



# Effects of an exercise and sport intervention among refugees living in a Greek refugee camp on mental health, physical fitness and cardiovascular risk markers

Dear Sir or Madam

In the coming weeks we would like to conduct a study with residents of the Koutsochero Camp. The main purpose of the study is to examine the effects of a sport and exercise intervention among refugees living in a Greek refugee camp on their mental health, physical fitness and cardiovascular risk.

We will first screen as many camp residents as possible to obtain reliable information about the socio-demographic background of the camp residents.

We will then randomly select participants (68 men, 68 women) who will take part in the baseline data assessment (February 2021). Half of them will then be randomly assigned to an intervention group, whereas the other half will be assigned to a wait-list control group.

The intervention group will take part in a 3-month exercise and sport intervention (at least two times per week for 60 minutes at moderate intensity). In June 2021, the second data assessment will take place. After a short summer break and the third data assessment (September 2021), the wait-list control group will start the exercise and sport intervention. Participants of the initial intervention group are free to decide whether or not they want to continue participation. The wait-list control group will then take part in the fourth and last data assessment in December 2021.

As part of the data assessment, you will complete a series of questionnaires, perform two fitness tests (cardiorespiratory fitness, grip strength), perform a cognitive performance test and wear an accelerometer device for 7 days. Additionally, we will prick your finger in order to take some drops of blood. Completing all tests will take 90-120 minutes.

**Participation in the study is voluntary. It is important that you answer all questions truthfully. The answers will be treated as strictly confidential. Nobody outside of the project team has access to your data. This applies in particular to the camp management or other authorities that may decide on your asylum application. Your personal details are encrypted and entered in a data file. This means that it will not be possible to draw conclusions about your person from the data file.**



## Detailed information

### 1. Purpose of the project

The main purpose of the study is to examine the effects of a sport and exercise intervention among refugees living in a Greek refugee camp on their mental health, physical fitness and cardiovascular risk.

### 2. Selection of participants

The following criteria need to be fulfilled in order to take part in the study: (a) signed informed consent, (b) aged 16-59 years, (c) living in the Koutsochero refugee camp, (d) not having any contra-indications for moderate-intensity physical activity, and (e) being able to exercise at least two times per week for 60 minutes at moderate intensity. In case of contra-indications, consultation with a medical doctor will be held.

### 3. General information about the project

The planned project aims at finding out whether a sport and exercise intervention among refugees living in a Greek refugee camp has positive effects on their mental health, physical fitness and cardiovascular risk. The data assessment lasts from February 2021 until December 2021. In total, 136 camp residents (50% men/women) will be randomly selected and assigned to an intervention and wait-list control group. After completion of the trial, the program will be accessible for all camp residents. The responsible ethics committee has examined and approved this project.

### 4. Procedure

During the intervention phase, exercise and sport activities will be offered five times per week (60 min / session) for three months. Separate programs will be offered for men and women. Participants should participate in at least two sessions per week. Participants can choose between a range of activities. As part of the data assessment, you will complete a series of questionnaires, perform two fitness tests (cardiorespiratory fitness, grip strength), perform a cognitive performance test and wear an accelerometer device for 7 days. Additionally, we will prick your finger in order to take some drops of blood. Completing all tests will take 90-120 minutes.

### 5. Benefits

Your personal benefit of participating in the study is that you can participate in a 3-month structured exercise and sport program at least 2 times per week for 60 minutes. You will also have the possibility to continue your participation after the end of the trial (at least until December 2022). Regular participation in physical activity is recommended by the World Health Organization to maintain good health. As scientists, we will receive important information regarding the potential of regular exercise and sport participation to improve refugees' health.

### 6. Rights

You take part in the study voluntarily. If you do not want to take part or later withdraw your participation, you do not have to give a reason. You have no disadvantages if you decide not to participate in the study or to stop it prematurely. You can ask questions about participation and the project at any time. To do this, please contact the person named at the end of this information letter now or at a later date.

### 7. Obligations

As a participant, it is necessary that you adhere to the necessary specifications and requirements of the project management (e.g. answer interview questions honestly, wear the accelerometer device, etc.).



## 8. Risks

Risks for capillary blood sampling are minimal and present a frequently used procedure. Nevertheless, finger prick might be a slightly uncomfortable procedure. Moreover, you will fill in a Physical Activity Readiness questionnaire before study enrolment. In case of contra-indications, consultation with a medical doctor will be held.

## 9. Sharing of the results

The project management will inform you during the project of any new findings that may affect the benefit or your safety and thus your consent to participate. If we find that you have an elevated cardiovascular risk with regard to one or several indicators, we will inform you personally and explain the results.

## 10. Confidentiality of data and samples

Your personal data will be recorded for this project. Very few people will see your unencrypted data, and only for the purpose of performing tasks on the project. Other people who are also involved in the study project will only see your encrypted data. Neither the camp management nor other authorities that may decide on your asylum application can see the raw data. All persons who have access to your data are subject to strict confidentiality. As a participant, you have the right to inspect your data at any time. Upon request, this study project can be reviewed by the responsible ethics committee. The responsible investigator may need to disclose your personal information for such controls.

## 11. Right to withdraw

You can stop and withdraw from the project at any time if you wish. The data and samples collected up to that point will still be evaluated in encrypted form, otherwise the entire project will lose its value.

## 12. Compensation

You will not receive any financial compensation for participating in this project. However, as an acknowledgment of your participation, you will receive a small gift after each data assessment.

## 13. Liability

Although the risk potential is minimal, the responsible investigators will ensure obtaining required insurance coverage for the trial under applicable laws.

## 14. Funding

The project is financed by the Swiss Network for International Studies (Switzerland) as well as internal contributions from the participating universities.

## 15. Who to contact

If you have any doubts, concerns or emergencies that arise during or after the project, you can contact these persons at any time:

Prof. Dr. Markus Gerber, Principal Investigator (Switzerland), Department of Sport, Exercise and Health, University of Basel, Basel Switzerland, [markus.gerber@unibas.ch](mailto:markus.gerber@unibas.ch)

Prof. Dr. Antonis Hatzigeorgiadis, Principal Investigator (Greece), Department of Physical Education and Sport Science, University of Thessaly, Trikala, Greece, [ahatzi@pe.uth.gr](mailto:ahatzi@pe.uth.gr)



## Informed consent sheet

### Written declaration of consent to participate in a study project

Please read this form carefully. Please ask if you do not understand something or if you would like to know something.

<b>BASEC number (after submission):</b>	
<b>Study title (scientific and lay language):</b>	Effects of an exercise and sport intervention among refugees living in a Greek refugee camp on mental health, physical fitness and cardiovascular risk markers
<b>Responsible institution (Project management with address):</b>	Departement for Sport, Exercise and Health, University of Basel, Basel, Switzerland  Department of Physical Education and Sport Science, University of Thessaly, Trikala, Greece
<b>Place of implementation:</b>	Koutsochero refugee camp, Greece
<b>Responsible investigators:</b>	Prof. Dr. Markus Gerber, Principal Investigator (Switzerland), Department of Sport, Exercise and Health, University of Basel, Basel Switzerland  Prof. Dr. Antonis Hatzigeorgiadis, Principal Investigator (Greece), Department of Physical Education and Sport Science, University of Thessaly, Trikala, Greece

### Study participant:

First name: \_\_\_\_\_

Family name: \_\_\_\_\_

Email address: \_\_\_\_\_

Mobile phone number: \_\_\_\_\_

- I was informed orally and in writing by the undersigned examiner about the purpose, the course of the project, about possible advantages and disadvantages as well as possible risks.
- I take part in this project voluntarily and accept the content of the written information given on the above project. I have had enough time to make my decision.
- My questions in connection with participating in this project have been answered. I keep the written information and receive a copy of my written declaration of consent.
- I agree that the responsible experts in the project management of the study and the ethics committee responsible for this project may inspect my unencrypted data for testing and control purposes, but subject to strict confidentiality.



- I know that my health-related and personal data can only be passed on in encrypted form for research purposes for this study project (also abroad).
- I can withdraw from participation at any time and without giving reasons, without being disadvantaged. The data and samples collected up to that point will still be used to evaluate the study.
- The responsible investigators provide insurance coverage that covers any damage resulting from participation in the intervention program.
- I am aware that the obligations stated in the participant information must be observed.

Place, Date	Signature of study participant:

**Confirmation of the examiner:** I hereby confirm that I have explained the nature, meaning and scope of the project to this participant. I affirm that I will meet all obligations in connection with this project in accordance with applicable law. If at any point during the implementation of the project I learn of any aspects that could influence the participant's willingness to participate in the study, I will inform him / her immediately.

Place, Date	First name and family name of the informing examiner in block letters:
	Signature of the examiner: