

Prevention of knee injury in handball

Submission date 06/04/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 22/07/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 22/07/2022	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Handball is associated with a high risk of knee injury that needs to be reduced. The purpose of this study is to show how an injury-prevention programme effectively reduces knee injury in adult and adolescent handball players.

Who can participate?

Any active handball player aged 14 years or older in any of the German-speaking handball leagues with at least one competitive match during the interventional season 2022-23

What does the study involve?

Teams register for the study and are allocated randomly in either the intervention arm or control arm. Players of the intervention group regularly participate in an injury-prevention programme for one season. Handball exposure and sustained injuries are documented for both groups on a regular basis.

What are the possible benefits and risks of participating?

Possible benefits of the intervention arm are the reduction of knee injury or reduction in prevalence/intensity of overuse knee injury symptoms. No risk are reported to date for neuromuscular injury prevention programmes.

Where is the study run from?

1. Dpt. of Orthopaedic Surgery, König-Ludwig-Haus, University Würzburg, Würzburg, Germany
2. Dpt. of Trauma, Hand, Plastic and Reconstructive Surgery, University Medical Center Würzburg, Germany

When is the study starting and how long is it expected to run for?

March 2019 to June 2023

Who is funding the study?

Bundesinstitut für Sportwissenschaft / German Federal Institute for Sports Sciences

Who is the main contact?

Dr Leonard Achenbach
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Contact information

Type(s)

Principal Investigator

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

2022-04

Study information

Scientific Title

Prevention of acute severe knee injury in handball: a cluster randomised controlled trial

Study objectives

The purpose of this study is to show how an injury prevention programme specific for knee effectively reduces acute knee injury in handball players

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 13/03/2019, Ethical committee of the University of Regensburg (D-93040 Regensburg, Germany; +49 (0)941 943 5370; ethikkommission@klinik.uni-regensburg.de), ref: 15-101-0137

Study design

Prospective cluster-randomised controlled trial

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

Community

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Musculoskeletal knee injury

Interventions

Intervention arm: teams are given a neuromuscular training programme. this should be implemented at least twice per week during the whole course of the season

Control arm: teams proceed with their normal training without any instructions

Total duration: season 2022/23 (July 2022 - May 2023)

Injuries of all participating teams/players are assessed on a regular basis (every six weeks) during the whole season by means of standardised injury questionnaires.

Stratified cluster randomisation is carried out and a 1:1 randomisation in both arms is scheduled. Stratification is based on sex (male/female), age (under-15/under-17/under-19/senior) and level of professionalism (league 1-3/4-6/7 or lower).

Intervention Type

Behavioural

Primary outcome measure

Number of new acute severe knee injuries sustained per 1000 h of handball throughout the intervention season, such as intraarticular fracture, patella dislocation, rupture of the collateral or cruciate ligament, meniscus tear, cartilage injury or any injury resulting in absence from training session or match for more than 28 days. Measured by online questionnaires and personal contact of the study team with the handball teams.

Secondary outcome measures

1. Injury mechanism of knee injuries (contact, indirect contact, non-contact) throughout the intervention season, measured by online questionnaires and personal contact of the study team

with the handball teams

2. Prevalence of overuse knee injury throughout the intervention season, measured by online questionnaires and personal contact of the study team with the handball teams

Overall study start date

13/03/2019

Completion date

30/06/2023

Eligibility

Key inclusion criteria

1. Active male or female handball player in any of the German-speaking handball leagues with at least one competitive match during the interventional season 2022/23
2. Aged 14 years or older

Participant type(s)

Other

Age group

Mixed

Sex

Both

Target number of participants

Sample size was calculated based on the primary endpoint of incidence of acute severe injury to the knee in handball athletes within one season. The incidence of 0.33 per 1000h was based on the incidence reported in the recent literature. The study aimed to achieve a reduction to 0.04 per 1000h. To achieve this effect with a power of 80%, an estimated intraclass correlation coefficient of 0.10, and an average team size of 10 athletes with an error type 1 of maximum 5%, 30 teams per group and thus a total of 60 teams with n=662 athletes have to be included.

Key exclusion criteria

1. Inability to understand German
2. No signed consent

Date of first enrolment

01/05/2022

Date of final enrolment

30/05/2023

Locations

Countries of recruitment

Austria

Germany

Switzerland

Study participating centre

Dpt. of Trauma, Hand, Plastic and Reconstructive Surgery, University Medical Center Wuerzburg, Germany
Oberdürrbacher Straße 6
Würzburg
Germany
97080

Study participating centre

König-Ludwig-Haus, Department of Orthopaedics
Brettreichstraße 11
Würzburg
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97074

Sponsor information

Organisation

University Medical Center Würzburg

Sponsor details

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Sponsor type

Hospital/treatment centre

Funder(s)

Funder type

Government

Funder Name

Bundesinstitut für Sportwissenschaft

Alternative Name(s)

German Federal Institute of Sport Science, BISp

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Germany

Results and Publications

Publication and dissemination plan

Planned publication in a peer-reviewed journal.

Intention to publish date

30/05/2024

Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date