Statistical analysis plan for The Health And Performance Promotion in Youth (Happy) study: A hybrid effectiveness-implementation study investigating the effectiveness of an implementation-supported injury prevention exercise program in Danish youth handball

Møller, Merete; Andersen, Lotte Nygaard; Möller, Sören; Juhl, Carsten; Kongsted, Alice; Roos, Ewa Maria

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Section 1: Administrative information

Trial and trial registration

- 1.a: Title: The Health and Performance Promotion in youth (Happy) study. Happy is a hybrid effectiveness-implementation study evaluating if the combination of access to the Happy Injury Prevention Exercise Program and the Happy implementation strategy (intervention group) is superior to a strategy of access to the Happy Injury Prevention Exercise Program only (control group) in improving team adherence and in reducing the shoulder, knee and ankle injuries in young handball players aged 11-17 years.
- 1.b: Trial registration number: ClinicalTrials.gov ID: NCT05294237

SAP version

- 2: Version 1.0. Date: 18.05.2022

Protocol version

- 3: This statistical analysis plan (SAP) has been written based on the PhD protocol approved by the Graduate School of Health, University of Southern Denmark, entitled “Injury prevention in Danish youth handball – a hybrid effectiveness-implementation study”. This SAP adheres to the Guidelines for the Content of Statistical analysis plans in Clinical trials (1). The SAP was made publicly available at the conclusion of the data collection and before any analyses commenced.

SAP revisions

- 4a: Revision history
- 4b: Justification for revision
- 4c: Timing of revision

This is the first version of this SAP. No revisions have been made.
Roles and responsibilities

- 5: Names, affiliations, and roles of SAP contributors

**Principal investigator**
Merete Møller, PT, Assistant professor, Department of Sports Science and Clinical Biomechanics, University of Southern Denmark, Odense, Denmark

**Senior investigator**
Ewa M. Roos, PT, Professor, Department of Sports Science and Clinical Biomechanics, University of Southern Denmark, Odense, Denmark

**Study chairs**
Lotte Nygaard Andersen, PT, Associate professor, Department of Sports Science and Clinical Biomechanics, University of Southern Denmark, Odense, Denmark

Carsten Juhl, PT, Associate Professor, Department of Sports Science and Clinical Biomechanics, University of Southern Denmark, Odense, Denmark

Alice Kongsted, Chiropractor, Professor, Department of Sports Science and Clinical Biomechanics, University of Southern Denmark, Odense, Denmark

**Statistician**
Martin Dalgaard Villumsen, PhD, Statistician, Post Doc, Department of Sports Science and Clinical Biomechanics, University of Southern Denmark, Odense, Denmark
Signatures

- 6a: SAP author:
  Date: 18/5-2022
  
  
  Merete Møller

- 6b: Statistician signature:
  Date: 18/5-2022
  
  
  Martin Dalgaard Villumsen

- 6c: Primary investigator signature:
  Date: 18/05.2022
  
  
  Merete Møller
Section 2: Introduction

Background

- 7: Synopsis of trial background

Background and rationale

Handball is one of the most popular organised sports in Denmark, but also a sport with some of the highest injury rates (2-4). According to a recent report on sports injuries among 3,498 adults and 3,221 children, Danish youth and senior handball players reported the highest prevalence of injuries in the past 12 months compared to 49 other sports (3). Fifty percent of these injuries are in the ankle, knee and shoulder joint (4). Injuries can lead to absence from sport for more extended periods or complete discontinuance with the sport, leading to risk of social isolation and inactivity with the consequences of poor mental and physical health (5). In the long term, injuries can lead to chronic pain, decreased function, and early development of osteoarthritis (6-8) with associated reduction of quality of life.

Injury prevention exercise programs (IPEPs) can reduce the risk of injury in the ankle and knee by up to 68% in both youth and senior players in soccer, handball, basketball, and volleyball (9-14). Studies have demonstrated that, in youth and senior handball, the risk of knee, ankle, and shoulder injuries can be reduced by up to 50% under ideal conditions in randomised controlled trials (9, 15-17). While these programs have been shown to be effective under controlled conditions, the effectiveness of IPEPs in a real-world setting is lacking in handball (18). A proposed reason for the lack of translation is that interventions shown to be efficacious in trials have had a biomedical focus and failed to systematically examine and address the influence critical contextual components have on real-world implementation (19). To successfully translate the genuine knowledge of injury prevention from research to a real-world practice context, it is essential to understand the contextual and facilitating factors that might help bridge the gap from research to practice (20).

Happy is an end-user, evidence-based and context-specific injury prevention initiative co-developed in a Danish youth handball setting. Guided by intervention mapping (21) as a theoretical framework, we have in previous steps investigated existing knowledge on the
effectiveness and implementation of injury prevention initiatives. We have collected data on injury prevention perspectives from players, coaches, clubs, and other relevant stakeholders from the handball environment through workshops, questionnaires, and interviews. While other studies in handball generally have developed and evaluated an Injury Prevention Exercise Program (IPEP) only, our acquisition of knowledge this far has resulted in a multifaceted intervention featuring an IPEP (Happy IPEP) and a Happy implementation strategy. Our multifaceted Happy intervention is based on behavioral and social science theories which addresses the barriers we have identified in Danish youth handball environments to a widespread, sustained, and high-fidelity use of injury prevention training.

The **Happy IPEP** is available online via the Happysport webpage (www.happysport.dk) and via a booklet emailed to all accepting coaches. It consists of seven warm-up components and four resistance training components to be completed after handball practice. The warm-up program has three to four exercise variations for each of the seven components and can be completed with no equipment other than handballs. A modified warm-up program with the same focus areas will be available when the warm-up must take place in a confined space e.g., a hallway where balls are not allowed.

The coaches may deliver the four resistance training components in the field or in the gym. The resistance training components in the field and the gym targets the same four body areas but differs in that the components in the gym are performed with equipment, while the components in the field can be performed without equipment or with elastic bands. The four focus areas of the Happy resistance training program are exercises targeting the 1) quadriceps, 2) hamstrings, 3) external shoulder rotators and 4) core and posterior shoulder muscles. Each resistance training component has three levels.

The **Happy implementation strategy** involves:

- "Train-the-trainer” workshop (3 hours).
- Coach support via phone (1 hour)
- On-field supervision midseason (2,5 hours)
- Online support via Teams or msn group with all involved coaches in the club (2,5 hours)
The Happy implementation strategy is delivered by Happy ambassadors (health professionals and physical trainers with a handball background) who oversee the train-the-train workshop and provide the coach support in the intervention group during the full handball season. The Happy ambassadors was educated at a seminar at the University of Southern Denmark (SDU) in late August 2021. In the beginning of the season, the ambassadors carried out the train-the-trainer workshop for coaches in each of their allocated clubs. All members of the club was invited to participate in the workshop, e.g., coaches of other teams than in the target age-group, club management, players, and other interested club members.

In this study, we aim to evaluate the effectiveness of our multifaceted intervention, featuring the Happy IPEP and the Happy implementation strategy, on implementation and injury outcomes.

This SAP describes the objectives and corresponding analyses for the primary report of the study.

Objectives and hypotheses

- **8: Description of specific objectives and hypotheses**

*Primary objectives*

*Implementation*

The primary implementation objective is to evaluate if access to the Happy IPEP in combination with applying the Happy implementation strategy (intervention group) is superior to a strategy of only getting access to the Happy IPEP (control group) on improving *adherence* to the Happy IPEP at team level during one season.

*Effectiveness*

The primary effectiveness objective is to evaluate if access to the Happy IPEP in combination with applying the Happy implementation strategy (intervention group) is superior to a strategy of only getting access to the Happy IPEP (control group) in reducing *shoulder, knee and ankle injuries* among young Danish handball players aged 11-17 years old during one season.
Primary hypotheses

We hypothesize that access to the Happy IPEP plus the Happy implementation strategy delivered and overseen by Happy ambassadors is more successful in terms of team adherence and in terms of reducing shoulder, knee and ankle injuries during a season when compared to access to the Happy IPEP only.

Secondary objectives

Implementation

Secondary implementation objectives are to evaluate if access to the Happy IPEP in combination with applying the Happy implementation strategy (intervention group) is superior to a strategy of only getting access to the Happy IPEP (control group) in improving:

- adherence to the warm-up part of the Happy IPEP at team level
- adherence to the resistance training part of the Happy IPEP at team level
- adherence to the resistance training part of the Happy IPEP at player level

Effectiveness

Secondary effectiveness objective is to evaluate if access to the Happy IPEP in combination with applying the Happy implementation strategy (intervention group) is superior to a strategy of only getting access to the Happy IPEP (control group) in reducing substantial handball related ankle, knee and shoulder injuries in young handball players aged 11-17 years old during one season.

Section 3: Trial methods

Trial design

- 9.0 Brief description of design

This study is a pragmatic hybrid effectiveness-implementation cluster randomised type 2 (RCT) study. Participating clubs were allocated (1:1 ratio) to either an intervention group receiving the Happy implementation strategy in combination with access to the Happy IPEP or to control group getting access to the Happy IPEP only. The study involves Danish handball clubs with teams at
the youth level (age groups under (u) 13, u15, u17) during one full season from October 2021 to May 2022 (plus recruitment period).

The primary endpoints are:

- the between-group difference in team adherence between the group randomised to receive the Happy IPEP plus HAPPY Implementation strategy and the group randomised to receive the Happy IPEP over one season.
- the between-group difference in shoulder, knee and ankle injuries between the group randomised to receive the Happy IPEP plus the HAPPY implementation strategy and the group randomised to receive the Happy IPEP only over one season.

Randomization

10: Randomization details
The clubs were randomly assigned to either the control or intervention group at a 1:1 allocation ratio, using a computer-generated cluster randomisation schedule, taking difference in cluster size into account. The randomisation was performed by a statistician, who received a blinded list of participating clubs and the number of players participating in each club.

Sample size

11. Full sample size calculation
The sample size calculation for adherence outcomes is based on a recent report using a similar approach with a mean team adherence to an IPEP in the group receiving access to an IPEP via a webpage of 55% and a mean team adherence in the group receiving IPEP + workshop in the beginning of the season of 75% (22). We expect a standard deviation of 1.0, a cluster size of 4 teams and cluster variation of 1.5. To detect a difference in adherence between groups at a 0.05 significance level, and with power 0.80, a sample size of 9.1 clubs in each arm are necessary. To allow for 10% dropouts, 10 clubs with a minimum of 4 teams in each arm are necessary.
Effectiveness
The sample size calculation for the primary effectiveness outcomes follows the formula suggested by Jahn-Eimermacher et al. (23). When considering time to first injury of interest (shoulder, knee, or ankle) in our balanced clustered design with an expected cluster size of 40 players, assuming data to follow a proportional hazards model and an overall 50% probability of censoring due to other injuries or lost to follow up before end of season, we derived that 6 or more clubs per arm would be needed to detect a hazard ratio of 0.5 at the significance level of 5% and power of 80% with a presumed cluster variation of 0.3.

Framework

• 12. Description of hypothesis testing framework
Both primary and secondary outcomes will be assessed using a superiority framework, expecting that teams in the intervention group receiving the Happy IPEP plus the Happy implementation strategy will have a higher adherence compared to teams in the control group receiving the Happy IPEP only.
Similarly, we expect players in intervention group will have a lower risk of shoulder, knee and ankle injury compared to players in control group.

Statistical interim analysis and stopping rules

• 13. Statistical interim analysis and stopping guidance
No stopping rules or statistical interim analyses were applied.

Timing of outcome assessments

• 14. Timing of final analysis
The follow-up period extends for 7 months after season start (October 1st, 2021) and all primary and secondary outcomes will be analyzed collectively by an independent statistician. Data from baseline and the weekly reports collected during the 7-months season will be included in the analyses.
15. Timing of outcome assessments

Table 1 presents an overview of baseline characteristics and outcomes assessed and their timing. The inclusion period started from mid of May 2021 until the first week in October 2021. At physical inclusion meetings starting at end of August 2021, coaches for each team received access to the level 1 resistance training exercises, and players and coaches were asked to answer an online baseline questionnaire. The randomization was conducted by a blinded statistician the last week of September 2021, when all teams had accepted to participate. The weekly reports of adherence, injury and handball exposure started at inclusion to the study, however, only reports from October 1st (the official study start) will be included in the analyses. On October 1st all coaches from each team received access to the full Happy IPEP.

Tabel 1: Baseline characteristics and outcomes of the Happy-study

<table>
<thead>
<tr>
<th>Coaches</th>
<th>Baseline characteristics</th>
<th>Weekly</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Age (years)</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Gender (male, female, binary/non-binary, other, prefer not to answer)</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Postal code (4 digits)</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Educational level (elementary school, high school, vocational education, higher education (short) higher education (middle), higher education (long))</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Club (string)</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Experience as handball coach for youth players (years)</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Experience as handball coach for senior players (years)</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Handball experience as player (years)</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Coach education (yes+within DHF*, yes+not within DHF*, no)</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Knowledge of IPEP** (yes, no, don’t know)</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Team they are coaching the following season (string)</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Number of times per week they have planned to train handball in the next season (n)</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Number of times per week they have planned to do resistance training in the next season (n)</td>
<td>X</td>
</tr>
</tbody>
</table>

Adherence

| Number of times they have performed each Happy IPEP** component in the past 7 days | X |

Players

<table>
<thead>
<tr>
<th>Baseline characteristics</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of birth (8 digits)</td>
<td>X</td>
</tr>
<tr>
<td>Gender (male, female, binary/non-binary, other, prefer not to answer)</td>
<td>X</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>X</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>X</td>
</tr>
<tr>
<td>Club (string)</td>
<td>X</td>
</tr>
<tr>
<td>Team (string)</td>
<td>X</td>
</tr>
<tr>
<td>Player position (keeper, wing, back, playmaker, streg, no permanent position, don’t know)</td>
<td>X</td>
</tr>
<tr>
<td>Preferred throwing arm (right, left, both)</td>
<td>X</td>
</tr>
<tr>
<td>Handball experience (years)</td>
<td>X</td>
</tr>
</tbody>
</table>
### Section 4: Statistical principals

**Confidence intervals and p values**
- 16. Level of statistical significance and confidence intervals
  A significance level of 5% is chosen.
- 17. Adjustment for multiplicity
  No adjustment for multiplicity will be performed
- 18. Confidence intervals
  Confidence intervals will be presented.

---

<table>
<thead>
<tr>
<th>Expected number of handball training sessions per week (1, 2, 3, &gt;3)</th>
<th>X</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participation on other handball teams (talent training, national teams, senior team, older teams, younger teams, other, none of the above)</td>
<td>X</td>
</tr>
<tr>
<td>Participation in other sports (yes, no)</td>
<td>X</td>
</tr>
<tr>
<td>If yes:</td>
<td>X</td>
</tr>
<tr>
<td>What other sports (string)</td>
<td></td>
</tr>
<tr>
<td>How many times a week (1 every other week, 1, 2, &gt;2, don’t know)</td>
<td>X</td>
</tr>
<tr>
<td>Resistance training (times per week) in the last season (1 every other week, 1, 2, &gt;2, don’t know)</td>
<td>X</td>
</tr>
<tr>
<td>Knowledge on IPEP** (yes, no)</td>
<td>X</td>
</tr>
<tr>
<td>If yes:</td>
<td>X</td>
</tr>
<tr>
<td>Name of program(s) (string)</td>
<td>X</td>
</tr>
<tr>
<td>How many times a week in the last season (1 every other week, 1, 2, &gt;2, don’t know)</td>
<td>X</td>
</tr>
<tr>
<td>Injuries within the past year (have had an injury, body regions and body side)</td>
<td>X</td>
</tr>
<tr>
<td>Current injuries within the last two weeks (OSTRC-H2 responses (24))</td>
<td>X</td>
</tr>
<tr>
<td><strong>Adherence</strong></td>
<td></td>
</tr>
<tr>
<td>Happy resistance training exercises times per week</td>
<td>X</td>
</tr>
<tr>
<td><strong>Health problems (injuries and illnesses), and handball exposure (training and match)</strong></td>
<td></td>
</tr>
<tr>
<td>Any health problems during the past 7 days based on the OSTRC-H2 questionnaire (24)</td>
<td>X</td>
</tr>
<tr>
<td>If players report anything but “full participation without any health problems” to the first question in the OSTRC-H2 questionnaire:</td>
<td></td>
</tr>
<tr>
<td>Modified training/competition</td>
<td></td>
</tr>
<tr>
<td>Affected performance</td>
<td></td>
</tr>
<tr>
<td>Extent of experienced pain</td>
<td></td>
</tr>
<tr>
<td>New or previously reported health problem within the past 14 days</td>
<td></td>
</tr>
<tr>
<td>Injury or illness</td>
<td></td>
</tr>
<tr>
<td>If injury, body region for injury</td>
<td></td>
</tr>
<tr>
<td>Number of training hours the past 7 days (hours)</td>
<td>X</td>
</tr>
<tr>
<td>Number of match minutes the past 7 days (minutes)</td>
<td>X</td>
</tr>
</tbody>
</table>

*DHF=Danish Handball Federation, **IPEP= Injury Prevention Exercise Program*
**Adherence and protocol deviations**

- **19a. Definition of adherence to the intervention**
  
  Optimal adherence to the Happy implementation strategy is defined as when minimum one coach from each team in the intervention group participate in the train-the-trainer workshop and in the mid-season supervision.
  
  Sub-optimal adherence to the Happy implementation strategy is defined as when minimum one coach from each team in the intervention group participate in the train-the-trainer workshop but not in the mid-season supervision.
  
  Poor adherence to the Happy implementation strategy is when no coaches from teams in the intervention group participate in the train-the-trainer workshop and the mid-season supervision.
  
- **19b. Description of how adherence to the intervention will be presented**
  
  Adherence to the intervention will be presented as the number and percentage of coaches that have optimal, sub-optimal and poor adherence to the intervention.
  
- **19c & 19d. Definition of protocol deviations and how they will be reported**
  
  A major protocol deviation is a protocol deviation that might significantly affect the results. All major protocol deviations will be reported in the primary report.

**Analysis population**

- **20. Definition of analysis population**
  
  **Intention to Treat Analysis**
  
  In the primary analyses of the trial outcomes, all coaches and players will be included according to the group they were randomized, following the Intention-To-Treat (ITT) principle. This is the full analysis set, defined as an analysis set being as complete and as close to the ITT principle of including all randomized individuals as possible (25).
  
  **Per protocol analysis**
  
  In addition, a per protocol analysis will be performed. The as treated population excludes players and coaches from teams in the intervention group where no coaches from the team attended the the train-the-trainer workshop (poor adherence to the intervention) and the mid-
season supervision. It is not possible that players/coaches in the control have received the workshops and ambassador guidance received in the intervention group, therefore the control group will remain the same in the per protocol analysis as in the intention to treat analysis.

Section 5: Trial population

Screening data

- 21. Reporting of screening data
  
  The duration of the recruitment period (start and end date) and the total number of subjects screened for eligibility throughout the recruitment period will be reported. See also item 23 & 24.

Eligibility

- 22. Summary of eligibility criteria
  
  This injury prevention initiative's primary beneficiaries are young handball players aged 11-17 years. All players irrespective of current or previous injuries were eligible for participation in the study. The study's target group also includes handball coaches as primary program deliverers. The desired teams are youth teams from the age groups under (u)13, u15, and u17. Handball clubs with at least four teams in the desired age groups, regardless of playing level, will be eligible for participation in the study. We aim to have clubs participating in all five regions of Denmark and include clubs from different municipalities in terms of economic resources to make sure that the participating groups are broadly representative of the Danish handball community. Also, we aim to obtain an equal distribution of female and male players included in the study.

Recruitment and withdrawals

- 23+24. Information to be included in the CONSORT flow diagram
  
  The CONSORT flow diagram will consist of the following:
- All clubs invited to participate
- All clubs declining to participate
- All eligible coaches not consenting
- All eligible players (or legal guardians when below age of 15) not consenting
- All clubs, coaches and players randomized for intervention and control arms
- All clubs, coaches and players not receiving the allocated strategy in the supported implementation arm
- All clubs, coaches and players with follow-up assessments at the 7 months follow-up (end of the season).
- Withdrawals/lost to follow-up with reasons and timing for both treatment arms.
- Clubs, coaches, and players included in the ITT, per protocol and as treated analyses for both treatment arms.

We invited clubs that met the eligibility criteria via the Danish Handball Federation (DHF). The recruitment period started May 2021. During the inclusion period introduction meetings for coaches, players, parents, and club management was held online by the principal investigator (MM) with the duration of 30 minutes to inform the potential participants on the study, data collection and data management. Hereafter, a link was sent out to all parents with eligible players to collect consent from the parents or legal guardians. The eligible coaches received a link to collect consent and baseline data. In August, the research group visited all the included clubs to ensure the following: 1) baseline data collection on players, 2) introduction to weekly data collection by players 3) baseline data collection on coaches 4) introduction to data collection by coaches.

Baseline patient characteristics

- 25a. List of baseline characteristics to be summarized
  Table 1 presents an overview of baseline characteristics that will be presented in the primary report.
- 25b. Details on descriptive summary of baseline characteristics
  Categorical and binary data will be summarized by absolute and relative frequencies. Continuous data will be summarized by mean (SD) if data are normally distributed and median
(IQR) if data are skewed. No formal tests for significant differences between groups at baseline will be performed, as this is not recommended by CONSORT (26).

Section 6: Analysis

Outcome definitions

- 26: Specification of outcomes and timing

Primary implementation outcome measure
Team adherence will be evaluated as the number of Happy components delivered per week at team level over the full season.

Reports of Happy program usage will be recorded electronically on a weekly basis by the head coach of each team using the web application REDcap. Each Sunday evening the head coach of each team will be asked to report how many times he or she has used each Happy component during the past 7 days.

Primary effectiveness outcome measure
For evaluation of effectiveness on injury outcomes, the primary outcome will be time to any new handball-related ankle, knee and shoulder injury defined as any tissue damage or other derangement of normal physical function due to participation in handball, resulting from rapid or repetitive transfer of kinetic energy, following a recent consensus statement from the International Olympic Committee (27).

Each week during the handball season, players will be asked to complete the updated version of the Oslo Sports Trauma Research Centre Questionnaire on Health Problems (OSTRC-H2) via SMS messages (24). We have previously demonstrated this approach to be a feasible and valid option for injury surveillance in youth handball players (28, 29). OSTRC-H is translated into Danish and has been validated and reliability tested among Danish athletes (30).

Players reporting anything but “full participation without any health problems” to the first question in the OSTRC-H2 questionnaire (24), and further classify the health problem as a new shoulder, knee or ankle injury is included as primary outcome.
Secondary implementation outcome measures

Secondary implementation outcome measures will be:

• number of Happy warm-up components delivered per week at team level over the full season.
• number of Happy resistance training components delivered per week at team level over the full season.
• number of Happy resistance training components completed per week at player level over the full season.

Secondary effectiveness outcome measure

Secondary effectiveness outcome will be time to any substantial handball related ankle, knee and shoulder injury. Players reporting at least a moderate reduction in training volume or performance due to a health problem with the OSTRC-H2 questionnaire (24) and further classify the health problem as a new shoulder, knee or ankle injury is defined as an substantial injury.

Analysis methods

• 27: What analysis methods will be used

Implementation

The longitudinal continuous adherence measure is modelled as linear combinations of intervention groups, sex, club and time using mixed effects linear regressions to account for the between subject variation.

Effectiveness

The recurrent time-to-injury data is analysed with multistate models considering injuries of interests and other injuries as events while adjusting for sex, club and time to study effects across intervention groups. Players will be censored if the player stops responding to the weekly questionnaires, drops out during the season, or by the end of 7 months follow-up, whichever comes first.

Missing data

• 28: Handling of missing data
No imputation methods will be applied, as the repeated measures mixed model allows inclusion of all subjects if there is at least a baseline measurement, or one follow up measurement (31).

- 29: Additional analyses

Other outcome measures at ClinicalTrials.gov (ID: NCT05294237) will be reported in subsequent, secondary reports. We have planned the following subsequent, secondary reports with the following aims:

1) to evaluate if applying the Happy implementation strategy in combination with access to the Happy IPEP is superior to a strategy of only getting access to the Happy IPEP on improving behavioural constructs like intentions, outcome expectancies, self-efficacy, social influences, action planning and coping planning among coaches.

2) To evaluate team and player adherence with the Happy IPEP and to study the associations between adherence and injury rates.

3) To evaluate if players with optimal adherence to the Happy IPEP have a lower risk for any handball-related injuries compared to players with non-optimal adherence who comparably change their weekly training load.

In aim 2+3 we will evaluate associations as a prospective cohort based on the cluster-randomized trial.

Harms

- 30: Handling adverse events

Adverse events are not reported in this study.

Statistical software

- 31: Details of the statistical package used for the analysis
Statistical analysis plan – HAPPY.

STATA 17.0 (or an updated version if applicable) (StataCorp, College Station, TX, USA) or other statistical analyses packages (such as R, SAS, SPSS) if needed.

Operating procedures

- 32: Data management

The procedures for data collection and management were approved by the Research and Innovation Office at the University of Southern Denmark, ensuring that it is organised following current GDPR rules (number 10.925). Personal information about patients is kept separate from the main data set and will not be shared with anyone outside the central study team. To protect confidentiality before, during and after the trial, all personal data is stored securely.

This SAP will form the basis for analyses of the described primary endpoints, which will be carried out by the same independent statistician, without any involvement from the investigators or study chairs. A study coordinator will code the two implementation arms into ‘Group A’ and Group B’ before handing the data over to the statistician. This will help ensure that the statistical analyses will be performed blinded from group (intervention/control) allocation.

To reduce risk of interpretation bias, blinded results from the ITT analysis (Group A vs. Group B) will be presented to all authors, who will agree on two alternative written interpretations, one where group A is the intervention group (teams receiving the Happy implementation strategy and Happy IPEP) and one where Group A is the control group (teams receiving the Happy IPEP only). After finalizing the blinded interpretation, the study coordinator will unblind who is Group A and Group B.
References


