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

Submission date
15/11/2021

Recruitment status
No longer recruiting

Registration date
17/12/2021

Overall study status
Ongoing

Last Edited
23/02/2024

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English Summary
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?
1. Dr Christian Raeder, christian.raeder@bg-klinikum-duisburg.de
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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 hypothesis
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

Condition
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

Overall study end date
30/11/2025

Eligibility

Participant 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

Participant 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

Recruitment start date
03/01/2022

Recruitment end date
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
BG Klinikum Duisburg

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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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Sponsor type
Hospital/treatment centre

Website
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ROR
https://ror.org/03vc76c84

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