ISRCTN47734782 https://doi.org/10.1186/ISRCTN47734782

Testing training programs for the prevention of running-related injuries

Submission date
23/02/2021

Recruitment status
No longer recruiting

Registration date
26/02/2021

Overall study status
Completed

Last Edited
05/11/2024

Condition category
Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Running is one of the most popular sports worldwide. Regular running has many important implications for individual physical and mental health, both of which are related to longevity. However, running is also linked to musculoskeletal injuries, especially to the lower extremities (from the hip to the toes). Running-related injuries can lead to people temporarily or completely stopping running and can have a financial impact associated with required medical treatments. Currently, there is a lack of research evaluating injury prevention in runners and this proposed study will fill this gap. This study will be the first randomized controlled trial (RCT) to investigate the prevention of running-related injuries through neuromuscular training (NMT) in adult recreational runners. The aim of this study is to investigate the effectiveness of two new targeted injury prevention NMT warm-up programs in reducing the risk of running-related lower extremity injuries in adult female and male recreational runners.

Who can participate?
Healthy female and male recreational runners (18–55 years of age)

What does the study involve?
The participants will be randomly assigned to one of three groups: intervention group 1 (ankle strength program), intervention group 2 (core and hip strength program), or the control group (placebo stretching program). Participants will be asked to participate in physiotherapist-supervised warm-up training sessions before their running training twice a week (20–30 min each) through an intervention period (May–October). All injuries and exposure hours will be recorded weekly. Physiotherapists will document adherence to the training program. In addition, all participants will complete online questionnaires (survey at 6 months and 12 months after the intervention) about their utilization of the injury prevention training program, possible modifications of program/exercises, as well as perceived advantages, disadvantages of the program, and challenges and barriers of using the program in their everyday training.

What are the possible benefits and risks of participating?
The participants will not get any direct benefits (financial or other incentives) for being in the study. However, the results of the study may be useful to them in the future. There are no anticipated risks for the participants. All outcome measures have been previously used in a sport

setting with no negative side effects. Although it is unlikely, there may be a risk of injury when performing baseline and follow-up performance tests. Participants will have the right to stop the performance tests and their participation in the study at any point in time. They will be monitored throughout the tests and training sessions by trained physiotherapists. Based on previous studies, it is not expected that any participant will be injured during the training programs that will be evaluated. The potential risks associated with these training programs are considered significantly less than the risk associated with running or playing sports. However, participants will be asked to report to the study coordinator or physiotherapist any experience of pain, discomfort, or injury associated with any component of the study.

Where is the study run from?
1. University of Calgary (Canada)
2. UKK Institute (Finland)

When is the study starting and how long is it expected to run for?
September 2019 to October 2023

Who is funding the study?
Finnish Ministry of Education and Culture (Finland)

Who is the main contact?
Dr Kati Pasanen
kati.pasanen@ukkinstituutti.fi, kati.pasanen@ucalgary.ca

Contact information

Type(s)
Scientific

Contact name
Dr Kati Pasanen

ORCID ID
https://orcid.org/0000-0002-0427-2877

Contact details
2500 University Drive, NW
Calgary
Canada
T2N 1N4
+1 (0)14032205674
kati.pasanen@ucalgary.ca

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
OKM/1100/626/2020

Study information

Scientific Title
Neuromuscular training in novice recreational runners: a randomized controlled trial

Acronym
RUN-RCT Finland

Study objectives
It is hypothesized that participants in intervention groups 1 and 2 will exhibit a significantly lower number of lower extremity (LE) injuries and a significantly lower number of severe LE injuries than participants in the control group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/08/2020, Ethics Committee of Pirkanmaa Hospital District (PO Box 2000, Tampere, Fin-33521, Finland; +358 (0)3 311 66 910; minna.maa.lahtinen@pshp.fi), ref: ETL-code R20042

Study design
Randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Prevention of injuries in adult recreational runners

Interventions
This is a three-arm, randomized controlled trial designed in accordance with the CONSORT statement guidelines. The study will include two intervention periods: (1) May–October 2021 (n=150); and (2) May–October 2022 (n=150). 150 participants will be recruited for each intervention period. Participants will be randomized into three groups: intervention 1 (IG1), intervention 2 (IG2), and the control group (CG). Participants allocated to IG1 will receive a neuromuscular training (NMT) warm-up program focusing on ankle strength and stability (IG1: Ankle Program). Participants allocated to IG2 will receive an NMT warm-up program focusing on core and hip strength and stability (IG2: Core & Hip Program). Participants allocated to the CG will receive a placebo static stretching warm-up program focusing on the flexibility of the main LE/core muscle groups (CG: Stretching Program). A statistician who will carry out the computer-generated randomization will not be involved in the intervention. During the intervention period the groups will do the warm-up training before their running training twice a week and 20–30 minutes each. Each training session will be supervised by a study physiotherapist.

The primary outcome for this study is a running-related lower extremity injury. A running-related injury is defined as any musculoskeletal complaint caused as a result of running. An acute injury (sudden onset) is a result of a single, specific and identifiable event whereas overuse injury (gradual onset) is caused by repeated microtraumas without a single, specific and identifiable event responsible for the injury. Injuries will be classified by location, type, body side, and mechanism of injury, and whether the injury is a recurrent injury. The severity of the injury will be defined as the number of days (time-loss from running). The severity of overuse injuries will be based on the prevalence of physical complaints (e.g., pain, ache, swelling) and its consequences on sport participation and participant's performance. All injuries will be registered on a weekly basis. Each week all participants will complete a validated online questionnaire (Oslo Sports Trauma Research Center Overuse Injury Questionnaire, OSTRC-Q), including four key questions on the consequences of injuries (all complaints) on: (1) sports participation, (2) training volume, (3) performance, and (4) perceived pain/symptoms. A study physiotherapist will contact participants who have reported an injury to collect more detailed information on each injury using a validated Injury Report Form (IRF). All injuries will be registered with the structured IRF, including time and place of occurrence, cause, type, recurrence, location and severity of the injury (time-loss from training). In addition, individual exposure hours (training hours) will be registered (online questionnaire). The incidence rate and corresponding 95 % CI of acute injuries will be expressed as the number of injuries per 1000 exposure hours. The prevalence of overuse injuries will be calculated for each anatomical area each study week.

During the intervention period the study physiotherapists will document the execution of each intervention training session on the attendance form (e.g., date, duration, exercises completed, participation of each runner). The adherence will be based on the total number of training sessions completed, total number of training program components completed, and the total time for training completed. Prior to the start of the intervention and at the end of the intervention period, all participants will be asked to complete a survey to evaluate knowledge, attitudes and beliefs to injury prevention. In addition, all participants will complete questionnaires (surveys at 6 and 12 months after the intervention) about their utilization of the injury prevention training program, possible modifications of program/exercises, as well as perceived advantages, disadvantages of the program, and challenges and barriers of using the program in their everyday training. Physical activity, sedentary behavior and sleep will be measured with tri-axial accelerometers. Sensors will be used at the waist during wake-time and at the wrist when sleeping. The accelerometers will be attached to a flexible belt and writs band, and each participant will be asked to wear the belt for seven consecutive days and night. The classification of the body posture into lying, sitting, and standing is based on an algorithm, which has shown about 90% accuracy. A sub-cohort of the participants will complete maximal oxygen uptake tests on a treadmill at the baseline and at the end of the intervention. Breath-by-breath expired Vo2 and VCo2, blood lactate, as well as RR-intervals, will be collected continuously during the exercise tests. Heart rate variability will be analyzed with the short-time Fourier transform method.

The power calculation for the two-center RCT is based on the assumption that the trial would detect at least a 40% reduction in the incidence of LE injuries, from 0.4 injuries per person in the control group to 0.24 per person in the intervention group. The researchers also estimate the design effect due to two countries to be 1.05 (with ICC=0.05) and the drop-out rate to be 35%. A statistical power of 0.81 is achieved with a total of 750 participants by setting the significance level to 0.05, and the coefficient of variation of incidence rate between clusters to 0.08. The recruitment plan for this two-center study is 750 recreational runners (Finland n=300; Canada n=450).

Intervention Type

Behavioural

Primary outcome(s)
Running-related lower extremity injuries measured using a validated Oslo Sports Trauma Research Centre Injury questionnaire (OSTRC-Q) every week for the duration of the study. In addition, a study physiotherapist will interview each injured player using a validated Injury Report Form (IRF) including questions of time and place of occurrence, cause, type, location and severity of the injury.

Key secondary outcome(s))
1. Performance measures, such as kinematics and kinetics during running, strength of hip, knee and ankle muscles, and single-leg balance:
1.1. Running kinematics and kinetics measured using three-dimensional motion analysis (Vicon) at baseline and at the end of the intervention period
1.2. Isokinetic strength of lower extremity muscles measured using an isokinetic dynamometer (Biodex) at baseline and at the end of the intervention period
1.3. Single leg postural stability measured using a balance platform (Metitur) at baseline and at the end of the intervention period
2. Adherence to NMT training documented using an attendance form including the date and duration of the session, exercises completed and participation of each participant, after each session
3. Knowledge, attitudes and beliefs to injury prevention measured using a structured questionnaire (7-point Likert scale) prior to and at the end of the intervention period
4. Adoption and maintenance of injury prevention training measured using a structured questionnaire at 6 months and 12 months after the end of the intervention period, including questions about the utilization of the injury prevention training program, possible modifications of program/exercises, as well as perceived advantages, disadvantages of the program, and challenges and barriers of using the program in their everyday training.
5. Physical activity, sedentary behaviour and sleep measured using a tri-axial accelerometer for seven consecutive days and nights
6. Maximal oxygen uptake measured using a treadmill test (breath by breath expired VO_2 and VCO_2, blood lactate, and RR intervals collected continuously during the test) at the baseline and at the end of the intervention
7. Heart rate variability (HRV) measured using an HRV recording device (Firstbeat Bodyguard) at baseline and the end of the intervention. Participants will be asked to wear the device for about 2 hours (length of performance testing session)

Completion date
31/10/2023

Eligibility

Key inclusion criteria
1. 18–55 years of age
2. Less than 2 years of weekly running exposure
3. Running is the primary form of exercise
4. No musculoskeletal injuries within 3 months at the time of study onset
5. No major surgery to the lower extremities within the previous 6 months
6. No history of systemic disease (e.g., cardiac disease) or neurological disorder (e.g., concussion)
7. No history of bone fracture in the spine, pelvis or lower extremity in the past year
8. Final participation will be based on the informed consent of each individual runner

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
55 years

Sex
All

Total final enrolment
325

Key exclusion criteria
1. Younger than 18 or older than 55 at the time of recruitment
2. More than two years of weekly running exposure
3. Running is not the primary form of exercise
4. History of musculoskeletal injury within 3 months at the time of study onset
5. History of surgery to the lower extremities within 6 months at the time of study onset
6. History of systemic or neurological disorder that might influence the outcome
7. History of bone fracture in the spine, pelvis or lower extremity in the past year

Date of first enrolment
09/01/2021

Date of final enrolment
30/04/2022

Locations

Countries of recruitment
Canada

Finland

Study participating centre
UKK Institute
Kaupinpuistonkatu 1

Tampere
Finland
FIN-33501

Study participating centre
University of Calgary
2500 University Drive, NW
Calgary
Canada
T2N 1N4

Sponsor information

Organisation
Urho Kaleva Kekkonen Institute for Health Promotion Research

ROR
https://ror.org/05ydecq02

Funder(s)

Funder type
Government

Funder Name
Opetus- ja Kulttuuriministeriö

Alternative Name(s)
Ministry of Education and Culture, Finland

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Finland

Results and Publications

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?
Results article		20/06/2024	05/11/2024	Yes	No
Participant information sheet			01/03/2021	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes