Prevention of overuse shoulder injury in handball

Submission date	Recruitment status No longer recruiting	Prospectively registered	
15/01/2020		☐ Protocol	
Registration date	Overall study status Completed	Statistical analysis plan	
06/02/2020		[X] Results	
Last Edited	Condition category	Individual participant data	
25/03/2022	Musculoskeletal Diseases		

Plain English summary of protocol

Background and study aims

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

Who can participate?

Any active handball player aged 18 years or older in any of the German-speaking handball leagues with at least one competitive match during the interventional season 2019-20

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 biweekly basis.

What are the possible benefits and risks of participating?

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

Where is the study run from?

- 1. Department of Trauma Surgery, University Medical Center Regensburg, Germany
- 2. Dpt. of Trauma, Hand, Plastic and Reconstructive Surgery, University Medical Center Wuerzburg, Germany

When is the study starting and how long is it expected to run for? May 2019 to April 2020

Who is funding the study?

Bundesinstitut für Sportwissenschaft / German Federal Institute for Sports Sciences

Who is the main contact? Dr Leonard Achenbach leonard@dr-achenbach.eu

Contact information

Type(s)

Scientific

Contact name

Dr Leonard Achenbach

ORCID ID

http://orcid.org/0000-0002-9053-0624

Contact details

Josef-Schneider-Straße 2 Wuerzburg Germany 97080 +49 941 9446805 leonard@dr-achenbach.eu

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

2019-02

Study information

Scientific Title

Prevention of overuse shoulder 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 shoulder effectively reduces overuse throwing shoulder injury in handball players.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 16.05.2019, Ethics Committee of the University of Regensburg (Universität Regensburg, ETHIKKOMMISSION, 93049 Regensburg, Germany; +49 941 943 5370; ethikkommission@klinik.uni-regensburg.de), ref: ID 17-894 1-101

Study design

Prospective cluster-randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Community

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet (in German)

Health condition(s) or problem(s) studied

Overuse throwing shoulder 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 2019/20 (July 2019 - April 2020)

Both arms have a follow-up during the season every two weeks by means of a standardised injury questionnaire, until the end of the study (April 2020)

Due to the low number of expected teams, 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-19/senior) and level of professionalism (league 1-3 / 4-6 / 7 or lower).

Intervention Type

Behavioural

Primary outcome measure

Prevalence and intensity of overuse throwing shoulder injury measured using the OSTRC (Oslo Trauma Research Center) Overuse questionnaire as well as short handball-specific WOSI (Western Ontario Shoulder Index) every two weeks throughout the study.

Secondary outcome measures

Measured using the OSTRC (Oslo Trauma Research Center) Overuse questionnaire as well as short handball-specific WOSI (Western Ontario Shoulder Index) every two weeks throughout the study:

- 1. Prevalence and intensity of severe overuse throwing shoulder injury
- 2. Prevalence and intensity of overuse elbow injury

Overall study start date

01/07/2019

Completion date

30/04/2020

Eligibility

Key inclusion criteria

- 1. Active handball player in any of the German-speaking handball leagues with at least one competitive match during the interventional season 2019-20
- 2. Male or female
- 3. Willingness to implement biweekly prevention exercises into training and match warm-up

Participant type(s)

Healthy volunteer

Age group

Adult

Sex

Both

Target number of participants

600 players

Total final enrolment

579

Key exclusion criteria

- 1. Inability to understand written German
- 2. No signed consent

Date of first enrolment

01/05/2019

Date of final enrolment

30/06/2019

Locations

Countries of recruitment

Germany

Study participating centre University Medical Center Regensburg

Department of Trauma Surgery Franz-Josef-Strauss Allee 11 Regensburg Germany 93053

Study participating centre University Medical Center Wuerzburg

Dpt. of Trauma, Hand, Plastic and Reconstructive Surgery Josef-Schneider-Straße 2 Wuerzburg Germany 87080

Sponsor information

Organisation

University Hospital Regensburg

Sponsor details

Federal Institute for Sports Sciences Franz-Josef-Strauss Allee 11 Regensburg Germany 93053 +49 941 9446805 Peter.Stehle@bisp.de

Sponsor type

Hospital/treatment centre

Website

http://www.uniklinikum-regensburg.de/e/

ROR

https://ror.org/01226dv09

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 high-impact peer-reviewed journal.

Intention to publish date

30/04/2021

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		11/03/2022	25/03/2022	Yes	No