


Implementing injury prevention training in youth handball (I-PROTECT) in Sweden: study protocol for a cluster randomised trial

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ABSTRACT

Introduction Efficacy trials show that evidence-based injury prevention training reduces injuries in youth athletes but effectiveness, that is, outside the controlled setting, is lower and, consequently this training has had limited public health impact. Insufficient involvement of end-users at the individual and organisational levels is identified as a main barrier to successful implementation. The ‘Implementing injury Prevention training Routines in TEams and Clubs in youth Team handball (I-PROTECT)’ uses an ecological participatory design incorporating the perspectives of multiple stakeholders throughout the project. Within the I-PROTECT research project, the specific aim of this study is to investigate the implementation of the end-user-targeted I-PROTECT programme.

Methods and analysis This pragmatic two-armed cluster randomised controlled trial is conducted collaboratively with the Swedish Handball Federation that has overall responsibility for handball in Sweden. Randomly selected clubs in Sweden offering handball for both female and male youth players are invited to participate. 18 clubs are randomised (stratified by club size) to intervention (I-PROTECT plus tailored implementation support) or control (injury prevention programme currently available through the Swedish Handball Federation). The anticipated total number of potential participants (players, coaches, club administrators, parents/guardians) is ~3500. The I-PROTECT programme includes end-user-targeted information and physical and psychological injury prevention training available in a specifically developed interactive mobile application. Implementation strategies were selected from the Expert Recommendations for Implementing Change discrete implementation strategy compilation, based on feedback from end-users. Implementation outcomes will be investigated at the end of the handball season using the Reach, Effectiveness, Adoption, Implementation and Maintenance implementation evaluation framework. A study-specific questionnaire, app downloads and/or workshops will be used to collect data.

Ethics and dissemination The Swedish Ethical Review Authority approved the study. Results will be disseminated in peer-reviewed scientific journals, as popular science articles, at international conferences and communicated via the Swedish Handball Federation.

WHAT IS ALREADY KNOWN ON THIS TOPIC

- ⇒ Evidence-based injury prevention training is effective in reducing musculoskeletal injuries in youth team ball sports under controlled conditions but has had limited public health impact due to poor implementation in real-world settings.
- ⇒ Interventions that are cocreated with end-users enhance implementation in real-world settings, yet involvement of end-users is often lacking or not sufficiently described.
- ⇒ Knowledge about barriers and facilitators of implementation is important for intervention development and designing appropriate intervention implementation strategies.
- ⇒ The ‘Implementing injury Prevention training Routines in TEams and Clubs in youth Team handball (I-PROTECT)’ research project has an ecological participatory design incorporating the perspectives of multiple stakeholders (health beneficiaries, programme deliverers, policy-makers) throughout the project.

Trial registration number [NCT05696119](https://clinicaltrials.gov/ct2/show/study/NCT05696119).

INTRODUCTION

Musculoskeletal injuries are prevalent among youth athletes, contributing to both physical and mental health problems.¹ Injuries may end the youth’s sports participation and even prevent the person from participating in recreational sports or other moderately demanding physical activities. Injuries cause pain and disability, along with psychological suffering, for example, negative emotions, fear of reinjury, lack of confidence, mood disturbance and mental health problems, as well as loss of identity and social connections.^{1–3} Moreover, previous injury is a strong risk factor for recurrent injuries,^{4 5} further

WHAT THIS STUDY ADDS

- ⇒ This cluster-RCT randomised controlled trial will investigate the implementation of the I-PROTECT programme that was co-created by researchers/experts and end-users, and includes both physical and psychological aspects of injury prevention targeting the individual, team, and organisational levels. Comparison will be existing injury prevention training.
- ⇒ Tailored implementation support will be developed based on identified barriers and facilitators in previous I-PROTECT project studies, and from a consensus implementation strategy compilation.
- ⇒ Implementation outcomes will be investigated (questionnaires, workshops) in terms of the Reach, Effectiveness, Adoption, Implementation and Maintenance implementation evaluation framework with end-users (players, coaches, and club administrators) over one season.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

- ⇒ The overall goal of the I-PROTECT project, agreed with the Swedish Handball Federation, is to make injury prevention training an integral part of regular handball practice in youth handball in Sweden.
- ⇒ The current study will inform the Swedish Handball Federation about how injury prevention training can be implemented widely within Swedish youth handball.
- ⇒ Successful implementation of injury prevention training has the potential to reduce the risk of injuries, enhance athletic performance, promote physical and mental health, and enhance conditions for sustainable participation in sport.

joint problems⁶ and developing mental health problems.⁷ Thus, injuries cause negative effects on the youth's physiological, psychological and social health in both the short and long term.

Injury prevention training programmes addressing both physical and psychological aspects have proven effective in reducing injury under controlled/ideal conditions,^{8 9} however, their public health impact remains limited due to inadequate, improper or unsustainable implementation outside these controlled settings.^{10 11} In other words, the effectiveness ('real-world' settings) of injury prevention training is lower than the efficacy (controlled conditions) of such training. Insufficient involvement of end-users in programme development and implementation planning at the individual and organisational levels has been identified as a main barrier to successful implementation.¹² A proposed approach is to involve stakeholders from the start and throughout the project, as this may support implementation of an intervention.¹³

Against this backdrop, the 'Implementing injury Prevention training ROutines in TEams and Clubs in youth Team handball (I-PROTECT)' research project was initiated in 2015 through dialogue between end-users and researchers with the overall goal to make injury prevention training an integral part of regular practice in youth handball through a series of studies.¹⁴ In previous studies, injury prevention programmes for youth athletes have typically been developed by experts with no or insufficiently described end-user involvement.¹⁵⁻¹⁷ In contrast, I-PROTECT has an ecological participatory

design incorporating the perspectives of multiple stakeholders (health beneficiaries, programme deliverers and policy-makers) throughout the project, and the project integrates behavioural and social science theories with medicine and public health perspectives.¹⁴ While previous injury prevention programmes focus on physical aspects of injury prevention of either lower or upper extremities, performed as a separate warm-up,¹⁵⁻¹⁷ the I-PROTECT intervention includes both physical and psychological aspects of injury prevention integrated within warm-up and handball skills training.¹⁸ Also, the I-PROTECT intervention (information and training) is unique in that it targets the individual, team and organisational levels and was developed in a cocreating process involving end-users (coaches and players) and researchers/experts (sports medicine, sport psychology, handball, physical therapy and/or strength and conditioning).¹⁸

We have conducted mixed-methods and qualitative studies within I-PROTECT and identified numerous implementation barriers and facilitators.¹⁸⁻²¹ These can be categorised according to the five major determinant domains of the Consolidated Framework for Implementation Research (CFIR), that is, intervention characteristics, outer setting, inner setting, characteristics of the individuals involved and the process of implementation.^{22 23} CFIR is a widely used determinant framework in implementation science.²⁴ Knowledge about the determinants (ie, barriers and facilitators) of implementation is important to develop appropriate strategies to enhance implementation of the intervention. In our previous I-PROTECT studies, barriers were mainly related to lack of knowledge and time, other priorities and challenges to creating new habits and routines.¹⁸⁻²¹ Facilitators were principally about being well informed, having an end-user-targeted intervention and supportive material, and clear support and priority from the club.¹⁸⁻²¹ The current project will account for these determinants when designing and executing context-specific strategies aimed to overcome the barriers and harness the facilitators for implementing the training intervention.

It is widely recognised that the implementation of interventions often yields suboptimal results when compared with interventions in controlled trials—this is also the case in the context of injury prevention training.^{11 25} The Dynamic Sustainability Framework refers to 'voltage drop' (interventions are expected to yield lower benefits as they move from efficacy to effectiveness and on to implementation and sustainability) and 'programme drift' (deviation from the original protocols is assumed to decrease benefit) to explain the loss of impact of health interventions.²⁶ Frequent occurrences of implementation failure are acknowledged²⁷ and implementation science emphasises that evidence of effectiveness alone is insufficient to drive real-world adoption and use of interventions.²⁴ The use of theory-informed and evidence-informed strategies that address relevant context-specific barriers and facilitators is crucial to supporting the implementation of interventions. Implementation-supportive strategies

can be various activities, methods or techniques used to enhance the adoption, implementation and sustainability of interventions.²⁸ Tailored implementation support for the end-user-targeted I-PROTECT intervention will be developed in the present study.

The current study was planned collaboratively with the Swedish Handball Federation (SHF) to investigate how I-PROTECT will work under real-world conditions and become part of regular handball practice. Collaboration with SHF is important as this organisation has overall responsibility for handball in Sweden, and key representatives from SHF can help identify priorities and find solutions to potential problems that may make a difference in implementation in the real world. The specific aim is to investigate the implementation of I-PROTECT using the RE-AIM evaluation framework that addresses five dimensions of intervention implementation: Reach, Effectiveness, Adoption, Implementation and Maintenance.

METHODS AND ANALYSIS

Study design

This is a pragmatic two-armed cluster randomised controlled trial (cluster-RCT) conforming to the Consolidated Standards of Reporting Trials statement extension to cluster-randomised trials.²⁹ The protocol

adheres to the Standard Protocol Items Recommendations for Interventional Trials guidelines³⁰ (figure 1). The trial was prospectively registered (ClinicalTrials.gov NCT05696119).

Patient and public involvement

This study was planned and conducted collaboratively with the SHF, which has overall responsibility for handball in Sweden. Key representatives from SHF (JL, RW and PE) are involved as coauthors to include perspectives from those directly connected to the handball community. They participated in designing the study, selected the control intervention to enable evaluation of a programme that was currently available through SHF's coach education material, contributed to identifying outcomes, recruited clubs and had contact with club representatives and coaches throughout the study. Collaborating with SHF makes the study more relevant for handball in Sweden and gains valuable insights from the organisation, such as finding solutions to potential problems for conducting the study and identifying relevant and appropriate implementation strategies. SHF's involvement also improves the chances of successful implementation and enhances the dissemination of findings within the handball community.

TIMEPOINT	STUDY PERIOD			
	Enrolment	Allocation	Post-allocation	
	-t ₁	0	Baseline	End of season
ENROLMENT				
Eligibility screen	X			
Informed consent	X			
Allocation		X		
INTERVENTIONS				
<i>I-PROTECT + tailored implementation strategies</i>			◀──▶	
<i>Control</i>			◀──▶	
ASSESSMENTS				
<i>Club demographics</i>			X	
<i>Participant demographics</i>				X
<i>Implementation outcomes using the RE-AIM implementation evaluation framework</i>				X

Figure 1 Protocol schedule of forms and procedures. I-PROTECT, Implementing injury Prevention training ROutines in TEams and Clubs in youth Team.

Setting, participants and randomisation

Clubs in Sweden offering handball for both female and male youth players (teams aged 12–16 years during the season 2023/2024) will be eligible for inclusion. All clubs offering handball for youth players are identified (n=144) from a list provided by SHF, and a random selection is invited to participate in this RCT. The number of teams in different clubs varies greatly, and larger and smaller clubs are often organised in different ways (eg, employed staff vs unpaid work). Given this, clubs are stratified by size based on the total number of teams in the clubs as follows: small clubs (≤ 37 teams) or large clubs (> 37 teams) (based on a list from SHF of clubs from the season 2022/2023). Teams in the age range 12–16 years usually accounted for less than half of the total number of teams in a club. For the age range 12–16 years, 75% of clubs have 13 teams or fewer. The intention is to include three large clubs and six small clubs in each study arm. Recruitment is performed in two steps: (1) In a random order, clubs will be asked to participate until enough clubs have been accepted (January–March 2023) and (2) Clubs will be distributed randomly to either intervention or control (April 2023). Exclusion criteria for clubs are (1) previous involvement in developing and/or testing I-PROTECT and (2) handball offered exclusively for either female or male players. An independent statistician will perform the randomisation.

Clubs will receive an invitation phone call and email from the SHF with information about the study, along with information to research participants approved by The Swedish Ethical Review Authority and a consent form. Clubs will be included if (1) the club's usual point of contact from the Federation (eg, the chair of the club committee/board and/or the key administrator) consents to participate in the RCT and follow the intervention they are assigned to after randomisation; (2) they are willing to support coaches of youth teams to participate in the study and (3) they are willing to complete a questionnaire during study. Teams will be included if (1) they train ≥ 2 times per week, (2) the team's head coach consents for the team to participate and (3) one coach in each team is willing to complete a questionnaire during the study. Teams will be excluded if they have players who are 17 years and older, as they often train with adult teams not eligible for the present study.

Intervention

The study will run over the handball season 2023/2024 (September 2023–May 2024). The intervention group will be offered I-PROTECT plus tailored implementation support while the control group will be offered injury prevention training currently available through the SHF's coach education material.

I-PROTECT intervention

I-PROTECT includes end-user targeted physical and psychological injury prevention information and training, made available in a specifically developed

interactive mobile application (I-PROTECT GO) as recently described in detail elsewhere.¹⁸ This interactive app includes modules for coaches, players, club administrators and parents/guardians. All modules include information about I-PROTECT and end-user-targeted information about injury prevention training (eg, benefits, physical and psychological principles, load management).¹⁸

Additional content is available in I-PROTECT GO for coaches, players and club administrators as follows:

- ▶ The coach module includes injury prevention physical and psychological training, with all physical exercises, and several sport psychology exercises, integrated within warm-up and handball skills training for their team(s) to perform.
- ▶ The player module includes injury prevention handball-specific strength exercises (to perform at the gym), sport-psychology exercises (to perform at home) and small set of handball-specific injury prevention exercises from the coach module (to perform during holiday breaks).
- ▶ The club administrator module includes information about implementing I-PROTECT at the club level including key components of strategies, processes and actions for implementation (eg, describe goals, identify possible barriers and solutions to address these, describe follow-up, maintenance, activities, roles and responsibilities).

Consistent with requests from coaches and players, different programmes are provided in the app over the season to support self-management and adoption of I-PROTECT. For handball-specific exercises to be integrated within warm-up or skills training, a set of 3 example programmes (one programme for each training session per week) is provided every 6 weeks over 6 periods over the season, yielding a total of 18 example programmes (ie, 3 programmes delivered over 6 weeks, and then a new set of 3 programmes delivered over 6 weeks and so on).¹⁸ To increase motivation, the three basic psychological needs of self-determination theory (ie, autonomy, perceived competence and relatedness)³¹ are used as follows: Players and coaches can change (autonomy), add (autonomy) or progress the difficulty of exercises (competence) and build their own programmes (autonomy, competence). Also, coaches within a team can build and share joint programmes (relatedness), and players are encouraged to provide peer-feedback if they conduct exercises with teammate(s) (relatedness). The content of I-PROTECT GO is described in detail elsewhere.¹⁸

Control intervention

Coaches of youth teams in the control group clubs are offered currently available injury prevention training (ie, 'Redo för Handboll', English: 'Ready for Handball'), accessible online through the SHF's coach education material. This training was developed by clinically active physical therapists with knowledge in handball. It includes physical principles of injury prevention (eg,

movement technique and muscle strength) but has not been evaluated. It consists of a bank of 118 exercises (warm-up, strength, flexibility and jumps) and two programmes with 15 or 16 exercises in each programme. The exercises have two levels of difficulty (level 1 n=61 exercises, level 2 n=57 exercises). Coaches are encouraged to read information about the training before starting with the programmes. This control intervention targets coaches only (not players or club administrators) and no implementation support is available. The control clubs will be asked to distribute information to coaches about 'Ready for Handball' the way they usually provide similar information (eg, email, meetings, social media). If teams already use an existing injury prevention training programme, they can choose to continue doing that instead of using 'Ready for Handball'.

Implementation strategies

Several tailored implementation strategies are used to support the implementation and use of I-PROTECT. The following implementation strategies were selected by three authors (EA, PN and AD) from the Expert Recommendations for Implementing Change discrete implementation strategy compilation,²⁸ based on feedback from end-users in our previous studies^{18 20 21} and the SHF key representatives (JL, RW and PE) (ie, information about I-PROTECT for clubs, coaches, players and parents/guardians, education for coaches, clear roles and responsibilities in clubs and teams, respectively) and confirmed by two authors (SB and KM): develop a formal implementation blueprint; use mass media; conduct educational meetings and intervene with end-users; distribute educational material and centralise technical assistance; promote adaptability; create or change credentialing and/or licensure standards; change physical structure and equipment; remind end-users and audit and provide feedback. Details of the implementation strategies are provided in [table 1](#).

To facilitate sustainability, the SHF requested that information meetings and educational activities were in digital format and that the educational material to support the content in the app was made available on the SHF's educational platform. Four authors (EA, SB, JL and KM) developed the online end-user targeted educational material. To enhance end-user ownership, an SHF key representative will provide each club administrator with a unique code for each team to download the app. The club administrator will distribute the codes to coaches, who then will share the code with players and parents/guardians of their team ([table 1](#)).

Previous study participants and the SHF key representatives emphasised the importance of the head coach supporting the use of I-PROTECT, and of at least one other coach being able to carry out the training with the team. Therefore, the head coach and at least one other coach in each team are encouraged to participate in the educational activities. We also encourage administrators and coaches of the same club, or at least coaches of the same team, to participate in educational activities

together, as this facilitates discussions and peer-support within the club and teams. The actors responsible for the strategies ([table 1](#)) will include researchers and key representatives from the SHF, to incorporate both research and context-specific experience and expertise. In general, the researchers will draft all written material and SHF representatives will provide feedback. SHF representatives will distribute material (written material, emails, codes for mobile application, equipment) to clubs and have contact with club administrators throughout the study. Information meetings with clubs will be held by an SHF representative and a researcher. Implementation strategy details are provided in [table 1](#).

Evaluation of implementation outcomes

RE-AIM evaluation framework

Implementation outcomes will be investigated using the RE-AIM implementation evaluation framework.³² An extended RE-AIM matrix for interventions delivered through community sports—the RE-AIM Sport Setting Matrix—will be used to guide the targeted sports system delivery level(s), as successful implementation of most sports injury prevention interventions needs action at multiple levels.³³ Given that the ultimate impact of an intervention is conceptualised as the combined effects of the five dimensions of RE-AIM, no main outcome is selected.

The definition for each RE-AIM dimension developed by re-aim.org is given below (in italics), followed by a description of how each dimension is operationalised in the present study, with a summary provided in [table 2](#). Data for Reach will be collected through existing records to identify eligible participants and app downloads. Data for Effectiveness, Adoption, Implementation and Maintenance will be collected using a study-specific questionnaire ([table 2](#), online supplemental files 1–3). Adapted questions will be used for coaches in the control group (online supplemental file 4). Players and club administrators in the control group will not complete a questionnaire because the control intervention does not include player or club administrator-specific material.

Reach

'The absolute number, proportion, and representativeness of individuals who are willing to participate in a given initiative, intervention or programme, and reasons why or why not.'

In the present study, Reach data will be the proportion of eligible stakeholders that consent to participate in the study, participate in educational activities and download the app. Completing educational activities and/or downloading the app will be considered an active demonstration of willingness to participate in the intervention. We selected these criteria because they indicate greater willingness to participate than simply consenting. Registering to use the app will be recorded in the app database, and educational activity completion will be recorded through the issuing of certificates. Participating in educational activities and downloading the app will be considered full

Table 1 Implementation strategies for I-PROTECT selected from the ERIC discrete implementation strategy compilation,²⁸ based on feedback from end-users

Implementation-support strategy	Actor(s) responsible for the strategy	Action(s) involved in the strategy	Target(s) of the strategy	Time point when the strategy will be executed
Develop a formal implementation blueprint	Researchers and SHF key representatives	The blueprint will include (1) background, aim/purpose, benefits of implementing I-PROTECT; (2) content of I-PROTECT; (3) scope of the change (eg, what organisational units are affected); (4) timeframe and milestones and (5) appropriate performance/progress measures (evaluation)	Club administrators	Before study start
Develop and use mass media	Researchers and SHF communications officer	Newsletters on SHF homepage and social media	All stakeholders	Before study start and regularly during study
Conduct educational meetings and intervene with end-users	Researchers and SHF key representatives	Online information meetings to support clubs to implement intervention with email/telephone follow-up to answer questions. Provide coaches with information to distribute to players and parents/guardians	Club administrators, coaches, players, parents/guardians	After randomisation
Develop and distribute educational material and centralise technical assistance	Researchers, SHF key representatives, club administrators and coaches	Develop end-user-targeted educational material: Make it available for coaches and club administrators on SHF digital learning platform. Distribute to players and parents/guardians through clubs and coaches. Downloading of mobile application I-PROTECT GO: Distribute codes to clubs, clubs to coaches and coaches to players and parents/guardians	Club administrators, coaches, players, parents/guardians	After randomisation
Promote adaptability	Researchers and SHF key representatives	Develop and distribute implementation checklist including key components of strategies, processes and actions for implementation (eg, describe goals, identify possible barriers and solutions to address these, describe follow-up, maintenance, activities, roles and responsibilities) for club administrators to complete. Follow-up email/telephone/online to answer questions	Club administrators	After digital information meeting and educational activities
Create or change credentialing and/or licensure standards	Researchers and SHF key representatives	Issue certificates for clubs and coaches, provided through the SHF digital learning platform after education	Club administrators and coaches	After education
Change physical structure and equipment	SHF key representatives	Distributes elastic bands and printed material to clubs for coaches and players to use in some exercises	Coaches through clubs	After digital information meeting and educational activities
Remind end-users	Researchers and SHF key representatives through clubs	Send reminder email to encourage use of intervention to clubs by SHF for further distribution to coaches	Coaches	At start of season after summer break and mid-period of study
Audit and provide feedback	Researchers and SHF key representatives	Provide: (1) Audit and feedback of the implementation checklist. (2) Audit and feedback on the progress against the implementation checklist. (3) Summary of results, distribute to clubs via email	1, 2. Club administrators. 3. Clubs for further distribution to coaches, players and parents/guardians through each club's preferred source (ie, email, club/team homepage)	1, 2. Start and mid-period of study End of study

Strategies are provided in chronological order. ERIC, Expert Recommendations for Implementing Change; I-PROTECT, Implementing injury Prevention training ROoutines in TEams and Clubs in youth Team; SHF, Swedish Handball Federation.

Table 2 Mapping the study outcomes to the RE-AIM implementation evaluation framework.³²

RE-AIM dimension	Definition and source	Outcome(s) in the present study for targeted stakeholder group(s)			
		Players	Coaches	Club administrators	Parents/guardians
Reach*	The absolute number, proportion and representativeness of individuals who are willing to participate in the intervention or programme ³²	Proportion of eligible players that register to use the app	Proportion of eligible coaches that consent to participate, attend online education and/or register to use the app	Proportion of eligible club administrators that consent to participate and/or register to use the app	Number of parents/guardians that register to use the app in proportion to number of eligible players
Effectiveness	The reported or perceived impact of intervention on injuries ³²	Risk perception, outcome expectancies, perceived effectiveness	Risk perception, outcome expectancies, perceived effectiveness	Risk perception, outcome expectancies, perceived effectiveness	Not relevant
Adoption	Adoption, ³² self-efficacy ³⁵ and acceptability ⁴⁷	Adoption, affective attitude, self-efficacy, perceived ease of use	Adoption, affective attitude, intervention coherence, self-efficacy, burden, opportunity costs, perceived ease of use	Adoption, affective attitude, intervention coherence, self-efficacy, burden, opportunity costs, perceived ease of use	Not relevant
Implementation	Adherence, ³⁴ fidelity, that is, whether the intervention was used as intended, ³⁷ and motivation and volition ³⁵ to use the intervention	Adherence, fidelity	Adherence, fidelity, coping planning	Adherence, fidelity, coping planning	Not relevant
Maintenance	Intention ³⁵ to use the intervention and actual maintenance, in the long-term	Intention	Intention, self-efficacy	Intention, self-efficacy	Not relevant

The RE-AIM Sport Setting Matrix was used to guide the targeted level(s) within the sport delivery system, as implementation of most sports injury prevention interventions needs action at multiple levels.³³

*Applies to intervention group while the control group (coaches only) will be asked questions about awareness.

RE-AIM, Reach, Effectiveness, Adoption, Implementation and Maintenance.

reach. Only consenting will be considered partial reach. For the control group, Reach (in terms of awareness) will be collected through the questionnaire (online supplemental file 4).

Effectiveness

'The impact of an intervention on important individual outcomes, including potential negative effects and broader impact including quality of life and economic outcomes; and variability across subgroups (generalisability or heterogeneity of effects).'

Given that the exercises in I-PROTECT are based on established injury prevention principles,²⁰ we argue that the training will have a positive effect if the exercises are used. Therefore, we will first evaluate if I-PROTECT is used within handball practice. Previous studies report that factors such as risk perception, outcome expectancies and acceptability predict implementation of an

intervention.^{34–36} Therefore, we have defined effectiveness for the present evaluation as positive responses to risk perception, perceived effectiveness and outcome expectancies as proxy indicators of likelihood of implementing I-PROTECT. If the present study shows that I-PROTECT is successfully implemented, further studies will include objective assessment of effectiveness (ie, changes in injury incidence data).

Adoption

'(Setting levels) The absolute number, proportion and representativeness of settings and intervention agents (people who deliver the programme) who are willing to initiate a programme and why.'

We will collect the following adoption data via questionnaire: adoption, affective attitude, intervention coherence, self-efficacy, burden, opportunity costs, ease of use. For players and coaches, adoption will be defined

as having used any components and/or exercises of I-PROTECT. For administrators, adoption will be defined as having sent information about I-PROTECT to their coaches during the past handball season.

Implementation

'At the setting level, implementation refers to the intervention agents' fidelity to the various elements of an intervention's key functions or components, including consistency of delivery as intended and the time and cost of the intervention. Importantly, it also includes adaptations made to interventions and implementation strategies.'

Frequency (how often), fidelity,³⁷ to programme and exercises (coaches and players), fidelity to tailored implementation checklist (club administrators) and/or coping planning will be collected will be collected through the questionnaire.

Maintenance

'At the setting level, the extent to which a programme or policy becomes institutionalised or part of the routine organisational practices and policies. Within the RE-AIM framework, maintenance also applies at the individual level. At the individual level, maintenance has been defined as the long-term effects of a programme on outcomes after a programme is completed. The specific time frame for assessment of maintenance or sustainment varies across projects.'

The intention (maintenance intention) and confidence (self-efficacy) of doing I-PROTECT exercises the next season will be collected through the questionnaire.

Stakeholders

There are four stakeholder groups with the intervention group (I-PROTECT) in the present study: players (participant level), coaches (team level), club administrators (club level)³³ and parents/guardians (online supplemental files 1–3). Coaches are the main target because they are critical to ensuring that injury prevention training is implemented in teams.³⁸ In our pilot study (ClinicalTrials.gov Identifier: NCT05304507), parents/guardians indicated they did not think questions about the implementation of the intervention were relevant for them to answer. Therefore, only Reach data will be recorded for parents/guardians. The RE-AIM-informed questionnaire will be sent at the end of the 2023/2024 handball season (April–May 2024) as we want to minimise the burden on end-users. Each club will be asked to send a list of teams, including the number of coaches and players in each team, and an email address and mobile phone number of one coach of each team who is willing to complete the questionnaire. Players, coaches and club administrators will be selected as follows:

- ▶ **Players:** Players aged 15–16 years who have downloaded the app, will be asked to complete the questionnaire. From 15 years of age, individuals can consent to participate in a study in Sweden without informed consent from a parent/guardian. They will

report data from the time that they downloaded the app.

- ▶ **Coaches:** We will ask one coach in each team to complete the questionnaire, and thus, represent the whole team. They will report data from the time that they downloaded the app (the whole season or shorter). This approach was chosen to avoid multiple responses from the same team which would introduce bias (eg, less variation in responses within a team than between teams, and potential conflicting responses).
- ▶ **Club administrators:** One administrator in each participating club will be asked to complete the questionnaire.

In the control group (Ready for Handball), a questionnaire will be sent to one coach of each team who is willing to represent the whole team and consents to complete the questionnaire (online supplemental file 4), that is, the same approach as for coaches in the I-PROTECT group. The anticipated total number of potential participants in the intervention group (players, coaches, club administrators, parents/guardians) and control group (coaches) is ~3500. This number is based on the following estimations for Reach (respond to questionnaire and/or download app): 100 teams (equals the number of coaches that will be asked to respond to questionnaire), approx. 25 players in each team (total ~2500), 9 club administrators and parents/guardians who can download the app (~1000).

Questionnaire

Previous studies evaluating the implementation of injury prevention training are either cross-sectional studies with retrospectively collected data^{39–41} or prospective studies with data from RCTs collected at preseason and post-season.^{42–43} There are also prospective studies that collect adherence data every week. However, these studies often include coaches who are paid employees⁴⁴ rather than unpaid volunteers as in our study. In Sweden, club coaches of youth teams are unpaid. Therefore, filling out a weekly questionnaire may be a considerable burden for them. We conducted a pilot study (ClinicalTrials.gov Identifier: NCT05304507) to explore if coaches and players would complete a short questionnaire (sent through text message) weekly. Players were generally not willing to respond to a weekly questionnaire. For coaches (n=18), although there were only 3–6 questions, the response rate was <48% which we deemed too low to achieve robust data in future studies. Also, coaches reported that it was too burdensome to report weekly. We independently asked five handball coaches not involved in the pilot study, their opinion on a retrospective time frame to provide valid responses for adherence to injury prevention training, all reported that they could recall a season, without recall bias. Based on this information, the experiences from this pilot study, and taking into account what has been done in previous studies,^{39–41} we will collect RE-AIM data at the end of the handball season only (retrospective questionnaire) in an effort to achieve

a high response rate and a low burden on participants in the current study. The SHF supports using a retrospective questionnaire as it could be relatively easily implemented as routine practice within Swedish youth handball in the future, and, therefore, represents a sustainable approach to data collection in the real-world context in which the intervention will be implemented.

An electronic questionnaire will be distributed (via the REDCap electronic data capture tool,^{45 46} hosted by Lund University). Participant characteristics data will include age, sex, years of handball experience, education (coaches, club administrators) and previous use of injury prevention training (coaches, players, club administrators). The intervention questions are informed by two theories: The behavioural theory Health Action Process Approach (HAPA)³⁵ that includes strategies to convert intentions into the desired behaviour, and the Theoretical Framework of Acceptability (TFA), which was developed for assessing acceptability of any healthcare intervention.⁴⁷ HAPA is used to evaluate behaviour change strategies³⁵ related to the intervention in the current study. The HAPA theory distinguishes between preintenders, intenders and actors and includes both motivational and volitional strategies. Questions will include relevant motivational strategies (risk perception, outcome expectancies, intention) and volitional strategies (coping planning, maintenance self-efficacy). If available, we will use or translate questions from previous studies.^{43 48} TFA is used in the current study to assess the acceptability of the intervention and identify any characteristics of the intervention that can be improved.⁴⁷ Relevant constructs (perceived effectiveness, affective attitude, burden, intervention coherence, self-efficacy, opportunity costs) and items from the generic TFA questionnaire⁴⁷ will be used to evaluate acceptability of the intervention. Perceived ease of use will be used to evaluate the mobile application. The study outcomes are mapped to the RE-AIM framework for each stakeholder group in [table 2](#). Questions (English, Swedish), along with the construct they explore and the underpinning theory (if applicable), are outlined in online supplemental files 1–4.

Workshops

Workshops will be conducted with players, coaches and club representatives, respectively, to enable an in-depth understanding of actual barriers and facilitators to implementing I-PROTECT and the acceptability, usability and sustainability of I-PROTECT, including both the programme (content and delivery) and the accompanying implementation strategies (May–June 2024). Workshop data will be analysed using reflexive thematic analysis.⁴⁹

Statistical analysis

To account for the cluster randomisation, and the different cluster sizes that required a stratified sample, the sample size was simulated rather than calculated. In the simulation, the adoption was estimated to be 80% in

the intervention group and 40% in the control group. Data from our pilot study were used to modify these estimated adoption rates. Due to the low number of participants in the pilot study, the measured adoption rates from the pilot were given a weight of 15% and the previously mentioned estimated adoption rates were given a weight of 85%, resulting in estimated adoption rates of 72.3% and 34.0%, respectively. Cluster sizes were sampled from the actual available clusters.

Based on these parameters, data were simulated, a logistic mixed model was fitted and the significance assessed. This process was repeated 10 000 times for each sample size considered, and the proportion of significant results is the estimated power. This was performed for several different club sizes, resulting in 6 large and 12 small clubs with a corresponding power of 96%. Since the main target (coaches) is defined at the team level, we performed the power calculations with regard to number of teams, rather than the number of players. Due to the nature of simulations, the number of teams included varied, however, 95% of the simulations yielded between 164 and 237 teams. To account for possible drop-out, a higher level of power than normal was chosen. Drop-outs to consider include individual players, teams and/or clubs. Drop-out of individual players will have a minimal impact as the main target is coaches, that is, the team level. Since the impact of drop-out of an entire club is much larger than the loss of a team, we have examined the impact of losing a club. This was done by simulations of a smaller sample size with fewer clubs included. The simulations showed that even with the loss of several clubs in each arm, the study will have sufficient power (the exact loss of power depends on whether the clubs lost are small or large and if the loss is symmetrical between the arms).

Statistical analysis will be conducted in R (V.4.2.2).⁵⁰ Frequencies and proportions for categorical variables and means and SD or medians and IQRs for continuous variables will be calculated after checking normality assumptions. Parametric and non-parametric tests will be used as appropriate. Data monitoring will be done by EA and KL, and any abnormalities will be discussed with two researchers in the team (AD and PN). Final data analysis will be performed by a statistician blinded to group allocation.

ETHICS AND DISSEMINATION

Any questions about the research study are referred to the study principal investigator (EA), whereas questions specifically related to practical issues (eg, distribution of mobile application codes and equipment) are referred to a SHF key representative (JL). Contact information for researchers (EA and KL) and SHF representatives (RW and JL) are clearly provided in all written material (eg, blueprint and emails).

At the club level, the club's usual point of contact from the SHF (eg, chair of the club committee/board and/or the key administrator) will provide informed consent to

participate in the study. At the team level, the head coach of each team will provide informed consent for the team to participate. The intervention will be conducted within regular handball practice, and the risk of injury for injury prevention training is deemed lower than for handball training. Given this and the difficulty obtaining written consent from each person in a large-scale implementation study across a whole country, informed consent from each player was not required for the training conducted within regular handball practice. However, players could choose to not do an exercise. Nonetheless, participants will provide informed consent to take part in the study if they access the intervention when downloading the app, respond to questionnaire and/or participate in a workshop. Participants can choose to take part in one or several parts of the study (eg, download the app but not respond to questionnaire). The information to research participants approved by The Swedish Ethical Review Authority will be provided in the app and in the questionnaire and will also be sent through email when participants are recruited for workshops. In Sweden, participants from the age of 15 years can give consent to participate in a study without informed consent also being required from parents/guardians. In the current study, The Swedish Ethical Review Authority approved that players younger than 15 years (ie, 12–14 years) can provide informed consent to download the app without consent also being required from parents/guardians. This was because the app is a complement to training, and all players should be able to access it on equal terms (eg, as some players in a team are 15 years while others are 14 years). Clubs in the control group will be offered the I-PROTECT programme after the handball season to acknowledge their contribution to the study and emphasise the ethical principles beyond the study's duration.

To ensure confidentiality, each participant will be provided with a code, and all information will be securely stored separately from any identifying information, accessible only by the primary investigator (EA) and researchers involved in data analysis. Data will be stored in a highly secure data management platform at Lund University, Lund, Sweden, in accordance with current regulations, that is, EU's General Data Protection Regulation, and the requirements from The Swedish Civil Contingencies Agency (MSB).

Results will be published in peer-reviewed scientific journals, as popular science articles, and presented at national and international scientific conferences, and at sector-specific conferences and events. The SHF will also communicate plain language results to participants and the broader handball community.

STRENGTHS AND LIMITATIONS

The main strength of this real-world pragmatic trial is the engagement of the SHF (secretary general, development manager and project leader) throughout, to ensure the study is relevant to the handball community and to

facilitate implementation. It needs to be considered that participants are mainly unpaid volunteers (although some club administrators may be employed by the club), and that we have no control over other aspects they are involved in, for example, if clubs and/or coaches have other priorities. Together with the SHF, we have tried to limit the burden of the study participants, in terms of time and effort required to participate in the education, intervention and evaluation. Another strength is that the RE-AIM framework was used to guide the implementation outcomes and that two theories (HAPA and TFA) informed the questions.

An alternate design was discussed in the team of researchers and key representatives from SHF; to evaluate I-PROTECT with versus without implementation support. However, the strength of the chosen design is that the new intervention (I-PROTECT) will be compared with a programme (Ready for Handball) that is currently available for coaches but has not previously been evaluated in terms of implementation. None of the interventions have been included in efficacy trials, however, both include principles of injury prevention (Ready for Handball only includes physical principles), so it was argued that the training will have a positive effect if the exercises are used.

The fact that the I-PROTECT group will incorporate implementation strategies, and the control group will not, may be seen as a limitation. However, we identified in the first I-PROTECT study¹⁹ that end-users needed strategies to support implementation, and this also emerged in the pilot study. There are challenges matching determinants with the most appropriate implementation strategies.⁵¹ The strategies in the present study are identified in collaboration with the SHF, and the planned workshops may identify potential improvements that can be made after this study.

Another limitation is that injuries will not be registered in the present study. However, if the present study shows that I-PROTECT is successfully implemented, further studies will include objective assessment of injury incidence as the primary outcome of interest.

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Contributors EA designed the study with input from PN and AD. EA is principal investigator (PI) and has the main responsibility for planning recruitment, data collection, outcomes, data analysis and drafted the manuscript. PN and AD provided input on outcomes, data analysis and versions of drafts. AS conducted the sample size calculation and provided input on study design, outcomes, data analysis and later versions of drafts. KL provided input on and assisted in finalising outcomes and provided input on later draft versions. JL recruited clubs and

provided input on study design, outcomes and later draft versions. KM, SB, RW and PE provided input on study design, outcomes and later draft versions. All authors read and approved the final version of the manuscript. EA is the guarantor of the study.

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Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants and is conducted in accordance with the Declaration of Helsinki and is approved by the Swedish Ethical Review Authority (Reference numbers: EPN 2014/713 (4 March 2015), 2020–02952 (8 June 2020) and 2022-06148-02 (6 December 2022)). Information about the study, along with information to research participants approved by The Swedish Ethical Review Authority, will be sent to clubs for further distribution to coaches, players and parents/guardians.

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