UKK-instituutti
Tampereen Urheilulääkäriasema

RUN-RTC Finland
Consent for Participants

TITLE: Neuromuscular training in novice recreational runners: a randomized controlled trial

INVESTIGATORS

Principal Investigators: Dr. Kati Pasanen, Dr. Jari Parkkari
Co-Investigators: Dr. Tommi Vasankari, Dr. Mari Leppanen, Dr. Piia Kaikkonen, Dr. Penny Werthner, Dr. Tron Krosshaug, Dr. Benno Nigg

This consent form should give you the basic idea of what the research is about and what your participation will involve. For further details about this study, or to have your questions addressed please contact us. Take the time to read this carefully and to understand any accompanying information. ***If you choose to participate, please complete this form. You may choose to keep a copy for your records.***

WHAT IS THE PURPOSE OF THE STUDY?

This study specifically aims to: (1) Examine the impact of three different warm-up training programs in reducing injury risk in adult recreational runners; (2) Explore the effect of three different warm-up training programs on running technique and performance in adult recreational runners. The study has been approved by the Ethics Committee of the Pirkanmaa Hospital District.

RESEARCH CENTERS

This study is carried out in Tampere Research Center of Sports Medicine, at the UKK Institute in collaboration with the University of Calgary, Norwegian School of Sports Sciences and University of Jyväskylä. This study is part of a two-center study between the University of Calgary and the UKK Institute in Finland, and it is proposed that these two centers will carry out two similar studies (one in Calgary, Alberta and another in Tampere, Finland). The Principal Investigators of the study are Dr. Kati Pasanen (University of Calgary; Tampere Research Center of Sports Medicine) and Dr. Jari Parkkari (Tampere Research Center of Sports Medicine). The registrar of the study is the UKK Institute, which is responsible for the lawfulness of the processing of personal data during the study.

TIMELINE AND DATA COLLECTION

The study will start with baseline test measures in March–April. The baseline test measures will be conducted at the UKK Institute during one visit (the duration of the measurement is

approximately two hours). Baseline test measures include (1) three-dimensional running gait analysis, (2) strength tests of the hip, knee and ankle, and (3) single leg balance tests. In addition, some participants will perform a maximal oxygen uptake test and heart rate variability measurements. The measurements are repeated at the end of the intervention period. Prior to (and following) the commencement of the running season, the participants will be required to complete some pre-season and post-season questionnaires.

After the baseline test measures, the participants will be randomly assigned into three groups. Each group will receive a different warm-up training program that will be carried out before group's running training session. In addition, all groups will receive a running training program aimed at improving endurance and running fitness.

All participants will be asked to participate in physiotherapist-supervised warm-up training sessions twice a week (20–30 min each) at the UKK Institute (or another sport facility near Tampere City center) through the intervention period (May–October). One training session includes warm-up training (20–30 min) and a group running exercise (40–60 min). In addition, participants will be asked to do additional individual training sessions (1 – 3 times per week). During summer vacation time in July (or in a situation where training in groups is not possible due to a coronavirus epidemic, for example), supervised training sessions will be carried out remotely.

During the study, data will be collected from the participants through online questionnaires. At the beginning of the study, the participants will complete a baseline questionnaire including questions about their background information, such as training history, previous injuries and health. In addition, participants will complete three follow-up questionnaires (at the end of the intervention; and six months and twelve months after the end of intervention). The aim of these questionnaires is to assess knowledge, attitudes, and beliefs of recreational runners related to sport injury prevention strategies, and to explore adoption and maintenance of the warm-up training program six and twelve months after the end of intervention period in recreational runners.

Injuries to the participants will be registered by weekly online questionnaires (a mobile application: Athlete Monitoring, FITSTATS Technologies, Canada). Every Sunday, the participants will receive a reminder (short message service) to answer the survey. If they have not sustained any injuries in the past week, the survey will end. If the participants report that they have experienced an injury, the questionnaire is directed to additional questions that elucidate the nature of the problem in more detail. It will take up to five minutes to complete the questionnaire. Participants will also report data on the last week's training volumes (training hours) via the mobile application.

In addition to the mobile application, the physical activity of the participants will be monitored with an accelerometer attached to the waist. The amount and quality of a night's sleep is assessed by moving the meter to the wrist overnight.

ARE THERE ANY RISKS RELATED TO THE STUDY?

There are no anticipated risks for the participants who consent to participating in this study. All outcome measures have been previously used in 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 terminate 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 our previous studies, it is not expected that any participant will be injured during the warm-up training programs that will be evaluated. The potential risks associated with these warm-up training programs are considered significantly less than the risk associated with running or playing sports. In the beginning of the study the participants may feel muscle soreness which is not dangerous and goes away on its own. 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.

ARE THERE ANY BENEFITS FOR THE PARTICIPANTS?

The information we get from this study will provide a clear understanding of running related injuries in recreational runners, and whether the tested prevention strategies are effective in injury prevention in recreational runners. These study results will then inform the implementation of strategies for prevention of injuries in the future. There will not be direct benefits to the participants. However, performance testing and supervised research training programs are free of charge for the participants. In addition, the participants will receive a summary of their personal test results after the study has ended. Furthermore, participants will have free access to a mobile application that allows them to track their training.

CONFIDENTIALITY AND DATA PROCESSING

All information collected throughout the study period will be anonymous and will remain strictly confidential. Only the investigators responsible for this study, the research staff, and the statistician who will analyze the data will have access to this information. Confidentiality will be protected by using only study identification numbers in the database. Any results of the study, which are reported, will in no way identify study participants.

The participants personal information will be processed for the scientific research described above. Only participants' personal data necessary for the purpose of the investigation will be stored in the register. The information and research results collected will be treated confidentially as required by the legislation on the processing of personal data. In the study, the name, personal identity number and contact information of the individual participants will be replaced by a unique identification code. The information and results of the research measurements will be stored in the research material coded and will only be referred to by an identification code. The research material and data will be analyzed in coded form, so that an individual cannot be directly identified from them without a separate code key. This code key (information that allows the individual's identity and his or her research data to be linked to each other), is retained by limited and pre-defined members of the research team. This information will not be provided to persons outside the study.

The final study results will be reported mainly at the group level. It will not possible to identify participants from publications or research results. The study will collect the following information from participants using the following sources: questionnaires, performance test measurements, and

accelerometers. The information will be processed by the investigators and research staff conducting this study. Data will be disclosed coded to the following parties outside the UKK Institute for the original purpose: the material collected in the study will be utilized in an international two-center project, where a similar research will be carried out not only in Finland but also in Canada. The collected data may also be used in later national or international combined studies of several studies on the same research topic (e.g., systematic reviews and meta-analyses).

In the context of publishing, data will be transferred in coded form to countries outside the EU and the European Economic Area (EEA), where data protection will be at the same level as in the EU. Research material will always be provided using secure data transfer and in such a form that the data will not be combined with research participants without a code key. All parties and persons handling the information are bound by professional secrecy.

Storage of individual data: non-electronic material containing personal data will be stored in locked premises at the UKK-Institute, which can only be accessed by designated persons. The research data will be stored in the UKK Institute's electronic database, which can only be accessed by members of the research team working at the UKK Institute. The administrator of the mobile application used in data collection (Athlete Monitoring, FITSTATS Technologies) in Finland is the Kilpa- ja huippu-urheilun tutkimuskeskus (KIHU), Jyvaskyla.

The participants will sign into the mobile application with their own personal ID and password. The application will be used over a secure connection. The collected material will be regularly backed up in the UKK Institute's electronic archive, which is accessible only to members of the research team. The data collected by the mobile application will be stored on a secure electronic server (within the EU) for the duration of the investigation, after which the service provider deletes the material from its own server. Researcher Mari Leppänen is responsible for storing this information.

The retention period of the information is regulated by law and good clinical practice. Samples and data collected in connection with the study will be stored in the electronic archives of the UKK Institute for 10 years after the end of the study, after which they will be destroyed (estimated in 2033). Scientific research essentially involves the publication of research results in international scientific publications. Research results are always reported at the group level and it is not possible to identify individual participants.

PARTICIPATION

Participation in this study is voluntary and each participant may withdraw from the study at any time by contacting the study coordinator. Refusal of participation or withdrawal from the study will have no effect on participant’s playing of sports. Each participant can also withdraw this consent. Each participant can discontinue participation in the study at any stage before the end of the study period, with no disadvantageous consequences to them. If a participant decides to withdraw their consent, or if their participation in the study will be discontinued for some other reason, the research data collected by that date will be used as part of the research material.

Rights with regard to the processing of personal data, each participant has the right to be informed of the data collected, for whom they have been used, to whom they have been disclosed and for what purpose, and to request that their data be corrected or supplemented, for example if they find it incorrect or incomplete or inaccurate. Each participant will also have the right to request the deletion of their information from the study (the "right to be forgotten") or to restrict its use and to object to the processing by notifying the research staff. However, in the context of scientific research, these rights may be restricted. For example, legislation may oblige the controller to keep personal research data for a certain period of time, regardless of the data participants's rights, and allow exceptions to the data participants's rights where this is necessary to ensure scientific results and the safety of participants.

The participants have the right to contact the Data Protection Officer (Kari Tokola, UKK Institute, tietosuoja@ukkinstituutti.fi, tel. 03 282 9111). In addition, they have the right to complain to the supervisory authority if they consider that the processing of personal data violates the general EU data protection regulation (EU) 2016/679. In Finland, the supervisory authority is the data protection commissioner:

Office of the Data Protection Commissioner
Lintulahdenkuja 4, 00530 Helsinki, PO Box 800, FI-00531 Helsinki
Telephone exchange: 029 566 6700
E-mail: tietosuoja@om.fi

The participants may be contacted in the future and invited to take part in other research studies that are similar to this study, or which look at any specific type of injuries. Data collected during this study may be combined and reported with data from other studies conducted by this research team. We will not share participants' contact information with anyone outside the research team.

INSURANCE

The study related physical fitness measurement program can be used to make personal injury claim claimed by the institute's patient insurance. In accordance with the Patient Injury Act, it compensates for personal injuries in the area of health and medical care on the basis specified by law. The Patient Insurance Center takes care of compensation for patient injuries.

RESEARCH COSTS

There are no fees or expenses for participating in the study. Study visits are free of charge for the participants. The research is funded by the Finnish Ministry of Education and Culture.

RESEARCH RESULTS

Participants will be provided with feedback on the results of completed research measurements. The research results will be published through the websites and information channels of the UKK Institute and Terve urheilija.

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MORE INFORMATION

We will be happy to answer any questions you may have and provide additional information (contact information below). Research team contact information:

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jari.parkkari@ukkinstituutti

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Associate Professor
kati.pasanen@ukkinstituutti.fi

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SIGNATURE

Your signature (agreement) on this form indicates that you have understood to your satisfaction the information regarding your participation in the research project and agree to be a participant. In no way does this waive your legal rights nor release the investigators, or involved institutions from their legal and professional responsibilities. You are free to withdraw from the study at any time without jeopardizing your health care.

I have been requested to take part in the above-mentioned scientific study. I have read and understood the research information. I have received both written and oral information on the study as well as an opportunity to ask the researchers questions regarding the study. The information I have received is from the person in the research group.

I have received sufficient information of my rights as a participant, aim of the study and its implementation. I also know benefits and risks related to the study and I have had enough time to consider to take part in the study.

I understand that taking part in the study is voluntary and that I have the right to decline it or withdraw my consent at any time without having to give a reason. I can discontinue my participation in the study at any stage before the end of the study period, with no disadvantageous consequences to me by notifying the research staff.

I understand that my information will be treated confidentially. In connection with the research, my personal data may be transferred or disclosed encrypted, securely to parties outside the research team or outside the EU / EEA or used in scientific publishing activities as described in the research bulletin.

Refusing to participate in the study or withdrawing consent will not have any negative consequences for me and will not affect my treatment or treatment in any way. I am aware that if I withdraw my consent or my participation in the study is interrupted for any other reason, by that time my information collected can be processed further in this study, if the implementation of the study and it requires legislation permits it or requires it.

Hereby I declare my consent to the sections of the study. I consent to participate in the Run RTC Finland study, in which information is collected on sports injuries, state of health and participation in sport.

Tampere __ . __ 20__
I consent to participate in the study:

_____
Signature of participant

_____
Printed name

_____
Date of birth

_____
Telephone number

_____
Email address

_____
Home address, postal code and city

Tampere __ . __ 20__
The recipient of consent:

_____
Signature of researcher

_____
Printed name

_____
Job