STATISTICAL ANALYSIS PLAN for Effectiveness of the Injury-preventive Program #Utviklingsklar

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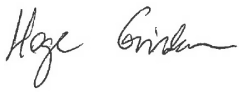

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1. Introduction

1.1 Background and rationale

The majority of injuries in Norwegian youth occur in a sports setting (1). Sports injuries are a significant public burden in terms of healthcare costs and place the individual youth at higher risk of developing subsequent health problems (2, 3). Additionally, sports-active youth often reduce or altogether cease their engagement in sports and physical activities following injury (4). The down-stream consequences of injuries sustained during sports should therefore not be underestimated. Handball and football are the most popular sports among Norwegian youth. The combination of the high physical demands inherent to these sports and the ongoing process of growth and maturation makes youth handball and football players notably susceptible to injury (5-7). Common injuries observed among youth who play handball and football encompass muscular and ligamentous ruptures, bone stress injuries, and injuries to the growing physes (5, 8).

Several injury prevention programs are effective in reducing injury occurrences. Soligard, Myklebust (9) showed a reduction in injuries overall, overuse injuries, and severe injuries in youth female football by implementing the FIFA 11+ injury prevention program. This multicomponent program, which targets both neuromuscular control and muscle strength, was subsequently adapted for specific populations, such as FIFA 11+ Kids (10) and a tailored shoulder injury prevention program for goalkeepers (11). Other efficacious injury prevention programs targeting specific injuries include the Nordic Hamstring for hamstring muscle ruptures (12) and Copenhagen Adductor Exercise for adductor muscle ruptures (13). In handball, structured warm up programs have proven efficacious in preventing lower extremity injuries and shoulder injuries (14-16). However, the gap between efficacy trials and real-world implementation remains a significant challenge.

Against this backdrop, the #Utviklingsklar project commenced in 2021. It is a collaborative and knowledge-sharing project funded by the Research Council of Norway. The overall aim of the project is to develop and evaluate a new program, based on interdisciplinary program theory from sport sociology, biomedicine, and health behavior, to reduce first-time and recurrent injury in youth handball and football. The project follows the UK Medical Research Council (MRC) framework for developing complex health interventions (17). The MRC framework emphasizes the importance of research methods that focus not solely on efficacy, but also on the mechanistic workings of an intervention, and whether it can be implemented in a real-world setting (17).

During the first two years of the project, we undertook development and feasibility testing of the novel #Utviklingsklar intervention. *#Utviklingsklar* is a club-based intervention designed to improve injury-preventive coaching practices. By participating in the intervention, coaches and club leaders develop plans and practices for injury-preventive warm-ups, strength training, and management of players with current pain and injury. The program theory underpinning the intervention is based on previous research within this field, preliminary work conducted in the research project, public involvement, and established theoretical

frameworks. First, we conducted a comprehensive literature review to dissect the biomedical mechanisms underlying the effect of injury prevention programs in handball and football. This review culminated in the formulation of causal biomedical models informed by previous research. Second, a cross-sectional study on behavioral constructs using the Health Action Process Approach was conducted, garnering responses from 865 youth handball and football coaches and players. Outcomes revealed a distinct need for increased knowledge, self-efficacy, and tools to aid coaches in managing pain and injuries in youth players. Third, a second literature review was conducted, focusing on the influence of sociocultural forces on injuries in the youth sport context. Critical to the developmental process was extensive knowledge exchange with the sporting community through meetings and discussion with project partners NIF, NHF, NFF, and key end users (club leaders, coaches, youth players, and their parents). Results from the preliminary work and feedback from stakeholders guided intervention development and content. The feasibility assessment, conducted with participation of three clubs from youth handball and football, prompted minor program revisions and indicated that a large-scale evaluation was warranted.

The current statistical analysis plan describes the evaluation of *#Utviklingsklar* in handball. The project is embedded within the context of Norwegian youth sport. Findings from this evaluation will guide future initiatives to protect youth health among project partners NIF, NHF and NFF. It is therefore of primary interest to investigate how injuries are affected by the #Utviklingsklar program compared to usual practice, which may or may not involve other initiatives to prevent injury.

Central to the evaluation is the hypothesis that injuries in the youth sporting context are influenced by injury-preventive coaching practices. These practices encompass injury-preventive warm-ups, injury-preventive strength training, and management of players with pain and injury, including adjusting training and match loads and guiding youth towards appropriate medical care when necessary. Moreover, these coaching practices are hypothesized to be influenced by specific behavioral determinants, alongside the broader sociocultural context and interpersonal dynamics inherent in the youth sport setting. The current evaluation aims not only to produce knowledge on how injuries are affected by the implemented intervention, but also how injuries are affected by factors in the proposed causal pathway, as outlined in the program theory.

1.2 Trial Objectives

1.2.1 Primary Objective

The primary objective is to compare the effectiveness of *#Utviklingsklar* to usual practice on the weekly injury severity score in youth handball players over one season.

1.2.2 Secondary Objectives

The secondary objectives are:

- To compare the effectiveness of *#Utviklingsklar* versus usual practice on injury consequences in youth handball players over one season.

- To compare the effectiveness of *#Utviklingsklar* versus usual practice on handball youth coaches' determinants of injury-preventive behavior at mid-season and end of season.
- To compare the effectiveness of *#Utviklingsklar* versus usual practice on injury-preventive coaching practice among youth handball coaches over one season.

2. Trial Methods

2.1 Trial Design

The evaluation follows the MRC framework for complex interventions (17). The study is conducted by a parallel two-armed, pragmatic, superiority cluster-RCTs. Clubs are randomised to either the control group that continue their activity as normal or the intervention group participating in *#Utviklingsklar. #Utviklingsklar* includes a digital e-learning course, an in-person workshop, and a club meeting, all three activities involving participation of one club leader and a minimum of one coach from each participating team within each club.

2.2 Randomisation

Upon enrolment, clubs will be randomly assigned to either the control or intervention group in a 1:1 allocation ratio, using a computer-generated cluster randomisation schedule, taking differences in cluster size into account and stratified by geographical region. The biostatistician responsible for the randomisation and primary statistical analysis will be blinded to group allocation. It is impossible to blind players, coaches, and clubs to group allocation. For practical reasons (i.e., data monitoring and participant follow-up), neither the PhD students nor the principal investigator will be blinded.

2.3 Sample size

Sample size calculation has been based on the primary endpoint (using player average weekly injury severity score during the study period of one season). Sample size estimations under varying assumptions for cluster size and effect were performed by the project biostatistician. Data from one previous study in the target population were used to estimate the average weekly injury severity score in the control group and expected standard deviation. Assuming club sizes of 64 players, 13 clubs in each trial arm are sufficient to detect a difference between the average weekly injury severity score of 34 (intervention group) and 25.5 (control group), with a pooled standard deviation of 30, 80% power, 2-tailed alpha of 0.05, and an ICC of 0.05 or less. This corresponds to a relative reduction of 25%. We will overshoot recruitment by four clubs to allow for potential withdrawal of clusters. The target number of clubs to recruit is therefore 15 in each trial arm. As cluster sizes are large, the risk of type II errors due to individual participant data loss is minor.

2.4 Statistical Framework

2.4.1 Hypothesis Test

The primary null hypothesis is that there is no difference between #Utviklingsklar and usual practice in the injury severity score in youth handball players over one season. There is only

one identified primary analysis. All other effectiveness analyses will be regarded as supportive.

2.4.2 Decision Rule

This trial is designed to address a single primary outcome. A group difference is claimed if the primary null hypothesis is rejected on the significance level (alpha) of 0.05 (two-sided).

2.5 Statistical Interim Analyses and Stopping Guidance

There will be no interim analysis in this trial. Due to the projects' assumed low risk of harm or unforeseen events for participants, along with a short project duration and data collection period, the establishment of an independent data monitoring committee is not deemed necessary. There is also no perceived necessity for routine collection and evaluation of adverse events.

2.6 Timing of Outcome Assessments

All planned measures and data collection are scheduled according to figure 1. Besides the baseline data collection, questionnaires are kept open for submission for two weeks (players) and three weeks (coaches) at each data collection timepoint. These periods are referred to as outcome assessment windows.

		-1	0	T1	T2	T3
Activities	**Participant**	Pre study Recruitment and consent	Pre study Baseline	Study Pre-season	Study In-season	Study Post-season
Recruitment and consent	Players, parents, coaches, club leaders	x				
Randomization	Club		x			
Quantitative data collection						
Demographics questionnaire	Players, coaches, club leaders		x			
Injury surveillance*	Players				x	
Behavior questionnaire	Coaches		x		x	x
Injury-preventive coaching practices	Coaches		x			x

*Conducted with biweekly measurements through the season

Figure 1. Timeline of outcome assessments of #Utviklingsklar.

- Pre-study baseline coaches: 13.05.2024.-29.08.2024
- Pre-study baseline players: 26.08.2024- 17.11.2024
- Study in season coaches: 06.02.2025-02.03.2025
- Study in season players: week 42, 44, 46, 48, 50, 52 of 2024 and 2, 4, 6, 8, 10, 12, 14 of 2025. Players pilot tested their questionnaire during the recruitment phase, these data are not included in the data collection time periods.
- Study post-season coaches: 21.04.2025-07.05.2025

2.7 Timing of Final Analysis

The main analysis is planned when all clubs have been given the opportunity to attend/conduct all parts of the intervention, data at the post-season assessments have been entered, verified and validated and the primary database has been locked.

3. Statistical Principles

3.1 Confidence Intervals and p-values

All calculated p-values will be two-sided and compared to a 5% significance level. If a p-value is less than 0.05, the corresponding group difference will be denoted as statistically significant. All effectiveness estimates will be presented with two-sided 95% confidence intervals. As there is only one primary hypothesis to be tested in this trial, there will be no adjustments for multiplicity.

3.2 Adherence and Protocol Deviations

Adherence to the intervention will be based on the description of fidelity and dose of #Utviklingsklar's three main components: 1) the e-learning, 2) the workshop, 3) the mid-season meeting. No cut-off for adherence will be defined.

3.3 Analysis Populations

The Enrolled Set will include all participants who have provided informed consent and have been included in the study database. The Full Analysis Set (FAS) will be defined as all participants randomly assigned to the groups having responded to the OSTRC questionnaire on health problems at least once (see Sections 2.6 and 5.1.1.4).

4. Trial Population

4.1 Screening Data, Eligibility and Recruitment

Clubs will be eligible for participation if they are able to participate with one club leader, 2-6 teams (teams from at least two different age groups (13-17) and both the boy and girl league should ideally be represented), and a minimum of one coach from each of the participating teams.

A CONSORT flow diagram (18) will be used to summarize the number of participants who were:

- Included and randomised
- Received the intervention
- Lost to follow-up (reasons will be provided)
- Randomised and included in the primary analysis

4.2 Withdrawal/Follow-up

The status of included and randomised participants will be tabulated by group according to:

- Completed intervention and assessments
- Completed assessments but not intervention
- Withdrew consent
- Lost to follow-up

Timing of withdrawal will be presented with numbers and reasons for withdrawal (and exclusion from analysis) given at each stage.

4.3 Baseline Participant Characteristics

The baseline participant characteristics to be summarized include:

Players	Age, gender, player position (handball), previous injury, player experience (years), participation in other sports and weekly hours of participation in other sports.
Coaches	Age, gender, education in health-related field, education within injury diagnosis/treatment/prevention, university-level coaching education, completed coaching courses, satisfaction with injury prevention knowledge in coaching courses, coaching experience (years), receiving salary for coaching, employed by club in full-time position, possessing multiple club roles.
Clubs	Club member fee (kroner), club provides coach salary, club employs full time coaches, number of fulltime coaches, club employs fulltime leaders, number of fulltime leaders, the club possesses an injury preventive plan, club teams' participation in *Skadefri* club event within previous two years.

Demographics and baseline characteristics will be summarized by randomised group using descriptive statistics (N, mean, standard deviation, median, 25/75 percentiles) for continuous variables, and number and percentages of participants for categorical variables.

5. Analysis

5.1 Outcome Definitions

All definitions and variables for players are based on the IOC consensus statement on methods for recording and reporting of epidemiological data on injury and illness in sport (19) and its adaptation to team ball sports (20). Definitions and variables for coaches behavioral determinants builds on the Health Action Process Approach (HAPA-model) (21).

5.1.1 General Definitions and Derived Variables

5.1.1.1 Health problems

A *health problem* is defined as any condition that reduces an athlete's normal state of full health, irrespective of its consequences on the athlete's sports participation or performance or whether the athlete sought medical attention. This constitutes an umbrella term that includes, but is not limited to, injury and illness. A health problem is further divided into injury and illness. *Injury* is defined as tissue damage or other derangement of normal physical function due to participation in sports, resulting from rapid or repetitive transfer of kinetic energy. *Illness* is defined as a complaint or disorder experienced by an athlete, not related to injury. Illnesses include health-related problems in physical, mental or social well-being, or removal or loss of vital elements.

5.1.1.2 Exposure

Exposure is defined as the time during which athletes are at risk of injury and is recorded for each individual within a team. *Training exposure* is quantified as the weekly hours of training during the observation period. *Match exposure* is quantified as the weekly minutes of match play during the observation period.

5.1.1.3 Match season

The match season is defined as the week the most teams start their regular league season and the week where this season ends.

5.1.1.4 The Oslo Sports Trauma Research Center Questionnaire on Health Problems

The Oslo Sports Trauma Research Center Questionnaire on Health Problems (OSTRC-H2) is used to collect all player data. It consists of four key questions about health problems impact on 1) participation in sports, 2) training volume, 3) performance, and 4) symptoms of health problems during the past 7 days. It also contains additional questions on injury and exposure. The questionnaire is self-reported by players and is administrated biweekly throughout the match season.

5.1.2 Primary Outcome Definition

The primary outcome is the is the weekly injury severity score during the match season. The injury severity score is derived from responses to each of the four OSTRC-H2 questions, measured at 13 time points during the match season (see Section 2.6). Each question is assigned a score ranging from 0 to 25, culminating in a total injury severity score from 0 to 100 at each time point. If a player reports more than one injury at a given data collection timepoint, the injury severity score will be calculated as the maximum of the reported injury severity scores.

5.1.3 Secondary Outcomes Definitions

5.1.3.1 Injury consequence outcomes

1. The weekly injury severity score during the match season for sudden and gradual onset injuries.
2. The weekly injury severity score during the match season for lower leg, ankle/foot, knee and shoulder injuries.
3. The weekly injury severity score during the match season for sudden onset lower leg, ankle/foot, knee and shoulder injuries.
4. The weekly injury severity score during the match season for gradual-onset lower leg, ankle/foot, knee and shoulder injuries.
5. Injury burden, defined as the sum of injury severity score divided by the sum of exposure (per 1000 hours), where the sums are over team and over match season. The unit of analysis for burden is thus team and not player. Only pairs of severity score and exposure for each player will be counted (i.e. if a player has missing data for either the severity score or the exposure at a time point, neither will be counted for that timepoint).

5.1.3.2 Behavioral determinant outcomes

Behavioral determinant outcomes are defined as the coaches change in aggregated behavioral determinant scores from baseline to mid-season and from baseline to end-of season.
The aggregated scores include the determinants 1) risk perception, 2) intention, 3) outcome expectancies, 4) action self-efficacy, 5) maintenance self-efficacy, 6) coping self-efficacy, 7) recovery self-efficacy, 8) action plans 9) coping plans and 8) club social support at baseline, mid-season and at end of season. Behavioral determinants will be measured with the *Sports*

Injury Preventive Behavior Questionnaire containing 56 items with three to six items within each determinant, all assessed using a 7-point Likert scale. The 7-point Likert responses will be transformed into aggregate scores by summing the items related to each determinant and dividing this total by the maximum possible score, resulting in values ranging from 0.14 to 1.0.

5.1.3.4 Injury-preventive coaching practices outcomes

The injury-preventive coaching practice outcomes consist of:

1. The change in the extent to which teams complete warm-up as described in the intervention from baseline to end-of season.
2. The change in the extent to which teams complete strength training as described in the intervention from baseline to end-of season.
3. The change in the extent to which players with pain or injuries receive guidance on medical care from baseline to end-of season.
4. The change in the extent to which training and match participation is facilitated for players with pain or injuries from baseline to end-of season.

Coaches will report injury-preventive coaching practices in a study-specific 7-point Likert scale questionnaire at baseline and at end of season. The endpoint will be the change measured on a 7-point scale, which is then converted into a 13-point scale ranging from -6 to +6.

5.1.4 Overview of Outcomes

Level	Outcome	Timeframe	Type
Primary	Weekly injury severity score	Baseline to end-of season (measured biweekly)	Continuous
Secondary	Weekly injury severity score for sudden and gradual onset injuries.		
	Weekly injury severity score for lower leg, ankle/foot, knee and shoulder injuries.		
	Weekly injury severity score for gradual-onset lower leg, ankle/foot, knee and shoulder injuries.		
	Weekly injury severity score for sudden onset lower leg, ankle/foot, knee and shoulder injuries		
	Injury burden		
	Change in aggregated behavioral determinant scores	Baseline to mid-season and baseline to end of season	Continuous
	Extent to which teams complete warm-up as described in the intervention	Baseline to end-of season	Ordinal
	Extent to which teams complete strength training as described in the intervention.		
	Extent to which players with pain or injuries receive guidance on medical care.		
	Extent to which training and match participation is facilitated for players with pain or injuries.		

5.2 Analysis Methods

All statistical analyses will be performed on the full analysis set (FAS).

5.2.1 Primary Outcome

Analysis

The primary outcome (weekly injury severity score) will be analyzed with a linear mixed model. The model will include fixed effects for intervention (intervention vs control), time point, intervention x time point interaction, and geographical region (stratification factor in the randomisation). Time point is defined as 1 for the first response to the OSTRC questionnaire (week 42, 2024), 2 for the second response to the questionnaire (week 44, 2024), and so on until 13 for the last response (week 14, 2025). The model will include random intercepts for players nested within clubs. The predicted margins over all time points will be presented for intervention and control separately with 95% confidence intervals (CIs). The effect measure will be the difference between the weekly injury severity score for intervention and control, estimated as the predicted marginal effect of intervention over all time points, based on the fitted linear mixed model. The effect estimate will be presented with a 95% CI and a P-value for the null hypothesis of a difference equal to zero.
The predicted margins for intervention and control will be presented with 95% CIs for each time point in a plot. The estimated intervention effect (difference between intervention and control) with a 95% CI for each time point will also be shown in a plot.

Assumption checks

The distribution of the primary outcome (injury severity score) will be assessed with descriptive statistics and histograms. With a sample size of approximately 2000, the linear mixed model will be robust to quite large deviations from the normal distribution, and the injury severity score is bounded below at 0 and above at 100, so its distribution cannot be severely skewed. Still, in the unlikely case that the distribution of the outcome is deemed to deviate too much from the normal distribution, a log transformation of the outcome will be done prior to fitting the linear mixed model. In that case, an analysis of the untransformed data will be performed as an additional sensitivity analysis. After fitting the model (original scale or log transformed), plots of observed and model-fitted values (by intervention group and time point) will be compared to assess the fit of the model.

Missing data

The linear mixed model will handle missing data in one or more time points per player under the assumption of missing at random. No patient in the FAS has missing data on all fourteen time points, per the definition of FAS (see section 3.3).

Subgroup analysis

A subgroup analysis of the primary outcome will be performed by team gender. The analysis will be as described for the primary analysis of the primary outcome above; however, instead of an interaction term between intervention and time point, there will be a three-way interaction between intervention, time point, and team gender. The results will be a separate estimated intervention effect across all time points for each team gender and separate plots of estimated intervention effects for each time point for each team gender. No hypothesis tests for intervention effects will be performed.

A test for subgroup effect (i.e. a test for the null hypothesis of equal intervention effects for each team gender) will be calculated with a likelihood ratio test for the models with and without interaction by team gender.

Sensitivity analyses

The following sensitivity analyses will be performed for the primary outcome:

- Analysis restricted to the first part of the season (2024, time point 1-6)
- Analysis restricted to the second part of the season (2025, time point 7-14)
- Analysis on untransformed data (only if the primary analysis is done on log-transformed data)

5.2.2 Repeated Measures Continuous Secondary Outcomes

Analysis

The secondary injury consequences outcomes based on the injury severity score will be analyzed in the same manner as the primary outcome, except that no hypothesis test for intervention effect will be performed.

Assumption checks

The distributions and model fit of the secondary outcomes will be explored in the same manner as for the primary outcome.

Missing data

The linear mixed model will handle missing data in one or more time points per player under the assumption of missing at random. No patient in the FAS has missing data on all fourteen time points, per the definition of FAS (see section 3.3).

5.2.3 Continuous Secondary Outcomes Measured at a Single Time Point

Analysis

Injury burden is a single-measure continuous outcome, and the unit of analysis is team. It will be analyzed with a linear regression model with intervention (intervention vs control), geographical region (stratification factor in the randomisation), and number of players per team (due to potential large variation between teams) as the explanatory variables. The standard errors will be adjusted to account for clustering within clubs. Based on the fitted model, the predicted margins for intervention and control separately and the predicted marginal effect of intervention will be presented with 95% CIs.

Assumption checks

The distribution of the residuals from the fitted linear regression model will be assessed with descriptive statistics and histograms. If the distribution of the outcome is deemed to deviate too much from the normal distribution, median regression with bootstrap confidence intervals will be used instead of linear regression. Medians and differences of medians will be reported instead of means and differences in means.

Missing data

Since the analysis of burden will be performed on teams as the unit of analysis, we do not expect that there are teams with missing data on burden, which would indicate that there are no data on severity score and/or exposure for any players in the team.
In cases where data are missing between two consecutive reports of the same injury, values from the preceding report should be carried forward. Consecutive reports with identical classifications for Acute/Overuse, Body Area, and Activity are considered the as the same injury and the incidence ID assigned to the earliest report in the sequence will be carries forward on the preceding injuries.

5.2.4 Continuous Secondary Outcomes Measured at Three Time Points

Analysis

Two secondary outcomes on coach behavioural determinants are measured at three time points (baseline, mid-season, and end of season): change in aggregated behavioral determinant scores from baseline to mid-season and change in aggregated behavioral determinant scores from baseline to end of season. A linear mixed model will be fitted to the data from all three time points. The model will include fixed effects for intervention (intervention vs control), time point, intervention x time point interaction, and geographical region (stratification factor in the randomisation). The model will include random intercepts for coaches nested within clubs. The predicted margins over all time points will be presented for intervention and control separately with 95% confidence intervals (CIs). The effect measures will be the differences between the changes in aggregated behavioral determinant scores from baseline to mid-season and from baseline to end of season for intervention vs. control. The effect estimate will be based on the predicted margins from the fitted linear mixed model.

Assumption checks

The distribution of the aggregated behavioral determinant score will be assessed with descriptive statistics and histograms. The aggregated behavioral determinant score is bounded below at 0.14 and above at 1.0, so its distribution cannot be severely skewed. Still, in the case that the distribution of the outcome is deemed to deviate too much from the normal distribution, a log transformation of the outcome will be done prior to fitting the linear mixed model. After fitting the model (original scale or log transformed), plots of observed and model-fitted values (by intervention group and time point) will be compared to assess the fit of the model.

Missing data

The linear mixed model will handle missing data in one or two time points per coach under the assumption of missing at random. For some coaches, we may have missing data for all three time points. Because we expect this to apply to very few coaches, they will be excluded from the analysis.

5.2.5 Ordinal Secondary Outcomes

Analysis

The ordinal secondary outcomes on coach practices are measured as the change in an ordinal 7-point scale from baseline to end of season. The change (baseline minus end of season) will be an outcome ranging from -6 (score 1 at baseline and 7 at end of season) to 6 (score 7 at baseline and 1 at end of season). This outcome is an ordinal outcome with 13 categories. With approximately 120 coaches, many of the categories will be sparsely populated, and we believe that an ordinal regression model would be a poor choice with these many categories and so few data. Instead, we will compare the mean number of categories of change from baseline to end of season for intervention vs. control. The outcomes will be analyzed with linear regression models with intervention (intervention vs control) and geographical region (stratification factor in the randomisation) as the explanatory variables. The standard errors will be adjusted to account for clustering within clubs. Based on the fitted model, the predicted margins for intervention and control separately and the predicted marginal effect of intervention will be presented with 95% CIs. The observed counts (and percentages) on the original 13-point ordinal scale will be presented for intervention and control.

Assumption checks

The distributions of the residuals from the fitted linear regression models will be assessed with descriptive statistics and histograms. With only 13 possible outcomes, it is very unlikely that the distribution of the residuals will exhibit any signs of large deviations from the normal distributions. Still, in the case that the distribution of the outcome is deemed to deviate too much from the normal distribution, a log transformation of the outcome will be done prior to fitting the model.

Missing data

The main analysis of the ordinal secondary outcomes will be performed on the complete case sample. As a sensitivity analysis, we will impute missing data with multiple imputation. The imputation model will be multinomial logistic regression, stratified by intervention/control, and it will include the following explanatory variables:

-Age level (team)
-Sex (team)
-Education in injury diagnosis/treatment/prevention (coach)
-Access to health personnel (team)
-Coaching experience (coach)
-University-level coaching education (coach)
-Completed coaching courses (coach)
-Satisfaction with injury prevention knowledge in coaching courses (coach)
-Education in health-related field (coach)
-Injury prevention plan (club)
-Participation in injury prevention (Skadefri) club event the last two years (club)
-Employed by club in full-time position (coach)
-Receiving salary for coaching (coach)
-Possessing multiple club roles (coach)
-Number of full-time leaders (club)

-Member fee (club)
-Age (coach)
-Gender (coach)
-Club
-Region

The number of imputations will equal the percentage of missing values, i.e. 20 imputations for 20% missing data, as per the rule of thumb in (22). In case the imputation model fails to converge, the model will be reduced by one explanatory variable at a time, starting with the last variable listed above and continuing in opposite order as listed.

6. Statistical Software

All statistical analyses will be done in Stata version 17 (StataCorp LLC, College Station, TX, USA).

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STATISTICAL ANALYSIS PLAN for Effectiveness of the Injury-preventive Program #Utviklingsklar

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SIGNATURE PAGE

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1. Introduction

1.1 Background and rationale

The majority of injuries in Norwegian youth occur in a sports setting (1). Sports injuries are a significant public burden in terms of healthcare costs and place the individual youth at higher risk of developing subsequent health problems (2, 3). Additionally, sports-active youth often reduce or altogether cease their engagement in sports and physical activities following injury (4). The down-stream consequences of injuries sustained during sports should therefore not be underestimated. Football and handball are the most popular sports among Norwegian youth. The combination of the high physical demands inherent to these sports and the ongoing process of growth and maturation makes youth football and handball players notably susceptible to injury (5-7). Common injuries observed among youth who play football and handball encompass muscular and ligamentous ruptures, bone stress injuries, and injuries to the growing physes (5, 8).

Several injury prevention programs are effective in reducing injury occurrences. Soligard, Myklebust (9) showed a reduction in injuries overall, overuse injuries, and severe injuries in youth female football by implementing the FIFA 11+ injury prevention program. This multicomponent program, which targets both neuromuscular control and muscle strength, was subsequently adapted for specific populations, such as FIFA 11+ Kids (10) and a tailored shoulder injury prevention program for goalkeepers (11). Other efficacious injury prevention programs targeting specific injuries include the Nordic Hamstring for hamstring muscle ruptures (12) and Copenhagen Adductor Exercise for adductor muscle ruptures (13). In handball, structured warm up programs have proven efficacious in preventing lower extremity injuries and shoulder injuries (14-16). However, the gap between efficacy trials and real-world implementation remains a significant challenge.

Against this backdrop, the #Utviklingsklar project commenced in 2021. It is a collaborative and knowledge-sharing project funded by the Research Council of Norway. The overall aim of the project is to develop and evaluate a new program, based on interdisciplinary program theory from sport sociology, biomedicine, and health behavior, to reduce first-time and recurrent injury in youth football and handball. The project follows the UK Medical Research Council (MRC) framework for developing complex health interventions (17). The MRC framework emphasizes the importance of research methods that focus not solely on efficacy, but also on the mechanistic workings of an intervention, and whether it can be implemented in a real-world setting (17).

During the first two years of the project, we undertook development and feasibility testing of the novel #Utviklingsklar intervention. *#Utviklingsklar* is a club-based intervention designed to improve injury-preventive coaching practices. By participating in the intervention, coaches and club leaders develop plans and practices for injury-preventive warm-ups, strength training, and management of players with current pain and injury. The program theory underpinning the intervention is based on previous research within this field, preliminary work conducted in the research project, public involvement, and established theoretical

frameworks. First, we conducted a comprehensive literature review to dissect the biomedical mechanisms underlying the effect of injury prevention programs in football and handball. This review culminated in the formulation of causal biomedical models informed by previous research. Second, a cross-sectional study on behavioral constructs using the Health Action Process Approach was conducted, garnering responses from 865 youth football and handball coaches and players. Outcomes revealed a distinct need for increased knowledge, self-efficacy, and tools to aid coaches in managing pain and injuries in youth players. Third, a second literature review was conducted, focusing on the influence of sociocultural forces on injuries in the youth sport context. Critical to the developmental process was extensive knowledge exchange with the sporting community through meetings and discussion with project partners NIF, NHF, NFF, and key end users (club leaders, coaches, youth players, and their parents). Results from the preliminary work and feedback from stakeholders guided intervention development and content. The feasibility assessment, conducted with participation of three clubs from youth football and handball, prompted minor program revisions and indicated that a large-scale evaluation was warranted.

The current statistical analysis plan describes the evaluation of *#Utviklingsklar* in football. The project is embedded within the context of Norwegian youth sport. Findings from this evaluation will guide future initiatives to protect youth health among project partners NIF, NHF and NFF. It is therefore of primary interest to investigate how injuries are affected by the #Utviklingsklar program compared to usual practice, which may or may not involve other initiatives to prevent injury.

Central to the evaluation is the hypothesis that injuries in the youth sporting context are influenced by injury-preventive coaching practices. These practices encompass injury-preventive warm-ups, injury-preventive strength training, and management of players with pain and injury, including adjusting training and match loads and guiding youth towards appropriate medical care when necessary. Moreover, these coaching practices are hypothesized to be influenced by specific behavioral determinants, alongside the broader sociocultural context and interpersonal dynamics inherent in the youth sport setting. The current evaluation aims not only to produce knowledge on how injuries are affected by the implemented intervention, but also how the intervention affects factors in the proposed causal pathway, as outlined in the program theory.

1.2 Trial Objectives

1.2.1 Primary Objective

The primary objective is to compare the effectiveness of *#Utviklingsklar* to usual practice on the weekly injury severity score in youth football players over one season.

1.2.2 Secondary Objectives

The secondary objectives are:

- To compare the effectiveness of *#Utviklingsklar* versus usual practice on injury consequences in youth football players over one season.
- To compare the effectiveness of *#Utviklingsklar* versus usual practice on football youth coaches' determinants of injury-preventive behavior at mid-season and end of season.
- To compare the effectiveness of *#Utviklingsklar* versus usual practice on injury-preventive coaching practice among youth football coaches over one season.

2. Trial Methods

2.1 Trial Design

The evaluation follows the MRC framework for complex interventions (17). The study is conducted by a parallel two-armed, pragmatic, superiority cluster-RCTs. Clubs are randomised to either the control group that continue their activity as normal or the intervention group participating in *#Utviklingsklar. #Utviklingsklar* includes a digital e-learning course, an in-person workshop, and a club meeting, all three activities involving participation of one club leader and a minimum of one coach from each participating team within each club.

2.2 Randomisation

Upon enrolment, clubs will be randomly assigned to either the control or intervention group in a 1:1 allocation ratio, using a computer-generated cluster randomisation schedule, taking differences in cluster size into account and stratified by geographical region. The biostatistician responsible for the randomisation and primary statistical analysis will be blinded to group allocation. It is impossible to blind players, coaches, and clubs to group allocation. For practical reasons (i.e., data monitoring and participant follow-up), neither the PhD students nor the principal investigator will be blinded.

2.3 Sample size

Sample size calculation has been based on the primary endpoint (using player weekly injury severity score during the study period of one season). Sample size estimations under varying assumptions for cluster size and effect were performed by the project biostatistician. Data from one previous study in the target population were used to estimate the average weekly injury severity score in the control group and expected standard deviation. Assuming club sizes of 64 players, 13 clubs in each trial arm are sufficient to detect a difference between the average weekly injury severity score of 34 (intervention group) and 25.5 (control group), with a pooled standard deviation of 30, 80% power, 2-tailed alpha of 0.05, and an ICC of

0.05 or less. This corresponds to a relative reduction of 25%. We will overshoot recruitment by four clubs to allow for potential withdrawal of clusters. The target number of clubs to recruit is therefore 15 in each trial arm. As cluster sizes are large, the risk of type II errors due to individual participant data loss is minor.

2.4 Statistical Framework

2.4.1 Hypothesis Test

The primary null hypothesis is that there is no difference between #Utviklingsklar and usual practice in the injury severity score in youth football players over one season. There is only one identified primary analysis. All other effectiveness analyses will be regarded as supportive.

2.4.2 Decision Rule

This trial is designed to address a single primary outcome. A group difference is claimed if the primary null hypothesis is rejected on the significance level (alpha) of 0.05 (two-sided).

2.5 Statistical Interim Analyses and Stopping Guidance

There will be no interim analysis in this trial. Due to the projects' assumed low risk of harm or unforeseen events for participants, along with a short project duration and data collection period, the establishment of an independent data monitoring committee is not deemed necessary. There is also no perceived necessity for routine collection and evaluation of adverse events.

2.6 Timing of Outcome Assessments

All planned measures and data collection are scheduled according to figure 1. Besides the baseline data collection, questionnaires are kept open for submission for two weeks (players) and three weeks (coaches) at each data collection timepoint. These periods are referred to as outcome assessment windows.

		-1	0	T1	T2	T3
Activities	**Participant**	Pre study Recruitment and consent	Pre study Baseline	Study Pre-season	Study In-season	Study Post-season
Recruitment and consent	Players, parents, coaches, club leaders	x				
Randomization	Club		x			
Quantitative data collection						
Demographics questionnaire	Players, coaches, club leaders		x			
Injury surveillance*	Players				x	
Behavior questionnaire	Coaches		x		x	x
Injury-preventive coaching practices	Coaches		x			x

**Conducted with biweekly measurements through the season*

Figure 1. Timeline of outcome assessments of #Utviklingsklar.

- Pre-study baseline coaches: 11.02.2025.-31.03.2025
- Pre-study baseline players: 23.03.2025- 08.05.2025
- Study in season coaches: 23.09.2025-21.10.2025

- Study in season players: week 17, 19, 21, 23, 25, 27, 29, 31, 33, 35, 37, 39, 41 and 43 of 2025. Players piloted their questionnaire during the recruitment phase, these data are not included in the data collection time periods.
- Study post-season coaches: 06.11.2025-30.11.2025

2.7 Timing of Final Analysis

The main analysis is planned when all clubs have been given the opportunity to attend/conduct all parts of the intervention, data at the post-season assessments have been entered, verified and validated and the primary database has been locked.

3. Statistical Principles

3.1 Confidence Intervals and p-values

All calculated p-values will be two-sided and compared to a 5% significance level. If a p-value is less than 0.05, the corresponding group difference will be denoted as statistically significant. All effectiveness estimates will be presented with two-sided 95% confidence intervals. As there is only one primary hypothesis to be tested in this trial, there will be no adjustments for multiplicity.

3.2 Adherence and Protocol Deviations

Adherence to the intervention will be based on the description of fidelity and dose of #Utviklingsklar's three main components: 1) the e-learning, 2) the workshop, 3) the mid-season meeting. No cut-off for adherence will be defined.

3.3 Analysis Populations

The Enrolled Set will include all participants who have provided informed consent and have been included in the study database. The Full Analysis Set (FAS) will be defined as all participants randomly assigned to the groups having responded to the OSTRC questionnaire on health problems at least once (see Sections 2.6 and 5.1.1.4).

4. Trial Population

4.1 Screening Data, Eligibility and Recruitment

Clubs will be eligible for participation if they are able to participate with one club leader, 2-6 teams (teams from at least two different age groups (13-17) and both the boy and girl league should ideally be represented), and a minimum of one coach from each of the participating teams.

A CONSORT flow diagram (18) will be used to summarize the number of participants who were:

- Included and randomised
- Received the intervention
- Lost to follow-up (reasons will be provided)
- Included in the primary analysis

4.2 Withdrawal/Follow-up

The status of included and randomised participants will be tabulated by group according to:

- Completed intervention and assessments
- Completed assessments but not intervention
- Withdrew consent
- Lost to follow-up

Timing of withdrawal will be presented with numbers and reasons for withdrawal (and exclusion from analysis) given at each stage.

4.3 Baseline Participant Characteristics

The baseline participant characteristics to be summarized include:

Players	Age, gender, player position (football), previous injury, player experience (years), participation in other sports and weekly hours of participation in other sports.
Coaches	Age, gender, education in health-related field, education within injury diagnosis/treatment/prevention, university-level coaching education, completed coaching courses, satisfaction with injury prevention knowledge in coaching courses, coaching experience (years), receiving salary for coaching, employed by club in full-time position, possessing multiple club roles.
Clubs	Club member fee (kroner), club provides coach salary, club employs full time coaches, number of fulltime coaches, club employs fulltime leaders, number of fulltime leaders, the club possesses an injury preventive plan, club teams' participation in *Skadefri* club event within previous two years.

Demographics and baseline characteristics will be summarized by randomised group using descriptive statistics (N, mean, standard deviation, median, 25/75 percentiles) for continuous variables, and number and percentages of participants for categorical variables.

5. Analysis

5.1 Outcome Definitions

All definitions and variables for players are based on the IOC consensus statement on methods for recording and reporting of epidemiological data on injury and illness in sport (19) and its adaptation to team ball sports (20). Definitions and variables for coaches behavioral determinants builds on the Health Action Process Approach (HAPA-model) (21).

5.1.1 General Definitions and Derived Variables

5.1.1.1 Health problems

A *health problem* is defined as any condition that reduces an athlete's normal state of full health, irrespective of its consequences on the athlete's sports participation or performance or whether the athlete sought medical attention. This constitutes an umbrella term that includes, but is not limited to, injury and illness. A health problem is further divided into injury and illness. *Injury* is defined as tissue damage or other derangement of normal physical function due to participation in sports, resulting from rapid or repetitive transfer of kinetic energy. *Illness* is defined as a complaint or disorder experienced by an athlete, not related to injury.

Illnesses include health-related problems in physical, mental or social well-being, or removal or loss of vital elements.

5.1.1.2 Exposure

Exposure is defined as the time during which athletes are at risk of injury and is recorded for each individual within a team. *Training exposure* is quantified as the weekly hours of training during the observation period. *Match exposure* is quantified as the weekly minutes of match play during the observation period.

5.1.1.3 Match season

The match season is defined as the week the most teams start their regular league season and the week where this season ends.

5.1.1.4 The Oslo Sports Trauma Research Center Questionnaire on Health Problems

The Oslo Sports Trauma Research Center Questionnaire on Health Problems (OSTRC-H2) is used to collect all player data. It consists of four key questions about health problems impact on 1) participation in sports, 2) training volume, 3) performance, and 4) symptoms of health problems during the past 7 days. It also contains additional questions on injury and exposure. The questionnaire is self-reported by players and is administrated biweekly throughout the match season.

5.1.2 Primary Outcome Definition

The primary outcome is the is the weekly injury severity score during the match season. The injury severity score is derived from responses to each of the four OSTRC-H2 questions, measured at 14 time points during the match season (see Section 2.6). Each question is assigned a score ranging from 0 to 25, culminating in a total injury severity score from 0 to 100 at each time point. If a player reports more than one injury at a given data collection timepoint, the injury severity score will be calculated as the maximum of the reported injury severity scores.

5.1.3 Secondary Outcomes Definitions

5.1.3.1 Injury consequence outcomes

1. The weekly injury severity score during the match season for sudden and gradual onset injuries.
2. The weekly injury severity score during the match season for ankle/foot, lower leg, knee, thigh, hip/groin, lumbosacral, and head injuries.
3. The weekly injury severity score during the match season for sudden onset ankle/foot, lower leg, knee, thigh, hip/groin, lumbosacral injuries.
4. The weekly injury severity score during the match season for gradual-onset ankle/foot, lower leg, knee, thigh, hip/groin, lumbosacral injuries.
5. Injury burden, defined as the sum of injury severity score divided by the sum of exposure (per 1000 hours), where the sums are over team and over match season. The unit of analysis for burden is thus team and not player. Only pairs of severity score and exposure for each player will be counted (i.e. if a player has missing data for

either the severity score or the exposure at a time point, neither will be counted for that timepoint).

5.1.3.2 Behavioral determinant outcomes

Behavioral determinant outcomes are defined as the coaches change in aggregated behavioral determinant scores from baseline to mid-season and from baseline to end-of season.
The aggregated scores represent the determinants 1) risk perception, 2) intention, 3) outcome expectancies, 4) action self-efficacy, 5) maintenance self-efficacy, 6) coping self-efficacy, 7) recovery self-efficacy, 8) action plans 9) coping plans and 10) club social support at baseline, mid-season and at end of season. Behavioral determinants will be measured with the *Sports Injury Preventive Behavior Questionnaire* containing 56 items with three to six items within each determinant, all assessed using a 7-point Likert scale. The 7-point Likert responses will be transformed into aggregate scores by summing the items related to each determinant and dividing this total by the maximum possible score, resulting in values ranging from 0.14 to 1.0.

5.1.3.4 Injury-preventive coaching practices outcomes

The injury-preventive coaching practice outcomes consist of:

1. The change in the extent to which teams complete warm-up as described in the intervention from baseline to end-of season.
2. The change in the extent to which teams complete strength training as described in the intervention from baseline to end-of season.
3. The change in the extent to which players with pain or injuries receive guidance on medical care from baseline to end-of season.
4. The change in the extent to which training and match participation is facilitated for players with pain or injuries from baseline to end-of season.

Coaches will report injury-preventive coaching practices in a study-specific 7-point Likert scale questionnaire at baseline and at end of season. The endpoint will be the change measured on a 7-point scale, which is then converted into a 13-point scale ranging from -6 to +6.

5.1.4 Overview of Outcomes

Level	Outcome	Timeframe	Type
Primary	Weekly injury severity score	Baseline to end-of season (measured biweekly)	Continuous
Secondary	Weekly injury severity score for sudden and gradual onset injuries.		
	Weekly injury severity score for ankle/foot, lower leg, knee, thigh, hip/groin, lumbosacral, and head injuries		
	Weekly injury severity score for gradual-onset ankle/foot, lower leg, knee, thigh, hip/groin, lumbosacral injuries		

	Weekly injury severity score for sudden onset ankle/foot, lower leg, knee, thigh, hip/groin, lumbosacral injuries		
	Injury burden		
	Change in aggregated behavioral determinant scores: 1) risk perception, 2) intention, 3) outcome expectancies, 4) action self-efficacy, 5) maintenance self-efficacy, 6) coping self-efficacy, 7) recovery self-efficacy, 8) action plans 9) coping plans and 10) club social support	Baseline to mid-season and baseline to end of season	Continuous
	Extent to which teams complete warm-up as described in the intervention	Baseline to end-of season	Ordinal
	Extent to which teams complete strength training as described in the intervention.		
	Extent to which players with pain or injuries receive guidance on medical care.		
	Extent to which training and match participation is facilitated for players with pain or injuries.		

5.2 Analysis Methods

All statistical analyses will be performed on the full analysis set (FAS).

5.2.1 Primary Outcome

Analysis

The primary outcome (weekly injury severity score) will be analyzed with a linear mixed model. The model will include fixed effects for intervention (intervention vs control), time point, intervention x time point interaction, and geographical region (stratification factor in the randomisation). Time point is defined as 1 for the first response to the OSTRC questionnaire (week 17, 2025), 2 for the second response to the questionnaire (week 19, 2025), and so on until the last response (week 43, 2025). The model will include random intercepts for players nested within clubs. The predicted margins over all time points will be presented for intervention and control separately with 95% confidence intervals (CIs).
The effect measure will be the difference between the weekly injury severity score for intervention and control, estimated as the predicted marginal effect of intervention over all time points, based on the fitted linear mixed model. The effect estimate will be presented with a 95% CI and a P-value for the null hypothesis of a difference equal to zero.
The predicted margins for intervention and control will be presented with 95% CIs for each time point in a plot. The estimated intervention effect (difference between intervention and control) with a 95% CI for each time point will also be shown in a plot.

Assumption checks

The distribution of the primary outcome (injury severity score) will be assessed with descriptive statistics and histograms. With a sample size of approximately 2000, the linear mixed model will be robust to quite large deviations from the normal distribution, and the injury severity score is bounded below at 0 and above at 100, so its distribution cannot be

severely skewed. Still, in the unlikely case that the distribution of the outcome is deemed to deviate too much from the normal distribution, a log transformation of the outcome will be done prior to fitting the linear mixed model. In that case, an analysis of the untransformed data will be performed as an additional sensitivity analysis. After fitting the model (original scale or log transformed), plots of observed and model-fitted values (by intervention group and time point) will be compared to assess the fit of the model.

Missing data
The linear mixed model will handle missing data in one or more time points per player under the assumption of missing at random. No patient in the FAS has missing data on all 14 time points, per the definition of FAS (see section 3.3).

Subgroup analysis
A subgroup analysis of the primary outcome will be performed by team gender. The analysis will be as described for the primary analysis of the primary outcome above; however, instead of an interaction term between intervention and time point, there will be a three-way interaction between intervention, time point, and team gender. The results will be a separate estimated intervention effect across all time points for each team gender and separate plots of estimated intervention effects for each time point for each team gender. No hypothesis tests for intervention effects will be performed. A test for subgroup effect (i.e. a test for the null hypothesis of equal intervention effects for each team gender) will be calculated with a likelihood ratio test for the models with and without interaction by team gender.

Sensitivity analyses
The following sensitivity analyses will be performed for the primary outcome:

- Analysis restricted to the first part of the season (2025, time point 1-7)
- Analysis restricted to the second part of the season (2025, time point 8-14)
- Analysis on untransformed data (only if the primary analysis is done on log-transformed data)

5.2.2 Repeated Measures Continuous Secondary Outcomes

Analysis
The secondary injury consequences outcomes based on the injury severity score will be analyzed in the same manner as the primary outcome, except that no hypothesis test for intervention effect will be performed.

Assumption checks
The distributions and model fit of the secondary outcomes will be explored in the same manner as for the primary outcome.

Missing data
The linear mixed model will handle missing data in one or more time points per player under the assumption of missing at random. No patient in the FAS has missing data on all fourteen time points, per the definition of FAS (see section 3.3).

5.2.3 Continuous Secondary Outcomes Measured at a Single Time Point

Analysis

Injury burden is a single-measure continuous outcome, and the unit of analysis is team. It will be analyzed with a linear regression model with intervention (intervention vs control), geographical region (stratification factor in the randomisation), and number of players per team (due to potential large variation between teams) as the explanatory variables. The standard errors will be adjusted to account for clustering within clubs. Based on the fitted model, the predicted margins for intervention and control separately and the predicted marginal effect of intervention will be presented with 95% CIs.

Assumption checks

The distribution of the residuals from the fitted linear regression model will be assessed with descriptive statistics and histograms. If the distribution of the outcome is deemed to deviate too much from the normal distribution, median regression with bootstrap confidence intervals will be used instead of linear regression. Medians and differences of medians will be reported instead of means and differences in means.

Missing data

Since the analysis of burden will be performed on teams as the unit of analysis, we do not expect that there are teams with missing data on burden, which would indicate that there are no data on severity score and/or exposure for any players in the team.
In cases where data are missing between two consecutive reports of the same injury, values from the preceding report will be carried forward. Consecutive reports with identical classifications for Acute/Overuse, Body Area, and Activity will be considered as the same injury and the incidence ID assigned to the earliest report in the sequence will be carried forward to all subsequent reports.

5.2.4 Continuous Secondary Outcomes Measured at Three Time Points

Analysis

Secondary outcomes on ten coach behavioural determinants are measured at three time points (baseline, mid-season, and end of season): change in aggregated behavioral determinant scores from baseline to mid-season and change in aggregated behavioral determinant scores from baseline to end of season. A linear mixed model will be fitted to the data from all three time points. The model will include fixed effects for intervention (intervention vs control), time point, intervention x time point interaction, and geographical region (stratification factor in the randomisation). The model will include random intercepts for coaches nested within clubs. The predicted margins over all time points will be presented for intervention and control separately with 95% confidence intervals (CIs). The effect measures will be the differences between the changes in each of the aggregated behavioral determinant scores from baseline to mid-season and from baseline to end of season for intervention vs. control. The effect estimate will be based on the predicted margins from the fitted linear mixed model.

Assumption checks

The distribution of the aggregated behavioral determinant scores will be assessed with descriptive statistics and histograms. The aggregated behavioral determinant score is bounded below at 0.14 and above at 1.0, so its distribution cannot be severely skewed. Still, in the case that the distribution of the outcome is deemed to deviate too much from the normal distribution, a log transformation of the outcome will be done prior to fitting the linear mixed model. After fitting the model (original scale or log transformed), plots of observed and model-fitted values (by intervention group and time point) will be compared to assess the fit of the model.

Missing data

The linear mixed model will handle missing data in one or two time points per coach under the assumption of missing at random. For some coaches, we may have missing data for all three time points. Because we expect this to apply to very few coaches, they will be excluded from the analysis.

5.2.5 Ordinal Secondary Outcomes

Analysis

The ordinal secondary outcomes on coach practices are measured as the change in an ordinal 7-point scale from baseline to end of season. The change (baseline minus end of season) will be an outcome ranging from -6 (score 1 at baseline and 7 at end of season) to 6 (score 7 at baseline and 1 at end of season). This outcome is an ordinal outcome with 13 categories. With approximately 120 coaches, many of the categories will be sparsely populated, and we believe that an ordinal regression model would be a poor choice with these many categories and so few data. Instead, we will compare the mean number of categories of change from baseline to end of season for intervention vs. control. The outcomes will be analyzed with linear regression models with intervention (intervention vs control) and geographical region (stratification factor in the randomisation) as the explanatory variables. The standard errors will be adjusted to account for clustering within clubs. Based on the fitted model, the predicted margins for intervention and control separately and the predicted marginal effect of intervention will be presented with 95% CIs. The observed counts (and percentages) on the original 13-point ordinal scale will be presented for intervention and control.

Assumption checks

The distributions of the residuals from the fitted linear regression models will be assessed with descriptive statistics and histograms. With only 13 possible outcomes, it is very unlikely that the distribution of the residuals will exhibit any signs of large deviations from the normal distributions. Still, in the case that the distribution of the outcome is deemed to deviate too much from the normal distribution, a log transformation of the outcome will be done prior to fitting the model.

Missing data

The main analysis of the ordinal secondary outcomes will be performed on the complete case sample. As a sensitivity analysis, we will impute missing data with multiple imputation. The

imputation model will be multinomial logistic regression, stratified by intervention/control, and it will include the following explanatory variables:
-Age level (team)
-Sex (team)
-Education in injury diagnosis/treatment/prevention (coach)
-Access to health personnel (team)
-Coaching experience (coach)
-University-level coaching education (coach)
-Completed coaching courses (coach)
-Satisfaction with injury prevention knowledge in coaching courses (coach)
-Education in health-related field (coach)
-Injury prevention plan (club)
-Participation in injury prevention (Skadefri) club event the last two years (club)
-Employed by club in full-time position (coach)
-Receiving salary for coaching (coach)
-Possessing multiple club roles (coach)
-Number of full-time leaders (club)
-Member fee (club)
-Age (coach)
-Gender (coach)
-Club
-Region

The number of imputations will equal the percentage of missing values, i.e. 20 imputations for 20% missing data, as per the rule of thumb in (22). In case the imputation model fails to converge, the model will be reduced by one explanatory variable at a time, starting with the last variable listed above and continuing in opposite order as listed.

6. Statistical Software

All statistical analyses will be done in Stata version 17 (StataCorp LLC, College Station, TX, USA).

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