

Acute ankle sprain and rehabilitation – effectiveness of a training intervention on ankle joint function

Submission date 15/11/2021	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 17/12/2021	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 23/02/2024	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

The lateral ankle sprain (LAS) is one of the most common injuries in everyday and sports activities. There is a high rate of recurrent ankle sprains and about 20-40% of patients with LAS develop chronic ankle instability. Up to now LAS is still handled as a minor injury that will resolve quickly with limited treatment although the primary LAS is often the start point for severe and long-lasting symptoms. Currently, there is no treatment that effectively reduces chronic symptoms after LAS. Furthermore, there is no effective inventory that can be used for the diagnostic of functional ankle instability. Therefore the aim of this study is to develop an evidence-based and functional training program for the conservative treatment of an acute lateral ankle sprain. Appropriate markers for measuring functional ankle instability will be determined in parallel with the study.

Who can participate?

Patients with first-time ankle sprains (aged 14-41 years; BMI 19-30 kg/m²) with rupture of at least one lateral ligament (diagnosed by an MRI scan) of the ankle joint

What does the study involve?

Patients will be randomly allocated to receive the SMART treatment or standard therapy (NORMT). Functional impairments, muscle strength, postural control and gait/run/jump analyses will be assessed before and after the 6-week intervention as well as 6, 12 and 24 months later.

What are the possible benefits and risks of participating?

The benefits of the study are a diagnostic beyond standard care including an MRI scan which is also not part of the standard care for ankle sprains in Germany. There are minor risks for falling during performing the functional tests (jumps).

Where does the study run from?

BG Klinikum Duisburg (Germany)

When is the study starting and how long is it expected to run for?
May 2020 to November 2025

Who is funding the study?
DGUV – Forschungsförderung (FR-329 - German Social Accident Insurance) (Germany)

Who is the main contact?
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers

DRKS00026049

Study information

Scientific Title

Effectiveness of the SMART training intervention compared to standard therapy on the subjective ankle joint function of patients with first-time acute lateral ankle sprain

Acronym

OSGAR

Study objectives

The SMART training intervention is a more effective method than standard therapy to improve subjective ankle joint function.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 28/09/2021, Ärztekammer Nordrhein ethics commission (Tersteegenstraße 9, 40474 Düsseldorf, Germany; +49 (0)211 4302 2273; ethic@aekno.de), ref: 2021236

Study design

Single-centre interventional (1:1 allocation) randomized controlled trial with an active control group

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

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

Sprain and strain of ankle

Interventions

Pre-testing will be done for all primary and secondary outcome measures:

1. Cumberland Ankle Instability Tool (CAIT) & Foot and Ankle Ability Measure (FAAM)
2. Isometric/isokinetic measurements

3. Postural control
4. Gait/run analysis
5. Jump analysis

Participants with a CAIT-score ≤ 24 two weeks after the initial injury are randomized by an independent researcher in a 1:1 allocation ratio to either the experimental group (SMART treatment, SMART) or the control group (normal treatment, NORMT) using computer-generated simple scheme randomization.

Group 1: Experimental group

SMART: In this group, the participants receive a 6-week sensorimotor training intervention. This consists of the following domains:

S = Sensory Stimulation

M = Mobilization

A = Activation & Balance

R = Resistance & Re-Integration

T = Transfer to Function & Performance

The training will partly be performed supervised in the lab and partly at home without supervision. The proportion of supervised training will be highest in the first 2 weeks and will decrease after that. The progression of the training will be individualized.

Group 2: Control group

NORMT: In this group, the participants receive physiotherapy as a standard therapy to reduce swelling and pain as well as to improve ankle mobility.

Both interventions (experimental and control) last 6 weeks. Before and after the treatment, all outcome measures will be recorded.

There will be a 6-, 12- and 24-month follow-up for all participants. The 12- and 24-months follow-ups only include the CAIT and FAAM measurements.

There will be a control group with no history of lateral ankle sprain which serves as external criteria to develop a valid test battery to diagnose functional ankle instability.

Intervention Type

Procedure/Surgery

Primary outcome measure

The impairments of ankle joint function subjectively assessed by the CAIT questionnaire pre and post intervention as well as 6, 12 and 24 months post

Secondary outcome measures

1. The impairments of ankle joint function subjectively assessed by the FAAM questionnaire pre and post intervention as well as 6, 12 and 24 months post
2. Muscle strength assessed by isometric and isokinetic measurements pre and post intervention as well as 6 months post
3. Postural control measured using the star excursion balance test and COP-analyses pre and post intervention as well as 6 months post
4. Performance and movement quality assessed by gait/run and jump analysis pre and post intervention as well as 6 months post

Overall study start date

29/05/2020

Completion date

30/11/2025

Eligibility

Key inclusion criteria

1. ICD-Code S93.4x "sprain of the ankle"
2. Aged 14-41 years
3. BMI 19-30 kg/m²
4. Rupture of at least one lateral ligament of the ankle joint

Participant type(s)

Patient

Age group

Mixed

Lower age limit

14 Years

Upper age limit

41 Years

Sex

Both

Target number of participants

82

Key exclusion criteria

1. Acute concomitant injuries of the ankle (fractures, syndesmosis ligament injury, osteochondral lesions)
2. Pre-injuries of the injured and non-injured ankle
3. Serious lower-extremity injuries in the last 6 months (e.g. fractures, ligament ruptures)
4. Lower-extremity surgery (e.g. anterior cruciate ligament reconstruction) neurological diseases or impairments of the vestibular system which could influence the physiological performance

Date of first enrolment

03/01/2022

Date of final enrolment

30/09/2024

Locations

Countries of recruitment

Germany

Study participating centre**BG Klinikum Duisburg**

Klinik für Arthroskopische Chirurgie, Sporttraumatologie und Sportmedizin (Clinic for Arthroscopic Surgery, Sports Traumatology & Sports Medicine)

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Sponsor information

Organisation

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Sponsor type

Hospital/treatment centre

Website

<https://www.bg-klinikum-duisburg.de>

ROR

<https://ror.org/03vc76c84>

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Funder(s)

Funder type

Other

Funder Name

Deutsche Gesetzliche Unfallversicherung

Alternative Name(s)

German Social Accident Insurance, DGUV

Funding Body Type

Private sector organisation

Funding Body Subtype

Associations and societies (private and public)

Location

Germany

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal. Additional documents (such as study protocol, statistical analysis plan etc) are available on request.

Intention to publish date

30/04/2026

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made 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?
Protocol article		03/03/2023	08/03/2023	Yes	No