RTS, leaving a large gap between best practice recommendations and usual care practice (Barber-Westin & Noyes, 2011).

A study by Kyritsis et al. (2016) found that athletes who did not meet all the objective discharge criteria, including muscle strength and functional tests, before returning to sports had four times greater risk of sustaining an ACL graft rupture (Kyritsis et al., 2016). Additionally, Grindem er al. (2020) found that passing RTS criteria prior to RTS was associated with a 92% lower rate of a second ACL injury in young athletes. Still,

80-86% of athletes following usual care attempts to RTS without passing the criteria of functional RTS test batteries (Beischer et al., 2018; Toole et al., 2017).

Additionally, the reinjury is being significantly reduced by 51% for each month the RTS is delayed until 9 months postoperative (Grindem et al., 2016). The practice guideline proposed by Van Melick et al. (2016) recommends that rehabilitation should last 9-12 months before RTS, considering the specific demands placed on the knee by the athlete's chosen activity. However, a previous study investigating the discharge timing among Australian physical therapists found that almost one out of four were willing to discharge the athletes for RTS between 6 and 9 months after surgery (Ebert et al., 2019).

1.5.2 Subjective measures

Subjective evaluations capture different aspects of function compared to clinical performance-based outcomes, which makes a combination of outcome measures most likely to provide a successful evaluation (Eitzen et al., 2010). To evaluate the patient's perception of important consequences after ACLR, knee function and psychological readiness, the International Knee Documentation Committee Subjective Knee form (IKDC-SKF) and ACL- Return to Sports after Injury (RSI) questionnaires is usually being used (van Meer et al., 2013; Webster & Feller, 2022).

The IKDC-SFK questionnaire is specifically designed to measure symptoms, function, and activities for patients with knee problems, scoring from 0-100 points (Irrgang et al., 2001). The questionnaire is recommended for evaluation of patient-reported knee function within the first year after ACLR (van Meer et al., 2013). The patient's perspective of their own knee function has shown to have stronger association with patient satisfaction compared to standard clinical measures (Kocher et al., 2002). Several studies indicated that athletes returning to their previous level of sports achieve significantly higher scores on IKDC-SKF compared to athletes who do not return to sports (Ardern et al., 2013; Lentz et al., 2012; Moksnes & Risberg, 2009; Sonesson et al., 2017). Furthermore, the IKDC-SKF score may identify athletes who fail RTS criteria up to one year after ACLR (Logerstedt et al., 2014).

Recovery of physical function is not sufficient to ensure RTS due to the complex and multifactorial interaction in RTS (Ardern, 2015). To ensure RTS and reduce the reinjury rates and the need for subsequent surgery, both physical and psychological factors for sports participation needs to be utilized (Czuppon et al., 2014). Modifiable psychological factors like fear of reinjury, fear of pain and lack of confidence affects RTS after ACLR (Ardern et al., 2013; Ardern et al., 2011; te Wierike et al., 2013). Psychological factors commonly used in terms of RTS is psychological readiness and its importance in RTS decision making is well recognized (Ardern, Österberg, et al., 2014; Webster & Feller, 2022). The ACL-Return to Sport after Injury (RSI) questionnaire evaluates psychological readiness and has demonstrated the best discriminative capabilities regarding RTS compared to other questionnaires (Ardern et al., 2013). High score on patient-reported psychological readiness and low fear of reinjury is connected to high RTS rate to athletes' preinjury level (Ardern, Taylor, et al., 2014; Ardern et al., 2011; Webster et al., 2008). Variations in psychological readiness can occur as early as 6 months postoperative, and the 6 months postoperative ACL-RSI score has shown to be a significant predictor of RTS (Kitaguchi et al., 2020; Langford et al., 2009; Müller et al., 2015). High score on psychological readiness has also been found to be positively associated with higher patient-reported knee function (Webster et al., 2018).

1.6 Literature search

Table 1 presents my literature search conducted in this study. The literature search aimed to identify relevant studies involving athletes or adolescents who underwent ACLR being evaluated 6 and 12 months postoperative using by IKDC-SKF for patient-reported knee function, and by ACL-RSI for psychological readiness.

The search was performed in PubMed containing mainly medical research and comprises more than 35 million citations for biomedical literature (Pubmed, 2023). The systematic search generated 768 studies. Following the screening of abstract and titles, 754 articles were excluded, resulting in 14 articles selected for full-text reading. Ultimately, ten studies were identified to meet the inclusion criteria for my literature search.

***Table 1**. Search word included in my literature search*

Athlete **OR** adolescent
AND
ACL reconstruction **OR** ACLR **OR** anterior cruciate ligament reconstruction
AND
IKDC **OR** IKDC 2000 **OR** IKDC-2000 **OR** ACL-RSI **OR** psychological readiness

ACL = anterior cruciate ligament, ACLR = anterior cruciate ligament reconstruction, IKDC = International Knee Documentation Committee, ACL-RSI = anterior cruciate ligament – return to sport after injury

1.6.1 Patient-reported knee function

Table 2 displays the findings of five studies investigating patient-reported knee function by IKDC-SKF, 6 and 12 months after ACLR. Magnitskaya et al. (2020) conducted a study to establish reference values for patient-reported knee function the first year after ACLR, dependent on athlete characteristics. Athletes involved in high level sports including pivoting and cutting movements before the injury showed the highest 6 and 12 month scores of 83 and 94 points (Magnitskaya et al., 2020).

In the study by Johnston et al. (2021), patient-reported outcomes and functional knee recovery after ACLR were compared between two different graft type: quadriceps tendon (QT) graft and hamstring tendon (HT) graft. The athletes underwent the same postoperative rehabilitation including gym exercising after 5 weeks, running after 12-16 weeks and sport specific drills from 4 months. Non-contact training could commence after 6 months with gradual progression towards full contact training over 3-4 months (Johnston et al., 2022).

Logerstedt et al. (2012) investigated if single leg hop tests at 6 months postoperative could predict knee function 12- months after ACLR. All patients underwent a 10-session preoperative rehabilitation program consisting of progressive exercise training. After surgery all patients followed rehabilitation guidelines with systematically progression based on clinical outcomes (Logerstedt et al., 2012).

Wallace et al. (2021) examined the changes in infrapatellar fat pad volume to knee function. No patient characteristics of preinjury activity level or postoperative rehabilitation was described and participants who sustained a second ACL injury at any

point during the study was excluded. The study displayed the lowest 6 and 12 months scores (Wallace et al., 2021).

Table 2. *Previous literature including IKDC-SKF scores 6 and 12 months after ACLR.*

Studies	Study design	Population	IKDC score 6 months postop.	IKDC score 12 months postop.	Difference 6 to 12 months postop.
Magnitskaya et al. (2020)	Retrospectively extracted data from a prospective hospital-based survey	298 athletes with a mean age of 28 (male) and 30 (female) years with primary ACLR participating in sports.	Median: 80.0	Median: 93.0	13.0
Johnston et al. (2021)	Retrospective matched cohort study	105 athletes aged 15-40 years with primary ACLR treated with HT or QT graft frequently participating in high level sports.	QT, mean: 79.2 HT, mean: 79.3	QT, mean: 88.5 HT, mean: 89.1	QT: 9.3 HT: 9.8
Logerstedt et al. (2012)	Prospective international cohort study	120 athletes aged 15-54 years with unilateral ACLR from high level sports.	Mean: 83.0	Mean: 90.8	7.8
Wallace et al. (2021)	Prospective cohort study	26 patients aged 18-35 years with primary unilateral ACLR.	Mean: 73.4	Mean: 86.1	12.7
Ra et al. (2014)	Retrospective cohort study	134 athletes with a mean age of 27.2 years with ACLR participating in sports.	Mean: 84.5	Mean: 89.8	5.3

QT = quadriceps tendon, HT: hamstrings tendon, ACLR = anterior cruciate ligament reconstruction, postop = postoperative, IKDC = International Knee Documentation Committee

Finally, the study of Ra et al. (2014) investigated the ceiling effects in IKDC-SKF at 6 and 12 months postoperative and found it to be 5.2% and 17.2 %, respectively (Ra et al., 2014). The study included both professional and nonprofessional athletes and showed the lowest difference in 6 and 12 months scores.

Previous studies show that 6 months scores in knee function ranged from 73.4 to 84.5, while the 12 months scores ranged from 86.1 to 93.0 (Johnston et al., 2022; Logerstedt et al., 2012; Magnitskaya et al., 2020; Ra et al., 2014; Wallace et al., 2021). All the studies reported an increase in score from 6 to 12 months postoperative. The difference

between 6 and 12 months varied between 5.3 and 13. Two of the included studies are prospective cohort studies and three are retrospective cohort studies.

1.6.2 Psychological readiness

In Table 3, the findings from five studies investigating 6 and 12 months postoperative psychological readiness by ACL-RSI in athletes are presented. Webster & Feller (2021) investigated the ACL-RSI questionnaires responsiveness to change. Patients sustaining a second ACL injury or had any further surgeries during follow up were excluded. The athletes followed the same rehabilitation protocol based on evidence-based guidelines. The findings revealed that a change score of 13.4 from 6 to 12 month postoperative was considered a minimally important change (MIC) in psychological readiness at a group level. Still only 21% in the study achieved this score (Webster & Feller, 2021). In a subsequent study by Webster & Feller in 2022, athletes under the age of 18 years from the same cohort were examined. This study found generally higher scores at both 6 and 12 months, as well as a greater difference between 6 and 12 months (Webster & Feller, 2022).

The study of Johnston et al. (2022), previously mentioned in relation to knee function, also investigated psychological readiness at the same timepoints. This study identified the highest 12 months score and the largest difference between 6 and 12 months among the included studies in the group of athletes receiving hamstrings tendon graft (Johnston et al., 2022).

Sadeqi et al. (2018) investigated progression of ACL-RSI scores from preoperative to 2-year postoperative. The study had a large number of participants and reported the lowest 12 months score as well as the smallest difference between 6 to 12 months (Sadeqi et al., 2018).

Langford et al. (2009) investigated how ACL-RSI during rehabilitation is related to returning to competitive sports. Athletes with repaired meniscal tears was excluded. The athletes followed the same rehabilitation protocol and were allowed running and sport-specific drills at 3 months, resume training, and commence competitive sport at 6 months if they have been training for one month without problems (Langford et al., 2009).

Table 3. *Previous literature including ACL-RSI scores 6 and 12 months after ACLR.*

Studies	Study design	Population	ACL-RSI score 6 months postop.	ACL-RSI score 12 months postop.	Difference 6 to 12 months postop.
Webster & Feller (2021)	Prospective cohort study	441 athletes with a mean age of 24.6 with primary ACLR mainly participating in pivoting sports.	Mean: 54.4	Mean: 66.8	12.4
Webster & Feller (2022)	Prospective cohort study	115 athletes under 18 years with a primary ACLR mainly participating in pivoting sports.	Mean: 55.3	Mean: 71.1	15.8
Johnston et al. (2022)	Retrospective matched cohort study	105 patients aged 15-40 years with primary ACLR treated with HT or QT graft frequently participating in high level sports.	QT, mean: 59.2 HT, mean: 57.2	QT, mean: 73.3 HT, mean: 75.0	QT: 14.1 HT: 17.8
Sadeqi et al. (2018)	Prospective cohort study	681 patients with a mean age of 30.2 years with either primary (611) or revision (70) ACLR mainly participating in pivoting sports.	Mean: 58.3	Mean: 64.7	6.4
Langford et al. (2009)	Prospective cohort study	100 patients between 18 and 40 years old with primary ACLR participating in high level sports on a weekly basis prior to injury.	Mean: 57.6	Mean: 65.4	7.8

QT = Quadriceps tendon, HT= hamstrings tendon, ACLR = anterior cruciate ligament reconstruction, postop = postoperative, ACL-RSI = anterior cruciate ligament – return to sport after injury.

Previous studies show that 6 months psychological readiness score ranged from 55.3 to 59.2, while the 12 months score ranged from 64.7 to 75.0 (Johnston et al., 2022; Langford et al., 2009; Sadeqi et al., 2018; Webster & Feller, 2021, 2022). All the included studies display an increased score from 6 to 12 months with a variating difference ranging from 6.4 to 17.8.

2. Extended Methods

This chapter presents extended methods to my scientific article. The chapter starts with presentation of the main project and the study design. Subsequently, the BEAST tool and the comparison group representing usual care, are presented. Following this, a comprehensive description of the outcome measures is provided. I will then describe the propensity score adjustment made to the main analysis, and what influence the Covid-19 pandemic might have had on this study. Data collection and ethical considerations will then be addressed before I conclude this chapter by outlining my contributions to this study.

2.1 Main Project

This study is a part of the BEAST project, a research project started in 2018 at the Oslo Sport Trauma Research Center, Norwegian School of Sports Sciences (NIH). The main project is a larger prospective cohort study describing 2-year outcomes of reinjuries, participation in sports, patient-reported knee function and psychological readiness to return to sports in athletes following the BEAST tool versus usual care. The BEAST project group consists of experienced professors and researchers specialized in sports medicine; Hege Grindem, Håvard Moksnes, Arnlaug Wangensteen, Grethe Myklebust, Lars Engebretsen, May Arna Risberg, Joanna Kvist and Clare Ardern.

2.2 Study design

This study compares data from two prospective cohort studies, the BEtter And Safer return to sporT (BEAST, clinical trials #NCT04049292) study and the Participation in physical activity and sports 3 years after ACL-reconstruction (SPARX Dnr 2019-04546) study. Athletes in the BEAST cohort have followed a rehabilitation and RTS decision (BEAST) tool (Moksnes et al., 2021). The athletes in the SPARX cohort were recruited from the Swedish Knee Ligament register and represents usual care. The objectives of this study are to compare the 6 to 12 month postoperative change in patient-reported knee function and psychological readiness to RTS after ACLR between nonprofessional pivoting sport athletes who followed the BEAST tool versus usual care.

2.3 BEAST tool

The BEAST tool is described in Figure 1, and the terms used in the BEAST tool are described in Table 4. The development and final BEAST tool are described in detail in Moksnes et al (2021). The athletes went through a standardized RTS knee assessment every two months from 6 to 12 months after ACLR, or until the athlete was cleared for RTS. The knee assessment consisted of clinical knee examination, quadriceps strength tests and hop tests, and were performed at "Norsk Idrettsmedisinsk Institutt" (NIMI) or "Idrettens Helsesenter" (IHS) with follow up by a sports physical therapy specialist. The knee assessment was designed to ensure that the most important information could be obtained in a single 60-min session to make decisions about rehabilitation and RTS progression. The assessment does not require expensive equipment, making it a useful tool in daily clinical practice for a nonspecialist physical therapist, in a nonspecialist center. The decision tool prescribed an individual rehabilitation plan including specific protocols based on the criteria that the athlete had failed to meet. If the athletes failed the criteria of knee effusion, quadriceps strength or hop tests, they were given standardized protocols for effusion management (Appendix 8), strength (Appendix 9) or plyometric training (Appendix 10) respectively. They had to work on these protocols for the next two months. These specific protocols are based on best practice and current evidence-based guidelines and have been developed in collaboration with primary physical therapists and athletes with ACLR. If the athlete received rehabilitation from a clinician, the athlete had to share the rehabilitation and RTS plan with the clinician to ensure supervision. If the athletes had positive Lachman or effusion grade 2+ at knee assessment, they were referred to an orthopedic surgeon for evaluation.

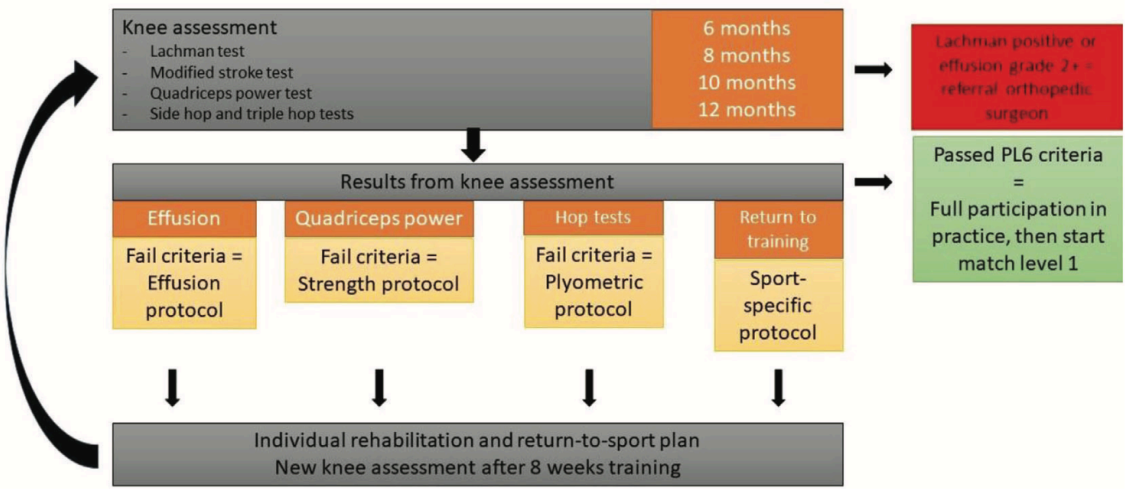

Figure 1. *Overview of the BEAST tool.*
PL = practice level. From Moksnes et al (2021)

Table 4. *Description of terms.*

Term	Description
Rehabilitation and RTS decision tool (BEAST tool)	The tool determines what the athlete should do in terms of rehabilitation and RTS
Knee assessment	The 60-min session in the clinic that includes a clinical knee examination, quadriceps power test and hop tests, which produces the athlete's individual rehabilitation and RTS plan
Individual rehabilitation and RTS plan	The product of the decision tool and knee assessment. The plan is made up of one or multiple protocols
Sport-specific protocol	The detailed progression in sports participation. The protocol specifies which sport-specific skill the athlete should work on and limits what the athlete can do at team practice and matches
Effusion protocol	Actions to undertake when there is knee effusion grade 0 to 3
Strength protocol	The exercises the athlete performs if his or her quadriceps power test results are < 90% limb symmetry index
Plyometric protocol	The exercises the athlete performs if his or her hop test results are < 90% limb symmetry index

RTS = return to sports. BEAST = better and safer return to sport. From Moksnes et al (2021)

The athletes were also provided with a sport specific progression protocol made specifically for football, handball, basketball, or floorball (Appendix 4-7). These protocols consist of six progressive practice levels designed to facilitate step wise tasks during sports, aiming to increase athletic confidence and trust in the knee by gradually increasing risk during sports activity (Moksnes et al., 2021). The sports specific protocol for football is shown in Table 5. To move on to the next level, the athletes had to participate in at least four training sessions over two weeks without pain or effusion in their knees. The sports specific progression tool was reviewed by a nonprofessional coach from the respective sports to clarify language and ensure that the plan was understandable to all parties involved when returning to team practices.

***Table 5**. Practice level 1-6 in the football specific protocol.*

Practice level	Activities on the field
1	Simple passing drills, running/dribbling without rapid change of direction
2	Passing drills movement before/after passing, shooting/finishing, running/dribbling with change of direction but no opponent
3	All technical drills with the team, 1-on-1 drills, stand on the outside in square possession and similar drills (do not chase the ball)
4	All drills with the team, participate as back or wing in full-sided play
5	All drills with the team, full participation in full-sided play
6	Full participation, including small-sided play

From Moksnes et al (2021)

Cut off scores were set for return to restricted practice (PL4) and full unrestricted practice (PL6), as shown in Table 6. The athletes had to pass seven time-based, load-based, clinical, and functional criteria, and participated in restricted practice with low-risk and non-contact until all the criteria were passed for PL4. The athletes could progress to match level 1 (ML1) out of 6 levels when they had been a minimum of four weeks at PL6.

***Table 6**. Criteria in the BEAST tool to progress to restricted participation during team practice (PL4) and full participation during team practice (PL6) in the sport-specific protocol.*

	Time from ACLR	Sport-specific training	Modified stroke	Lachman	Side hop	Triple hop	Quadriceps power
Cutoff for PL4	≥ 8 months	PL3 completed	Grade 0	Negative	LSI ≥ 80%	LSI ≥ 80%	LSI ≥ 80%
Cutoff for PL6	≥ 9 months	PL5 completed	Grade 0	Negative	LSI ≥ 90%	LSI ≥ 90%	LSI ≥ 90%

ACLR = anterior cruciate ligament reconstruction, PL = practice level, LSI = limb symmetry index. From Moksnes et al (2021)

The BEAST tool has been assessed regarding implementation, limited efficacy and acceptability and has shown few challenges and necessary adjustments. The athletes believed that the BEAST tool would facilitate RTS and reduce injury risk (Moksnes et al., 2021).

2.3.1 Clinical and performance-based testing

The clinical and performance-based tests used in the BEAST tool were the modified stroke test for effusion, the Lachman test for ACL integrity, quadriceps power test and side-hop and triple-hop-tests. Physical therapists with extensive experience in the test methods performed the testing.

The knee effusion was assessed with the modified stroke test, and was performed with the athlete in a relaxed supine position with the knee fully extended (Sturgill et al., 2009). The clinician performed an upward stroke from the medial tibiofemoral joint line to the suprapatellar pouch, before giving a downward stroke from the distal lateral thigh

from the suprapatellar pouch to the lateral joint line. The clinician watches for a wave of fluid on the medial side of the knee. The modified stroke test is a 5-point grading scale (Table 7) and has good inter-rater reliability, making it a reliable method to assess knee joint effusion (Sturgill et al., 2009).

***Table** 7. Modified stroke test grading scale.*

Grade	Result
0	No wave produced on downstroke
Trace	Small wave on medial side with downstroke
1+	Larger bulge on medial side with downstroke
2+	Effusion spontaneously returns to medial side after upstroke (no downstroke necessary)
3+	So much fluid in the knee that it is not possible to move the effusion out of the medial aspect

From Sturgill et al (2009).

The Lachman test was chosen to test the integrity of the ACL based on a sensitivity of 85% and a specificity of 94%, making it the most valid test to determine ACL integrity (Benjaminse et al., 2006). The test is performed with the athlete in a supine position on the bench, and the knee in 20-39 degree of flexion. While the femur is stabilized, the proximal part of the tibia is pulled anteriorly. The test is positive if there is a soft end point, and an increased amount of tibial displacement (Benjaminse et al., 2006).

Quadriceps strength was tested with “Musclelab”, a linear encoder connected to the leg extension machine (Technogym). The linear encoder can detect interlimb differences after ACLR and has high test-retest reliability with an ICC of 0.97 (95% CI: 0.94 to 0.99) (Neeter et al., 2006). The test was performed on each leg with maximal repetition at each load, increased by 5kg until failure. The athlete was given the instruction to extend the knee quickly and forcefully from 100 to 0 degrees of knee flexion. Peak power was measured and represented in watts, as well as estimated 1 repetition maximum (RM) was recorded.

The side-hop and triple-hop-tests have also shown a high test-retest reliability as well as a high ability to discriminate the hop performance between the injured and the uninjured side in athletes who have undergone ACLR (Gustavsson et al., 2006). The tests are performed on the uninjured side followed by the injured leg. The side-hop test measures the athletes’ ability to hop sideways on a single leg over a distance of minimum 40cm in

30 seconds (Gustavsson et al., 2006). The triple-hop-test requires the athlete to hop as far as possible forward (Noyes et al., 1991). If the landing is with excessive balance maneuvers, the test is repeated. The distance from the tip of the toe in the starting position, to the tip of the toe in the landing position was measured as the result of the triple-hop-test.

2.4 Usual care

The data from the SPARX cohort was provided from athletes with ACLR from the Swedish Knee Ligament Registry. The SPARX data reflects outcomes after usual care in Sweden and was collected around the same period as the BEAST cohort using the same patient-reported outcome measures. Knee Ligament Registry data can be used as control material to prospective studies with more structured interventions to compare treatment outcomes (Grindem et al., 2015). Consequently, the SPARX cohort served as an optimal choice for providing comparative data for athletes who followed the BEAST tool.

2.5 Outcome measures

The outcome measures for patient-reported knee function and psychological readiness used in this study was the IKDC-SKF, and the ACL-RSI.

2.5.1 IKDC-SKF

The IKDC-SKF is a knee specific, not a disease specific questionnaire designed by a committee of international knee experts formed in 1987 to evaluate symptoms, function and sports activity (Irrgang et al., 2001). The IKDC-SKF was published in 2001 and is developed to fit a broad variety of knee disorders, including cartilage injuries, meniscal problems, ligaments, arthritis, and patellofemoral pain (Irrgang et al., 2001).

The questionnaire consists of 19 items, and the total score is calculated based on 18 of these. The total score goes from 0 to 100 where 100 is no limitation with activities of daily living or in sports, in addition to the absence of symptoms. Each question scores from 0 to 1, 4 or 10 points (Collins et al., 2011). The content of the form is based on three domains; 1: symptoms, including knee pain, swelling, giving way, stiffness or locking, 2: sports and daily activities, 3: current knee function, and knee function before the injury (Collins et al., 2011). Calculating the score is done by summing each item to

a total score, excluding the question about prior knee function, divided by the maximum possible score (87), multiplied by 100:

(Sum of all items/maximum score (87)) x 100

The IKDC-SKF questionnaire is considered a valid and reliable measuring tool of symptoms, function and sports activity in patients with a broad specter of knee injuries (Irrgang et al., 2001). The questionnaire has good construct validity, high test-retest reliability with an ICC of 0.93 and has shown a good ability to detect changes over time (van Meer et al., 2013). The questions are also perceived relevant in patients with an ACL injury, making it a recommended questionnaire the first year after ACLR (van Meer et al., 2013).

The IKDC-SKF has a standards error of measurement (SEM) of 4.6 calculated with the test-retest coefficient. Change of 12 points or higher is considered a clinically relevant difference (Irrgang et al., 2006). To detect a group difference of 12 points or higher it can be used a SD of 15, *a* level of 0.05, and a *b* of 0.8 (Irrgang et al., 2006). The IKDC-SKF is translated to Norwegian by the NAR-orthopedic center, UUS, Oslo; 2005, from step I to IV with guidelines prepared by using standardized guidelines for translation of measuring tools (Guillemin et al., 1993). The questionnaire is also translated to Swedish according to guidelines and shows high internal consistency (Cronbach´s alpha 0.9), and test-retest reliability by ICC of 0.92 (95% CI: 0.81-0.97) (Tigerstrand Grevnerts et al., 2017).

2.5.2 ACL-RSI

The ACL-RSI is a screening tool developed specifically to measure the psychological impact of returning to sport after ACL reconstruction surgery and contributes to identifying athletes in risk of not returning to their preinjury sport and level (Ardern et al., 2013; Webster et al., 2008). The questionnaire is developed around three types of psychological responses the literature has found associated with the resumption of sport following an injury; emotions, confidence and risk appraisal (Webster et al., 2008).

The questionnaire is a 12-item scale where each item scores from 0-100 where 0 is extremely negative psychological factors, and 100 is the absence of negative

psychological factors (Webster et al., 2008). Five items (1-5) measures emotions like fear of reinjury, nervousness and tension. Five items (6-10) cover two aspect of sports confidence; confidence in performance, and confidence in knee function. Two items (11-12) investigate the athletes cognitive risk appraisal to re-injury (Webster et al., 2008).

ACL-RSI has been translated to Norwegian using international guidelines and shows good measurement properties which involves good construct validity and a test-retest reliability by ICC of 0.94 (95% CI: 0.84 – 0.97), standard error of measurement (SEM) of 5.7 (Faleide et al., 2020). This implicates that change in score for one individual needs to exceed 15.8 points, and on a group level 2.0 to be considered a true change (Faleide et al., 2020). The ACL-RSI has also been translated to Swedish showing good face and construct validity and good internal consistency (Cronbach´s alpha 0.95), and high test-retest reliability by ICC of 0.89 (Kvist et al., 2013).

2.6 Propensity score adjustment

In observational studies, confounding factors can exert a direct or indirect influence on both the outcome and the exposure, potentially altering the strength, direction, or even reversing the association we seek to establish between the exposure and outcome if left unadjusted (Assimon, 2021). Propensity score adjustment has gained increasing attention due to its ability to eliminate or reduce the effect of the known confounders in observational studies (Austin, 2011). Randomized controlled trials is considered the gold standard for estimating treatment effects on outcomes, as random treatment allocation ensures that baseline characteristics do not confound the treatment status (Austin, 2011). Propensity score adjustment allows observational studies to mimic certain characteristics of a randomized controlled trial to give unbiased estimates of the treatment effects. However, if there are substantially differences in baseline confounders between the groups the propensity score might not be enough to adjust for the differences (Austin, 2011). In this study, the propensity score represents the probability of a subject receiving the BEAST intervention or usual care in the SPARX cohort, based on a set of baseline confounders (Benedetto et al., 2018). Typically, the score is estimated using a logistic regression model (Benedetto et al., 2018).

2.7 Covid – 19

In 2020, the Covid-19 pandemic had a large impact on various aspects of people's lives, including interpersonal interactions, work, school, hobbies and sports participation (Bouguennec et al., 2023). The pandemic led to lockdowns in many countries which severely affected the health care services and patients with ACL reconstructions (Bouguennec et al., 2023). Norway was one of the countries having a complete lockdown during the pandemic. The 12th of March 2020 the Norwegian government introduced the strongest and most invasive measures in Norway during peace time. Therefore, gyms across the nation remained closed for a period of three months. During this period the BEAST study was temporarily put on hold due to challenges assessing inclusion because of different rules for seniors and adolescents, differences across municipalities, and which sport the athlete participated in. The athletes had no opportunity to access rehabilitation facilities or any postoperative examinations.

A previous study investigating the athletes experiences following the BEAST tool found that the athletes changed their training routines and compliance to the BEAST tool during Covid-19 (Legernes, 2021, p. 42). The athletes reported fewer sessions at training centers and sports-fields as well as fewer supervised sessions with physical therapist. The athletes felt less motivated for rehabilitation and experienced Covid-19 as a major obstacle for their rehabilitation (Legernes, 2021, p. 42).

Although Sweden did not have a lockdown the same way Norway did, the pandemic is thought to have had a substantial impact on sports and physical activity in the country (Zelleroth, 2020, p. 13). The athletes from SPARX were asked between June and October 2020, mean 6.4 months after ACLR, if their rehabilitation was negatively affected by the pandemic. Approximately one out of three (36%) athletes from SPARX answered that their rehabilitation has been negatively affected by the pandemic. The primary reasons were closed gyms or no sports practice, not wanting to go to the gym because of the contamination risk and less time with their physical therapist (Zelleroth, 2020, p. 13).

2.8 Data Collection

The recruitment and data collection for the BEAST study was done by Hege Grindem, Håvard Moksnes, Arnlaug Wangensteen and Bjørnar Haaland. Baseline descriptive data was gathered from the athletes at the initial assessment 6 months postoperative (Appendix 14), including data from the surgery with graft type and concomitant injuries. At each knee assessment the athletes were asked if they wished to RTS, and deviations from the BEAST tool were documented for the athletes. The results from the knee assessment were filled out in a standardized form, and protocols and practice levels were prescribed at the end of the session (Appendix 15).

The data from SPARX was collected by Joanna Kvist and Daniel Castellanos. The baseline descriptive data was obtained through a questionnaire at three months postoperative via Briteback Explore platform (Briteback AB; Norrköping, Sweden). Information on the surgical procedure, including graft type and concomitant injuries, was extracted from the Swedish ACL registry.

Quantitative data with the outcome measures IKDC-SKF (Appendix 13) and ACL-RSI (Appendix 12) were electronically collected 6 and 12 months postoperative using the Briteback Explore platform in both cohorts.

2.9 Ethics

The BEAST study was approved by The Norwegian Regional committees for medical and health research ethics in October 2018 (Appendix 1), and the Norwegian Centre for Research data (Norsk Senter for Forskningsdata - NSD) gave their approval in January 2019 (Appendix 2). Prior to participating in the study, the athletes were provided with information with a detailed description of the study (Appendix 11). They signed a written consent, and if the participant was 15 years old at the time of injury, written consent was obtained from both parents and the athlete. The athletes were informed that there were no consequences in declining participation or withdrawing from the study after enrollment. The physical tests used in this study could cause the participants a slight risk of injury or discomfort. However, the tests are far less demanding than the loads the athletes face when they return to sports, and the tests are used routinely by clinicians worldwide. If the athletes changed their mind in wanting to return to pivoting

sports during rehabilitation, the intervention continued without the sport-specific progression plan.

The SPARX study was approved by The Swedish committees for medical and health research ethics (etiksprövingsmyndigheten) in October 2019 (Appendix 3). Detailed project information was sent to the athletes via mail, and subsequently, they were contacted through e-mail, SMS and/or telephone to provide them the opportunity to participate in the study. Written consent was gathered electronically in the baseline assessment at three months postoperative.

Patient data were carefully managed according to General Data Protection Regulation (GDPR) laws in both the BEAST and SPARX studies. All data was coded and stored in a pseudo-anonymized database where a keycode was needed for access. The study received financially support from Norwegian Fund for Post-Graduate Training in Physiotherapy, the International Olympic Committee, the Swedish Council of Sport Science, Karolinska Institute, Linköping University and Örebro University. Software for statistical analysis was covered by Linköping University and the Norwegian School of Sport Sciences.

2.10 My contributions

In this study, my role included the responsibility for processing and cleaning the data in both the BEAST and the SPARX cohorts, as well as systematizing and making the data ready for statistical analysis. This involved not only cleansing the descriptive data and the IKDC-SKF and ACL-RSI outcomes at 6 and 12 months postoperative for my study, but also a substantial amount of data collected for the main projects. The data processing took place over a few months including several meetings with the leaders of the project in BEAST and SPARX, Hege Grindem and Joanna Kvist. Throughout this process, correct, standardized, and consistent cleaning of the data in both cohorts was ensured. The planning of how to present the results was conducted in collaboration with Hege Grindem and Morten Wand Fagerland, a biostatistician from the Department of Sports Medicine, Norwegian School of Sports Sciense. While the main statistical analysis was performed by Morten Wang Fagerland, I was responsible for conducting the descriptive data analysis.

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4. Scientific article

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Title:

Knee function and psychological readiness 6 to 12 months after ACLR – a comparison between nonprofessional pivoting sport athletes who followed a rehabilitation and RTS decision tool and usual care.

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Anterior cruciate ligament reconstruction, ACLR, athletes, nonprofessional, psychological readiness, knee function, IKDC, ACL-RSI

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Abstract

Background: The better and safer return to sports (BEAST) - a rehabilitation and return to sports (RTS) decision tool has been designed to facilitate athletes returning safely to sports after anterior cruciate ligament reconstruction (ACLR). There is a need to investigate and compare knee function and psychological readiness during the return to sport phase in athletes following the BEAST tool and usual care.

Objective: To compare change in knee function and psychological readiness to RTS 6 to 12 months after ACLR between nonprofessional pivoting sport athletes who followed the BEAST tool versus usual care.

Design: A comparison between two prospective cohort studies

Method: Nonprofessional pivoting sport athletes aged 15-40 years with a primary unilateral ACLR were included. Out of 247 athletes, 77 followed the BEAST tool, and 170 received usual care (SPARX cohort). The International Knee Documentation Committee subjective knee form (IKDC-SKF) and ACL- Return to Sport after Injury (RSI) was answered at 6 and 12 months postoperative. The 6 to 12 months change between the groups was analyzed, adjusted for age, sex, preinjury sport, family history of ACL injury, time from injury to surgery, ACL graft type, concomitant meniscus and/or cartilage injury yes/no, and meniscal repair yes/no.

Results: No difference in change in knee function ($p=0.722$) or psychological readiness ($p=0.518$) was found between the groups. At 6 and 12 months postoperative, the IKDC-SKF scores in BEAST athletes increased from 72.3 to 85.3, and usual care from 67.3 to 79.9. The ACL-RSI scores in BEAST athletes increased from 60.3 to 71.6, and usual care from 48.4 to 56.3. At 12 months postoperative, 48% and 35% of the BEAST athletes had not achieved symmetrical quadriceps strength and hop performance, respectively.

Conclusion: Nonprofessional pivoting sport athletes with ACLR who followed the BEAST tool have comparable 6 to 12 months change in knee function and psychological readiness to RTS when compared to usual care. Few athletes following the BEAST tool achieved the functional goals within 12 months postoperative.

Introduction

Anterior cruciate ligament reconstruction (ACLR) is usually recommended for athletes aiming to return to pivoting sports (Grindem et al., 2014). A common expectation is to return to sports 6-9 months after surgery, but ACLR is not exactly a one-way ticket back to preinjury level of sports (Ardern, 2015; Barber-Westin & Noyes, 2011). Among those undergoing ACLR, nonprofessional athletes represent the largest group, yet systematic reviews show that only 42% of nonprofessional compared to 83% of professional athletes return to competitive sports (Ardern, Taylor, et al., 2014; Lai et al., 2018). The main reasons for not returning to sports are negative psychological responses like anxiety and lack of trust in the knee, which are common responses after ACLR (Ardern, Taylor, et al., 2014; Ardern, Österberg, et al., 2014). Additionally, nearly one in four young athletes returning to high-risk sports sustain a secondary ACL injury (Wiggins et al., 2016).

Nonprofessional athletes who do not receive high-quality rehabilitation are often discharged to return to sports with poor knee function (Beischer et al., 2018; Ebert et al., 2018; Toole et al., 2017). Previous research has found reduced quadriceps strength to independently increase the risk of knee reinjuries in athletes returning to pivoting sports (Grindem et al., 2016). Urgent attention is required to improve knee function and psychological readiness in nonprofessional athletes, with the goal of facilitating a safer RTS for a larger number of individuals in this population.

A rehabilitation and RTS decision-making tool for nonprofessional athletes has therefore been designed; the BEtter And Safer reTurn to sport (BEAST) tool (Moksnes et al., 2021). The BEAST tool provides an individual protocol-based rehabilitation with a RTS plan based on a knee assessment that includes a functional test battery. By emphasizing targeted rehabilitation in the RTS phase including gradual progression in sport-specific training, the BEAST tool might improve psychological readiness and ultimately the RTS rate among nonprofessional athletes. Knee function is addressed by a functional RTS test battery including strength and hop tests. A previous study has demonstrated that athletes who fail a functional test battery before RTS are up to six times more likely to sustain a knee reinjury compared to those who pass the tests (Grindem et al., 2016). However, 80-86% of athletes following usual care attempt RTS without passing the criteria of functional RTS test batteries (Beischer et al., 2018; Toole

et al., 2017). Knee function and psychological readiness during the return to sport phase needs to be investigated in athletes following the BEAST tool and athletes receiving usual care.

The establishment of the National Knee Ligament Registries has provided valuable data on outcomes after usual care following ACLR (Granan et al., 2009). Data from Knee Ligament Registries has been utilized in previous studies as control material reflecting usual care, enabling comparisons of treatment outcomes to prospective studies with more structured interventions (Grindem et al., 2015). To the best of our knowledge, no previous studies have investigated outcomes for athletes with ACLR following a rehabilitation and RTS decision tool compared to usual care treatment.

Therefore, the objective of this study was to compare the change in knee function and psychological readiness 6 to 12 months postoperative between nonprofessional athletes returning to pivoting sports after ACLR, following the BEAST tool and those receiving usual care. The predefined hypothesis was that the athletes who followed the BEAST tool would have larger change in knee function and psychological readiness compared to usual care.

Methods

This study compares data from two prospective cohorts: the BEtter And Safer reTurn to sport after anterior cruciate ligament reconstruction (BEAST) study (clinical trials #NCT04049292) and the Participation in physical activity and sports 3 years after ACL-reconstruction (SPARX) study (Dnr 2019-04546). The BEAST cohort consists of athletes who have followed a protocol-based rehabilitation and RTS decision tool, aiming to facilitate nonprofessional athletes to return better and safer to sports after ACLR. The SPARX cohort were recruited from the Swedish Knee Ligament registry and represent usual care, with no controlled rehabilitation or RTS.

Participants

The inclusion criteria for this study were the same as for those included in the BEAST study. Athletes were eligible for inclusion if they had undergone a primary, unilateral ACLR and were ≤ 6 months from surgery. They had to be 15-40 years at the time of ACL injury, engaging in nonprofessional soccer, handball, basketball, or floorball ≥ 2

times per week prior to the injury. An athlete was considered a professional if they had access to specialist medicine care, derived their primary income from sports participation, or had health team present at most of the team practices. At 6 months postoperative the athletes must have expressed a goal to return to pivoting sport. Athletes were excluded if they had grade 3 tears of medial collateral ligament (MCL), lateral collateral ligament (LCL) and/or posterior cruciate ligament (PCL), other serious injuries or illnesses that impaired function, or inability to understand the native language in the country of recruitment. The athletes included in the BEAST cohort were recruited from all over Norway. The athletes from SPARX who fulfilled the inclusion criteria were extracted and included in this study. Prior to data collection, approval from the Committee for Medical Research Ethics was obtained in both cohorts, and the athletes signed a written consent form.

BEAST data were collected between November 2018 and August 2022. Descriptive data including surgical descriptions was obtained from the athletes at the 6 month assessment. The SPARX data was collected between November 2019 and July 2022 and the descriptive data was obtained by a questionnaire at 3 months postoperative and surgical data was extracted from the Swedish ACL registry. At 6 and 12 months postoperative, the athletes in both cohorts completed the International Knee Documentation Committee Subjective Knee Form (IKDC-SFK), and the ACL – Return to Sport after Injury (RSI) questionnaires electronically by Briteback (Briteback AB, Norrköping, Sweden). The athletes were sent a text message containing a link to the questionnaire, and a reminder was dispatched if the athlete did not answer.

Rehabilitation and RTS decision (BEAST) tool

The athletes commenced a standardized RTS assessment every two months, starting from 6 to 12 months after ACLR, or to the athlete was cleared for RTS. These assessments were performed at “Norsk idrettsmedisinsk institutt (NIMI)” and “Idrettens helsesenter (IHS)” in Oslo by a sports physical therapy specialist. The RTS assessment consisted of clinical examination, side-hop and triple-hop-tests, and quadriceps strength test with “Musclelab”, a linear encoder connected to the leg extension machine (Technogym) (Gustavsson et al., 2006; Neeter et al., 2006). If the athlete failed any of the assessment criteria, an individualized rehabilitation plan was provided determined by the decision tool, including one or multiple protocols based on which criteria the

athlete had failed. If the athletes failed the criteria of no knee effusion, hop tests or quadriceps strength with a limb symmetry index (LSI) ≤ 90%, they were given standardized protocols for effusion management, strength, or plyometric training respectively. Additionally, the athletes were given a sport specific progression protocol developed to gradually increase risk by step wise tasks consisting of six practice levels (PL). These protocols were made specifically for football, handball, basketball, and floorball to increase athletic confidence and trust in the knee during sports activities. To progress to the next practice level the athlete had to participate in at least four training sessions over two weeks without pain or effusion in their knee. Before the athletes could return to full unrestricted practice (PL6), they had to be ≥ 9 months after ACLR, modified stroke grad 0, negative Lachman test, PL5 completed and LSI ≥ 90% on side-hop, triple-hop, and quadriceps power. Further details of the BEAST tool have been published in Moksnes et al. (2021).

Outcome measures

The IKDC-SFK is a knee-specific self-assessment measure of symptoms, function and sports activity (Irrgang et al., 2001). The questionnaire consists of 19 items, and is a reliable and valid measure of knee function after ACLR (Irrgang et al., 2001). IKDC-SFK is translated to Norwegian by the NAR-orthopedic center using international guidelines (Guillemin et al., 1993). The questionnaire is also translated to Swedish according to guidelines and shows good measurement properties (Tigerstrand Grevnerts et al., 2017).

The ACL-RSI is a measure of psychological readiness to RTS after ACL injury and reconstruction surgery (Webster et al., 2008). The ACL-RSI is a unidimensional 12-item scale created around three types of psychological responses believed to be associated with the resumption of sport: emotions (5 items), confidence in performance (5 items), and risk appraisal (2 items). The ACL-RSI is translated into Norwegian and Swedish and displays reliable and valid measurement properties making it a useful tool to assess psychological readiness to RTS after ACLR (Faleide et al., 2020; Kvist et al., 2013).

Statistics

The sample size was calculated from IKDC-SFK based on study objectives from the main BEAST study. Change of 12 points or higher were considered a clinically relevant difference (Irrgang et al., 2006). To detect a group difference of 12 points or higher with a conservative SD of 15, *a* level of 0.05, *b* of 0.8, and considering the use of a propensity score variable increasing the sample size with 20%, and 80% power, the a priori sample size calculation showed that 32 patients were needed in each group. A statistical analysis plan was published before the analysis were made (Appendix 16). Descriptive analysis was performed using Mann Whitney U-test, Chi-Square test, and independent sample T-test. The main analysis was performed using linear regression adjusted for a propensity score including the predefined confounders. The propensity score was computed with logistic regression where group was the dependent variable. A priori independent variables for the propensity score were age, sex, preinjury sport, family history of ACL injury, time from injury to surgery, ACL graft type, concomitant meniscus or cartilage injury, and meniscal repair. Two sensitivity analysis were performed; 1: trimming non-overlapping regions of the propensity score, 2: excluding study participants who performed their rehabilitation while there was a 3-month long nationwide lockdown of gyms during Covid-19. Study analysis was performed in The Statistical Product and Service Solutions (SPSS, Chicago, Illinois, USA) and Stata (Texas, USA).

Results

Figure 1 displays the participant flowchart from the BEAST and SPARX cohorts. A total of 247 athletes were included. In the BEAST cohort, 77 out of 106 athletes screened for participation were included. Nineteen athletes did not meet the selection criteria, and ten athletes were unable to participate due to various reasons such as unable to reach, not wishing to participate, test cancelled or not contacted due to project on hold because of Covid-19. All 77 included athletes underwent the 6 months knee assessment and baseline questionnaire. The main analysis included 64 (83%) athletes who completed the 6 and 12 months postoperative IKDC-SFK and ACL-RSI. Thirteen athletes had missing data for one or both questionnaires. In the SPARX cohort, a total of 1041 athletes were included out of 3225 athletes invited from the Swedish ACL registry. Among the 1041, 170 met the selection criteria for the BEAST cohort and were included in this study. For the main analysis, 167 (98%) were included for IKDC-SFK,

and 163 (96%) athletes for the ACL-RSI. Two athletes had missing data on IKDC-SFK, six athletes had missing data on ACL-RSI, and one had missing data of family history of ACL injury required for the propensity score variable.

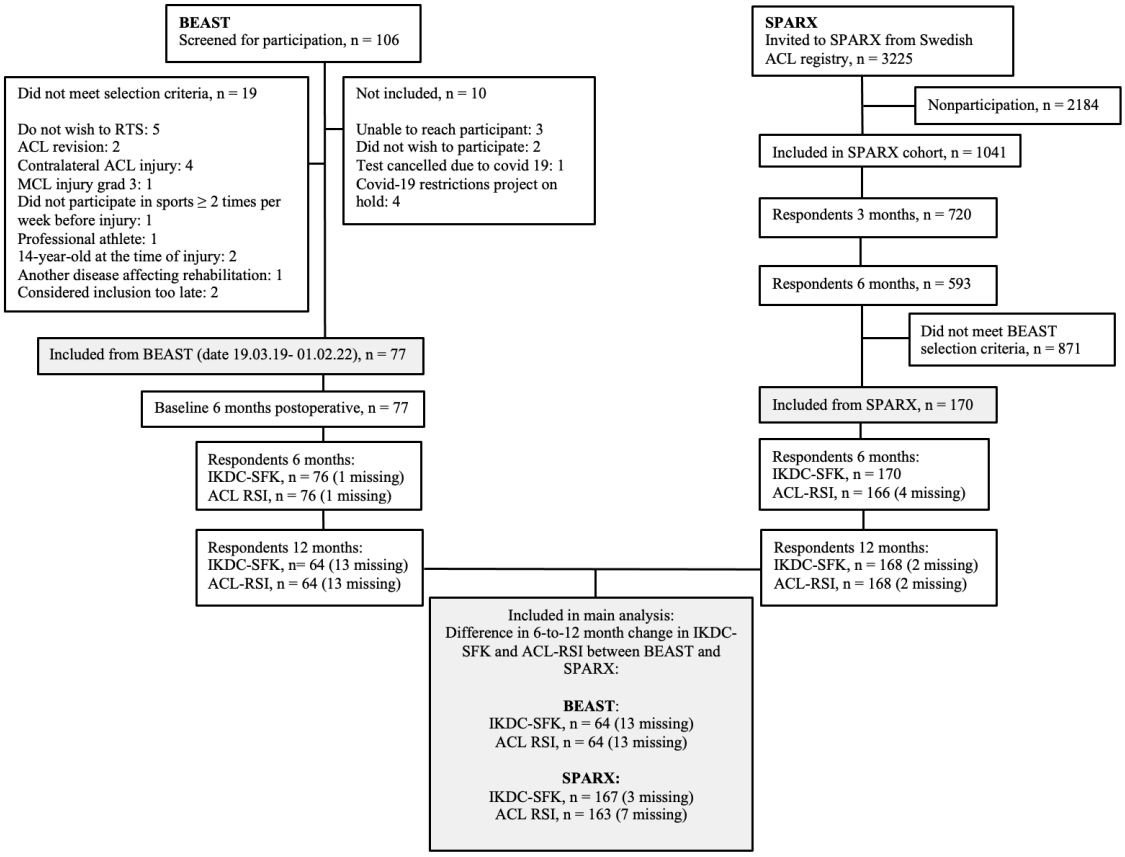

***Figure 1**. Flow chart over athletes included in the study and the main analysis from the BEAST and SPARX cohorts.*

IKDC-SFK = International Knee Documentation Committee Subjective Knee Form, ACL-RSI = anterior cruciate ligament – Return to Sports After Injury, RTS = return to sports, ACL = anterior cruciate ligament, MCL = medial collateral ligament, BEAST = better and safer return to sports, SPARX = Participation in physical activity and sports 3 years after ACL-reconstruction

Table 1 presents the demographical characteristics of the included athletes. In the BEAST cohort, the athletes were generally younger, with a majority receiving the patellar tendon graft (78%), and most of them participated in football and handball before injury. The athletes following usual care were mainly given hamstrings graft (83%), had longer time between injury and reconstruction, and most of them participated in football before injury. They had more registered cartilage injuries although there was no significant difference between the groups when considering meniscus and cartilage injuries combined (concomitant cartilage or meniscus injury). A higher proportion of the athletes in the BEAST cohort had their meniscal injuries repaired (43%) compared to usual care (20%), who underwent meniscal resection to a

greater extent. Apart from concomitant cartilage or meniscus injury, there were no significant difference between the two cohorts in sex, weight, height, BMI, meniscal injury (both medial and lateral) or family history of ACL injury. The mean frequency of sports participation before injury was 8 hours per week (SD 3.5) for the BEAST cohort and 3.7 times per week (SD 1.2) for the usual care group. Most of the athletes in BEAST reported their preinjury level in sports to be senior: lower level (40%) and junior competitive league (33%). The remaining 27% were categorized as senior: national or elite team (9%), senior: first division (4%), junior national team (3%), company sports team (4%) or "other level" (8%). Most of the athletes following usual care reported preinjury sports level to be training or competition on lower levels (92%), with the remaining 8% categorized as exercising level (5%), or "other level" (3%).

Table 1. *Characteristics of the included athletes following the BEAST tool and usual care.*

Athlete characteristics (n= 247)	**BEAST tool (n=77)**	**Usual care (n=170)**	**p-value**
Age (years), mean (SD)	20 (5)	24 (7)	< 0.001
Sex, n women (%)	50 (65)	103 (61)	0.515
Weight (kg), mean (SD)	72 (12)	72 (12)	0.805
Height (cm), mean (SD)	174 (9)	173 (9)	0.570
BMI (kg/m^2), mean (SD)	24 (3)	24 (3)	0.309
Preinjury sport, n (%):			< 0.001
Football	42 (55)	123 (72)	
Handball	28 (36)	15 (9)	
Floorball	5 (6)	27 (16)	
Basketball	2 (3)	5 (3)	
ACL graft type, n (%):			< 0.001
Patellar	60 (78)	17 (10)	
Hamstring	6 (8)	141 (83)	
Quadriceps	11 (14)	12 (7)	
Concomitant cartilage or meniscus injury, n (%)	46 (58)	100 (59)	0.892
Cartilage, n (%)	8 (10)	37 (22)	0.032
Meniscus injury, n (%)	42 (55)	86 (51)	0.564
Medial meniscus, n (%)	25 (33)	45 (27)	0.333
Lateral meniscus, n (%)	26 (34)	62 (37)	0.681
Meniscal repair, n (%)	33 (43)	34 (20)	< 0.001
Meniscal resection, n (%)	10 (13)	44 (26)	0.023
Time from injury to ACLR, median (Q1-Q3)	3 (2-6)	5 (3-9)	< 0.001
Family history of ACL injury, n (%)	18 (23)	39 (23)	0.959

The p-value represents either chi-square test, Mann-Whitney U-test or independent T-test, family history of ACL injury missing data from 1 athlete from SPARX, ACL = anterior cruciate ligament, ACLR = anterior cruciate ligament reconstruction, BMI = body mass index, Kg = kilogram, m = meter, cm = centimeter, SD = standard deviation, BEAST = better and safer return to sports, Q = quartile

The results of the knee assessment in athletes following the BEAST tool are presented in Table 2. Seventy-seven (100%) underwent the 6 months knee assessment. At 12 months, 56 athletes were tested, but thirteen athletes were not tested due to previously passed testing, and nine were not tested due to other reasons. Few athletes were given the effusion protocol during follow up. The strength protocol was given to 71 (92%) at 6 months, and 37 (48%) at 12 months follow up. The plyometric protocol was given to 64 (83%) at 6 months and 27 (35%) at 12 months. The athletes gradually progressed to higher practice levels every two months according to the sport-specific protocol. Twenty (26%) athletes had passed the criteria for PL6 at 12 months, equivalent to passing the criteria for full participation in team practice. Deviations from the BEAST tool due to Covid-19 were reported for 14 (18%) athletes at 8 months, 16 (21%) athletes at 10 months, and 18 (23%) athletes at 12 months postoperative. Seven athletes changed their mind about RTS during follow up.

Table 2. *Results from the BEAST knee assessment 6, 8, 10 and 12 months postoperative.*

BEAST tool	**6 months, n = 77**	**8 months, n = 73**	**10 months, n = 66**	**12 months, n = 55**
Effusion protocol	5	3	1	1
Strength protocol	71	67	46	37
Plyometric protocol	64	59	33	27
Sport-specific protocol	No plan: 8	No plan: 1	No plan: 2	No plan: 2
	PL 1: 47	PL 1: 7	PL 1: 3	PL 1: 3
	PL 2: 16	PL 2: 13	PL 2: 5	PL 2: 0
	PL 3: 4	PL 3: 24	PL 3: 15	PL 3: 6
		PL 4: 25	PL 4: 15	PL 4: 10
		PL 5: 1	PL 5: 10	PL 5: 9
		PL 6: 2	PL 6: 14	PL 6: 20
Not tested: previously passed the clinical and functional aims	0	2	4	13
Not tested: other reasons	0	2	7	9

Missing sport specific protocol for 2 athletes at 10 months, and 6 athletes at 12 months. BEAST = better and safer return to sports, PL = practice level, RTS = return to sport.

Knee function

Knee function, as measured by IKDC-SFK, 6 and 12 months postoperative are presented in Figure 2. The figure includes all athletes with data for either 6 and/or 12 months follow up. The mean score for athletes following the BEAST tool increased from 72.3 to 85.3 with a 6 to 12 months difference of 13. The mean score for athletes receiving usual care increased from 67.3 to 79.9 with a difference of 12.6. Figure 4

presents the 6 to 12 month change scores in knee function between the groups, specifically including athletes with data on both 6 and 12 months. Mean change score of athletes following the BEAST tool was 12.2, and athletes following usual care was 12.5.

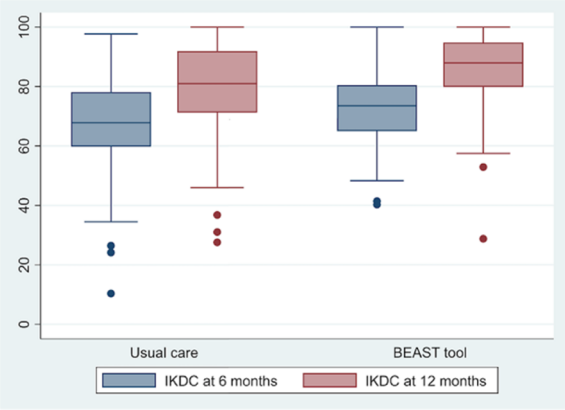

***Figure 2**. Knee function 6 and 12 months postoperative in athletes following the BEAST tool and usual care.*
Usual care 6 months, n: 170, missing: 0
Usual care 12 months, n:168, missing: 2
BEAST 6 months, n: 76, missing: 1
BEAST 12 months, n: 64, missing: 13
The median marks the mid-point dividing the box plot in two parts. The box represents Q1-Q3, the middle 50% of the scores for the group. Vertical lines from the box, represents the minimum and maximum, excluded outliers. Dots represent outliers that is numerically distant from the rest of the data. IKDC = International Knee Documentation Committee, BEAST = better and safter return to sports, Q = quartile

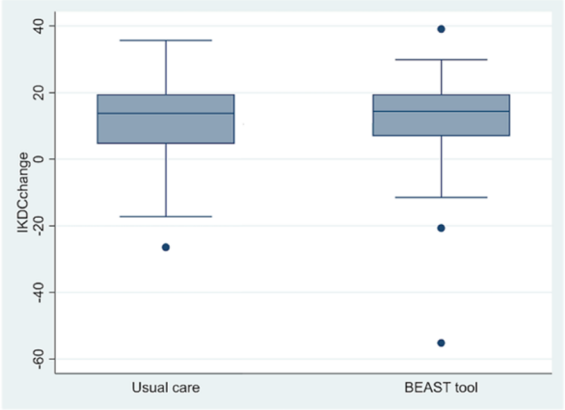

***Figure 3**. Change in knee function from 6 to 12 months postoperative between the BEAST athletes and usual care.*
Usual care, n: 167, missing: 3
BEAST, n: 64, missing: 13
The median marks the mid-point dividing the box plot in two parts. The box represents Q1-Q3, the middle 50% of the scores for the group. Vertical lines from the box, represents the minimum and maximum, excluded outliers. Dots represent outliers that is numerically distant from the rest of the data. IKDC = International Knee Documentation Committee, BEAST = better and safter return to sports, Q = quartile

Table 3 presents the main analysis, the comparison of IKDC-SKF change score between the groups, adjusted for known confounders by a propensity score. The analysis included 231 athletes and revealed that athletes following the BEAST tool had a change score of -0.80 compared to usual care. However, no statistically significant difference was observed between the groups.

***Table 3**. Comparison of 6 to 12 months postoperative change in knee function between the groups, propensity score adjusted.*

n=231	n BEAST (n usual care)	Change coefficient	Std.err	95% CI	p-value
Group BEAST	64 (167)	-0.80	2.25	(-5.23 to 3.63)	0.722

P-value representing the linear regression analysis adjusted for a propensity score. Missing data from 16 participants, 13 from BEAST, and 3 from usual care. BEAST = better and safer return to sports, Std.err = standard error, CI = confidence interval

Psychological readiness

Psychological readiness, as measured by ACL-RSI, 6 and 12 months postoperative are presented in Figure 4. When including all athletes with data for either 6 and/or 12 months follow up, the mean score for athletes following the BEAST tool increased from 60.3 to 71.6, with a 6 to 12 months difference of 11.3. The mean score for athletes receiving usual care increased from 48.4 to 56.3 with a difference of 7.9. Figure 5 presents 6 to 12 months change scores in psychological readiness between the groups, specifically including athletes with data on both 6 and 12 months. Mean change score of athletes following the BEAST tool was 7.3, and athletes following usual care was 7.9.

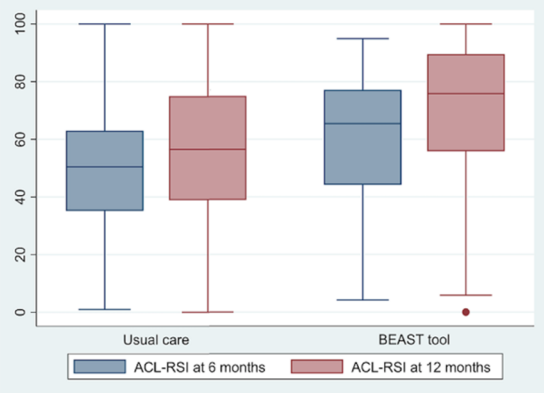

Figure 4. *Psychological readiness 6 and 12 months postoperative in athletes following the BEAST tool and usual care.*
Usual care 6 months, n: 166, missing: 4
Usual care 12 months, n:168, missing: 2
BEAST 6 months, n: 76, missing: 1
BEAST 12 months, n: 64, missing: 13
The median marks the mid-point dividing the box plot in two parts. The box represents Q1-Q3, the middle 50% of the scores for the group. Whiskers, vertical lines from the box, represents the minimum and maximum, excluded outliers. Dots represent outliers that is numerically distant from the rest of the data. ACL-RSI = anterior cruciate ligament – return to sports after injury, BEAST = better and safter return to sports, Q = quartile

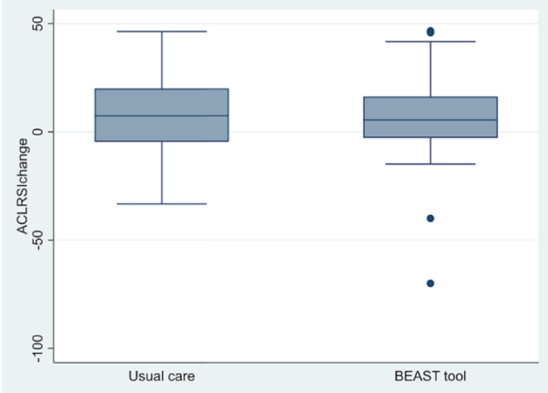

Figure 5. *Change in psychological readiness from 6 to 12 months postoperative between the BEAST athletes and usual care.*
Usual care, n: 167, missing: 6
BEAST, n: 64, missing: 13
The median marks the mid-point dividing the box plot in two parts. The box represents Q1-Q3, the middle 50% of the scores for the group. Vertical lines from the box, represents the minimum and maximum, excluded outliers. Dots represent outliers that is numerically distant from the rest of the data. ACL-RSI = anterior cruciate ligament – return to sports after injury, BEAST = better and safter return to sports, Q = quartile

Table 4 presents the main analysis, the comparison of ACL-RSI change score between the groups, adjusted for known confounders by a propensity score. The analysis included 227 athletes and revealed that athletes following the BEAST tool had a change score of -2.10 compared to usual care. However, no statistically significant difference was observed between the groups.

***Table 4**. Comparison of 6 to 12 months postoperative change in psychological readiness between the groups, propensity score adjusted.*

n = 227	n BEAST (n usual care)	Change coefficient	Std.err	95% CI	p-value
Group BEAST	64 (163)	-2.10	3.25	(-8.50 to 4.30)	0.518

P-value representing the linear regression analysis adjusted for a propensity score. Missing data from 20 athletes, 13 from BEAST, and 7 from SPARX. BEAST = better and safer return to sports, Std.err = standard error, CI = confidence interval

Sensitivity analyses

When trimming non-overlapping regions of the propensity score in sensitivity analysis 1, 204 (83%) athletes were retained. In sensitivity analysis 2, athletes who underwent rehabilitation while there was a 3-month long nationwide lockdown of gyms during Covid-19 was excluded, resulting in 197 (80%) athletes were retained. None of the sensitivity analyses demonstrated a statistically significant difference in change scores between the groups in either knee function or psychological readiness.

Discussion

This study found no statistically significant difference in 6 to 12 months change in knee function or psychological readiness between athletes following the BEAST tool and usual care. At 6 and 12 months postoperative, the IKDC-SKF scores in BEAST athletes increased from 72.3 to 85.3, and usual care from 67.3 to 79.9. The ACL-RSI scores in BEAST athletes increased from 60.3 to 71.6, and usual care from 48.4 to 56.3. Only 26% of the athletes following the BEAST tool achieved the criteria for full participation in team practice during the follow-up period. At 12 months postoperative, half (48%) the athletes were given the strength protocol, and one out of three (35%) were given the plyometric protocol.

Previous studies

Patient-reported evaluation of change in knee function and psychological readiness is clinically important factors for the individual after ACLR (van Meer et al., 2013; Webster & Feller, 2022). Improvement of 12 points or higher has been considered a clinically relevant change after ACLR (Irrgang et al., 2006). Both groups achieved this threshold, indicating they achieved a clinically relevant change in knee function, despite no statistically significant difference in change between the groups was found. When compared to previous studies, athletes from both groups exhibited lower scores of knee function at 6 and 12 months postoperative (Johnston et al., 2022; Logerstedt et al.,

2012; Magnitskaya et al., 2020; Ra et al., 2014; Wallace et al., 2021). These previous studies reported differences in 6 to 12 months scores ranging from 5.3 to 13. In comparison, both groups in this study achieved similar difference as reported by Magnitskaya et al. (2020), which had the highest difference among the previous studies. However, athletes from Magnitskaya et al. (2020) obtained scores approximately 10 points higher at each time point compared to the BEAST athletes, and 13 points higher compared to usual care, suggesting a higher potential influence of ceiling effects (Magnitskaya et al., 2020). In relation to previous studies, both groups in our study exhibited lower knee function scores at each time point but achieved a good improvement when comparing the difference from 6 to 12 months postoperative.

Regarding psychological readiness, Webster & Feller (2021) identified a minimally important change (MIC) of 13.4 as a significant change from 6 to 12 months after ACLR at a group level. Both groups fell short of this proposed MIC, with the BEAST athletes achieving a change score of 7.3, and usual care 7.9. It should be noted that the perception of what is considered a significant change can vary individually for athletes, and MIC values should be interpreted with caution (Wright et al., 2012). When compared to previous studies, the BEAST athletes achieved high scores in psychological readiness at 6 months, but comparable scores at 12 months postoperative (Johnston et al., 2022; Langford et al., 2009; Sadeqi et al., 2018; Webster & Feller, 2021, 2022). On the other hand, the usual care group obtained lower scores at both 6 and 12 months. These previous studies reported 6 to 12 months difference scores ranging from 6.4 to 17.8, and both groups in our study fell within these scores with a difference of 11.3 (BEAST) and 7.9 (usual care). In our study, the difference from 6 to 12 months postoperative scores in psychological readiness can be regarded as average when compared to previous studies.

Why did not the outcomes differ between the groups?

The athletes following the BEAST tool improved their functional performance during follow up but did not reach the expected functional goals. Nine athletes who had not previously passed the test battery were not tested at twelve months postoperative. If all the athletes were assessed, a higher proportion of athletes receiving the strength and plyometric protocol could have been observed. Furthermore, we expected more comparable scores between the groups at 6 months postoperative. The BEAST athletes

exhibited higher scores in knee function and psychological readiness at this timepoint. The greatest difference was observed in psychological readiness with a difference of 12.1 points compared to athletes receiving usual care. One explanation of this discrepancy could be higher internal motivation for rehabilitation and RTS among the athletes in the BEAST cohort. Despite being recruited from various regions in Norway, these athletes willingly participated in a project that required regular visits to a sports clinic every two months for clinical knee assessments, in addition to attending physical therapy at their local location. This level of commitment would be challenging to maintain without internal motivation for rehabilitation and RTS, and it introduces a potential selection bias that was not accounted for in this study.

Clinical implications

The BEAST tool provided targeted rehabilitation from 6 months postoperative. Still, only half (52%), and two-thirds (65%) of the athletes achieved symmetrical quadriceps strength and hop performance, respectively, at the 12 months knee assessment. In comparison, athletes receiving usual care rehabilitation demonstrated inferior results, with only 31% achieving symmetrical quadriceps strength, and 47-55% achieving symmetrical hop tests at 12 months postoperative (Ebert et al., 2018). However, when compared to athletes receiving targeted pre- and postoperative rehabilitation, the BEAST athletes show inferior functional outcomes (Logerstedt et al., 2013). At 6 months, 73% of these athletes had symmetrical quadriceps strength, and 79-81% had symmetrical hop-tests. The 12 month mark, 79% had symmetrical quadriceps strength, and 89-95% exhibited symmetrical hop performance (Logerstedt et al., 2013). Notably, during the 6 months RTS assessment, only 8% of athletes had symmetrical quadriceps strength, and 17% had symmetrical hop tests.

Additionally, a low percentage of BEAST athletes (26%) met the criteria for full return to team participation in sports within 12 months after ACLR. This is noteworthy as athletes typically anticipate RTS within 6-9 months after ACLR, and studies have shown that athletes who fail a RTS test battery prior to returning are up to six times more likely to sustain a knee reinjury compared to those who pass (Barber-Westin & Noyes, 2011; Grindem et al., 2016). Several studies recommend rehabilitation for 9-12 months before RTS (Filbay & Grindem, 2019; van Melick et al., 2016). The implementation of targeted rehabilitation using the BEAST tool starting at 6 months

postoperative may not be sufficient to ensure that the majority of nonprofessional athletes meet the recommended criteria for RTS within 12 months after ACLR. Further investigation is needed to explore ways to improve postoperative functional outcomes in nonprofessional athletes, the largest group of athletes with ACLR.

Strengths/weaknesses

This study is the first to investigate patient-reported outcomes and functional performance in athletes following a protocol-based rehabilitation with a RTS decision tool, capturing different clinical important aspects for the individual during rehabilitation and RTS. The main strengths in this study are the prospective type of design and the utilization of validated and reliable patient-reported outcome measures (Guillemin et al., 1993; Irrgang et al., 2001; Tigerstrand Grevnerts et al., 2017). Although the specific rehabilitation received by the usual care group remains undisclosed, the implementation of the BEAST tool was effectively withheld from publication or presentation until after the completion of data collection for the SPARX study.

The Covid-19 pandemic came to Scandinavia during follow up in both cohorts affecting athletes during their rehabilitation. Covid-19-related deviations from the BEAST tool were reported for 14 athletes at 8 months, 16 athletes at 10 months, and 18 athletes at 12 months postoperative. A previous study by Legernes (2021, p 42) revealed that athletes following the BEAST tool considered the pandemic to be a major obstacle for their rehabilitation, resulting in deviations from the recommended exercises and return to sport plan with modified training and reduced compliance. Similarly, athletes in the SPARX cohort receiving usual care reported the pandemic to have a negative affection on their rehabilitation, with approximately one-third (36%) experiencing these effects (Zelleroth, 2020, p. 13). The specific impact of Covid-19 on the study´s results remain uncertain. However, both the present study´s findings and previous research indicate that the athletes were affected by the pandemic. Consequently, the results of this study should be interpreted in the context of these findings.

The change score in psychological readiness within the BEAST group, encompassing athletes with data available for both 6 and 12 months, demonstrates a notably lower

score compared to the 6 to 12 months difference score, which includes all athletes with data available at either 6 or 12 months. This discrepancy suggests that the missing data in the main analysis were not at random, indicating a potential bias to the results. Another weakness is the observational study design entailing speaking of causality with caution (Austin, 2011). It is important to note that the study was not a randomized controlled trial, which is widely considered the gold standard for estimating true effects (Austin, 2011). However, the main analysis were adjusted for known confounders, aiming to reducing their direct or indirect influence on both the outcome and exposure (Assimon, 2021).

Conclusion

Nonprofessional pivoting sport athletes with ACLR who follow a rehabilitation and RTS decision (BEAST) tool have comparable 6 to 12 months change in patient-reported knee function and psychological readiness to RTS when compared to usual care. Few athletes following the BEAST tool achieved the functional goals within 12 months after ACLR. Further investigation is required to find methods for improving functional performance in the largest group of athletes with ACLR, achieving the lowest RTS rates.

Contributorship and acknowledgments

The scientific article was authored by Martin Thorborg Johansen, with feedback for revisions from Hege Grindem. The main statistical analyses were performed by Morten Wang Fagerland.

The BEAST project was initiated and designed by Hege Grindem, and the SPARX project by Joanna Kvist. Project members are Håvard Moksnes, Arnlaug Wangensteen, Grethe Myklebust, Lars Engebretsen, May Arna Risberg, Clare Ardern, Joanna Kvist and Daniel Castellanos.

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5. Table overview

Theory:

Extended methods:

Scientific article:

6. Figure overview

Extended methods:

Scientific article:

7. Abbreviations

ACL	Anterior Cruciate Ligament
ACLR	Anterior Cruciate Ligament Reconstruction
ACL-RSI	Anterior Cruciate Ligament return to Sport after Injury Scale
IKDC-SKF	International Knee Documentations Committee Subjective Knee Form
REK	Regional Committees for medical and health research ethics
NSD	Norwegian Centre for Research data
MCL	Medial Collateral Ligament
LCL	Lateral Collateral Ligament
PCL	Posterior Cruciate Ligament
BMI	Body Mass Index
LSI	Limb Symmetry Index
NIMI	Norsk Idrettsmedisinsk Institutt
IHS	Idrettenes Helsesenter
SD	Standard deviation
QT	Quadriceps tendon
HT	Hamstring tendon
GDPR	General Data Protection Regulation
NKLR	Norwegian Knee Ligament Registry
OA	Osteoarthritis
SEM	Standard error of measurement
ICC	Intraclass correlation coefficient
PL	Practice level
NIH	Norwegian School of Sports Sciences

8. Attachements

7.1 Appendix 1. REK approval BEAST

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Region:	Saksbehandler:	Telefon:	Vår dato:	Vår referanse:
REK sør-øst	Hege Cathrine Finholt, PhD	22857547	23.11.2018	2018/1886 REK sør-øst D
			Deres dato:	Deres referanse:
			25.09.2018	

Vår referanse må oppgis ved alle henvendelser

Hege Grindem
Norges idrettshøgskole

2018/1886 Bedre og tryggere retur til idrett etter fremre korsbåndoperasjon

Forskningsansvarlig: Norges idrettshøgskole
Prosjektleder: Hege Grindem

Vi viser til søknad om forhåndsgodkjenning av ovennevnte forskningsprosjekt. Søknaden ble behandlet av Regional komité for medisinsk og helsefaglig forskningsetikk (REK sør-øst D) i møtet 31.10.2018. Vurderingen er gjort med hjemmel i helseforskningsloven (hforsknl) § 10.

Prosjektleders prosjektbeskrivelse
Kun halvparten av idrettsutøvere med fremre korsbåndoperasjon returnerer til sin idrett etter operasjonen. Blant de som returnerer, får en av fem ny kneskade innen to år. Ikke-profesjonelle idrettsutøvere har ofte ingen medisinsk oppfølging i overgangen fra opptrening i klinikk til full aktivitet i idrett. Formålet med prosjektet er å beskrive 2-årsresultater hos utøvere med korsbåndoperasjon som følger spesifikke kriterier for opptrening av kneet og for gradvis opptrapping av idrettsaktivitet. Utøverne gjennomfører klinisk undersøkelse, test av muskelstyrke, og hinketester 6, 8, 10 og 12 måneder etter fremre korsbåndoperasjon. De vil motta en plan for videre opptrening av kneet og for gradvis opptrapping av idrettsaktivitet. Planen individualiseres basert på testresultatene. Vi vil samle inn data for å beskrive etterlevelse, barrierer for etterlevelse, knefunksjon, mentale aspekter ved retur til idrett, idrettsaktivitet og nye kneskader.

Vurdering
Formålet med det omsøkte prosjektet er å forbedre evnen til utøvere som har hatt en kneskade til å returnere til idrett med lav risiko for nye kneskader. Det skal rekrutteres 125 utøvere i alderen 15 – 40 år. I denne studien er det forsvarlig å inkludere mindreårige da disse er i en alder hvor risikoen for en ny skade er svært høy. Deltakerne vil bli rekruttert fra Norsk idrettsmedisinsk institutt og Idrettens helsesenter.

Komiteen har ingen innvendinger til at studien gjennomføres som beskrevet i søknad og protokoll. Komiteen ber imidlertid om at navn og kontaktinformasjon til personvernombud settes inn i informasjonsskrivet.

Vedtak
REK har gjort en helhetlig forskningsetisk vurdering av alle prosjektets sider. Prosjektet godkjennes med hjemmel i helseforskningsloven § 10.

Godkjenningen er gitt under forutsetning av at prosjektet gjennomføres slik det er beskrevet i søknad og protokoll, og de bestemmelser som følger av helseforskningsloven med forskrifter.

Besøksadresse: Gullhaugveien 1-3, 0484 Oslo
Telefon: 22845511
E-post: post@helseforskning.etikkom.no
Web: http://helseforskning.etikkom.no/

Tillatelsen gjelder til 31.12.2024. Av dokumentasjonshensyn skal opplysningene likevel bevares inntil 31.12.2029. Forskningsfilen skal oppbevares atskilt i en nøkkel- og en opplysningsfil. Opplysningene skal deretter slettes eller anonymiseres, senest innen et halvt år fra denne dato.

Forskningsprosjektets data skal oppbevares forsvarlig, se personopplysningsforskriften kapittel 2, og Helsedirektoratets veileder for «Personvern og informasjonssikkerhet i forskningsprosjekter innenfor helse og omsorgssektoren».

Dersom det skal gjøres vesentlige endringer i prosjektet i forhold til de opplysninger som er gitt i søknaden, må prosjektleder sende endringsmelding til REK.

Prosjektet skal sende sluttmelding på eget skjema, senest et halvt år etter prosjektslutt.

Komiteens avgjørelse var enstemmig.

Klageadgang
REKs vedtak kan påklages, jf. forvaltningslovens § 28 flg. Klagen sendes til REK sør-øst D. Klagefristen er tre uker fra du mottar dette brevet. Dersom vedtaket opprettholdes av REK sør-øst D, sendes klagen videre til Den nasjonale forskningsetiske komité for medisin og helsefag for endelig vurdering.

Vi ber om at alle henvendelser sendes inn på korrekt skjema via vår saksportal: http://helseforskning.etikkom.no. Dersom det ikke finnes passende skjema kan henvendelsen rettes på e-post til: post@helseforskning.etikkom.no.

Vennligst oppgi vårt referansenummer i korrespondansen.

Med vennlig hilsen

Finn Wisløff
Professor em. dr. med.
Leder

Hege Cathrine Finholt, PhD
Rådgiver

Kopi til: sigmund.anderssen@nih.no
Norges idrettshøgskole ved øverste administrative ledelse: postmottak@nih.no

7.2 Appendix 2 - NSD approval BEAST

NSD NORSK SENTER FOR FORSKNINGSDATA

Vurdering

Referansenummer

220546

Prosjekttittel

Bedre og tryggere retur til idrett etter fremre korsbåndoperasjon

Behandlingsansvarlig institusjon

Norges idrettshøgskole / Senter for idrettsskadeforskning

Prosjektansvarlig (vitenskapelig ansatt/veileder eller stipendiat)

Hege Grindem, hege.grindem@nih.no, tlf: 95106154

Type prosjekt

Forskerprosjekt

Prosjektperiode

18.10.2018 - 31.12.2024

Vurdering (2)

09.07.2020 - Vurdert

NSD har vurdert endringen registrert 12.06.2020.

Det er vår vurdering at behandlingen av personopplysninger i prosjektet vil være i samsvar med personvernlovgivningen så fremt den gjennomføres i tråd med det som er dokumentert i meldeskjemaet med vedlegg den 09.07.2020. Behandlingen kan fortsette.

Endringene gjelder et er lagt til to datainnsamlinger (et fokusgruppeintervju og et en-til-en intervju) med 6-8 deltagere fra den opprinnelige kohorten (utvalg 2 og 3). Disse dataene vil resultere i to mastergradsoppgaver og det er utarbeidet nye samtykkeskjema for intervjuene da disse ikke var del av det opprinnelige samtykket. Vi har lagt til et tilleggsskjema som måler knefunksjon (KOOS) for utvalg 1 ved 24 mnd etter operasjonen.

Vi forutsetter at REK godkjenner endringene i prosjektet. Dersom REK ber om endringer i prosjektet, må meldeskjema også oppdateres i tråd med dette.

OPPFØLGING AV PROSJEKTET
NSD vil følge opp underveis (hvert annet år) og ved planlagt avslutning for å avklare om behandlingen av personopplysningene er avsluttet/pågår i tråd med den behandlingen som er dokumentert.

Lykke til med prosjektet!

Kontaktperson hos NSD: Jørgen Wincentsen

Tlf. Personverntjenester: 55 58 21 17 (tast 1)

07.01.2019 - Vurdert

Det er vår vurdering at behandlingen vil være i samsvar med personvernlovgivningen, så fremt den gjennomføres i tråd med det som er dokumentert i meldeskjemaet 3.1.2019 med vedlegg, samt i meldingsdialogen mellom innmelder og NSD. Behandlingen kan starte.

MELD ENDRINGER
Dersom behandlingen av personopplysninger endrer seg, kan det være nødvendig å melde dette til NSD ved å oppdatere meldeskjemaet. På våre nettsider informerer vi om hvilke endringer som må meldes. Vent på svar før endringen gjennomføres.

TYPE OPPLYSNINGER OG VARIGHET
Prosjektet vil behandle særlige kategorier av personopplysninger om helse, og alminnelige personopplysninger, frem til 31.12.2024. Opplysningene skal deretter lagres på forskningsserver i fem år, for etterkontroll. Vi minner om at nye prosjekter på dataene skal meldes til NSD fortløpende.

LOVLIG GRUNNLAG
Prosjektet vil innhente samtykke fra de registrerte til behandlingen av personopplysninger. Vår vurdering er at prosjektet legger opp til et samtykke i samsvar med kravene i art. 4 nr. 11 og art. 7, ved at det er en frivillig, spesifikk, informert og utvetydig bekreftelse, som kan dokumenteres, og som den registrerte kan trekke tilbake.

Lovlig grunnlag for behandlingen vil dermed være den registrertes uttrykkelige samtykke, jf. personvernforordningen art. 6 nr. 1 a), jf. art. 9 nr. 2 bokstav a, jf. personopplysningsloven § 10, jf. § 9 (2).

PERSONVERNPRINSIPPER
NSD vurderer at den planlagte behandlingen av personopplysninger vil følge prinsippene i personvernforordningen:

- om lovlighet, rettferdighet og åpenhet (art. 5.1 a), ved at de registrerte får tilfredsstillende informasjon om og samtykker til behandlingen
- formålsbegrensning (art. 5.1 b), ved at personopplysninger samles inn for spesifikke, uttrykkelig angitte og berettigede formål, og ikke viderebehandles til nye uforenlige formål
- dataminimering (art. 5.1 c), ved at det kun behandles opplysninger som er adekvate, relevante og nødvendige for formålet med prosjektet
- lagringsbegrensning (art. 5.1 e), ved at personopplysningene ikke lagres lengre enn nødvendig for å oppfylle formålet

DE REGISTRERTES RETTIGHETER
Så lenge de registrerte kan identifiseres i datamaterialet vil de ha følgende rettigheter: åpenhet (art. 12), informasjon (art. 13), innsyn (art. 15), retting (art. 16), sletting (art. 17), begrensning (art. 18), underretning (art. 19), dataportabilitet (art. 20).

NSD vurderer at informasjonen som de registrerte vil motta oppfyller lovens krav til form og innhold, jf. art. 12.1 og art. 13.

Vi minner om at hvis en registrert tar kontakt om sine rettigheter, har behandlingsansvarlig institusjon plikt til å svare innen en måned.

FØLG DIN INSTITUSJONS RETNINGSLINJER
NSD legger til grunn at behandlingen oppfyller kravene i personvernforordningen om riktighet (art. 5.1 d), integritet og konfidensialitet (art. 5.1. f) og sikkerhet (art. 32).

Universitetet i Lindköping, Norsk idrettsmedisinsk institutt, samt Biriteback AB er databehandlere i prosjektet. NSD legger til grunn at behandlingen oppfyller kravene til bruk av databehandler, jf. art 28 og 29.

For å forsikre dere om at kravene oppfylles, må prosjektansvarlig følge interne retningslinjer/rådføre seg med behandlingsansvarlig institusjon.

OPPFØLGING AV PROSJEKTET
NSD vil følge opp underveis (hvert annet år) og ved planlagt avslutning for å avklare om behandlingen av personopplysningene pågår i tråd med den behandlingen som er dokumentert.

Lykke til med prosjektet!

Kontaktperson hos NSD: Pernille E. Grøndal
Tlf. Personverntjenester: 55 58 21 17 (tast 1)

7.3 Appendix 3 - REK approval SPARX

Dnr 2022-02592-02

Linköping avdelning övrig

BESLUT

2022-05-27

Sökande forskningshuvudman
Karolinska Institutet

Organisation som ansöker om att bli ny huvudman
Linköpings universitet

Forskare som genomför projektet
Joanna Kvist

Projekttitel
Deltagande i fysisk aktivitet och idrott under 3 år efter rekonstruktion av främre korsbandet

Uppgifter om ansökan
Ansökan om ändring inkom till Etikprövningsmyndigheten 2022-05-06 och blev valid 2022-05-13. Grundansökan med diarienummer 2019-04546 blev godkänd 2019-10-11 av Etikprövningsmyndigheten.

Ändringen avser 1. byte av forskningshuvudman 2. nya analyser där resultat (frågeformulär) från denna studie kommer att användas för jämförelser med en annan studie

---

Etikprövningsmyndigheten beslutar enligt nedan.

BESLUT

Etikprövningsmyndigheten godkänner den forskning som anges i ansökan.

På Etikprövningsmyndighetens vägnar

Owe Horned
Ordförande

Beslutet har fattats efter föredragning av vetenskaplig sekreterare
Susanne Severinsson

Beslutet sänds till

Ansvarig forskare: Joanna Kvist

Forskningshuvudmannens företrädare: Maria Margareta Ankarcrona, Sussanne Börjeson

7.4 Appendix 4 - Sport-specific protocol football

«Bedre og tryggere retur til idrett etter korsbåndoperasjon»

SENTER FOR Idrettsskadeforskning KLOKE AV SKADE

PROTOKOLL FOR OPPTRAPPING I FOTBALL

-Hvilket nivå utøver starter på bestemmes ut fra testene som er gjennomført på Nimi eller IHS

-Utøver skal trene på ett nivå i **minimum 2 uker OG minimum 4 treninger** før han/hun går videre til neste nivå

-Nivå 4 starter tidligst 8 måneder etter korsbåndoperasjon og etter godkjent test på Nimi eller IHS.

-Nivå 6 starter tidligst 9 måneder etter korsbåndoperasjon og etter godkjent test på Nimi eller IHS.

Nivå	Aktiviteter på trening
1	Enkle pasningsøvelser og løpe/føre ball uten vending
2	Pasningsøvelser med bevegelser i forkant/etterkant, skudd/avslutninger, løpsøvelser med ball og retningsforandringer uten motstander
3	All teknisk trening med laget, 1-mot-1 øvelser, stå på utsiden i firkant og lignende øvelser (ikke jage ball)
4	Alle øvelser med laget, med som back eller kantspiller i storbanespill
5	Alle øvelser med laget, full deltagelse i storbanespill
6	Full deltagelse, inkludert småbanespill

-Utøver skal delta fullt på trening i minst 4 uker uten smerter og hevelse før opptrapping i kampspill starter.

-Det spilles maksimalt en kamp i uken

Kamp	Spilletid
1	10 minutter
2	20 minutter
3	30 minutter
4	45 minutter
5	60 minutter
6	90 minutter

7.4 Appendix 5 - Sport specific protocol handball

«Bedre og tryggere retur til idrett etter korsbåndoperasjon»

SENTER FOR Idrettsskadeforskning KLOKE AV SKADE

PROTOKOLL FOR OPPTRAPPING I HÅNDBALL

-Hvilket nivå utøver starter på bestemmes ut fra testene som er gjennomført på Nimi eller IHS

-Utøver skal trene på ett nivå i **minimum 2 uker OG minimum 4 treninger** før han/hun går videre til neste nivå

-Nivå 4 starter tidligst 8 måneder etter korsbåndoperasjon og etter godkjent test på Nimi eller IHS.

-Nivå 6 starter tidligst 9 måneder etter korsbåndoperasjon og etter godkjent test på Nimi eller IHS.

Nivå	Aktiviteter på trening
1	Pasning mot vegg eller med medspiller, løp med og uten ball uten retningsforandringer
2	Pasningsøvelser med bevegelser i forkant/etterkant, kontra/returløp og skudd med innhopp uten motstander, løpsøvelser med ball og retningsforandringer uten motstander
3	All teknisk trening med laget, 1-mot-1 øvelser
4	Alle øvelser med laget; I spill: Med kun i forsvar
5	Alle øvelser med laget; i spill: Fullt med i forsvar, med i angrep kun med skudd fra avstand
6	Full deltagelse

-Utøver skal delta fullt på trening i minst 4 uker uten smerter og hevelse før opptrapping i kampspill starter.

-Det spilles maksimalt en kamp i uken de tre første månedene etter oppstart av opptrapping i kampspill

-Fordel gjerne spilletiden på begge omganger

Kamp	Spilletid
1	10 minutter
2	15 minutter
3	20 minutter
4	30 minutter
5	45 minutter
6	60 minutter

7.5 Appendix 6 - Sport-specific protocol floorball

«Bedre og tryggere retur til idrett etter korsbåndoperasjon»

SENTER FOR Idrettsskadeforskning KLOKE AV SKADE

PROTOKOLL FOR OPPTRAPPING I INNEBANDY

-Hvilket nivå utøver starter på bestemmes ut fra testene som er gjennomført på Nimi eller IHS

-Utøver skal trene på ett nivå i **minimum 2 uker OG minimum 4 treninger** før han/hun går videre til neste nivå

-Nivå 4 starter tidligst 8 måneder etter korsbåndoperasjon og etter godkjent test på Nimi eller IHS.

-Nivå 6 starter tidligst 9 måneder etter korsbåndoperasjon og etter godkjent test på Nimi eller IHS.

Nivå	Aktiviteter på trening
1	Enkle pasningsøvelser og løpe/føre ball uten vending
2	Pasningsøvelser med bevegelser i forkant/etterkant, enkle avslutningsøvelser (f.eks. føring av ball fra hjørnet i bue inn til skudd, pasning fra medspiller til skudd)
3	All teknisk trening med laget, 1-mot-1 øvelser, stå på utsiden i ranger og lignende øvelser (ikke jage ball)
4	Alle øvelser med laget, med som back i storbanespill
5	Alle øvelser med laget, full deltagelse i storbanespill
6	Full deltagelse, inkludert småbanespill

-Utøver skal delta fullt på trening i minst 4 uker uten smerter og hevelse før opptrapping i kampspill starter.

-Det spilles maksimalt en kamp i uken

Kamp	Spilletid
1	Tilgjengelig i en periode
2	Tilgjengelig i en periode
3	Tilgjengelig i en periode
4	Tilgjengelig i to perioder
5	Tilgjengelig i to perioder
6	Tilgjengelig i tre perioder

7.6 Appendix 7 - Sport-specific protocol basketball

«Bedre og tryggere retur til idrett etter korsbåndoperasjon»

SENTER FOR Idrettsskadeforskning KLOKE AV SKADE

PROTOKOLL FOR OPPTRAPPING I BASKETBALL

-Hvilket nivå utøver starter på bestemmes ut fra testene som er gjennomført på Nimi eller IHS

-Utøver skal trene på ett nivå i **minimum 2 uker OG minimum 4 treninger** før han/hun går videre til neste nivå

-Nivå 4 starter tidligst 8 måneder etter korsbåndoperasjon og etter godkjent test på Nimi eller IHS.

-Nivå 6 starter tidligst 9 måneder etter korsbåndoperasjon og etter godkjent test på Nimi eller IHS.

Nivå	Aktiviteter på trening
1	Pasning mot vegg eller med medspiller, skudd uten hopp, drible ball uten retningsforandringer
2	Pasning med weave, drible ball med retningsforandring uten motstander, layups uten motstander, hoppskudd uten motstander, fast breaks uten motstander
3	All teknisk trening med laget, 1-mot-1 øvelser
4	Alle øvelser med laget; I spill i guardposisjon: forsvar uten returdueller (kan bokse ut, men ikke hoppe opp på retur), angrep med skudd fra avstand (jobb med pasninger, screen, skudd fra avstand - ikke utfordre innover)
5	Alle øvelser med laget; I spill i guardposisjon: fullt med i forsvar, angrep med skudd fra avstand (jobb med pasninger, screen, skudd fra avstand - ikke utfordre innover)
6	Full deltagelse

-Utøver skal delta fullt på trening i minst 4 uker uten smerter og hevelse før opptrapping i kampspill starter.

-Det spilles maksimalt en kamp i uken

Kamp	Spilletid
1	Tilgjengelig i en periode
2	Tilgjengelig i en periode
3	Tilgjengelig i to perioder
4	Tilgjengelig i to perioder
5	Tilgjengelig i tre perioder
6	Tilgjengelig i fire perioder

7.7 Appendix 8 - Protocol knee effusion

«Bedre og tryggere retur til idrett etter korsbåndoperasjon»

SENTER FOR Idrettsskadeforskning KLOKE AV SKADE

PROTOKOLL FOR HEVELSE

Modified stroke test utføres og graderes etter Sturgill et al. (2008)

Grad	Avgjørelse
0	Ingen
Trace	Redusere mengde aktiviteter med løp og hopp 50% i en uke
1	Utøver skal ut av aktiviteter med løp og hopp i en uke
2	Utøver skal ut av aktiviteter med løp og hopp. Henvis ortoped eller annet helsepersonell for videre oppfølging
3	Utøver skal ut av aktiviteter med løp og hopp. Henvis ortoped eller annet helsepersonell for videre oppfølging

7.8 Appendix 9 - Protocol quadriceps strength

«Bedre og tryggere retur til idrett etter korsbåndoperasjon»

SENTER FOR Idrettsskadeforskning KLOKE AV SKADE

PROTOKOLL FOR STYRKETRENING

- Det gjennomføres tre treningsdager på en uke

- Ha en hviledag mellom hver styrketreningsøkt

- For hver øvelse utføres antall sett og repetisjoner som beskrevet under for benet som er operert. Utfør maksimalt ett sett med samme belastning på motsatt ben.

- Mellom hvert sett er det en hvileperiode på 90 sekunder

- Alle øvelser utføres til utmattelse i siste sett. Klarer du flere enn 2 repetisjoner over antallet i treningsplanen, økes belastningen neste gang du utfører øvelsen.

Treningsdag 1		
Øvelse	*Sett*	*Repetisjoner*
Utfall fremover	3	8
Hurtig oppsteg på høy kasse	3	6
Bulgarsk utfall	4	4

Treningsdag 2		
Øvelse	*Sett*	*Repetisjoner*
Oppsteg med vekt	3	6
Leg extension ett ben fra 90 til 45 grader knefleksjon	4	4
Ettbens knebøy på BOSU-ball	3	8

Treningsdag 3		
Øvelse	*Sett*	*Repetisjoner*
Leg extension eksentrisk mellom 45 og 90 grader knefleksjon	4	4
Ettbens benpress	3	6
Utfall til siden	3	8

7.9 Appendix 10 - Protocol plyometric

«Bedre og tryggere retur til idrett etter korsbåndoperasjon»

SENTER FOR Idrettsskadeforskning KLOKE AV SKADE

PROTOKOLL FOR TRENING AV KNEKONTROLL

- Det gjennomføres tre treningsdager på en uke

- Ha en hviledag mellom hver knekontrolløkt

- For ettbensøvelsene utføres antall sett og repetisjoner som beskrevet under for benet som er operert. Utfør øvelsen på motsatt ben i pausen.

- Mellom hvert sett er det en hvileperiode på minst 30 sekunder

- Om øvelsen er enkelt øker du hastighet og høyde på hink/hopp.

- Treningsdag 3 kan utføres på treningssenter, trening med laget, eller utendørs. Om du ikke har hoppetau kan øvelsen med hoppetau erstattes av raske ankelhopp på ett og to ben.

Treningsdag 1		
Øvelse	*Sett*	*Repetisjoner*
Sammenhengende spensthink over hinder/stepkasse	3	6
Hink sideveis opp og over stepkasse	3	6
Hink opp trappetrinn	3	6
Telemarkshopp på BOSU-ball	3	12 (6 landinger hvert ben)

Treningsdag 2		
Øvelse	*Sett*	*Repetisjoner*
Hink fremover og stopp	3	6
Hink fremover med 90 grader rotasjon og stopp	3	6
Skøytehopp	3	12 (6 landinger hvert ben)

Treningsdag 3		
Øvelse	*Sett*	*Repetisjoner*
Hoppe tau på ett og to ben	3	30 sek
Løp med kontrollert vending	6	50 meter
Triangelløp	6	50 meter

7.10 Appendix 11 - Informed consent BEAST

Vil du delta i forskningsprosjektet

"Bedre og tryggere retur til idrett etter korsbåndoperasjon"?

Dette er et spørsmål til deg om å delta i et forskningsprosjekt hvor formålet er å kartlegge resultatene hos korsbåndopererte idrettsutøvere som følger spesifikke kriterier for opptrening av kneet og opptrapping av idrettsaktivitet. I dette skrivet gir vi deg informasjon om målene for prosjektet og hva deltakelse vil innebære for deg.

Bakgrunn og formål
Idrettsutøvere som har hatt en fremre korsbåndoperasjon ønsker ofte å fortsette med sin idrett. Likevel er det bare halvparten som går tilbake til idretten sin etter operasjonen, og, av de som går tilbake, skader en av fem kneet sitt på nytt. I dette forskningsprosjektet følger vi opp idrettsutøvere som har hatt fremre korsbåndrekonstruksjon. Alle i prosjektet vil følge spesifikke kriterier for opptrening av kneet og opptrapping av idrettsaktivitet. Disse kriteriene er laget for å legge til rette for en bedre og tryggere retur til idrett. Hovedformålet med prosjektet er å beskrive knefunksjon, idrettsaktivitet og nye kneskader hos dere som følger disse kriteriene. Vi vil også beskrive hvor mange som følger kriteriene fullt ut, og eventuelle problemer som hindrer dere i å gjennomføre behandlingsopplegget. Resultatene hos dere som følger disse kriteriene vil også sammenlignes med resultatene hos idrettsutøvere som følger vanlig klinisk praksis i andre studier. Disse studiene utføres i Sverige av Linköpings Universitet. Femti personer i prosjektet vil også bli forespurt om å delta i en undersøkelse av to forskjellige metoder for å teste muskelstyrke. Formålet med dette er å undersøke om de to metodene er likeverdige. Kunnskapen fra dette prosjektet vil kunne bidra til å utvikle bedre behandling for idrettsutøvere som ønsker å fortsette med idrett etter en fremre korsbåndoperasjon.

Hvem er ansvarlig for forskningsprosjektet?
Senter for idrettsskadeforskning ved Norges Idrettshøgskole er ansvarlig for prosjektet.

Hvorfor får du spørsmål om å delta?
Du får denne henvendelsen fordi du har operert fremre korsbånd innen de siste 6 månedene og har vært i kontakt med Norsk idrettsmedisinsk institutt (Nimi) eller Idrettens Helsesenter (IHS). For å delta i dette prosjektet, skal du ha spilt fotball, håndball, basketball eller innebandy minst to ganger i uken før skade, og ha et ønske om å returnere til en av disse idrettene.

Hva innebærer det for deg å delta?
Med oppstart 6 måneder etter operasjonen, vil vi utføre en undersøkelse av kneet ditt som innebærer klinisk undersøkelse, test av muskelstyrke og test av hinkeevne. Basert på dine resultater på disse testene, vil du få et tilpasset opplegg for videre opptrening av kneet. Tiden du vil bruke på opptrening av kneet vil komme an på resultatene av undersøkelsen, men du bør regne med 60 minutter tre ganger i uken frem til du har god muskelstyrke og hinkeevne. Testresultatene vil også bestemme hva du skal utføre av idrettsaktivitet. Om du i løpet av prosjektet ikke lenger ønsker å returnere til din idrett, vil du kunne gjennomføre testing og opptrening uten å trappe opp idrettsaktivitet. Undersøkelsen av kneet gjentas 8, 10 og 12 måneder etter operasjonen – eller frem til du har oppfylt alle kriterier på testene til å gjenoppta full idrettsaktivitet. Denne undersøkelsen vil ta 60-90 minutter og gjennomføres på Nimi eller IHS. Som deltager i prosjektet vil du følge behandlingsprinsipper som allerede er i bruk for profesjonelle utøvere, og for ikke-profesjonelle utøvere ved Nimi og IHS. Om du deltar i den ekstra undersøkelsen av de to forskjellige metodene for å måle muskelstyrke, vil du utføre en ekstra test av muskelstyrke ved både 6 måneder og 12 måneder etter operasjonen. Den ekstra testen vil ta 15 minutter.

Vi vil følge deg opp månedlig frem til 2 år etter korsbåndoperasjonen for å registrere knefunksjon, hva du gjør av opptrening og idrettsaktivitet, og eventuelle nye kneskader. Du registrerer selv denne informasjonen elektronisk via spørreskjema på en app, og dette vil ta 5-10 minutter hver gang. Om du ønsker å se over spørsmålene på forhånd, kan du kontakte prosjektleder.

Vi ber også om tillatelse til å innhente informasjon fra din medisinske journal. Dette vil være opplysninger om operasjonen av ditt fremre korsbånd, samt journalopplysninger som beskriver eventuelt nye kneskader under prosjektperioden (for eksempel MR-svar og operasjonsbeskrivelser).

Mulige fordeler og ulemper
Som deltager i prosjektet vil du få regelmessig testing av kneets funksjon og mer tilpasset oppfølging i den siste delen av opptreningen enn det som er vanlig i klinisk praksis utenfor idrettsmedisinske klinikker. Testingen og opptreningen i prosjektet er likt det som blir brukt for andre korsbåndopererte idrettsutøvere på Nimi og IHS. Vi ønsker at deltagere i dette prosjektet følger spesifikke kriterier for opptrening av kneet og for opptrapping av idrettsaktivitet. Som deltager i prosjektet vil du derfor få klare retningslinjer for den siste delen av opptreningen av kneet, og for en gradvis økning i idrettsaktivitet. Disse prinsippene brukes av profesjonelle utøvere, men er hittil ikke like vanlig i breddeidrett. En gradvis tilnærming til idrettsaktivitet vil si at du i begynnelsen kun deltar i deler av din vanlige trening. Det vil være nødvendig å koordinere dette med treneren din.

Det kan være at du opplever ubehag i form av stølhet i etterkant av testene. Det kan også være at du opplever noe ubehag i kneet ved gjennomføring av hinketestene, men det er svært liten risiko for at dette skal føre til forverring av din skade. Dette er tester vi har lang erfaring med og som blir benyttet også internasjonalt til testing av utøvere med fremre korsbåndskade.

Det er frivillig å delta
Det er frivillig å delta i prosjektet. Hvis du velger å delta, kan du når som helst trekke samtykket tilbake uten å oppgi noen grunn. Alle opplysninger om deg vil da bli anonymisert. Det vil ikke ha noen negative konsekvenser for deg hvis du ikke vil delta eller senere velger å trekke deg. Dette vil heller ikke påvirke din behandling ved klinikken. Om du blir med i prosjektet og senere ønsker å trekke deg, ta kontakt med prosjektansvarlig Hege Grindem (tlf 95106154 epost hege.grindem@nih.no).

Forsikring
Du vil være dekket av pasientskadeloven under testing i prosjektet.

Oppfølgingsprosjekt
Vi ber om å få kontakte deg på nytt dersom bruk av data til andre formål eller langtidsoppfølging blir aktuelt.

Ditt personvern – hvordan vi oppbevarer og bruker dine opplysninger
Vi vil bare bruke opplysningene om deg til formålene vi har fortalt om i dette skrivet. Vi behandler opplysningene konfidensielt og i samsvar med personvernregelverket.

Prosjektgruppen ved Senter for idrettsskadeforskning, Norges idrettshøgskole, vil ha tilgang til data om deg. Dataene som innhentes vil lagres i manuelle arkiv med personidentifikasjon som låses inn. Testresultatene fra undersøkelsen av kneet ditt vil lagres elektronisk på klinikken der du er testet (Nimi eller IHS), samt på Norges Idrettshøgskole. Opplysningene du rapporterer elektronisk via appen vil behandles av Briteback (Briteback, Norrköping, Sverige, www.briteback.com). Data vil oppbevares midlertidig på deres server, og lagres på server på Norges Idrettshøgskole. Navnet og kontaktopplysningene dine vil erstattes med en kode som lagres på egen navneliste adskilt fra øvrige data.

Alle opplysninger vil bli behandlet uten navn og fødselsnummer eller andre direkte gjenkjennende opplysninger ved statistiske analyser. Du vil ikke kunne identifiseres i publikasjoner av resultatene fra dette prosjektet.

For å sammenligne resultatene av dette prosjektet med prosjektene i Sverige vil forskere ved Linköpings Universitet i Sverige (3 personer) ha tilgang til dataene.

Prosjektleder har hovedansvaret for forskningsprosjektet og at opplysninger om deg blir behandlet på en sikker måte.

Hva skjer med opplysningene dine når vi avslutter forskningsprosjektet?
Prosjektet skal etter planen avsluttes 31.12.2024. Ved prosjektslutt vil personopplysninger og data oppbevares på forskningsserver på Norges Idrettshøgskole i fem år for etterkontroll. Kun prosjektgruppen vil ha tilgang til dataene. Informasjon om deg vil bli anonymisert eller slettet senest fem år etter prosjektslutt i tråd med gjeldende forskrifter og lover for oppbevaring av data.

Dine rettigheter
Så lenge du kan identifiseres i datamaterialet, har du rett til:
- innsyn i hvilke personopplysninger som er registrert om deg,
- å få rettet personopplysninger om deg,
- få slettet personopplysninger om deg,
- få utlevert en kopi av dine personopplysninger (dataportabilitet), og
- å sende klage til personvernombudet eller Datatilsynet om behandlingen av dine personopplysninger.

Godkjenning
Prosjektet er godkjent av Regional Komite for Medisinsk og Helsefaglig Forskningsetikk Sør-Øst (saksnummer hos REK: 2018/1886 REK sør-øst D). På oppdrag fra Norges Idrettshøgskole har NSD – Norsk senter for forskningsdata AS vurdert at behandlingen av personopplysninger i dette prosjektet er i samsvar med personvernregelverket.

Hvor kan jeg finne ut mer?
Hvis du har spørsmål til studien, eller ønsker å benytte deg av dine rettigheter, ta kontakt med:
- *Senter for idrettsskadeforskning, Norges Idrettshøgskole* ved Hege Grindem tlf 95106154, epost hege.grindem@nih.no
- Vårt personvernombud: Karine Justad, epost karine.justad@nih.no
- NSD – Norsk senter for forskningsdata AS, på epost (personverntjenester@nsd.no) eller telefon: 55 58 21 17.

Med vennlig hilsen

Prosjektansvarlig

Hege Grindem,
Seniorforsker,
Senter for idrettsskadeforskning,
Norges Idrettshøgskole

Samtykkeerklæring

Jeg har mottatt og forstått informasjon om prosjektet «Bedre og tryggere retur til idrett etter korsbåndoperasjon», og har fått anledning til å stille spørsmål. Jeg samtykker til:

- ☐ å delta i prosjektet
- ☐ å delta i ekstra undersøkelse av to forskjellige metoder for å teste muskelstyrke
- ☐ at opplysninger om korsbåndoperasjonen og eventuelle nye kneskader kan innhentes fra journal
- ☐ at mine personopplysninger lagres etter prosjektslutt for etterprøvbarhet

Jeg samtykker til at mine opplysninger behandles frem til prosjektet er avsluttet, ca. 31.12.2024

(Signatur deltager, sted og dato)

(Signatur foresatt dersom deltager er under 16 år, sted og dato)

(Signatur foresatt dersom deltager er under 16 år, sted og dato)

Jeg bekrefter å ha gitt informasjon om prosjektet

(Signatur, sted og dato, rolle i prosjektet)

7.12 Appendix 12 - ACL- return to sports after injury (RSI)

BEAST:

ACL-RSI	Er du sikker på at du kan drive idretten din på samme nivå som tidligere?
ACL-RSI	Tror du det er sannsynlig at du kommer til å skade kneet ditt på nytt ved å delta i idretten din?
ACL-RSI	Er du engstelig for å drive med idretten din?
ACL-RSI	Føler du deg sikker på at kneet ikke vil gi etter når du driver med idretten din?
ACL-RSI	Føler du deg sikker på at du kunne drevet med idretten din uten å bekymre deg for kneet ditt?
ACL-RSI	Føler du deg komfortabel med tanke på å drive idretten din?
ACL-RSI	Synes du det er frustrerende å måtte ta hensyn til kneet ditt når det gjelder idretten din?
ACL-RSI	Er du engstelig for å skade kneet ditt på nytt når du driver med idretten din?
ACL-RSI	Er du sikker på at kneet ditt ikke vil svikte under store belastninger?
ACL-RSI	Er du engstelig for at du skal skade kneet ditt ved et uhell når du driver med idretten din?
ACL-RSI	Hindrer tanken på å måtte gjennomgå operasjon og gjenopptrening på nytt deg fra å drive med idretten din?
ACL-RSI	Er du trygg på din evne til å prestere bra i idretten din?

SPARX:

Är du säker på att du kan utöva din idrottsaktivitet på samma nivå som tidigare?	ACLRSI1
Tror du det är sannolikt att du skadar ditt knä igen genom att delta i din idrottsaktivitet?	ACLRSI2
Är du orolig för att utöva din idrottsaktivitet?	ACLRSI3
Är du säker på att ditt knä inte kommer att ge vika vid utövandet av din idrottsaktivitet?	ACLRSI4
Är du säker på att du kan utöva din idrottsaktivitet utan att bekymra dig för ditt knä?	ACLRSI5
Upplever du att det är frustrerande att behöva ta hänsyn till ditt knä med avseende på din idrottsaktivitet?	ACLRSI6
Är du rädd för att skada ditt knä igen vid utövandet av din idrottsaktivitet?	ACLRSI7
Är du säker på att ditt knä klarar att bibehålla kontroll under belastning?	ACLRSI8
Är du rädd att du, av en olyckshändelse, skadar ditt knä vid utövandet av din idrottsaktivitet?	ACLRSI9
Har tankar på att vara tvungen att genomgå operation och rehabilitering igen, hindrat dig från att utöva din idrottsaktivitet?	ACLRSI10
Är du säker på din förmåga att kunna prestera bra i din idrottsaktivitet?	ACLRSI11
Känner du dig avspänd inför att utöva din idrottsaktivitet?	ACLRSI12

7.13 Appendix 13 - Questionnaire International Knee Documentation Committee (IKDC-SKF)

BEAST:

IKDC	Hva er det høyeste aktivitetsnivået du tror du kan drive med uten betydelige smerter?
IKDC	I løpet av de siste 4 uker (eller siden kneskaden), hvor ofte har du hatt smerter?
IKDC	Hvis du har smerter, hvor intense er de?
IKDC	I løpet av de siste 4 uker, hvor stivt eller hovent har kneet ditt vært?
IKDC	Hva er det høyeste aktivitetsnivå du tror du kan drive med uten betydelig hevelse i kneet?
IKDC	I løpet av de siste 4 uker (eller siden kneskaden), har kneet låst seg?
IKDC	Hva er det høyeste aktivitetsnivået du tror du kan drive med uten betydelig svikt av kneet?
IKDC	Hva er det høyeste aktivitetsnivå du vanligvis kan delta i (nå)?
IKDC	Gå opp trapper
IKDC	Gå ned trapper
IKDC	Knele (gå ned på kne)
IKDC	Gå ned på huk
IKDC	Sitte med bøyd kne
IKDC	Reise deg opp fra stol
IKDC	Løpe rett frem
IKDC	Hinke på ditt skadede ben
IKDC	Starte og stoppe raskt
IKDC	FUNKSJON FØR KNESKADEN
IKDC	NÅVÆRENDE KNEFUNKSJON

SPARX:

Vilken är den högsta aktivitetsnivån du kan klara av att göra utan betydande knäsmärta?	IKDC1
Hur ofta har du haft knäsmärta under de senaste 4 veckorna eller sedan skadan?	IKDC2
Om du har smärta, hur mycket smärta har du?	IKDC3
Hur stelt eller svullet har ditt knä varit under de senaste 4 veckorna eller sedan skadan?	IKDC4
Vilken är den högsta aktivitetsnivån som du kan klara av utan betydande svullnad i knät	IKDC5
Har knät hakat upp sig eller låst sig under de senaste 4 veckorna eller sedan skadan?	IKDC6
Vilken är den högsta aktivitetsnivån som du kan klara av utan betydande instabilitet i knät (dvs att knät plötsligt viker sig)?	IKDC7
Vilken är den högsta aktivitetsnivån som du regelbundet kan delta i?	IKDC8
Hur påverkar din knäskada din förmåga att:	IKDC9
Gå upp för trappor	IKDC10
Gå nerför trappor	IKDC11
Stå på knä	IKDC12
Göra en knäböjning	IKDC13
Sitta med böjt knä	IKDC14
Resa dig upp från en stol	IKDC15
Springa rakt fram	IKDC16
Hoppa och landa på ditt skadade ben	IKDC17
Göra snabba starter och stopp	IKDC18
Funktion före knäskadan:	IKDC19
Nuvarande knäfunktion	IKDC20

7.14 Appendix 14 - Standarized form filled out at 6 months knee assessment

«Bedre og tryggere retur til idrett etter korsbåndoperasjon»

SENTER FOR Idrettsskadeforskning KLOKE AV SKADE

FOR PROSJEKTDELTAGEREN	
Navn:	Adresse:
Postnummer/sted:	Yrke:
Tlf:	Epost:

Fødselsdato:	Høyde:	Vekt:
Alder:	Kjønn: ☐ Kvinne ☐ Mann	
Skadet side: ☐ Høyre ☐ Venstre	Dato for skade:	Dato for korsbåndoperasjon:

Har noen i din nærmeste biologiske familie en fremre korsbåndskade?	☐ Nei ☐ Mor/far ☐ Søsken ☐ Barn ☐ Vet ikke
Hvilken idrett drev du med før skaden? *Vennligst velg en idrett*	☐ Basketball ☐ Fotball ☐ Håndball ☐ Innebandy
Hvor mange timer i uka drev du med din idrett før skade?	
På hvilket nivå spilte du før du ble skadet?	☐ Senior: landslag eller elite (øverste divisjon) ☐ Senior: nest øverste divisjon ☐ Senior: lavere divisjoner ☐ Aldersbestemt landslag ☐ Aldersbestemt seriespill ☐ Bedriftsidrett ☐ Annet
Har du som mål å fortsette med denne idretten?	☐ Ja ☐ Nei
Hvis nei, vennligst beskriv årsaken her:	

FOR FYSIOTERAPEUTEN				
Lachman test	☐ Positiv (ikke fast stopp) ☐ Negativ			
Modifisert stroke test	☐ 3 ☐ 2 ☐ 1 ☐ Trace ☐ 0			
Grafttype	☐ Patellarsene ☐ Hamstrings ☐ Quadriceps ☐ Allograft			
Tilleggsskader	☐ Medial menisk	☐ Sutur	☐ Reseksjon	☐ Ubehandlet
	☐ Lateral menisk	☐ Sutur	☐ Reseksjon	☐ Ubehandlet
	☐ MCL	☐ Grad 1	☐ Grad 2	☐ Grad 3
	☐ LCL	☐ Grad 1	☐ Grad 2	☐ Grad 3
	☐ Medial tibiofemoral bruskskade ☐ Lateral tibiofemoral bruskskade ☐ Patellofemoral bruskskade			
Husk å innhente operasjonsbeskrivelse				

7.15 Appendix 15 - Standardized form filled out at 8, 10 and 12 months knee assessment

«Bedre og tryggere retur til idrett etter korsbåndoperasjon»

SENTER FOR Idrettsskadeforskning KLOKE AV SKADE

FOR FYSIOTERAPEUTEN

Dato:	Deltager:
Tid fra operasjon:	Fysioterapeut:
Lachman test	☐ Positiv (ikke fast stopp) ☐ Negativ
Modifisert stroke test	☐ 3 ☐ 2 ☐ 1 ☐ Trace ☐ 0

	Ikke-skadet 1	Ikke-skadet 2	Skadet 1	Skadet 2
Trippelhopp (cm)				

	Ikke-skadet	Skadet
Sidehopp (antall)		
Quadriceps power		
Quadriceps 1RM		

Smerter/andre problemer under test?	☐ Nei ☐ Ja (spesifiser hva)

Deltager ønsker retur til idrett	☐ Ja ☐ Nei (spesifiser årsak)

Videre plan:	☐ Protokoll for hevelse ☐ Protokoll for muskelstyrke ☐ Protokoll for knekontroll ☐ Ingen	☐ Treningsnivå 1 ☐ Treningsnivå 2 ☐ Treningsnivå 3 ☐ Treningsnivå 4 ☐ Treningsnivå 5 ☐ Treningsnivå 6	☐ Kampnivå 1 ☐ Kampnivå 2 ☐ Kampnivå 3 ☐ Kampnivå 4 ☐ Kampnivå 5 ☐ Kampnivå 6

Er det avvik fra algoritmen?	☐ Nei ☐ Ja (spesifiser hva)

7.16 Appendix 16. Statistical analysis plan

Knee function and psychological readiness to return to sport after anterior cruciate ligament reconstruction – a comparison between nonprofessional pivoting sport athletes who followed treatment with the BEAST tool versus usual care

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Principal investigator: Hege Grindem, OSTRC, Department of Sports Medicine, Norwegian School of Sport Sciences.
Biostatistician: Morten Wang Fagerland, Department of Sports Medicine, Norwegian School of Sport Sciences.

This statistical analysis plan details the planned analysis of data from two prospective cohort studies, the BEtter And Safer return to sporT (BEAST, clinical trials #NCT04049292) study and the Participation in physical activity and sports 3 years after ACL-reconstruction (SPARX Dnr 2019-04546) study. Participants in the BEAST study have followed a treatment algorithm with the BEAST tool.[1] Participants in the SPARX study were recruited from the Swedish Knee Ligament register and represent usual care.

Study objectives

1) To compare the 6-12-month postoperative change in patient-reported knee function between nonprofessional pivoting sport athletes with anterior cruciate ligament reconstruction (ACLR) who follow a treatment algorithm with the BEAST tool and those who receive usual care.
2) To compare the 6-12-month postoperative change in patient-reported psychological readiness to return to sport between nonprofessional pivoting sport athletes with ACLR who follow a treatment algorithm with the BEAST tool and those who receive usual care.

Inclusion criteria

- Unilateral primary ACLR
- Age 15-40 years

- Preinjury participation in football, handball, basketball or floorball at least twice per week
- Six months after ACLR, participant expresses a goal to return to sport

Exclusion criteria

- Grade 3 MCL, LCL and/or PCL injury
- Contralateral ACL injury
- Inability to understand the native language in the country of recruitment
- Other serious injury or illness that impairs function
- Professional athlete

Outcome measures

Patient-reported knee function will be measured with the IKDC-SKF questionnaire.[2] Patient-reported psychological readiness to return to sport will be measured with the ACL-RSI questionnaire.[3]

Statistical analysis

The data will be analyzed with linear regression adjusted for a propensity score variable. If the residuals of the model are not normally distributed, a median regression will be performed.

The propensity score will be computed with logistic regression where group is the dependent variable. A priori independent variables for the propensity score are age, sex, preinjury sport, family history of ACL injury, time from injury to surgery, ACL graft type, concomitant meniscus or cartilage injury, and meniscal repair.

Sample size

The estimation of a minimum sample size for analysis was based on a mean difference in IKDC-SKF change of 12 or higher,[2 4 5] SD 15, alpha level 0.05 and beta level 0.8. At least 26 athletes would be needed in each group. The minimum sample size estimation was increased by 20% to compensate for potential loss of data and violation of statistical

assumptions. Therefore, the minimum sample size for analysis was set to 32 athletes in each group.

Sensitivity analyses

Two sensitivity analyses are planned where the results from the full dataset will be compared with results after:

1) Trimming non-overlapping regions of the propensity score
2) Excluding study participants who performed their rehabilitation while there was a 3-month long nationwide lockdown of gyms during Covid-19

Reporting

Observed data will be presented with box plots for 6 months, 12 months and change scores. The results of the statistical analyses will be reported in a table with estimates, 95% confidence intervals and p-values for null effect. Descriptive characteristics of the samples will also be presented.

References

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