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What is the effect of the FIFA 11+ injury prevention programme on eccentric knee flexor strength in adolescent elite male football players

A randomised controlled trial

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SUMMARY

Background: The FIFA 11+ programme has been developed as a complete warm-up programme to prevent injuries in amateur football for players aged 14 or older. The majority of studies examining the effect of the FIFA 11+ programme have shown an increase in isokinetic eccentric knee flexor strength, as well as a preventive effect on hamstring injuries (HI). No studies have examined the effect of the FIFA 11+ programme on eccentric knee flexor strength, as measured using the NordBord; a novel testing device designed specifically to obtain objective measurements of eccentric knee flexor strength and overcome the limitations of isokinetic measurements.

Objective: To examine the effect of the FIFA 11+ programme on eccentric knee flexor strength as measured using the NordBord in adolescent elite male football players. **Methods:** This study was part of a randomised controlled trial (RCT) where the overall aim was to examine the hip adductor strength effects of an exercise called the Copenhagen adduction exercise (CAE), using the same protocol as the Nordic Hamstring exercise (NHE) in the FIFA 11+ programme. Forty-five players were recruited form two U19 elite male football teams. Players were randomised into two groups; one group carried out the ordinary FIFA 11+ program, while the other carried out the FIFA 11+, but replacing the NHE with the CAE. Both groups performed the intervention three times weekly for 8 weeks. Players completed maximal eccentric knee flexor strength test using the NordBord. The primary outcome was relative eccentric knee flexor strength in Newton, corrected for body weight (N/kg). Per-protocol analyses were performed, with 10 players excluded due to low compliance (<67% of session completed).

Results: Between-group analyses showed that there was no significant difference in the change in eccentric knee flexor strength in the dominant leg (0.26, 95% CI: -0.14 to 0.65; p=0.19) nor the non-dominant leg (0.28, 95% CI: -0.01 to 0.56, p=0.05) between adolescent elite male football players performing the ordinary FIFA 11+ or the FIFA 11+ programme where the NHE was replaced by the CAE. There was, however, a within-group increase of 7.5% and 7.9% in the dominant and non-dominant leg, respectively.

Conclusion: This RCT showed no between-group difference in the change in eccentric knee flexor strength between football players performing the ordinary FIFA 11+ or the FIFA 11+ programme where the NHE was replaced by the CAE, but we observed a within-group increase of 7.5% in the dominant leg and 7.9% in the non-dominant leg.

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1.0 INTRODUCTION

Football is the most popular team sport in the world. In 2006, the Fédération Internationale de Football Association (FIFA) conducted a survey named FIFA Big Count which showed that there were 265 million footballers worldwide (FIFA, 2007). This represented a 10% increase from the first survey completed in 2000. The number of footballers have accordingly continued to rise in 2017. With increased participation, follows an increased risk of a rise in sports related injuries. Consequently, sports injury prevention programs have become a prime area of interest in sports medicine recent years (Bizzini, Junge, & Dvorak, 2013) and the development of the FIFA 11+ programme in the beginning of the 20th century came as a result of this.

1.1 The FIFA 11+ programme

"The FIFA 11+ injury prevention programme has been developed by an international group of experts based on their practical experience with various injury prevention programmes for amateur players aged 14 or older. It is a complete warm-up package and is designed for amateur or recreational players, who represent 99% of all football players worldwide." (FIFA, n.d.).

The FIFA 11+ programme consists of three parts, with a total of 15 exercises (see Appendix A) (Soligard et al., 2008). These should be performed in a specified sequence at the start of each training session at least twice a week (Soligard et al., 2008). The FIFA 11+ programme takes approximately 20 min to complete and includes the following three main components (Soligard et al., 2008):

- *Part 1* consists of running exercises at slow speed combined with active stretching and controlled partner contact
- *Part 2* consists of six exercises focusing on core and leg strength, balance and plyometric/agility, each with three levels of increasing difficulty
- *Part 3* consists of running exercise at moderate/high speed combined with planting/cutting movements

Of the six exercises in Part 2 of the FIFA 11+ programme, the NHE is the exercise which primarily is thought to target the eccentric knee flexor strength. The NHE should be done at three different levels; level 1 (3-5 rep), level 2 (7-10 rep) or level 3 (12-15 rep) and only one

set.

Three RCTs have reported increased eccentric knee flexor strength of 11-21% after using the NHE (Delahunt, McGroarty, De Vito, & Ditroilo, 2016; Iga, Fruer, Deighan, Croix, & James, 2012; Mjølsnes, Arnason, Osthagen, Raastad, & Bahr, 2004). In addition, two RCTs (Petersen, Thorborg, Nielsen, Budtz-Jorgensen, & Holmich, 2011; van der Horst, Smits, Petersen, Goedhart, & Backx, 2015) and one intervention study (Arnason, Andersen, Holme, Engebretsen, & Bahr, 2008) found that the NHE could prevent up to 70% of HI in football players.

Cohort studies have found that reduced eccentric knee flexor strength (Opar et al., 2015; Timmins et al., 2015; van Dyk et al., 2016), strength imbalance (hamstrings to quadriceps (H:Q) ratio) (Cameron, Adams, & Maher, 2003; Croisier, Ganteaume, Binet, Genty, & Ferret, 2008; Orchard, Marsden, Lord, & Garlick, 1997) and fatigue (Brooks, Fuller, Kemp, & Reddin, 2006; Ekstrand, Hägglund, & Walden, 2011b; Woods et al., 2004) are potential intrinsic risk factors for HI in various football codes. Previous studies examining the effect of the FIFA 11+ programme on eccentric knee flexor strength have shown a within-group increase ranging from 5.9-14.3% (Brito et al., 2010; Impellizzeri et al., 2013; Reis, Rebelo, Krustrup, & Brito, 2013), with the exception of Daneshjoo, Mokhtar, Rahnama, and Yusof (2013a) who found a reduction of 10.1%. These studies used isokinetic dynamometry as measurement of strength, which has been the gold standard measure for the last decades (Aagaard, Simonsen, Magnusson, Larsson, & Dyhre-Poulsen, 1998). Recently, a field testing device, called the NordBord, has been developed and designed specifically to obtain objective measurements of eccentric knee flexor strength and overcome the limitations of these isokinetic measurements (Opar, Piatkowski, Williams, & Shield, 2013).

The purpose of this RCT was therefore to examine the effect of the FIFA11+ programme on eccentric knee flexor strength as measured using the NordBord in adolescent elite male football players. To our knowledge, this was the first ever study to assess this. This master's thesis was part of an RCT where the overall aim was to examine the hip adductor strength effects of an exercise called the CAE, using the same protocol as the NHE in the FIFA 11+ programme.

2.0 OBJECTIVE

The purpose of this RCT was to examine the effect of the FIFA 11+ programme on eccentric knee flexor strength as measured using the NordBord in adolescent elite male football players.

2.1 Hypotheses

H_A: There would be an increase in eccentric knee flexor strength for adolescent elite male football players performing the ordinary FIFA 11+ programme.

H₀: There would be no change in eccentric knee flexor strength for adolescent elite male football players performing the FIFA 11+ programme, when replacing the NHE with the CAE.

3.0 THEORY BACKGROUND

3.1 Hamstring injury

3.1.1 Classification and definition

A sports injury may be categorised as being either an acute injury or overuse injury depending on the mechanism of injury and the onset of symptoms (Brukner & Khan, 2017). Acute injuries have a clear onset of pain, usually due to a direct blow or knock, while overuse injuries are more complex and develop over time as a result of several possible aspects (Bahr, McCrory, LaPrade, Meeuwisse, & Engebretsen, 2014). Acute muscle injuries are strains, contusions or cramps (Brukner & Khan, 2017). Overuse muscle injuries are usually presented as tendinopathies, delayed onset muscle soreness (DOMS), chronic compartment syndrome or focal tissue thickening/fibrosis (Brukner & Khan, 2017). Muscle injuries, defined as both acute and due to overuse, have a high incidence, constituting almost one-third of all time-loss injuries in men's professional football, and 92% of all injuries affect the four big muscle groups in the lower limb (hamstrings, adductors, quadriceps and calf muscles) (Ekstrand, Hägglund, & Walden, 2011a).

Different studies looking at HI both have, and have not, distinguished between acute muscle injuries and overuse muscle injuries in their definition of a HI. Due to this, the definition of HI in the current study follows Ekstrand, Waldén & Hägglund (2016), who defined HI as a traumatic distraction or overuse injury to the hamstring muscle group, including both first-time and recurrent injuries.

3.1.2 Epidemiology and injury consequences

HI is known to be the most common injury type in sports involving sudden acceleration and maximal sprinting such as the various football codes (Arnason et al., 2004; Brooks et al., 2006; Ekstrand et al., 2011b; Elliott, Zarins, Powell, & Kenyon, 2011; Gabbe, Bennell, Finch, Wajswelner, & Orchard, 2006), athletics (Alonso et al., 2010) and cricket (Orchard, James, & Portus, 2006). HI have increased by 4% annually in elite male football from 2001 to 2014 (Ekstrand, Waldén, & Hägglund, 2016), accounting for 12% of all injuries (Ekstrand et al., 2011a; Woods et al., 2004) and representing 37% of all muscle injuries sustained (Ekstrand et al., 2011a). A football team with 25 players typically suffers 5-7 HI each season (Ekstrand et al., 2011b; Ekstrand et al., 2016), equivalent to between 80-90 days lost due to injury (Ekstrand et al., 2016; Woods et al., 2004) and an average HI burden of 19.7 days per 1000 h (Ekstrand et al., 2016). This results in substantial financial losses for elite football clubs

(Woods, Hawkins, Hulse, & Hodson, 2002). HI also have a high recurrence rate, ranging from 12% to 63% across different sports (Brooks et al., 2006; Ekstrand et al., 2011b; Elliott et al., 2011; Hägglund, Waldén, & Ekstrand, 2006; Malliaropoulos, Isinkaye, Tsitas, & Maffulli, 2011; Petersen, Thorborg, Nielsen, & Holmich, 2010; Woods et al., 2004).

3.1.3 Anatomy

Biceps femoris, semitendinosus and semimembranosus make up the hamstring muscle group (see Figure 1) (Brukner & Khan, 2017). The biceps femoris muscle consist of two heads – a short and a long head where the long head share a common proximal tendon with semitendinosus (Brukner & Khan, 2017). While muscle fibers from the long head of the biceps femoris originate from the lateral aspect of the mutual tendon just below the ischial tuberosity, the short head originates from the linea aspera and only functions at the knee joint (Brukner & Khan, 2017). The two heads of the biceps femoris shape a mutual distal tendon that has several insertions, including the lateral femoral epicondyle, fibular head and popliteus tendon (Brukner & Khan, 2017). For semitendinosus, the muscle fibers originate from the ischial tuberosity and the medial aspect of the mutual tendon, and inserts onto the proximal tibia as part of the pes anserine (Brukner & Khan, 2017). The proximal semimembranosus tendon arises from the lateral facet of the ischial tuberosity and inserts distally onto the medial tibial condyle (Brukner & Khan, 2017).

In addition to the three main muscles, the posterior part of the adductor magnus functions as if it were a "hamstring" being a strong hip extensor muscle, especially when the hip is flexed (Brukner & Khan, 2017). The adductor magnus muscle is innervated by the tibial portion of the sciatic nerve, just like the majority of the hamstring muscles (Brukner & Khan, 2017).



Figure 1: The anatomy of the posterior thigh; muscles and proximal origin. Reproduced with permission from Brukner & Khan (2017) page 680 (see Appendix D).

3.1.4 Pathophysiology

Acute distractive injury to the hamstring muscle group

A muscle is strained when some of the fibers fail to cope with the excessive tensile and/or shear forces (Brukner & Khan, 2017). Brukner and Khan (2017) classify muscle strains into three grades. A grade I strain involves only a few muscle fibers and causes localised pain but none to minimal loss of strength. A grade II strain comprises a significant number of muscle fibers with associated pain and swelling which can be reproduced when clinically tested. A grade III strain is a complete tear of the muscle with a complete loss of function.

Acute hamstring strain injuries are generally divided into type I (see Figure 2) and type II (see Figure 3), based on the localization of the injury and injury mechanism (Brukner & Khan, 2017). Type I hamstring strain injury is the most prevalent and occur at high-speed running (Askling, Tengvar, Saartok, & Thorstensson, 2007a, 2007b; Askling & Thorstensson, 2008; Brooks et al., 2006; Gabbe, Bennell, Finch, et al., 2006; Verrall, Slavotinek, Barnes, & Fon, 2003; Woods et al., 2004) and commonly involve the proximal muscle-tendon junction of the long head of biceps femoris (Askling et al., 2007a; Askling & Thorstensson, 2008). The

presence of high eccentric forces and the long muscle length of the hamstrings during the terminal swing phase of gait (Chumanov, Heiderscheit, & Thelen, 2007, 2011; Thelen et al., 2005; Yu et al., 2008) are likely to contribute to this type of HI (Opar, Williams, & Shield, 2012). Acute hamstring strain injuries type II may occur at slow speed during movements leading to extensive lengthening of the hamstrings when in increased hip flexion combined with knee extension, such as sagittal splits, sliding tackles and high kicking (Askling, Lund, Saartok, & Thorstensson, 2002; Askling, Tengvar, Saartok, & Thorstensson, 2000; Askling et al., 2007a, 2007b; Askling & Thorstensson, 2008). Type II hamstring strains are accordingly called the stretching type and are often seen in gymnasts and ballet dancers with the injury typically located close to the ischial tuberosity with involvement of the proximal free tendon of the semimembranosus (Askling et al., 2007b; Askling, Tengvar, Saartok, & Thorstensson, 2008). Some studies looked into the consequences of involvement of the proximal free tendon of semimembranosus versus the proximal muscle-tendon junction of the long head of biceps femoris in hamstring strain injuries on recovery time (Askling et al., 2007b, 2008; Askling & Thorstensson, 2008). They showed that involvement of the proximal free tendon of semimembranosus was associated with a prolonged time to return to sport. The closer the site of maximum pain palpation was to the ischial tuberosity, the longer the rehabilitation period. The proximal free tendon of the semimembranosus has a length of more than 10 cm, so the stretching type of hamstring strain can in fact be considered a tendon injury (Woodley & Mercer, 2005).



Figure 2: Type I hamstring injury shown on MRI. Reproduced with permission from Brukner & Khan (2017) page 688 (see Appendix D).



Figure 3: Type II hamstring injury shown on MRI. Reproduced with permission from Brukner & Khan (2017) page 689 (see Appendix D).

Overuse injury to the hamstring muscle group

Overuse muscle injuries are frequently attributed to muscle imbalances (Brukner & Khan, 2017). Imbalance can lead to changes in muscle length and strength between the agonist and antagonist muscles (for HI, known as the H:Q strength ratio), which in turn can affect the overall muscle function (Brukner & Khan, 2017).

The hamstring muscle group might occasionally be affected by tendinopathies to the proximal tendon (Brukner & Khan, 2017). In the active population and especially in sports that involve jumping or long-distance running, proximal hamstring tendinopathy might be the main reason for long-term pain (Fredericson, Moore, Guillet, & Beaulieu, 2005; Lempainen, Sarimo, Mattila, Vaittinen, & Orava, 2009) but it can also affect people who do not participate in sport (Jesus et al., 2015; Lempainen et al., 2009). The location of proximal hamstring tendinopathy might vary between the different hamstring muscles (Benazzo, Marullo, Zanon, Indino, & Pelillo, 2013; Lempainen et al., 2009). The pain is exacerbated by repetitive activity, such as sitting and stretching, and characterised as a gradually increasing onset of pain in the deep buttock or posterior thigh (Brukner & Khan, 2017).

Soreness is often a factor that accompanies muscle strains (Brukner & Khan, 2017). Delayed onset muscle soreness (DOMS) is a well-known type of muscle soreness that develops 24 to 48 hours after unaccustomed high-intensity physical activity (Brukner & Khan, 2017).

Usually soreness arises within the first day after exercise and peaks approximately 48 hours after exercise (Herbert, de Noronha, & Kamper, 2011). DOMS appears to be more severe after eccentric exercise (Brukner & Khan, 2017) and this is further discussed in chapter *3.2.1*.

Chronic compartment syndrome is commonly found in the lower leg but can also rarely be seen in the hamstring muscle group (Brukner & Khan, 2017). Sportspeople with a history of HI and endurance sportspeople without a trauma are two groups of patients that have been reported with this syndrome (Brukner & Khan, 2017). The pain is characterised as a dull pain most often combined with cramps, weakness and stiffness of the hamstrings during and after training (Brukner & Khan, 2017).

Other conditions may also cause pain to the hamstring muscle group. This may typically be referred pain from the lumbar spine/nerve entrapments, sacroiliac joint or from different soft tissues (Brukner & Khan, 2017).

3.1.5 Risk factors for hamstring injury

Several different studies have examined the risk factors for HI in various football codes. Multiple potential intrinsic risk factors have been suggested (see Figure 4), such as higher age (Arnason et al., 2004; Freckleton & Pizzari, 2013; Gabbe, Bennell, & Finch, 2006; Gabbe, Bennell, Finch, et al., 2006; Gabbe, Finch, Bennell, & Wajswelner, 2005; Henderson, Barnes, & Portas, 2010; Hägglund et al., 2006; Orchard, 2001; Prior, Guerin, & Grimmer, 2009; Verrall, Slavotinek, Barnes, Fon, & Spriggins, 2001; Woods et al., 2004), ethnicity (Prior et al., 2009; Verrall et al., 2001; Woods et al., 2004), previous HI (Arnason et al., 2004; Bennell et al., 1998; Engebretsen, Myklebust, Holme, Engebretsen, & Bahr, 2010; Freckleton & Pizzari, 2013; Gabbe, Bennell, Finch, et al., 2006; Hägglund, Walden, & Ekstrand, 2013; Hägglund et al., 2006; Orchard, 2001; Prior et al., 2009; Verrall et al., 2001; Warren, Gabbe, Schneider-Kolsky, & Bennell, 2010), decreased hamstring flexibility (Bradley & Portas, 2007; Timmins et al., 2015; Witvrouw, Danneels, Asselman, D'Have, & Cambier, 2003), reduced eccentric knee flexor strength (Opar et al., 2015; Timmins et al., 2015; van Dyk et al., 2016), strength imbalance (H:Q strength ratio) (Cameron et al., 2003; Croisier et al., 2008; Orchard et al., 1997) and fatigue (Brooks et al., 2006; Ekstrand et al., 2011b; Woods et al., 2004). Extrinsic risk factors have barely been investigated, but higher level of competition (Prior et al., 2009; Verrall et al., 2001; Woods et al., 2004) and match play (Ekstrand et al.,

2011a; Ekstrand et al., 2016) are suggested to have an association with an increased rate of HI.



Figure 4: Intrinsic (blue circles) and extrinsic (orange circle) risk factors for HI.

Higher age

As mentioned earlier, higher age has a lot of support in the literature as an intrinsic risk factor for HI. Most of the studies did not consider the reasons behind this and instead made some vague hypotheses. One exception is the cohort study by Gabbe et al. (2006). The sample in this cohort was 448 Australian male amateur and professional football players. The results showed that increased body weight and decreased hip flexor flexibility were significant predictors of HI in players aged ≥ 25 years, but not in the younger players (aged ≤ 20 years). The cohort study by Orchard (2001), looking at 2255 matches/83 503 player-matches in the Australian Football League between 1992 and 1999, supports the finding of greater body weight (expressed as body mass index) as a predictive factor for HI in older players (<23 years). However, the study showed that body mass index correlated highly with player age and previous injury, being a possible confounding factor.

A cohort study by Brooks et al. (2006) looking at men's professional rugby in England and recording 16 782 hours of match exposure and 196 409 hours of training exposure, found no significant association between higher age and HI. Bradley and Partas' (2007) cohort study that examined 36 English professional football players showed similar results, as did the systematic review by Foreman et al. (2006). However, the systematic review by Prior et al. (2009) and the meta-analysis from Freckleton and Pizzari (2013) identified higher age as a risk factor for HI.

Ethnicity

Three cohort studies (Brooks et al., 2006; Verrall et al., 2001; Woods et al., 2004), two systematic reviews (Foreman et al., 2006; Prior et al., 2009) and one meta-analysis (Freckleton & Pizzari, 2013) have evaluated the ethnic origin of athletes as a potential intrinsic risk factor for HI. Verrall et al. (2001) found an increased risk of HI in players of Aboriginal descent, while Woods et al. (2004) showed identical risk in players of black origin. These findings are supported by the systematic review of Prior et al. (2009). Both excessive anterior pelvic tilt (Hennessey & Watson, 1993; Woods et al., 2004) and high proportions of type II fibers (Friden & Lieber, 1992) have been suggested as possible risk factors for HI in these populations. The cohort by Brooks et al. (2006) showed that the incidence of injury among people with Black African or Caribbean descent was almost four times that of people with white origin, but the difference was not significant. Ethnicity was not included in the meta-analysis by Freckleton and Prior (2013) due to limitations of studies, but their systematic review found conflicting evidenced regarding ethnicity as an intrinsic risk factor for HI.

Previous HI

16 studies have reported on previous HI as an potential intrinsic risk factor for a new HI (Arnason et al., 2004; Bennell et al., 1998; Engebretsen et al., 2010; Foreman et al., 2006; Fousekis, Tsepis, Poulmedis, Athanasopoulos, & Vagenas, 2011; Freckleton & Pizzari, 2013; Gabbe, Bennell, Finch, et al., 2006; Henderson et al., 2010; Hägglund et al., 2013; Hägglund et al., 2006; Koulouris, Connell, Brukner, & Schneider-Kolsky, 2007; Orchard, 2001; Orchard et al., 1997; Prior et al., 2009; Verrall et al., 2001; Warren et al., 2010). The studies looked at players participating in either football or Australian Rule Football. Of these, only four studies did not find an association between previous HI and a new HI (Fousekis et al., 2011; Henderson et al., 2010; Koulouris et al., 2007; Orchard et al., 1997). The study by Fousekis et al. (2011) even showed that a history of HI could be protective against recurrent HI.

To identify the predisposing factor(s) responsible for an HI should have the highest priority (Croisier, 2004a). A player will remain at a higher risk of getting a new HI despite being able to return to sport, if this factor is not taken care of (Croisier, 2004a). Several studies have examined the consequences of a HI on eccentric knee flexor strength and comparisons between previously injured and uninjured limbs or previously injured and between uninjured athletes identified substantial deficits in the previously injured hamstrings (Croisier, 2004a, 2004b; Croisier & Crielaard, 2000; Croisier, Forthomme, Namurois, Vanderthommen, & Crielaard, 2002; Dauty, Potiron-Josse, & Rochcongar, 2003; Jønhagen, Nemeth, & Eriksson, 1994; Lee, Reid, Elliott, & Lloyd, 2009; Opar, Williams, Timmins, Dear, & Shield, 2013; Tol et al., 2014). According to Sugiura, Saito, Sakuraba, Sakuma, and Suzuki (2008), between-leg strength asymmetries of around 4.5% in eccentric knee flexor strength after a HI was associated with re-injury. Croisier et al. (2002) found deficits of up to 22-24% after a HI. The majority of these studies used isokinetic strength measurements months to years after a HI and a long time after return to sport (Croisier & Crielaard, 2000; Croisier et al., 2002; Dauty et al., 2003; Jønhagen et al., 1994; Lee et al., 2009; Tol et al., 2014), which suggests that if reduced strength is a consequence of injury it appears to be long lasting (Fyfe, Opar, Williams, & Shield, 2013).

Decreased hamstrings flexibility

Three cohort studies (Bradley & Portas, 2007; Timmins et al., 2015; Witvrouw et al., 2003) and one case-control study (Watsford et al., 2010) looking at 470 football players in total from England, Australia and Belgium, identified decreased hamstring flexibility as an intrinsic risk factor for HI. Timmins et al. (2015) showed that biceps femoris long head fascicle length below 10.56 cm increased the risk of HI 4.1 fold. The methods and body positions used to measure hamstrings flexibility were different between the studies, making comparisons more difficult. While Witvrouw et al. (2003) measured hamstrings flexibility with a goniometer in a passive straight-leg raise test, Bradley and Portas (2007) used a 2-dimensional image-based analysis in a sitting position with the knee flexed. Timmins et al.

(2015) measured hamstrings flexibility through fascicle length of the biceps femoris long head using ultrasound with the person in prone and the knee fully extended and Watsford et al. (2010) used a submaximal Kham test with the athletes in prone lying. While Timmins et al. (2015) used biceps femoris long head fascicle length below 10.56 cm as a definition of decreased hamstrings flexibility, Witvrouw et al. (2003) used perhaps a more practical definition, showing that a hamstring flexibility less than 90° in a passive straight-leg raise correlated significantly with HI. To measure fascicle length is still a disputed method (Ema, Akagi, Wakahara, & Kawakami, 2016) and it also might be as a measurement of hamstrings flexibility.

Prospective studies examining a total of 404 Australian Rule footballers (Bennell, Tully, & Harvey, 1999; Gabbe, Bennell, & Finch, 2006; Gabbe et al., 2005; Orchard et al., 1997) and 306 Icelandic football players (Arnason et al., 2004), found no association between decreased hamstrings flexibility and increased risk of HI. However, according to Foreman et al. (2006), only Arnason et al. (2004) used reliable measures of hamstrings flexibility. Two systematic reviews (Foreman et al., 2006; Prior et al., 2009) and one meta-analysis (Freckleton & Pizzari, 2013) showed conflicting evidenced regarding decreased hamstrings flexibility as an intrinsic risk factor for HI.

Reduced eccentric knee flexor strength

Three cohort studies (Opar et al., 2015; Timmins et al., 2015; van Dyk et al., 2016) found reduced eccentric knee flexor strength to be associated with an increased risk of HI. The study by Opar et al. (2015) followed 210 elite Australian Rule footballers for one season and measured eccentric knee flexor strength using the NordBord at the commencement and conclusion of preseason training and at the midpoint of the season (Opar, Piatkowski, et al., 2013). Opar et al. (2015) reported eccentric knee flexor strength both in absolute terms (N) and corrected for bodyweight (N/kg), and found that eccentric knee flexor strength below 3.16 N/kg at the start of the preseason and 3.45 N/kg at the end of the preseason increased the risk of HI 3.1 fold and 5.0 fold, respectively. Interestingly, a between-limb imbalance of 10%, 15% or 20% in eccentric knee flexor strength did not increase the risk of HI and high eccentric knee flexor strength appeared to offset the inherently greater risk of HI associated with increasing age and previous HI (Opar et al., 2015). Timmins et al. (2015) examined 152 elite Australian football players during the preseason and in-season period, measuring eccentric knee flexor strength by using the NordBord. Their results showed that athletes with

eccentric knee flexor strength below 4.35 N/kg had 2.5 fold greater risk of HI than stronger players. Due to different sporting populations utilised in these two studies, the receiver operator characteristics curve determined threshold for an elevated risk of HI was different (3.16/3.45 N/kg vs 4.35 N/kg). While Opar et al. (2015) and Timmins et al. (2015) used the NordBord for measuring eccentric knee flexor strength, the 4-year cohort by van Dyk et al. (2016) used isokinetic testing procedures. This study of 614 elite football players from the Qatar Stars League, found that players with reduced eccentric knee flexor strength adjusted for bodyweight had a odds ratio of 1.37 for getting a HI (van Dyk et al., 2016).

Two systematic reviews (Foreman et al., 2006; Prior et al., 2009) showed conflicting evidence and two cohort studies (Bennell et al., 1998; Engebretsen et al., 2010) and one meta-analysis (Freckleton & Pizzari, 2013), found no association between eccentric knee flexor strength and increased risk for HI. All of these conclusions are based on isokinetic testing procedures as measurements of eccentric knee flexor strength. Opar et al. (2015) considered the different testing methods to be the most likely explanation of the contrasting findings between their study and the work from Bennell et al. (1998). However, van Dyk et al. (2016) used similar testing procedures as Bennell et al. (1998) and still found reduced eccentric knee flexor strength to be an intrinsic risk factor for HI. Different methods of measuring eccentric knee flexor strength and their validity and reliability are to be discussed in chapter *3.3*.

Strength imbalance (H:Q strength ratio)

There are different ways to measure H:Q strength ratio both in type of muscle contraction and speed of testing (Freckleton & Pizzari, 2013). The conventional hamstrings to quadriceps strength ratio (H: Q_{conv}), which describes the concentric strength imbalance, has traditionally been the measurement of choice (Burkett, 1970; Heiser, Weber, Sullivan, Clare, & Jacobs, 1984; Orchard et al., 1997). However, due to the powerful eccentric contraction of the hamstrings during the terminal swing phase of gait (Chumanov et al., 2007, 2011; Thelen et al., 2005; Yu et al., 2008) a more functional strength ratio (H: Q_{func}), describing the eccentric hamstrings to concentric quadriceps strength, has been popularised (Bennell et al., 1998; Croisier et al., 2003; Engebretsen et al., 2010; van Dyk et al., 2016).

The cohort study by Croisier et al. (2008) followed 462 football players from professional teams in Belgium, Brazil and France for one season and identified that strength imbalances, which included $H:Q_{conv}$ strength ratio below 0.45-0.47 Nm and $H:Q_{func}$ strength ratio below

0.80-0.89 Nm, increased the risk of HI. Athletes with untreated strength imbalances had a 4.7 times greater risk of suffering a HI compared with players showing no imbalance (Croisier et al., 2008). Similar findings had the cohort by Cameron et al. (2003), looking at 20 elite players of Australian football for one season, with their results showing that a reduced $H:Q_{conv}$ strength ratio gave an increased risk of HI. These results were supported by Orchard et al. (1997), who studied a cohort of 37 professional Australian Rule footballers over one season. Cameron et al. (2003) also developed cut-off values based on their findings and a $H:Q_{conv}$ strength ratio of 0.66 Nm was determined to be an optimum cut-off value. It is important to consider, however, that the study by Cameron et al. (2003) and Orchard et al. (1997) are small studies. Bahr and Holme (2003) suggests that prospective studies require 20-50 injured subjects to detect small to moderate associations between risk factors and injury risk.

Three cohort studies (Bennell et al., 1998; Henderson et al., 2010; van Dyk et al., 2016) examining 102 Australian Rule footballers and 650 football players concluded that reduced H:Q strength ratio was not an intrinsic risk factor for HI. This finding was supported by the meta-analysis of Freckleton and Pizzari (2013). Bennell et al. (1998) and van Dyk et al. (2016) measured both H:Q_{conv} and H:Q_{func} strength ratios, while Henderson et al. (2010) measured only H:Q_{conv}. The meta-analysis included studies which used a number of different methods to measure H:Q strength ratio. Two systematic reviews (Foreman et al., 2006; Prior et al., 2009) found no consistent association between reduced H:Q strength ratio and increased risk of HI.

Fatigue

The cohort study by Ekstrand et al. (2011b) of 23 European professional football clubs from 2001-2008 showed that the incidence of HI during matches increased during the latter stages of each half, suggesting that fatigue might be a predisposing factor for such injuries. These results are supported by Woods et al. (2004), who looked at 91 football clubs from England from 1997-1999 and Brooks et al. (2006), who studied 12 English rugby clubs from 2002-2004. In the study by Woods et al. (2004), 47% of HI sustained during matches occurred during the last third of the first and second halves of the match. Studies of physical demands in football have found that fatigue is developed towards the end of a match, and the amount of high-intensity running and technical performance is lowered (Bangsbo, Iaia, & Krustrup, 2007; Mohr, Krustrup, & Bangsbo, 2003; Rampinini, Impellizzeri, Castagna, Coutts, & Wisloff, 2009). Athletes who exhibit greater levels of eccentric hamstrings fatigue would be

expected to be at a higher risk of a HI with prolonged activity, given the association between eccentric knee flexor strength weakness and HI risk (Opar et al., 2015; Timmins et al., 2015; van Dyk et al., 2016). A laboratory study by Greig and Siegler (2009) of 10 male professional footballers showed that the eccentric knee flexor strength reduced over time and, in particular, after the half-time interval. Agre (1985) suggested that the association between fatigue and the increased risk for HI might be because muscle fatigue influences the neural system, specifically the dual innervation of the two heads of biceps femoris, which can cause a mistimed contraction of the muscles and a possibly reduced ability to generate sufficient force.

The systematic review by Prior et al. (2009) showed conflicting evidence regarding fatigue as an intrinsic risk factor for HI. Arnason et al. (2004) and Orchard et al. (1997) both found no association between poor aerobic capacity (described as decreased VO_2 max), which could be involved with general fatigue, and the risk for HI.

Higher level of competition and match play

In two cohort studies (Verrall et al., 2001; Woods et al., 2004) of 2490 professional footballers (football and Australian Rules) in total from England and Australia, the prevalence of HI was greater at higher levels of competition. The study by Verrall et al. (2001) showed a difference in prevalence by more than 20% between players at the highest level of play and players at the lower level of competition. In the study by Woods et al. (2004) HI were the most common in the Premiership and became less common in the lower leagues. The systematic review by Prior et al. (2009) supports the finding of higher level of competition as an extrinsic risk factor for HI. While infrequently reported, the prevalence of HI in amateur sport was at the lower end of the reported range of all studies (8-16%) (Gabbe, Branson, & Bennell, 2006; Gabbe et al., 2005). Verrall et al. (2001) suggested that since elite players were involved in longer and more frequent training sessions and played in matches that were more intense, they were at a higher risk of suffering a HI.

The cohort study by Ekstrand et al. (2016) and Ekstrand et al. (2011a), looking at 36 and 51 European football teams respectively, found match play to be an extrinsic risk factor for HI. Ekstrand et al. (2016) showed that playing a match gave an 9.4 times greater risk of getting a HI compared to completing a training session (4.77 vs 0.51 injuries per 1000 h). Similar findings had the study by Ekstrand et al. (2011a) with their results showing an incidence of HI during matches of 3.70 injuries per 1000 h vs 0.43 injuries per 1000 h in training. A lot of the reason behind this has been given to the high-intensity running distance and actions occurring during matches (Barnes, Archer, Hogg, Bush, & Bradley, 2014). Arnason et al. (2004), found in contrast, no association between match play and an increased risk of HI.

3.2 Eccentric resistance training

Resistance training includes the use of either concentric, eccentric or static muscle actions with or without an external load (Hoppeler, 2014; Roig et al., 2009). Eccentric resistance training is training using only the lowering phase of an exercise; lengthening the agonist and synergists (Hoppeler, 2014). Hather, Tesch, Buchanan, and Dudley (1991) suggested that eccentric resistance training could stimulate greater adoptions compared to concentric training. This is possibly explained by the higher magnitude of force developed during an eccentric muscle action, which is thought to be proportional to the increase in muscular strength (Hoppeler, 2014). Findings in the meta-analysis by Roig et al. (2009) showed that strength gains after eccentric resistance training appeared more specific in terms of velocity and mode of contraction compared to concentric training. Eccentric muscle actions of the quadriceps and hamstrings have shown higher absolute forces compared to concentric actions (Crenshaw, Karlsson, Styf, Backlund, & Friden, 1995; Westing, Cresswell, & Thorstensson, 1991; Westing & Seger, 1989). Subgroup analyses identified these higher loads as the reason for the superiority of eccentric resistance training to increase muscle strength and mass (Roig et al., 2009).

Compared with concentric muscle actions, eccentric actions have also shown to possess some distinct physiological properties regarding different neurological patterns (Enoka, 1996). Eccentric muscle actions have shown more rapid neural adaptions secondary to resistance training (Hortobagyi et al., 1996), enlarged cross-education effect (Hortobagyi, Lambert, & Hill, 1997) and a quicker and wider cortical activity as movements are being performed (Fang, Siemionow, Sahgal, Xiong, & Yue, 2001). This specialised neural pattern of eccentric muscle actions possibly explains the high specificity of strength gains after eccentric resistance training (Roig et al., 2009).

Guex, Degache, Morisod, Sailly, and Millet (2016) and Potier, Alexander, and Seynnes (2009) found an increase in biceps femoris long head fascicle length after eccentric resistance training using seated and prone hamstring curls, respectively. The same findings had the

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intervention study by Alonso-Fernandez, Docampo-Blanco, and Martinez-Fernandez (2017) using the NHE. Training at longer muscle lengths also lead to greater adaptions (Guex et al., 2016). These findings were, however, not supported by the RCT of Seymore, Domire, DeVita, Rider, and Kulas (2017) which used the NHE and found fascicle length of the biceps femoris long head not to increase. The review by Ema et al. (2016), concluded that further evidence is required for the association between eccentric resistance training and longer fascicle lengths.

3.2.1 Delayed onset muscle soreness

Eccentric resistance training that gives symptoms of DOMS will result in a decrease in muscular strength (Byrne, Twist, & Eston, 2004). Byrne et al. (2004) showed that outcomes of DOMS related to muscular strength, such as persistent losses of power and strength, impaired neuromuscular control, selective type II fiber damage and reflex inhibition, might negatively influence dynamic movements that are associated with athletic activity. An increase in subjective effort, as well as elevated physiological responses are consequences of performing endurance training in the presence of DOMS (Byrne et al., 2004). This is likely to impair performance and training. However, it is still unknown if DOMS represents a problem in an applied athletic setting even if the potential to adversely influence performance is evident (Byrne et al., 2004). Anyway, coaches and athletes should aspire to identify the possible negative effects of DOMS in different activities and adjust competition and training to accommodate exposure to DOMS (Byrne et al., 2004).

3.3 Strength measurements for eccentric knee flexor strength

3.3.1 Isokinetic dynamometry

For the last decades, and probably currently, the gold standard measure for the assessment of eccentric knee flexor strength has been isokinetic dynamometry (Aagaard et al., 1998). This is an objective testing method of human muscle function on variables related to torque, power and endurance with a constant velocity with accommodating resistance throughout a joint's range of motion (Drouin, Valovich-McLeod, Shultz, Gansneder, & Perrin, 2004). There are various types of isokinetic dynamometry devices and studies looking at their reliability have been completed (Drouin et al., 2004; Impellizzeri, Bizzini, Rampinini, Cereda, & Maffiuletti, 2008; Maffiuletti, Bizzini, Desbrosses, Babault, & Munzinger, 2007). The Con-Trex isokinetic dynamometer showed moderate to high reliability of concentric, eccentric and isometric knee flexor and extensor muscle strength (Maffiuletti et al., 2007). Impellizzeri et

al. (2008) studied the reliability of the Cybex Humac Norm dynamometer and found high to very high reliability for absolute concentric and eccentric muscle strength (peak torque) of the knee flexor and extensor muscles. Drouin et al. (2004) investigated the reliability and validity of the Biodex System 3 Pro quantitatively and their results showed that with the exception of a systematic decrease in velocity of 300°/s and higher, the testing device performed with acceptable mechanical reliability and validity on all variables tested. The eccentric mode was not evaluated (Drouin et al., 2004). A study of inter-machine reliability of the Biodex System 3 Pro and Cybex Humac Norm Model 770 indicated a high to very high reproducibility for isometric, concentric and eccentric knee flexor and extensor peak torques and moderate to high reliability for H:Q strength ratios (de Araujo Ribeiro Alvares et al., 2015). This suggests that it is possible to extrapolate individual values from one machine to another and compare results from studies and clinical testing using these two different testing devices with relative safety (de Araujo Ribeiro Alvares et al., 2015).

Even if isokinetic dynamometry has been found to be a valid and reliable testing method, it is limited by its high cost and therefore a lack of widespread availability (Opar, Piatkowski, et al., 2013). It has also showed to take up to 25 min per athlete assessed (Whiteley et al., 2012) making it more time-consuming in a clinical setting. In addition, regarding the use of isokinetic testing to determine the association between strength differences and HI, the cohort study by van Dyk et al. (2016) found this not be supported.

3.3.2 NordBord

NordBord is a recently developed field testing device, designed specifically to obtain objective measurements of eccentric knee flexor strength and overcome the limitations of isokinetic dynamometry (Opar, Piatkowski, et al., 2013). The NordBord is a 90 cm long and 60 cm wide padded board with two ankle hooks (see Figure 5). Since the exercise used for testing is the commonly employed NHE, the device has a special set-up (Opar, Piatkowski, et al., 2013). The ankle hooks are connected to two force cells that measure the force (in Newton) at which the ankle hooks are being pulled. The force measured by the two force cells is transmitted in real time to a host computer/tablet via a USB cable. The device is able to record various eccentric knee flexor strength values and between-limb imbalance, with the exception of angle of peak torque, (Opar, Piatkowski, et al., 2013). The time of an assessment has been found to take less than 2 min per athlete (Opar et al., 2015). The reliability and casecontrol injury study by Opar, Piatkowski et al. (2013) found the NordBord to have moderate to high test-retest reliability for measurements when the NHE was performed bilaterally, but poor reliability during unilateral testing. Regarding measurements of absolute eccentric knee flexor strength, the NordBord showed moderate reliability only when the NHE was completed bilaterally and peak force was averaged across six trials (two sets of three repetitions) (Opar, Piatkowski, et al., 2013). Compared to measurements made with an isokinetic (Drouin et al., 2004; Impellizzeri et al., 2008; Maffiuletti et al., 2007) or hand-held dynamometer (Whiteley et al., 2012), the NordBord showed similar or slightly lower levels of reliability (Opar, Piatkowski, et al., 2013). Impellizzeri et al. (2008) has been identified as the only study that examined the reliability of between-limb eccentric knee flexor strength ratios using an isokinetic dynamometer. Compared to Opar, Piatkowski et al. (2013) they reported a lower test-retest reliability. Findings regarding the correlation between the NordBord and isokinetic dynamometry, and the NordBord and hand-held dynamometry have, as far as our study concerned, yet to be reported.



Figure 5: The NordBord testing device seen from above and from the side.

3.3.3 Hand-held dynamometry

A hand-held dynamometer is a portable device that can be used to obtain objective measures of strength during manual muscle testing (Kelln, McKeon, Gontkof, & Hertel, 2008). Hand-held dynamometers have become a popular and inexpensive field-based alternative, shown to take less than 4 min per player to conduct (Whiteley et al., 2012). Previous research has shown hand-held dynamometers only to be reliable in experienced hands under controlled conditions (Kelln et al., 2008) and a certain degree of strength is required in the

implementation (Bohannon, 1990). However, in a recent observational and reliability study by Whiteley et al. (2012) this was proven wrong. The same study found hand-held dynamometry to have excellent inter-rater reliability and medium to high correlation with isokinetic dynamometry when looking at absolute concentric and eccentric muscle strength (peak torque) of the knee flexor and extensor muscles (Whiteley et al., 2012).

3.4 The FIFA injury prevention programmes

In the beginning of the 20th century, an expert group convened by FIFA developed the 11 programme (Steffen, Myklebust, Olsen, Holme, & Bahr, 2008). The FIFA 11 was developed as a structured warm-up programme on the basis of previous research on injury prevention, with the purpose to prevent the most common injuries in football, i.e. knee and ankle sprains, hamstring and groin strains (Steffen, Myklebust, et al., 2008). The FIFA 11 programme consisted of 10 exercises focusing on core stability, balance, dynamic stabilisation and eccentric hamstring strength (see Appendix B) (Steffen, Myklebust, et al., 2008). The RCT by Steffen et al. (2008), which examined the effect of the FIFA 11 on Norwegian youth female football players, found no difference in the injury risk between the intervention group and the control group, though the study was limited by low compliance (52%) among the intervention teams. Similarly, in a RCT on Dutch adult male amateur football players, there were no differences in the overall injury incidence or injury severity between the intervention that completed the FIFA 11 programme and the control group even if the compliance was 73% (van Beijsterveldt et al., 2012).

Since the FIFA 11 programme was found to be ineffective in preventing football injuries, the development of the revised FIFA 11+ programme took place (Soligard et al., 2008). The FIFA 11+ aimed to improve both the preventive effect and the compliance of the coaches and players (Soligard et al., 2008). In addition to key exercises and progressions and variations of these, the FIFA 11+ programme included a new set of structured running exercises making it better suited as a comprehensive warm-up programme for training and matches (Soligard et al., 2008).

3.4.1 Literature search

To identify all available research evaluating the effects of the FIFA 11 and the FIFA 11+ on injury risk and/or physical performance, I systematically searched the following bibliographic databases: MEDLINE via PubMed, EMBASE via OVID, PEDro, Web of Science,

SPORTDiscus via EBSCO and Cochrane Central Register of Controlled Trials from 2004 to 29. March 2017. Since the FIFA 11 programme was developed between 2004-2005 (Dvorak, Junge, & Grimm, 2005; Junge et al., 2011), earlier years were not included in the literature search. A hand search of the reference lists of relevant articles was also conducted for other potentially relevant references. The search strategy was reproduced from Thorborg et al. (2017) and contained the following words: (fifa OR f-marc OR fmarc OR prevention program* OR warm-up program* OR warmup program* OR the11) AND (football OR foot ball OR soccer). A total of 34 articles were included based on title and abstract. After full-text evaluation, a total of 12 articles were excluded. Three articles due to study design, eight articles were found as not appropriate and one article was found written in Japanese only. For the purpose of investigating the effect of the FIFA injury prevention programmes on injury risk, only RCTs were included. Articles examining the effect of the FIFA programmes on physical performance, were included regardless of study design. Only articles written in English, Norwegian, Swedish or Danish were included. Table 1-4 shows the complete list of studies included, a total of 22 studies.

Table 1: Summary of the studi	es included investigating	g the effects of	f the FIFA 1.	l programme .	on injury risk.	
Study & design	Population	Duration	Frequency (no. per week)	Compliance (%)	Outcome	 Main result Results regarding knee flexor strength or prevention of HI
<i>Steffen, Myklebust et al. (2008)</i> Cluster-randomised controlled trial	Female 13-17 years N = 2100	8 months	-	52	Injury risk	 No effect on the incidence of injuries No data
<i>van Beijsterveldt et al. (2012)</i> Cluster-randomised controlled trial	Male 18-40 years N = 487	33 weeks	2	73	Injury risk	 No effect on the incidence of injuries No data

Table 2: Summary of the studies included investigating the effects of the FIFA 11 programme on physical performance.

tudy & design	Population	Duration	Frequency (no. per week)	Compliance (%)	Outcome	 Main result Results regarding knee flexor Rrength or prevention of HI
'effen, Bakka et al. (2008) andomised controlled trial	Female 16-18 years N = 36	10 weeks	ω	No data	Physical performance	 No effect on physical performance No effect on isokinetic concentric, eccentric or isometric hamstring strength
<i>ilding et al. (2008)</i> andomised controlled trial	Male Mean age 10.5 years N = 24	6 weeks	Ś	72	Physical performance	 Improved 3 step jump, counter- movement jump (CMJ) and 20 m sprint No data

Study & design	Population	Duration	Frequency	Compliance	Outcome	1) Main result
oma) ↔ acoign			(no. per week)	(%)		2) Results regarding knee flexor strength or prevention of HI
<i>Soligard et al. (2008)</i> Cluster-randomised	Female 13-17 years	8 months	دى ا	77	Injury risk	1) Reduced the risk of injury by about 33% and the risk of severe injury by 50%
controlled trial	N = 2540					2) No effect on preventing HI
Steffen, Emery et al. (2013) Cluster-randomised controlled trial	Female 13-18 years N = 226	4.5 months	2-3	88	Injury risk and physical performance	 Improved dynamic and functional balance. Reduced the risk of injury by 72% for highly compliant players compared to those less compliant No data
<i>Owoeye et al. (2014)</i> Cluster-randomised controlled trial	Male 14-19 years N = 416	6 months	2	60	Injury risk	 Reduced the risk of injury by 41% and all lower extremity injuries by 48% No data
<i>Hammes et al. (2015)</i> Randomised controlled trial	Male ≥ 32 years N = 383	9 months	-	86	Injury risk	 No effect on the incidence of injuries No data
<i>Silvers-Granelli et al. (2015)</i> Cluster-randomised controlled trial	Male 18-25 years N = 1625	5 months	U)	47	Injury risk	 Reduced the risk of injury by 46% Reduced the risk of HI by 63%

Table 3: Summary of the studies included investigating the effects of the FIFA 11+ programme on injury risk.

Study & design	Population	Duration	Frequency (no. per week)	Compliance (%)	Outcome	 Main result Results regarding knee flexor strength or prevention of HI
Brito et al. (2010) Intervention study (pre-post design)	Male Mean age 22.5 years N = 20	10 weeks	ω	73	Physical performance	 Increased the strength in most isokinetic parameters Increased Hcon 60°/ s by 20.4% in dominant limb and by 14.6% in non- dominant limb, and Hcon 180°/s by 15%, Hecc 30°/s by 14.3%, H:Qcon 60°/s by 14.8 % and Hecc30°:Qcon180° by 3.8% in non-dominant limb
Daneshjoo et al. (2012a) Controlled trial	Male $17-20$ years $N = 36$	2 months	e	No data	Physical performance	Within-group results regarding the FIFA 11+ group only: 1) Improved proprioception and balance 2) No data
<i>Daneshjoo et al. (2012b)</i> Controlled trial	Male $17-20$ years $N = 36$	2 months	Ś	No data	Physical performance	Within-group results regarding the FIFA 11+ group only: 1) and 2) Between-group analyses only showed an effect in H:Qcon 60°/s in the non-dominant limb Within-group analyses showed an increased fast:slow speed ratio in the knee extensor muscles in the non- dominant limb by 8%, increased H:Qcon 60°/s in the non- dominant limb by 8% and reduced Hecc:Qcon 120°/s by 40% and 30% in the dominant and non-dominant limb, respectively

Table 4: Summary of the studies included investigating the effects of the FIFA 11+ programme on physical performance.

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Study & design	Population	Duration	Frequency (no. per week)	Compliance (%)	Outcome	 Main result Results regarding knee flexor strength or prevention of HI
<i>Daneshjoo, Rahnama et al.</i> (2013) Controlled trial	Male 17-20 years $N = 36$	2 months	ς	No data	Physical performance	Within-group results regarding the FIFA 11+ group only: 1) Within-group analyses showed increased isometric strength in the knee flexor and extensor muscles, but between-group analyses showed no difference 2) Increased the isometric knee flexor strength in the dominant limb by 24.8% and 19.8% at 30° and 60° knee flexion and 13.7% at 30° and 60° knee flexion, respectively Between-group analyses showed no difference
Daneshjoo, Mokhtar et al. (2013a) Controlled trial	Male 17-20 years N = 36	2 months	ς	No data	Physical performance	Within-group results regarding the FIFA 11+ group only: 1) and 2) Within-group analyses showed increased concentric knee flexor strength in the dominant limb by 22%, 21.4% and 22.1% at $60\circ$ /s, 180 \circ /s and 300 \circ /s, respectively, and by 22.3% and 15.7% at $60\circ$ /s and 180 \circ /s in the non-dominant limb. Eccentric knee flexor strength reduced in the dominant limb by 7.5% and in the non-dominant limb by 10.1% at 120 \circ /s Between-group analyses showed no difference

Study & design	Population	Duration	Frequency (no. per week)	Compliance (%)	Outcome	 Main result Results regarding knee flexor strength or prevention of HI
Daneshjoo, Mokhtar et al. (2013b) Controlled trial	Male 17-20 years N = 36	2 months	ε	No data	Physical performance	Within-group results regarding the FIFA 11+ group only: 1) Between-group analyses showed improved 10m speed test with and with- out the ball, 20m single sprint and Illinois agility test Within-group analyses showed improved vertical jump, Wall-Volley test and Illinois agility test 2) No data
<i>Bizzini et al. (2013)</i> Intervention study (within-subject pre-post design with double baseline)	Male Mean age 25 years N = 20	1 day		100	Physical performance	 Improved 20m sprint, agility, stiffness, CMJ, squat jump (SJ), balance, isometric voluntary contraction, oxygen uptake, lactate and core temperature No data
<i>Impellizzeri et al. (2013)</i> Randomised controlled trial	Male Mean age 23.5 years N = 81	9 weeks	ω	No data	Physical performance	1) Between-group analyses showed improved time-to-stabilisation, core stability, and eccentric and concentric knee flexor strength 2) Between-group difference (within- group difference), presented as mean values between limbs: Hcon $60^{\circ}/s = 3.2\%$ (5.9%), Hcon $180^{\circ}/s = 4.6\%$ (7.1%) and Hecc $60^{\circ}/s = 3.8\%$ (5.9%)

Study & design	Population	Duration	Frequency (no. per week)	Compliance (%)	Outcome	 Main result Results regarding knee flexor strength or prevention of HI
Reis et al. (2013) Cohort study	Male Mean age 17.5 years N = 36	12 weeks	0	06	Physical performance	 Within-group analyses showed improved CMJ, SJ, 5m and 30 m sprint, agility, slalom, concentric knee flexor and extensor strength, and eccentric knee flexor strength Increased the Hcon 60°/s by 13.3%, Hecc 30°/s by 12.7%, H:Qcon240°/s by 8.3% and Hecc30°:Qcon240°/s by 8.5% in the dominant limb, and Hecc30°/s by 9.3% in the non-dominant limb
<i>Steffen, Emery et al. (2013)</i> Cluster-randomised controlled trial	Female 13-18 years N = 226	4.5 months	2-3	85	Injury risk and physical performance	 Improved dynamic and functional balance. Reduced the risk of injury by 72% for highly compliant players compared to those less compliant No data
da Costa Silva et al. (2015) Randomised controlled trial	Male < 20 years N = 20	9 weeks	б	⊳85	Physical performance	 Between-group analyses showed improved CMJ and SJ No data
<i>Ayala et al. (2017)</i> Randomised controlled trial	Male Mean age 17 years N = 60	4 weeks	ς	No data	Physical performance	Within-group results regarding the FIFA 11+ group only: 1) Between-group analyses showed improved dynamic postural control, single legged hop limb symmetry, 10 and 20 m sprint and jumping height 2) No data

Study & design	Population	Duration	Frequency (no. per week)	Compliance (%)	Outcome	 Main result Results regarding knee flexor strength or prevention of HI
<i>Thompson et al. (2017)</i> Controlled trial	Female 10-12 years N = 51	7-8 weeks	7	70 %	Physical performance	 Between-group analyses showed reduced peak knee valgus movement during double-leg jump, peak ankle eversion moment after training during preplanned cutting, unanticipated cutting and double-leg jump Within-group analyses showed increase in peak knee valgus moment during unanticipated cutting 2) No data
<i>Ghareeb et al. (2017)</i> Controlled trial	Male Mean age 16.5 years N = 34	6 weeks	ς	No data	Physical performance	Within-group results regarding the FIFA 11+ group only: 1) and 2) Within- and between-group analyses showed no effect on balance Within-group analyses showed increased Hcon60°/s with 9.5% and 7.8% in dominant and non-dominant respectively, and Hcon180°/s and Hcon300°/s also increased in both dominant and non-dominant and non-dominant and non-dominant and non-dominant and non-dominant leg (no statistics given)

3.4.2 The FIFA 11 programme

Four RCTs were identified for studying the effects of the FIFA 11 programme on injury risk and/or physical performance (see Table 1 and Table 2) (Kilding, Tunstall, & Kuzmic, 2008; Steffen, Bakka, Myklebust, & Bahr, 2008; Steffen, Myklebust, et al., 2008; van Beijsterveldt et al., 2012). Of these, two investigated the effect of the FIFA 11 on injury risk (Steffen, Myklebust, et al., 2008; van Beijsterveldt et al., 2012) and both found the FIFA 11 programme to not reduce injury rate. The two studies were similar regarding duration (\approx 8 months), but differed in frequency (1 vs 2 times per week) and compliance (52% vs 73%). The population were mostly females (2100 vs 487) and age ranged from 13-40 years. Two meta-analyses (Al Attar, Soomro, Pappas, Sinclair, & Sanders, 2016; Thorborg et al., 2017) support the majority of the studies looking at the preventive effect of the FIFA 11, concluding that the programme have no effect on injury risk.

The two studies examining physical performance showed conflicting results. Kilding et al. (2008) showed that the FIFA 11 could improve 3 step jump, counter-movement jump and 20 m sprint, while Steffen, Bakka et al. (2008) found no effect on different physical performance measurements which also included isokinetic concentric, eccentric and isometric hamstring strength. No other studies reported any findings regarding the effects of the FIFA 11 programme on eccentric knee flexor strength or prevention of HI.

3.4.3 The FIFA 11+ programme

A total of 18 studies were identified investigating the effects of the FIFA 11+ programme on injury risk and/or physical performance (see Table 3 and Table 4) (Ayala et al., 2017; Bizzini, Impellizzeri, et al., 2013; Brito et al., 2010; da Costa Silva, da Silva, do Nascimento Salvador, & de la Rocha Freitas, 2015; Daneshjoo, Mokhtar, Rahnama, & Yusof, 2012a, 2012b; Daneshjoo, Mokhtar, et al., 2013a; Daneshjoo, Mokhtar, Rahnama, & Yusof, 2013b; Daneshjoo, Rahnama, Mokhtar, & Yusof, 2013; Ghareeb, McLaine, Wojcik, & Boyd, 2017; Hammes et al., 2015; Impellizzeri et al., 2013; Owoeye, Akinbo, Tella, & Olawale, 2014; Reis et al., 2013; Silvers-Granelli et al., 2015; Soligard et al., 2008; Steffen, Emery, et al., 2013; Thompson et al., 2017; Dive studies examined the effect of the FIFA 11+ programme on injury risk (Hammes et al., 2015; Owoeye et al., 2014; Silvers-Granelli et al., 2015; Soligard et al., 2008; Steffen, Emery, et al., 2013) with all of them showing a reduced risk of injury ranging from 33-72%, except the study by Hammes et al. (2015), which could not identify any effect on the risk of injury. Soligard et al. (2008) and Silvers-Granelli et al.
(2015) also found a reduction in the risk of HI by 43% and 63%, respectively. Duration, frequency and compliance between the studies ranged from 3-9 months, 1-3 times per week and 47-98%. The age ranged from 13-32 years and the number of females and males was almost equal (2766 vs 2424). The meta-analysis by Thorborg et al. (2017) also found the FIFA 11+ to prevent injuries, showing a reduced risk of injury by 39%, HI by 60%, hip/groin injuries by 41%, knee injuries by 48% and ankle injuries by 32%. Al Attar, Soomro, Pappas, et al. (2016) had similar findings with their meta-analysis showing a reduced risk of injury by 35% when performing the FIFA 11+. Interestingly, the results by Thorborg et al. (2017) were found even if less than 15% of the intervention teams reached the recommended dose for completing the FIFA 11+ programme.

13 studies investigated the effects of the FIFA 11+ programme on physical performance (Ayala et al., 2017; Bizzini, Impellizzeri, et al., 2013; Brito et al., 2010; da Costa Silva et al., 2015; Daneshjoo et al., 2012a, 2012b; Daneshjoo, Mokhtar, et al., 2013a, 2013b; Ghareeb et al., 2017; Impellizzeri et al., 2013; Reis et al., 2013; Thompson et al., 2017). Of these, seven studies examined the effect of the FIFA 11+ on a number of candidate isokinetic strength measurements (Brito et al., 2010; Daneshjoo et al., 2012a, 2012b; Daneshjoo, Mokhtar, et al., 2013a; Ghareeb et al., 2017; Impellizzeri et al., 2013; Reis et al., 2013) and four on the effect of the FIFA 11+ on isokinetic eccentric knee flexor strength (Brito et al., 2010; Daneshjoo, Mokhtar, et al., 2013a; Impellizzeri et al., 2013; Reis et al., 2013). Brito et al. (2010); Impellizzeri et al. (2013); Reis et al. (2013) found a within-group increase in eccentric knee flexor strength, ranging from 5.9-14.3%, while Daneshjoo, Mokhtar, et al. (2013a) found a reduction of 10.1%.

Compliance

Compliance with sport injury prevention interventions is important and can significantly affect study results (van Reijen, Vriend, van Mechelen, Finch, & Verhagen, 2016). Looking at the consequences of compliance with the FIFA 11+ programme, Steffen et al. (2013) and Soligard et al. (2008) have indicated that there is an association between compliance and the magnitude of the injury preventive effect. This suggests that the FIFA 11+ is the most efficacious in players with higher compliance rates. However, the meta-analysis by Thorborg et al. (2017) did not reveal any association between compliance and reduced injury risk, although the post hoc analysis pointed towards the possibility of a higher preventive effect among the studies with the highest compliance rates. One RCT has also examined whether

different implementation strategies of the FIFA 11+ could impact compliance and injury risk (Steffen, Meeuwisse, et al., 2013). Teams were introduced to the FIFA 11+ programme through either an unsupervised website (control group) or a coach-focused workshop with ("comprehensive" group) and without ("regular" group) additional supervisions by a physiotherapist. The results were equally successful with or without the additional field involvement of a physiotherapist, but a proper education of coaches during an extensive preseason workshop was more effective in terms of team compliance than an unsupervised delivery of the FIFA 11+ programme to the team. A sub cohort analysis by McKay, Steffen, Romiti, Finch, and Emery (2014) from the RCT by Steffen, Meeuwisse et al. (2013) studied how beliefs affect upon compliance and their results identified that beliefs did not affect the compliance to the FIFA 11+, suggesting that additional motivational factors should be considered.

3.5 The Nordic Hamstring exercise for increasing muscle strength and prevention

Of the six exercises in Part 2 of the FIFA 11+ programme, the NHE is the exercise which primarily targets the eccentric knee flexor strength. The NHE should be done at three different levels; level 1 (3-5 rep), level 2 (7-10 rep) or level 3 (12-15 rep) and only one set. Progressions should be made when the exercise can be performed without difficulty for the specified number of repetitions. Three RCTs reported increased eccentric knee flexor strength of 11-21% in various populations after using the NHE (Delahunt et al., 2016; Iga et al., 2012; Mjølsnes et al., 2004), however, with a different exercise prescription than the one recommended by the FIFA11+ programme. Mjølsnes et al. (2004), prescribed a gradual increase in the number of repetitions, sets and times per week over a 10-week period – from two sets of 5 reps one time per week to three sets of 8-12 reps three times per week. Delahunt et al. (2016) and Iga et al. (2012), followed the same protocol, but only up to and for 6 and 4 weeks, respectively. The subjects in the different studies varied between healthy recreational males (Delahunt et al., 2016), amateurs to elite football players (Mjølsnes et al., 2004) and elite players (Iga et al., 2012).

Regarding the preventive effect of the NHE on HI, two RCTs have shown that in male football players, the NHE prevents HI by 57-72% following the protocol by Mjølsnes et al. (2004) (Petersen et al., 2011; van der Horst et al., 2015). The intervention study by Arnason et al. (2008) had the similar findings (58%), however the NHE (using the same protocol) was used in a combination with warm-up stretching. The meta-analysis by Al Attar, Soomro,

Sinclair, Pappas, and Sanders (2016) showed that football teams who used the NHE in prevention programs reduced their HI rates up to 51%. This result was based on a mix of studies using either the FIFA 11+ protocol for the NHE or the protocol described by Mjølsnes et al. (2004). Similar findings were reported in the meta-analysis by Goode et al. (2015) who identified that when athletes were compliant with eccentric hamstring strengthening, there was a 65% reduction in the risk of getting a HI. However, their analysis included studies that accomplished eccentric strengthening of the hamstrings both with and without the NHE, making comparisons of a compliance effect with the NHE more difficult. The survey by McCall et al. (2014) on 93 premier league clubs internationally, identified the NHE to be one of the top five exercises chosen for injury prevention programmes in the 44 teams that completed the survey. Even with these findings, the incidence of HI continue to increase (Ekstrand et al., 2016). There could be many reasons behind this, i.e. the increased intensity in football over the years (Barnes et al., 2014), possibly higher activation of the semitendinosus muscle vs biceps femoris long head in the NHE (biceps femoris long head most often injured (Woods et al., 2004)) (Bourne, Duhig, et al., 2016; Bourne, Williams, et al., 2016), the possible lack of the NHE to target the more proximal part of the hamstrings (Brughelli & Cronin, 2007) or simply because the NHE prevention programme is not being used by teams and players (Bahr, Thorborg, & Ekstrand, 2015). The survey by Bahr et al. (2015) showed that of 150 club-seasons covered, the NHE programme was only completed in full in 16 (11%) seasons and in part in 9 (6%) seasons.

4.0 METHODS

4.1 Subjects and study design

The RCT, which the current study was a part of, was completed during the preseason of the Norwegian regional elite U19 league (January – March, 2016) with the intervention period lasting for 8 weeks. The complete results of this study will be published elsewhere. Two U19 elite male football teams in the Oslo region were invited and elected to take part in the study. Players were individually randomised into the different training groups, stratified according to team to either the FIFA 11+ or the FIFA 11+ with the CAE. We included a total of 23 and 22 players in each group, making the total number of subjects 45. The inclusion criteria was: Healthy male football players playing in the regional elite U19 (15-19 years) league in the Oslo region. The exclusion criteria were: Players with injury or illness which made them unavailable for testing, low compliance (<16 training sessions) and/or an ongoing rehabilitation of a hamstring or groin injury which included specific strength training of these muscles.

4.2 Intervention procedures

Players in both groups conducted the FIFA 11+ programme as a regular warm-up to three training sessions each week following Soligard et al. (2008), whereas the FIFA11 + CAE group replaced the NHE with the CAE following the same protocol as described for the NHE in the FIFA 11+ programme (see Table 5). The CAE is a partner exercise targeting the hip adductors (see Figure 6). Each team were allocated a master's student in sports physiotherapy who supervised each training session during the project and ensured that the players were given adequate instructions on how to perform the exercises correctly.

Level	Frequency (training sessions per week)	Number of sets each leg	Number of repetitions for each leg	
Beginner			3-5	
Intermediate	3	1	7-10	
Advanced			12-15	

 Table 5: Training protocol for the NHE and the CAE.



Figure 6: Starting/ending position (A) and mid position (B) of the CAE.

4.2.1 The Nordic Hamstring exercise

The NHE (see Figure 7) is a partner exercise where the subjects attempt to resist a forwardfalling motion by using their hamstrings to maximize loading in the eccentric phase. The subjects were asked to keep their trunk and hips in a neutral position throughout the whole range of motion, and to brake the forward fall for as long as possible using their hamstrings, and to try keeping tension in their hamstrings even after they have to "let go". They were asked to use their arms and hands to buffer the fall, let the chest touch the surface, and immediately get back to the starting position by forcefully pushing with their hands to minimise loading in the concentric phase.



Figure 7: Start (1) and end (2) position of the NHE.

4.3 Strength and performance testing

All tests were performed at the Norwegian Olympic Training Center (Olympiatoppen). Pretests were completed in January and post-tests in March 2016. The players performed testing four days prior to the intervention and within four days after completion of the last training session. Players were tested in groups of five. On arrival at the Olympiatoppen they were informed not to reveal at any time during the testing which exercise group they had been allocated to. The players were weighed and asked to complete a form with personal and demographic information. The principal investigator, one sports physiotherapist, two sports physiotherapy master's students and one tester employed at Olympiatoppen performed all tests. The players completed a 15 min standardised warm-up protocol which consisted of 15 min light running on treadmill at 11 km/h (PRO, Woodway, Waukesha, WI) before the testing. All tests were performed with jogging shoes, starting with the hip adduction muscle strength test, followed by a 40 m sprint test and finishing with the eccentric knee flexor strength test. For each test, all test procedures were standardised and the order was the same for the pre- and post-tests for all players. The players were not allowed to play matches the last two days prior to testing.

4.3.1 Eccentric knee flexor strength test

The testing set-up included a NordBord (VALD Performance, Brisbane, Australia). The NordBord was calibrated before testing, and all procedures were standardised. The two sports physiotherapy master's students performed both the pre- and post-tests. The physiotherapist assigned to team A performed testing on team B, and vice versa, to ensure that testers were blinded to group assignment. Legs were tested bilaterally for all players. The players were placed kneeling on a padded board, with the ankles secured immediately superior to the lateral malleolus by individual ankle braces. The players were told to gradually lean forward at the slowest possible speed while maximally resisting this movement with both legs, keeping the trunk and hips in a neutral position and the hands held along the body throughout the movement (see Figure 8) (Opar, Piatkowski, et al., 2013). When the players had been informed about the procedure, they were asked to perform one practice trial before performing one set of three maximal repetitions. The mean of these values was recorded. Force values were reported as relative eccentric knee flexor strength corrected for bodyweight (N/kg).



Figure 8: Eccentric knee flexor strength testing using the NordBord.

The standardised command by the examiner was "go ahead-hold-hold-hold." A trial was acceptable when the force output reached a distinctive peak (indicative of maximal eccentric strength), followed by a rapid decline in force, which occurs when the athlete is no longer able to resist the effects of gravity on the segment above the knee joint (Opar et al., 2015). The performance of all repetitions was monitored visually by the investigator, and a repetition was rejected if the participant displayed excessive arm movement, hip movement, or lack of controlling the descent from the beginning of the movement.

4.4 Statistics

4.4.1 Primary outcome

The primary outcome was eccentric knee flexor strength, quantified as maximum peak torque, corrected for bodyweight (N/kg).

4.4.2 Additional data registered

The sports physiotherapist assigned to each team registered demographic data, weekly compliance with the FIFA 11+, training and match exposure, and any potential individual hamstring or hip adduction strength training for all players included in the project. They also registered DOMS and any adverse effects related to performing the intervention, and specifically in relation to which part of the intervention and any reason why players did not perform the 11+ programme as planned.

4.4.3 Randomisation and blinding

A statistician at Oslo Sports Trauma Research Center (OSTRC) used SPSS (IBM Corp. Released 2013. IBM SPSS Statistics for Windows, V. 22.0. Armonk, NY: IBM Corp.) to computer-generate random numbers for randomisation stratified for team. An independent third person allocated group assignment in sealed envelopes. After pre-testing, each player received a sealed envelope from the principal investigator, with group assignment. To ensure blinding of the principal investigator to data management, all results from pre- and post-tests and data registered from the physiotherapist assigned to the clubs, was handled by an independent data manager at OSTRC. All testers were blinded to group allocation at both test days. Players and the sports physiotherapist performing the warm-up were not blinded to group assignment.

4.4.4 Sample size calculation

Since this master's thesis was part of an RCT where the overall aim was to examine the hip adductor strength effects of the Copenhagen adduction exercise using the same protocol as the NHE in the FIFA 11+, the sample size calculation was performed based on a previous study examining the effect on adduction strength (Ishoi et al., 2016). With a power of 80% and a 10% increase in eccentric hip adduction strength (Δ =0.28, SD=0.316) in the FIFA 11+ CAE group and no strength increase (Δ =0, SD = 0.295) in the FIFA 11+ group, they estimated that 20 players would be needed in each group.

4.4.5 Statistical analyses

All outcome variables were analysed using SPSS V. 22.0. Within-group differences were analysed using a paired Student's *t*-test. Between-group difference in strength were analysed using a repeated measure analysis of covariance (ANCOVA), with pre-test as a covariate (Vickers & Altman, 2001). Between-group difference in compliance and DOMS were analysed using an independent samples *t*-test. Between-group difference in baseline characteristics and exposure were assessed using independent samples *t*-test or chi-square, as appropriate. An α level of ≤ 0.05 was considered significant. Data are presented as mean values with their standard deviation (SD), unless otherwise stated. Analyses were assessed per protocol. By solely analysing adherers to the intervention, in this case participants with a minimum compliance of 16 training sessions (67%), the maximal achievable effect of the intervention is thought to be shown.

4.5 Ethical aspects

The study was approved by the Regional Committee for Medical Research Ethics (2015/1921/REK) South East and Norwegian Social Science and Data Service (45393/3/LT/LR) (see Appendix C), and in accordance with the Declaration of Helsinki all participants were given written and oral information about the purpose and content of the project. All participants gave their written informed consent to participate in the study. The trial was registered in The International Standard Randomised Controlled Trial Number registry (ISRCTN13731446).

5.0 RESULTS

5.1 Study flow and baseline characteristics

Figure 9 shows the flow of participants throughout the study. Of the 45 players invited and tested at baseline, one player (2.2%) in the FIFA 11+ group suffered a groin injury during the intervention period and one player (2.2%) in the FIFA 11+ CAE group suffered a knee injury; these two were unable to complete post-testing. A total of ten players (22%) were excluded from the per-protocol analyses: Two goalkeepers had individual warm-up, two players attended training with the clubs' senior squad for >4 weeks, two players had intensive groin rehabilitation and four players had long periods with illness or injury (3-7 weeks).



Figure 9: Flow of participants throughout the study.

As shown in table 6, statistical analysis revealed no differences in demographic data, exposure or leg dominance between the two groups at baseline.

	FIFA 11+ (n=16)	FIFA 11+ CAE (n=17)
Age (years)	16.9 (1.0)	16.7 (0.9)
Height (cm)	177.8 (6.0)	179.8 (8.0)
Weight (kg)	67.6 (10.0)	67.8 (8.9)
Weekly football training (h)	7.4 (1.8)	8.1 (2.2)
Weekly individual training (h)	2.2 (1.7)	1.6 (1.1)
Weekly match exposure (min)	40 (16)	45 (19)
Leg dominance (%)		
- Left side	2 (12.5)	2 (11.8)
- Right side	14 (87.5)	15 (88.2)

Table 6: Baseline characteristics shown as group means with SD or percentages, as appropriate.

5.2 Effects of training

Between-group analyses showed that there was no significant difference in the change in eccentric knee flexor strength in the dominant leg (0.26, 95% CI: -0.14 to 0.65; p=0.19) nor the non-dominant leg (0.28, 95% CI: -0.01 to 0.56, p=0.05). There was, however, a significant within-group difference in the change in eccentric knee flexor strength in both the dominant and non-dominant leg in the FIFA 11+ group. There was no significant within-group difference in the FIFA 11+ group (see Table 7).

Table 7: Within-group difference in the change in eccentric knee flexor strength in the dominant and non-dominant leg.

	FIFA 11+ (n=16)				FIFA 11+ CAE (n=17)					
	Test 1	Test 2	Difference	%	Р	Test 1	Test 2	Difference	%	Р
Dominant (N/kg)	5.22 (0.84)	5.61 (0.83)	0.39 (0.63)	7.5	0.03	5.11 (0.75)	5.26 (0.86)	0.15 (0.49)	3.0	0.22
Non-dominant (N/kg)	4.93 (0.52)	5.32 (0.61)	0.39 (0.48)	7.9	0.01	4.84 (0.75)	4.99 (0.54)	0.14 (0.42)	2.9	0.18

5.3 Compliance

Of the 24 training sessions planned, the average compliance was 21.0 ± 1.6 (88% of planned sessions) in the FIFA 11+ group and 21.5 ± 1.9 sessions (90% of planned sessions) in the FIFA 11+ CAE group. The average compliance was similar in both groups (p ranging between 0.30 and 0.94) and maintained as high throughout the whole intervention, with a minor drop in week 4 because of less training sessions due to winter holiday (see Figure 10).



Figure 10: Average compliance within the two groups throughout each week.

5.4 DOMS

DOMS was reported throughout the intervention period with 64-88% in each group reporting no DOMS at any time and 0-18% reporting values between 0-4 (see Figure 11). In the FIFA 11+ group no one reported DOMS values \geq 5, but 6% in the FIFA 11+ CAE group reported \geq 5 in week 1, week 2 and week 5. However, there was no significant between-group difference in DOMS values (p ranging between 0.20 and 0.53).

Figure 11: DOMS for hamstrings in the FIFA 11+ group (upper panel) and in the FIFA 11+ CAE group (lower panel), measured on a numeric rating scale (0-10). The bars showing distribution of mean DOMS in percentage for each week.



6.0 **DISCUSSION**

The purpose of the current study was to examine the effect of the FIFA 11+ programme on eccentric knee flexor strength in adolescent elite male football players using the NordBord as testing method. The results showed that there was no significant difference between the FIFA 11+ and the FIFA 11+ CAE group regarding the change in eccentric knee flexor strength in either the dominant or the non-dominant leg. Thus, our hypothesis that there would be greater increase in eccentric knee flexor strength for adolescent elite male football players performing the ordinary FIFA 11+ programme than players not doing the programme was rejected. However, there was a within-group difference in the change in eccentric knee flexor strength in the FIFA 11+ group of 7.5% and 7.9% in the dominant and non-dominant leg, respectively. The possible reasons behind these results and their methodological considerations will be discussed in detail in the following sections.

6.1 Discussion of results

6.1.1 Factors possibly influencing the results

Unexpected strength increases in the FIFA 11+ CAE group

Even if it was not statistically significant, the FIFA 11+ CAE group had an increase of 3.0% in eccentric knee flexor strength, which was just 4.5-5% lower than in the FIFA 11+ group. The effect of the Copenhagen adduction exercise on eccentric knee flexor strength is uncertain. Having the anatomy of the adductor magnus muscle in mind, with its posterior part functioning like it is a knee flexor, we cannot rule out that an increase in strength of this muscle might have contributed to the increase that was seen in eccentric knee flexor strength for the FIFA 11+ CAE group. This might especially be of significance considering the design of the study, where the two groups were equal regarding performing the FIFA 11+ programme, with the only difference being the completion of the NHE or the CAE.

Dose-response

The results from our study are in line with the majority of other studies examining the effect of the FIFA 11+ on eccentric knee flexor strength, with an increase ranging from 5.9-14.3% (Brito et al., 2010; Impellizzeri et al., 2013; Reis et al., 2013). These results are similar to studies following the protocol by Mjølsnes et al. (2004), giving an increase in eccentric knee flexor strength of 11-21% (Delahunt et al., 2016; Iga et al., 2012; Mjølsnes et al., 2004). Our result of values between 4.93-5.61 N/kg were also higher than the values (3.16/3.45 N/kg

and 4.35 N/kg) that Opar et al. (2015) and Timmins et al. (2015) found to be the threshold for giving a higher risk of future HI. Even if the purpose of the study was not to look at injury risk, these are interesting numbers. In addition, studies investigating the preventive effect of the FIFA 11+ found it to prevent HI by 43-63% (Silvers-Granelli et al., 2015; Soligard et al., 2008; Thorborg et al., 2017) while the protocol by Mjølsnes et al. (2004) has shown a preventive effect ranging from 57-72% (Arnason et al., 2008; Petersen et al., 2011; van der Horst et al., 2015). Based on these findings, a lower load to the hamstrings, as prescribed in the FIFA 11+, might be sufficient to give an increase in eccentric knee flexor strength to prevent HI.

Progression

While studies using the protocol by Mjølsnes et al. (2004) followed strict guidelines for the progression of load for the NHE, studies investigating the effect of the FIFA 11+ on eccentric knee flexor strength, including the current study, have not reported criteria for progression. This might have influenced the results to a certain degree. If a study progresses to level 3 after only two days of intervention and another study does not progress until after two weeks, which might be reasonable to think could have happened, then the difference in time at level 3 would be almost 20%, if the studies each last for ten weeks. That would result in a relatively big difference in training stimulus to the hamstring muscles and most likely influence the results of the two studies.

Intervention period

Another factor that might have affected the eccentric knee flexor strength is the timing of the intervention period. Our study was completed during the preseason, which, together with the off-season, is the period were players usually do a lot of resistance training. What the players had been doing during the off-season the month before our intervention, we had no control over. And even if we registered what kind of resistance training they were doing during the intervention period, there might always be players doing something different than what they were reporting. Compared to the other studies examining the effect of the FIFA 11+ on eccentric knee flexor strength, two studies did their intervention during the midseason (Brito et al., 2010; Daneshjoo, Mokhtar, et al., 2013a), one during the preseason and into the start of the competitive season (Impellizzeri et al., 2013) and one study did not report when the study was completed (Reis et al., 2013). However, with their results in mind (see Table 4), timing of the intervention period does not seem to matter.

Playing level

Playing level is another factor that could have influenced the effects on eccentric knee flexor strength. The FIFA11+ programme is designed for amateur or recreational players aged 14 years or older (FIFA, n.d.). Since the subjects in our study were adolescent elite players, it might be reasonable to think that the training stimulus following the exercise prescription for the NHE in the FIFA 11+ programme, was too low to give any significant increase in eccentric knee flexor strength. Daneshjoo, Mokhtar et al. (2013a) also examined elite players aged 17-20 and they even observed a reduction in eccentric knee flexor strength. Based on these findings, youth elite players might seem to have a better foundation regarding eccentric knee flexor strength, possibly explaining some of the reason for the lack of strength effects. These arguments are supported by the observation that the subjects in two of the studies that had some of the highest increase in eccentric knee flexor strength were either amateurs (Impellizzeri et al., 2013) or sub-elite players (Brito et al., 2010). The cohort study by Reis et al. (2013), which had the highest increase in strength, did not report what level their subjects were playing at.

Age

Looking at the association between the age of the player and the results in the various studies examining the effects of the FIFA 11+ on eccentric knee flexor strength, no conclusions could be drawn. However, compared to the mean age in the study by Brito et al. (2010) and Impellizzeri et al. (2013), 22.5 and 23.5 years respectively, the mean age in our study was 16.8 years, almost 6 and 7 years younger. With physical abilities developing considerably in this period of life, it might make comparisons with these studies more difficult.

6.1.2 DOMS

Players in both groups reported minimal numbers of DOMS and especially the FIFA 11+ group. In this group, no one reported DOMS values \geq 5 at any time during the intervention period. These numbers suggests that the FIFA 11+ programme could safely be implemented and adapted without having concerns about soreness, who often is a factor that accompanies muscle strains (Brukner & Khan, 2017). Taking the timing of the intervention period in mind, the DOMS values might just as well be a result of normal football training, since players came from the off-season. It might also point in the direction of an insufficient progression of the exercise prescription of the NHE. If the progression was tougher, maybe the increase in eccentric knee flexor strength would have been higher. Of the studies examining either the effect of the FIFA 11+ on eccentric knee flexor strength (Brito et al., 2010; Daneshjoo, Mokhtar, et al., 2013a; Impellizzeri et al., 2013; Reis et al., 2013), the effect of the NHE on eccentric knee flexor strength (Delahunt et al., 2016; Iga et al., 2012; Mjølsnes et al., 2004) or the preventive effect of the NHE (Arnason et al., 2008; Petersen et al., 2011; van der Horst et al., 2015), only three studies (Arnason et al., 2008; Mjølsnes et al., 2004; Petersen et al., 2011) reported DOMS and all of them followed the protocol by Mjølsnes et al. (2004). With the majority of the subjects being elite to sub-elite players, their results showed that this protocol gave none to a small, and not clinically relevant, degree of DOMS. Since the protocol by Mjølsnes et al. (2004) is considerably harder than the exercise prescription of the NHE in the FIFA 11+, but still showing small numbers of DOMS, it would be interesting to see the results of an intervention with a similar protocol of the NHE within the FIFA 11+.

6.1.3 Compliance

The compliance in our study was high for both the FIFA 11+ group and the FIFA 11+ CAE group (88% vs 90%) and remained stable throughout the whole intervention, with only a minor drop in week 4 because of less training sessions due to winter holiday. These are high rates compared to other studies examining the effect of the FIFA 11+ (see Table 3 and Table 4) and compared to the other studies examining the effect of the FIFA 11+ programme on eccentric knee flexor strength (Brito et al., 2010; Daneshjoo, Mokhtar, et al., 2013a; Impellizzeri et al., 2013; Reis et al., 2013), only Brito et al. (2010) and Reis et al. (2013) reported compliance, and they had a compliance rate of 73% and 90%, respectively.

Since compliance with sport injury prevention interventions is important and significantly can affect study results (van Reijen et al., 2016), and studies have indicated that there is an association between compliance of the FIFA 11+ programme and the injury preventive effect (Soligard et al., 2008; Steffen, Emery, et al., 2013), the compliance rates of our study increased our probability of getting a reliable result. In addition to the high compliance rates, we ensured that the completion of the FIFA 11+ programme and the quality of the different exercises were as high as possible by having two sports physiotherapists being present, responsible for and controlling every training.

6.2 Discussion of methods

6.2.1 Subjects

To secure a high internal validity, it is important that the subject group is homogenous (Laake, Olsen, & Benestad, 2013). In the current study, the two groups were similar in demographic data, exposure and leg dominance at baseline. The subjects are thought to be representative for elite adolescent football players, with an age range from 15-19 years and mean age of 16.8 years. There were only males, limiting the results to this gender. The subjects in our study are comparable to the subjects in the other studies examining the effect of the FIFA 11+ programme on eccentric knee flexor strength regarding gender and age (see Table 3 and Table 4), with a possible exception regarding the age difference between our study and the study by Brito et al. (2010) and Impellizzeri et al. (2013), as mentioned in chapter *6.1.1*. The subjects in our study were playing at elite level. This were different from the majority of the other studies investigating the effect of the FIFA 11+ programme on eccentric knee flexor strength and the study by Brito et al. (2010) and Impellizzeri et al. (2013), as mentioned in chapter *6.1.1*. The subjects in our study were playing at elite level. This were different from the majority of the other studies investigating the effect of the FIFA 11+ programme on eccentric knee flexor strength, possibly affecting the results and making comparisons more difficult.

The number of subjects in a study plays a significant role (Laake et al., 2013). The larger the sample is, the more accurately the observations are able to say something about the population (Laake et al., 2013). A total of 33 players were included in the per-protocol analyses in our study. This is a similar number compared to three of the other studies examining the effect of the FIFA 11+ on eccentric knee flexor strength, with their population ranging from 20 to 36 subjects (Brito et al., 2010; Daneshjoo, Mokhtar, et al., 2013a; Reis et al., 2013). The small numbers of subjects were a limitation and reduces the validity of the results in the current study.

6.2.2 Study design

The current study was part of an RCT. Since the purpose of the study was to examine the effect of an intervention, RCT is the preferred design to use (Laake et al., 2013). Of the other studies examining the effect of the FIFA 11+ programme on eccentric knee flexor strength, only Impellizzeri et al. (2013) used RCT as study design. By choosing RCT as a study design, we might have prevented systematic biases and could be more certain that the results are real effects of the intervention and not due to other factors (Jamtvedt, Hagen, & Bjørndal, 2015). This is considered to be a methodological strength of our study.

Randomisation and blinding

Randomisation is fundamental to ensure a high internal validity (Laake et al., 2013). When randomisation is done properly, comparisons of groups with selection biases might be prevented and we are able to get the true effect of an intervention (Jamtvedt et al., 2015). We randomised players individually to one of the two groups and stratified according to team. After pre-testing, each player received a sealed envelope with their group assignment, made from a computerised random number generator. By using these methods, we believe that the study had reliable randomisation procedures.

Blinding is necessary to make sure that registration and interpretation will not be influenced by subjective assumptions of the effect of the treatment (Lindbæk & Skovlund, 2002) and in this way strengthens the results and validity of a study. In our study, all testers were blinded to group allocation, and to ensure blinding of the principal investigator to data management, all results from pre- and post-tests and data registered from the physiotherapist assigned to the clubs, was handled by an independent data manager. Due to the intervention being examined, we were not able to blind the players and the sports physiotherapist performing the warm-up to group assignment. However, this should not be considered a limitation of the study, because the effect of the intervention on the two groups and the intervention itself, are thought to not being influenced by either a placebo effect nor the motivation of the players (since both groups did training exercises).

Control group

In our study, the two groups functioned liked each other's control group. We did not have a control group that only did a "normal" warm-up. To increase the validity of our study, we could have used a three-armed RCT, with two training groups and one control group. With a three-armed RCT we might have been able to get the real effects of the FIFA 11+ and the FIFA 11+ CAE compared to a "normal" control group, as well as compared to each other. However, this would require a significantly higher number of participants to obtain 80% power, which in turn would give higher financial costs.

6.2.3 Statistical analyses

All outcome variables were analysed according to the per-protocol principle, conducted with a pre-determined minimum compliance limit set at 16 training sessions (67%). Although the

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CONSORT statement advocates intention-to-treat analyses of RCT results (Schulz, Altman, & Moher, 2010), we chose to use per-protocol analyses which have a stronger focus on the potential efficacy of an intervention (Becque & White, 2008). Poor adherence to the intervention tends to dilute treatment effects when analyses are done by the intention-to-treat approach (Montori & Guyatt, 2001). We consider the per-protocol analyses conducted as a possible strength to our study, increasing the likelihood of getting a reliable result.

Sample size calculations

Since the current study was part of an RCT where the overall aim was to examine the hip adductor strength effects of the Copenhagen adduction exercise using the same protocol as the NHE in the FIFA 11+, the sample size calculation was performed based on a previous study examining the effect on adduction strength (Ishoi et al., 2016). This is a limitation of our study. Post hoc power calculations revealed that a minimum of 90 players in each group would have been needed to obtain a power of 80%, showing that the current study was underpowered.

6.2.4 Outcome measure

Eccentric knee flexor strength testing

The primary outcome of the study was eccentric knee flexor strength, quantified as maximum peak torque, corrected for bodyweight (N/kg). To measure this we used the NordBord, which is designed specifically to obtain objective measurements of eccentric knee flexor strength and overcome the limitations of isokinetic dynamometry (Opar, Piatkowski, et al., 2013). The NordBord has been found to have a minimal detectable change of 15.6% for the right leg and 20.5% for the left leg (Opar, Piatkowski, et al., 2013). These values are over twice as high as our within-group increase of 7.5% and 7.9%. However, the values found by Opar, Piatkowski et al. (2013) apply to an individual. When the numbers are re-calculated to be used for group analyses (as for the current study), the values are 2% and 2.35% for right and left leg, respectively. This is in line with the results from our study, increasing their reliability.

We performed the eccentric knee flexor strength tests bilaterally. The NordBord has shown to have moderate to high test-retest reliability regarding this type of measurements (Opar, Piatkowski, et al., 2013). Even if values regarding intrarater reliability would have been appreciated, no study has been identified for investigating this with the NordBord. A high intrarater reliability would have increased the reliability of our results.

Regarding measurements of absolute eccentric knee flexor strength, the NordBord showed moderate reliability only when the NHE was completed bilaterally and peak force was averaged across six trials (two sets of three repetitions) (Opar, Piatkowski, et al., 2013). The participants in Opar, Piatkowski et al. (2013) also undertook a familiarization session, with an unknown number of sets and repetitions. This may have led to a greater learning effect of the NHE compared to our study. However, this is suggested to not be of great significance since the differences were small and might have influenced the pre-test only, since the players in our study did the NHE for 8 weeks afterwards.

The correlation between the NordBord and isokinetic dynamometry have yet to be reported and is therefore currently unknown. This makes comparisons with the other studies examining the effect of the FIFA 11+ on eccentric knee flexor strength difficult, since all of them used isokinetic dynamometry as measurements. Opar et al. (2015) reported that whether a study uses the NordBord or an isokinetic dynamometry may be a contributing factor for different results between studies. They supported this argument by explaining that the eccentric knee flexor test is bilateral when using the NordBord, compared to the isokinetic testing which is unilateral. In addition, there is a difference regarding the demands of the external torque around the knee joint between the two measurements. The demands of the NordBord increases due to gravity as the knee flexion increases, while the isokinetic testing procedures requires a maximal effort throughout the whole range of motion (Opar et al., 2015).

6.3 Clinical implications

The current study showed that there was no between-group difference in the change in eccentric knee flexor strength between football players performing the ordinary FIFA 11+ or the FIFA 11+ programme where the NHE was replaced by the CAE. However, there was a within-group increase of 7.5% and 7.9% in the dominant and non-dominant leg, respectively. These results are in line with the majority of the other studies examining the effect of the FIFA 11+ on eccentric knee flexor strength. With studies also showing a preventive effect of the FIFA 11+ programme on HI, the results from our study add to the literature that the FIFA 11+ increases eccentric knee flexor strength, which in turn prevents HI.

6.4 Future research

More high-quality RCTs on dose-response and exercise intensity of the FIFA 11+ programme is needed to enhance the understanding of what the most important parameters are when the FIFA 11+ programme is implemented. Studies regarding the reliability of the NordBord, as well as correlation to other measurement methods for strength, to improve its validity and reliability, are also called for.

7.0 CONCLUSION

This RCT showed no between-group difference in the change in eccentric knee flexor strength between football players performing the ordinary FIFA 11+ or the FIFA 11+ programme where the NHE was replaced by the CAE, but we observed a within-group increase of 7.5% in the dominant leg and 7.9% in the non-dominant leg.

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ACRONYMS

CAE	Copenhagen Adduction exercise
DOMS	Delayed onset muscle soreness
FIFA	Fédération Internationale de Football Association
HI	Hamstring injury*
H:Q	Hamstring to quadriceps strength ratio
H:Q _{conv}	Conventional hamstrings to quadriceps strength ratio
H:Q _{func}	Functional hamstrings to quadriceps strength ratio
NHE	Nordic Hamstring exercise
OSTRC	Oslo Sports Trauma Research Center
RCT	Randomised controlled trial

APPENDIX

Appendix A: The FIFA 11+ programme

Appendix B: The FIFA 11 programme

Appendix C: Ethical committee approval scheme

Appendix D: Clinical Sports Medicine 5e, Injuries V1 reproduction approval scheme

Appendix A: The FIFA 11+ programme



Appendix B: The FIFA 11 programme



Appendix C: Ethical committee approval scheme



REK sør-øst

Regi

Saksbehandler: Jakob Elster Telefon

22845530

 Vår dato:
 Vår referanse:

 19.11.2015
 2015/1921 REK sør-øst B

 Deres dato:
 Deres referanse:

 22.09.2015
 2

Vår referanse må oppgis ved alle henvendelser

Joar Harøy Norges Idrettshøgskole

2015/1921 Bør Copenhagen adduction legges til The 11+

Forskningsansvarlig: Norges Idrettshøgskole Prosjektleder: Joar Harøy

Vi viser til søknad om forhåndsgodkjenning av ovennevnte forskningsprosjekt. Søknaden ble behandlet av Regional komité for medisinsk og helsefaglig forskningsetikk (REK sør-øst) i møtet 28.10.2015. Vurderingen er gjort med hjemmel i helseforskningsloven (hfl.) § 10, jf. forskningsetikkloven § 4.

Prosjektleders prosjektbeskrivelse

"Dette prosjektet bygger videre på resultatene fra prevalensstudien som vist høy forekomst av lyskeproblemer på flere nivå i norsk fotball. Vi mener at The 11+ mangler øvelser som øker styrken i hofteadduktorenen og ønsker derfor å undersøke om 8 uker med The 11+ med copenhagen adduction kan gi en styrkeøkning i hofteadduktorene. Et eventuelt positivt resultat vil brukes til å anbefale at copenhagen adduction bør inn i the 11+. Vi ønsker å gjennomføre en randomisert kontrollert studie med fotballspillere som deltagere der en gruppe gjennomføre The 11+ som normalt tre ganger i uken, mens den andre gruppen gjennomfører The 11+ der vi bytter nordic hamstrings med copenhagen adduction. Også denne gruppen gjennomfører tre ganger i uken. I begge gruppene vil en fysioterapeut stå for gjennomføringen av alle treningsøktene. Alle deltagere vil før og etter treningsperioden bli testet i hamstringsstyrke (nordboard) og styrke i hofteadduksjon (dynamometer) og 40m sprint."

Komiteens vurdering

Helseforskningsloven gjelder for medisinsk og helsefaglig forskning, det vil si «virksomhet som utføres med vitenskapelig metodikk for å skaffe til veie ny kunnskap om helse og sykdom», jf. helseforskningsloven § 2, jf. § 4. Dette prosjektet skal prøve ut et nytt treningsprogram for unge fotballspillere og måler styrkeeffekt som en følge av dette. Formålet med prosjektet er å redusere omfanget av lyskeskade, og måling av styrke er relevant, da redusert styrke i hofteadduktorer i henhold til søknaden er en risikofaktor for lyskeskader. Siden formålet med prosjektet er å undersøke effekten av at skadereduserende tiltak, anser komiteen at prosjektet omfates av helseforskningslovens virkeområde.

Frivillighet

Deltakere i prosjektet er mannlige fotballspillere som er tilknyttet fotballklubb i junior interkrets (U19) serie. Dette inkluderer deltakere mellom 16 og 18 år. Man skal inkludere 40-50 deltakere.

Deltakerne rekrutteres ved at man inviterer to fotballklubber med 20-25 spillere hver til å delta. Det ser her ut til at man regner med at alle som inviteres til å delta vil takke ja, i og med at man trenger 40-50 deltakere og skal invitere to klubber med til sammen 40-50 deltakere. Når spillerne rekrutteres via fotballklubben, kan

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Gullhaugveien 1-3, 0484 Oslo	E-post: post@helseforskning.etikkom.no	saksbehandlingen, bes adressert til REK	the Regional Ethics Committee, REK
0	Web: http://helseforskning.etikkom.no/	sør-øst og ikke til enkelte personer	sør-øst, not to individual staff

det også oppstå et visst press om å delta. Komiteen vil understreke at deltakelse i forskning skal være frivillig, og forutsetter at man bestreber seg på å unngå enhver form for press på fotballspillerne.

Under denne forutsetningen har prosjektet ingen forskningsetiske innvendinger til at prosjektet gjennomføres.

Informasjons- og samtykkeskriv

Det vedlagte informasjons- og samtykkeskrivet bør revideres på enkelte punkter:

- Det står at studien er «en viktig brikke i arbeidet med å redusere omfanget av skulderproblemer». Dette ser ikke ut til å passe med den aktuelle studien.

- Det står at hvis man trekker sitt samtykke, vil dette ikke få konsekvenser for videre behandling. I og med at det her ikke dreier seg om behandling, bør dette endres.

- Det kreves ikke skriftlig samtykke fra foresatte, i og med at deltakerne er fylt 16 år. Plass for underskrift fra foresatt bør derfor fjernes fra samtykkeskjemaet.

Ut fra dette setter komiteen følgende vilkår for prosjektet:

- Informasjonsskrivet revideres i tråd med komiteens merknader og sendes komiteen til orientering.

Vedtak

Komiteen godkjenner prosjektet i henhold til helseforskningsloven § 9 og § 33 under forutsetning av at ovennevnte vilkår oppfylles.

I tillegg til ovennevnte vilkår, er godkjenningen gitt under forutsetning av at prosjektet gjennomføres slik det er beskrevet i søknaden.

Tillatelsen gjelder til 01.08.2016. Av dokumentasjonshensyn skal opplysningene likevel bevares inntil 01.08.2021. Opplysningene skal lagres avidentifisert, dvs. 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 "Personvern og informasjonssikkerhet i forskningsprosjekter innenfor helse- og omsorgssektoren"

Sluttmelding og søknad om prosjektendring

Dersom det skal gjøres 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, se helseforskningsloven § 12, senest et halvt år etter prosjektslutt.

Klageadgang

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

Komiteens avgjørelse var enstemmig.

Med vennlig hilsen

Grete Dyb førsteamanuensis dr. med. leder REK sør-øst B

> Jakob Elster Seniorrådgiver

Appendix D: Clinical Sports Medicine 5e, Injuries V1 reproduction approval scheme



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