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

Submission date
15/12/2020

Recruitment status
No longer recruiting

Registration date
08/02/2021

Overall study status
Completed

Last Edited
16/09/2024

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol
Background and study aims
Due to ongoing political and social conflicts, the number of international refugees has been increasing. Refugees are exposed to severe mental and physical strain, as well as traumatic experiences during their flight. As a consequence, the risk of psychiatric disorders is markedly increased among international refugees with particularities based on gender. International organizations have criticized the lack of early interventions as a key problem because untreated mental disorders are often difficult to cure at a later stage. Today, exercise and sport have been successfully employed to treat a wide range of psychiatric disorders. With PTSD patients, however, very limited empirical evidence exists, and studies carried out with international refugees are nearly non-existent.

In 2017, the study team implemented a pilot study in a Greek refugee camp to investigate the potential benefits of exercise and sport on refugees' mental health and fitness. Therefore, the main purpose of this study is to invetsigate the effects of a sport and exercise intervention among refugees living in a Greek refugee camp on PTSD symptoms in a larger clinical trial. There is also a long term aim to develop a strategy to continue the exercise and sport program after the funding of the Swiss Network for International Studies (SNIS) comes to an end, and to scale up the program beyond the borders of the Koutsochero camp.

Who can participate?
People aged 16-59 years and living in the Koutsochero refugee camp who provide informed consent to participate will be eligible

What does the study involve?
The proposed study will take place in the Koutsochero refugee camp, located close to the city of Larissa (Greece). Participants in the study will be randomly allocated to either begin the exercise and sport program immediately or will be added to a wait-list to begin the program at a later date. Participants will be assessed three times, first, before beginning the program, then

immediately at the end of the program (after 3 months), and then after a further 3 months for a final follow-up (after 6 months from the beginning of the program). In the second year of study, the program will be opened to all camp residents. Exercise and sport will be offered five times per week for three months, with sessions lasting 60 min. Participants will participate in at least two sessions per week. The program is developed according to the participants' needs and preferences and they will be able to choose between a range of activities.

What are the possible benefits and risks of participating?
Personal benefits for participants are that they can participate in a 3-month structured exercise and sport program at least 2 times per week for 60 min. They will also have the possibility to continue their participation after the end of the trial (at least until February 2023). Regular participation in physical activity is recommended by the World Health Organization to maintain good health. It is hoped that the study will provide important information regarding the potential of regular exercise and sport participation to improve refugees' health.

Risks for capillary blood sampling are minimal and present a frequently used procedure. Nevertheless, finger prick might be a slightly uncomfortable procedure. Participants will fill in a Physical Activity Readiness questionnaire before study enrolment to ensure that they will be suitable to take part in the exercise program. In the case of contra-indications, consultation with a medical doctor will be held.

Where is the study run from?
The project is organized as a cooperation between the universities of Basel, Zürich, and Bern (Switzerland) and the University of Thessaly (Greece) and will be closely cooperating with the Ministry of Migration and Asylum (Greece), the municipality of Larissa (Greece), the Danish Refugee Council (Denmark), and other locally active NGOs.

When is the study starting and how long is it expected to run for?
From January 2020 to February 2023

Who is funding the study?
The Swiss Network for International Studies (Switzerland)

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

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

Acronym
SALEEM

Study objectives

The main purpose of the present study is to examine with a randomized controlled trial (RCT) the effects of a sport and exercise intervention among refugees living in a Greek refugee camp on PTSD symptoms (primary outcome). Based on an initial pilot study, our main hypothesis is that a sport and exercise intervention has a positive influence on both the primary and secondary outcomes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 26/11/2020, Ethikkommission Nordwest- und Zentralschweiz (EKNZ) (Hebelstrasse 53, 4056 Basel, Switzerland; +41 (0)61 268 13 50; eknz@bs.ch), ref: AO_2020_00036

Study design
Single-blind randomized wait-list controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Prevention of post-traumatic stress disorder symptoms among refugees living in a Greek refugee camp

Interventions
The study is designed as a randomized controlled trial (RCT) with an intervention group (IG, who will participate in the exercise and sport activities) and a wait-list control group (WLCG), with a 1:1 allocation ratio between the IC and WLCG, and with concealed allocation to groups. To ensure allocation concealment, allocation to groups will be done randomly by a computer-generated code after the baseline assessment has taken place. In order to reduce random differences between the two groups, we will use the "OxMaR" software (Oxford Minimization and Randomization), taking into account the following stratification variables: gender, age, time fleeing, and PTSD symptom severity.

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. Moreover, cultural particularities of the target population will be considered during program development. Participants are asked to participate in at least two sessions per week (but encouraged to do more). Participants can choose between a range of activities. Based on experience from a pilot study where 95% were satisfied or very satisfied, activities for males could include weight and endurance training, football, volleyball, or other activities depending on the needs and preferences of the participants. The program for female participants will also consider their needs and preferences. Thus, we will carry out individual interviews and organize focus group discussions in order to develop appropriate programs for male and female participants. Due to possible language barriers or inter-cultural difficulties due to multi-ethnic background of refugees, it is important that the activities are tailor-made, in particular, simple, acceptable, pleasant, and easy to understand and apply to meet individual, gender, age, ethnic/cultural-specific needs and preferences in the real-life (pragmatic) setting of a refugee camp with limited exercise/sport facilities. Tailor-made interventions are highlighted by international physical

activity guidelines for people with mental health problems and proved to provide mental health benefits in real-life settings.

After the 3 month program, all participants will be assessed, and then followed up again after 6 months. In the second year of the study, the program will be made available to the wait-list control group.

Intervention Type
Behavioural

Primary outcome(s)
1. Post-traumatic stress disorder symptoms measured using a self-report questionnaire at baseline, 3, 6, and 9 months

Key secondary outcome(s))
1. Perceived stress measured using self-report questionnaires at baseline, 3, 6, and 9 months
2. Depressive symptoms measured using self-report questionnaires at baseline, 3, 6, and 9 months
3. Anxiety symptoms measured using self-report questionnaires at baseline, 3, 6, and 9 months
4. Insomnia symptoms measured using self-report questionnaires at baseline, 3, 6, and 9 months
5. Health-related quality of life measured using self-report questionnaires at baseline, 3, 6, and 9 months
6. Pain measured using a visual analogue scale at baseline, 3, 6, and 9 months
7. Perceived fitness measured using self-report questionnaires at baseline, 3, 6, and 9 months
8. Cardiorespiratory fitness measured using a bicycle ergometer test at baseline, 3, 6, and 9 months
9. Hand grip strength measured using the hand grip strength test at baseline, 3, 6, and 9 months
10. Physical activity measured using 7-day accelerometry at baseline, 3, 6, and 9 months
11. Cognitive function measured using computerized tests at baseline, 3, 6, and 9 months
12. Cardiovascular risk markers:
12.1. Body weight and height measured using a digital weighing scale and a stadiometer at baseline, 3, 6, and 9 months
12.2. Body composition measured using a bioelectrical impedance analysis at baseline, 3, 6, and 9 months
12.3. Waist circumference measured using a flexible tape at baseline, 3, 6, and 9 months
12.4. Systolic and diastolic blood pressure measured using a digital blood pressure monitor at baseline, 3, 6, and 9 months
12.5. Anaemia measured using a HemoCue® Hb 301 system at baseline, 3, 6, and 9 months
12.6. Blood lipids, blood glucose, inflammatory cytokines measured using an Alere point-of-care (PAC) analyser at baseline, 3, 6, and 9 months
13. Participants socio-demographic background and potential confounders (age, nationality, religious background, marital status, number of children, educational background, time fleeing, time in camp, physical activity level during the past week, and PTSD symptoms) are assessed using an interview format before the baseline data assessment

Completion date
28/02/2023

Eligibility

Key inclusion criteria

1. Informed consent given
2. Aged 16-59 years
3. Living in the selected refugee camp

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
16 years

Upper age limit
59 years

Sex
All

Total final enrolment
143

Key exclusion criteria
1. Any contra-indications for moderate-intensity physical activity (based on the Physical Activity Readiness Questionnaire)
2. Unable to exercise at least two times per week for 60 min at moderate intensity

Date of first enrolment
01/03/2021

Date of final enrolment
31/08/2021

Locations

Countries of recruitment
Greece

Study participating centre
Koutsochero refugee camp
Koutsochero
Larissa
Greece
415 00

Sponsor information

Organisation
University of Basel

ROR
https://ror.org/02s6k3f65

Funder(s)

Funder type
Government

Funder Name
Swiss Network for International Studies

Results and Publications

Individual participant data (IPD) sharing plan
In line with the guidelines and open access policies of nationally and internationally recognized foundations and institutions, the published data from our project will be stored in a publically available repository, at https://fairsharing.org (individual participant data that underlie the results reported in an article, after deidentification; immediately following publication; anyone who wishes to access the data; for any purpose; data are available indefinitely).

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		12/09/2024	16/09/2024	Yes	No
Protocol article		21/11/2021	20/02/2023	Yes	No
Participant information sheet	version v2	24/11/2020	08/02/2021	No	Yes