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STUDY PROTOCOL



Moderate-intensity aerobic exercise training as an adjunct to trauma-focused psychotherapy in traumatized refugees and asylum seekers: study protocol of a randomized controlled trial

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ABSTRACT

Background: Refugees with exposure to multiple traumatic events are at high risk for developing posttraumatic stress disorder (PTSD) and depression. Narrative exposure therapy (NET) is an effective treatment for the core symptoms of PTSD, but it does not reliably reduce depressive symptoms. Endurance exercise on the other hand was consistently found to be effective in treating depression making it a promising adjunct to NET. Up to date, no studies exist investigating the combination of NET and endurance exercise in a sample of refugees with PTSD and comorbid depression.

Objectives: In the proposed randomized controlled trial, we aim to investigate whether a combination of NET and moderate-intensity aerobic exercise training (MAET) enhances treatment outcome for refugees with PTSD and comorbid depressive symptoms. We expect a greater improvement in psychopathology in participants who receive the combined

Methods and analysis: 68 refugees and asylum seekers with PTSD and clinically relevant depressive symptoms will be recruited in the proposed study. Participants will be randomly assigned to receive either NET only (NET-group) or NET plus MAET (NET+-group). All participants will receive 10 NET sessions. Participants in the NET+-group will additionally take part in MAET. Primary (PTSD, depression) and secondary (general mental distress, agoraphobia and somatoform complaints, sleep quality) outcome measures will be assessed before treatment, after treatment, and at six-month follow-up. The hypotheses will be tested with multiple 2×3 mixed ANOVA's.

Trial registration: German Clinical Trials Register identifier: DRKS00022145.

Entrenamiento con ejercicios aeróbicos de intensidad moderada como complemento de la psicoterapia centrada en el trauma en refugiados y solicitantes de asilo traumatizados: protocolo de estudio de un ensavo controlado aleatorizado

Antecedentes: Los refugiados expuestos a múltiples eventos traumáticos tienen un alto riesgo de desarrollar trastorno de estrés postraumático (TEPT) y depresión. La terapia de exposición narrativa (TEN) es un tratamiento eficaz para los síntomas centrales del TEPT, pero no reduce de manera confiable los síntomas depresivos. Por otro lado, se ha encontrado consistentemente que el ejercicio de resistencia es eficaz en el tratamiento de la depresión, lo que lo convierte en un complemento prometedor para la TEN. Hasta la fecha, no existen estudios que investiguen la combinación de TEN y ejercicio de resistencia en una muestra de refugiados con TEPT y depresión comórbida.

Objetivos: En el ensayo controlado aleatorizado propuesto, nuestro objetivo es investigar si una combinación de TEN y entrenamiento aeróbico de intensidad moderada (MAET por sus siglas en inglés) mejora el resultado del tratamiento para los refugiados con TEPT y síntomas depresivos comórbidos. Esperamos una mayor mejora en la psicopatología en los participantes que reciban el tratamiento combinado.

Métodos y análisis: Se reclutarán 68 refugiados y solicitantes de asilo con TEPT y síntomas depresivos clínicamente relevantes en el estudio propuesto. Los participantes serán asignados aleatoriamente para recibir solo TEN (grupo TEN) o TEN más MAET (grupo TEN+). Todos los participantes recibirán diez sesiones de TEN. Los participantes en el grupo TEN+ participarán adicionalmente en MAET. Las medidas de resultado primarias (TEPT, depresión)

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KEYWORDS

Trauma; PTSD; depression; adjuvant treatment; aerobic exercise training; narrative exposure therapy; traumafocused psychotherapy; refugee

PALABRAS CLAVE

trauma; TEPT; depresión; tratamiento adyuvante; entrenamiento aeróbico: terapia de exposición narrativa; psicoterapia enfocada en el trauma; refugiado

关键词

创伤; PTSD; 抑郁; 辅助治 疗; 有氧运动训练; 叙事暴 露疗法; 创伤聚焦心理治 疗; 难民

HIGHLIGHTS

- · Refugees are at particularly high risk of developing posttraumatic stress disorder and comorbid depressive symptoms due to exposure to multiple man-made traumatic events.
- Narrative exposure therapy reliably reduces symptoms of posttraumatic stress disorder, but many patients retain their clinical diagnosis, untreated comorbid depressive symptoms may interfere with treatment response.
- The randomized controlled trial aims to investigate whether combining narrative exposure therapy with moderate-intensity aerobic exercise training enhances treatment

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y secundarias (malestar mental general, agorafobia y quejas somatomorfas, calidad del sueño) se evaluarán antes del tratamiento, después del tratamiento y en un seguimiento de seis meses. Las hipótesis serán probadas con múltiples ANOVA mixtas de 2×3.

中等强度有氧运动训练作为经历创伤难民和寻求庇护者创伤聚焦心理治疗 的辅助手段:随机对照试验的研究方案

背景:经历过多次创伤事件的难民患创伤后应激障碍(PTSD)和抑郁的风险很高。叙事暴 露疗法(NET)是治疗PTSD核心症状的有效方法,但它并不能可靠地减轻抑郁症状。另 方面,耐力运动一直被认为可以有效治疗抑郁,使其成为 NET 的有前景的辅助疗法。至今 尚无研究在患有 PTSD 和共病抑郁难民样本中考查 NET 和耐力运动的结合。

目的: 在拟议的随机对照试验中,我们旨在考查 NET 和中等强度有氧运动训练 (MAET) 的结 合是否可以提高患有 PTSD 和共病抑郁症状难民的治疗结果。 我们预期接受联合治疗的参 与者的精神病症状会有更大的改善。

方法与分析: 拟议的研究将招募 68 名患有PTSD和临床相关抑郁症状的难民和寻求庇护 者。参与者将被随机分配接受仅 NET(NET 组)或 NET 加 MAET组(NET+-组)。所有参与 者将接受十次 NET 疗程。NET+- 组的参与者还将额外参加 MAET。主要(PTSD、抑郁)和次要(一般心理困扰、广场恐惧症和躯体症状、睡眠质量)结果指标将在治疗前、治疗后 和六个月随访时进行评估。这些假设将通过多个 2×3 混合方差分析进行检验。

outcomes for refugees with posttraumatic stress disorder and comorbid depressive symptoms, compared to narrative exposure therapy as a stand-alone treatment.

1. Background

An increasing number of people is forced to leave their homes because of war, human rights violations and natural disasters. Since 2020, the number of forcibly displaced people worldwide exceeded 1% of the world's population (UNHCR, 2021). The United Nations High Commissioner for Refugees (UNHCR) reported that in May 2022 over 26.3 million refugees were under UNHCR's mandate and that 4.5 Mio asylum seekers out of 101.1 Mio displaced people worldwide had to flee their hometowns due to war, violent conflicts, and persecution (UNHCR, 2022). Most of them have been exposed to traumatic events before, during and after their flight. A recent German study showed that 85.5% of newly arrived refugees reported having experienced at least one traumatic event (Nesterko et al., 2020): 75.7% of the participants reported interpersonal traumatic events. Physical assault was the most frequently experienced event, followed by interpersonal threat/assault with a weapon. Incidents of severe human suffering, and sexual assaults were also reported. Sexual assaults were more frequently reported by women than by men.

In fact, refugees tend to be exposed to multiple manmade traumatic events posing them at a particularly high risk for the development of posttraumatic stress disorder (PTSD) and comorbid depressive symptoms (Blackmore et al., 2020; Fazel et al., 2005; Nesterko et al., 2020). Two recent studies showed that 35-40% of refugees in Germany suffer from PTSD and 21.7% from depression (Gäbel et al., 2006; Nesterko et al., 2020). These high rates stand in contrast to the one-year prevalence rates of PTSD (2.3%) and depression (7.7%) in the general population in Germany (Jacobi et al., 2014). PTSD and depression often co-occur (e.g. Blackmore et al., 2020) and tend to maintain or even reinforce each other. PTSD

patients suffering from comorbid depression show a higher impairment in global functioning (Momartin et al., 2004) and a reduced treatment progression and treatment response (Haagen et al., 2017).

Trauma-focused psychotherapy (TFP) is the gold standard for treating PTSD (e.g. Lewis et al., 2020). For patients with PTSD and depression, the National Institute for Health and Care Excellence (NICE) recommends that PTSD is treated first unless the depression is severe enough to make psychotherapeutic treatment of PTSD difficult or puts the person at risk of harming themselves (NICE, 2018). Narrative exposure therapy (NET) is a TFP developed for survivors of traumatic events (Schauer et al., 2011). In NET, patients construct a chronological narrative of their lives with emphasis on the traumatic experiences. Research on the efficacy of NET in treating PTSD in refugees consistently show significant improvements in PTSD symptoms although not all patients achieve loss of diagnosis (Cusack et al., 2016).

Studies on the effects of NET on depression show mixed results (e.g. Kip et al., 2020; Nosè et al., 2017; Stenmark et al., 2013). While some studies found significant reduction of depression symptoms (e.g. Adenauer et al., 2011), others did not (Hensel-Dittmann et al., 2011) or found no long-term effects (Alghamdi et al., 2015).

Several adjuvant interventions have been proposed as boosters of TFP with respect to PTSD and comorbid symptoms (Michael et al., 2019). Of these possible adjuvant interventions aerobic exercise seems to be a particularly promising option (for example see Bryant et al., 2022). Exercise in general has been found to have beneficial effects on several psychological disorders, which may be explained by neurobiological mechanisms including modifications in the Hypothalamic-Pituitary-Adrenal (HPA) axis activity, monoamine metabolism (Alghadir & Gabr, 2020; Autry &

Monteggia, 2012; Ploski & Vaidya, 2021)., and Brain-Derived Neurotrophic Factors (BDNF) (Castrén & Monteggia, 2021; Knaepen et al., 2010; Powers et al., 2015). Additionally, psychological factors such as increased self-efficacy and self-esteem may also contribute to the effectiveness of exercise in treating psychological disorders (Asmundson et al., 2013; Holz & Michael, 2013).

2. Effects of exercise on depressive symptoms

Extensive empirical evidence shows that exercise significantly reduces depression (Schuch et al., 2016). Wegner et al. (2014) that synthesize meta-analyses on the effects of exercise on anxiety and depression found a moderate anti-depressant effect. A current systematic review and meta-analysis by Björkman and Ekblom (2022) on the effect of physical exercise on PTSD including different types of aerobic and resistance exercise also found a beneficial effect of exercise on depressive symptoms in PTSD patients. While the above-described studies and meta-analyses focus on exercise as a stand-alone treatment, there are a few studies focusing on exercise as an adjuvant treatment. Rosenbaum et al. (2015) investigated the effect of a 12-week exercise intervention (walking programme) in addition to treatment as usual (TAU) in a sample of PTSD patients and found a large effect favour combined intervention to decrease depressive symptoms. Nordbrandt et al. (2020) conducted a similar study in a refugee sample with PTSD but did not find an effect on mixed exercise as an adjunct to TAU on depression symptoms.

3. Effects of exercise on PTSD symptoms

There is preliminary evidence that exercise may also reduce PTSD symptomatology (Fetzner & Asmundson, 2015; Hegberg et al., 2019; Knappe et al., 2019).

A systematic review by Vancampfort et al. (2017) found that exercise is especially effective in reducing PTSD-symptomatology for patients with a lower baseline physical fitness. In the above-mentioned metaanalysis Björkman and Ekblom (2022) also reported a positive effect of physical exercise on PTSD as a primary outcome.

The effects of exercise as an adjunct to standard treatment for PTSD patients have rarely been investigated. Qualitative research focusing on exercise as a component of treatment for traumatized refugees provides support for the health-promoting effects of such interventions, as indicated by self-report measures. (e.g. Nilsson et al., 2019). Powers et al. (2015) found that TFP plus exercise led to a significant greater reduction in PTSD symptomatology as compared to TFP only. However, the validity of these results is limited due to the small sample size (n = 9). Furthermore, Rosenbaum et al. (2015) found a moderate effect

favouring a combined intervention in the decrease of PTSD symptoms. However, Nordbrandt et al. (2020) did not find a significant effect of adjuvant exercise on PTSD symptoms compared to TAU.

Given the heterogeneous nature of exercise interventions in different studies, it is difficult to determine the appropriate programme variables (frequency, intensity, duration, and type of exercise) for an effective exercise intervention. However, BDNF and HPA axis regulation as potential mechanisms of action point to a more beneficial effect of moderate to intense endurance exercise as compared to other types of exercise. In line with this, Stanton and Reaburn (2014) reviewed the evidence of five RCTs examining the characteristics of effective exercise in reducing depression. The review supports the notion that the most effective exercise programmes include aerobe endurance exercise of moderate intensity, three times weekly ranged from four to twelve weeks, with both individual and group training being effective. Furthermore, Wegner et al. (2020) reviewed several meta-analyses in a sample of depressed children and adolescents and summarized aerobic exercise as the most frequently implemented type of exercise (41 min, three times a week, over 11.5 weeks).

2. Summary and objectives

To summarize NET reduces consistently PTSD symptoms in refugees, but many keep PTSD diagnostic status. Further, there is insufficient evidence that NET improves depressive symptoms. Physical exercise, as an adjunct to NET seems a promising option to improve both PTSD and depression symptoms. Thus, the proposed randomized controlled trial (RCT) aims to investigate whether a combination of NET and moderate-intensity aerobic exercise training (MAET) (NET⁺-group) enhances treatment outcome for refugees with PTSD and comorbid depressive symptoms in comparison to NET as a stand-alone treatment (NET-group).

3. Hypotheses

Compared to the NET-group, participants in the NET⁺-group show greater improvement in primary (PTSD, depression) and secondary outcomes (general mental distress, agoraphobia and somatoform complaints, sleep quality) from pre to post treatment and at follow-up.

4. Trial design

The proposed study is a single-blind RCT comparing a combined treatment including NET and MAET (NET+group) with NET only (NET-group). All participants receive ten NET sessions. Participants in the NET⁺-group additionally participate in a MAET consisting of three weekly running exercises over a therapy period ranging from 10 to 15 weeks. Please note, the timing of each MAET session is unrelated to the weekly NET sessions. Outcome measures are assessed pre treatment (T0), after treatment completion (T1) and at sixmonth follow-up (T2). An overview of the RCT is given in the flowchart shown in Figure 1.

5. Methods

5.1. Study setting

NET is offered at the Psychotherapeutic Outpatient Clinic, which is part of the Department of Clinical Psychology and Psychotherapy at Saarland University. Medical diagnostic is performed at the Institute of Sports and Preventive Medicine at Saarland University.

5.2. Funding details and preregistration

The present trial is supported by the German Research Foundation (DFG) under Grant 426361032. The trial is preregistered in German Clinical Trials Register (DRKS) (DRKS ID: DRKS00022145).

5.3. Sample size and power calculation

Sample size was calculated using G*Power 3.1.9.2. (Faul et al., 2009) to detect the interaction in a 2×2

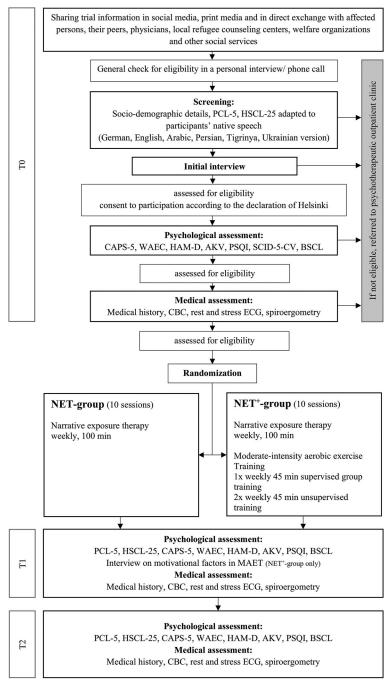


Figure 1. Flowchart of the procedure of the current clinical RCT.

ANOVA (group: NET+ vs. NET; time: pre vs. post) with a power of .80 ($\alpha = .025$ because of two primary outcomes). The a priori power calculation resulted in a total sample size of n = 68 assuming a moderate adjuvant effect and at least a small correlation between the test times (r = .15).

5.4. Recruitment and eligibility criteria

Multiple local social services and employment agencies are involved in the recruitment of participants, and study eligibility is determined by the criteria specified in Table 1.

5.5. Procedure

5.5.1. Screening

A first check of inclusion and exclusion criteria is assessed during a phone call before the screening questionnaires (PCL-5; Blevins et al., 2015; HSCL-25; Derogatis et al., 1974) are sent to potential participants. Screening questionnaires and diagnostic questionnaires are provided in participants' native languages. For illiterate people, the screening and diagnostic questionnaires are conducted as an interview supported by interpreters.

5.5.2. Initial interview

Participants, who report psychological distress in the screening questionnaires, are invited to an initial

Table 1. Eligibility and exclusion criteria.

Eligibility criteria

- (1) German health insurance (registration as a recognized refugee in Germany required)
- (2) Minimum age of 16 years
- (3) The diagnosis of PTSD
- (4) Clinically relevant depression symptoms
- (5) No endurance training in the one-year period prior to study
- (6) No experience of endurance training in the past (i.e. not more than one weekly unit of endurance sports during the last two years and no lifetime competitive practice in endurance sports)

Exclusion criteria

- (1) Physical constraints:
 - Cardiovascular diseases
 - Serious deviations in Complete Blood Count (CBC)
 - Further physical restrictions that preclude participation in moderate endurance training (e.g. serious systemic diseases, coronary stenosis with angina pectoris, cardiac insufficiency under resting conditions, severe cardiac arrhythmia, and acute illnesses, such as acute infections, severe electrolyte imbalance, recent heart attacks, heart wall aneurism)
- (2) Eating disorders (due to the risk of abusing physical activity for weight loss)
- (3) Acute psychosis
- (4) Acute suicidal behaviour
- (5) Substance abuse disorders/ drug and alcohol abuse
- (6) Pregnancy
- (7) Medication with of benzodiazepines

Notes: Participants currently undergoing pharmacological treatment will not be excluded from the study. However, it is requested that participants maintain a stable dosage and type of medication, with the exception of benzodiazepines, in order to include medication as a covariate in the final analyses. Participants receiving treatment with benzodiazepines cannot be included in the randomized controlled trial (RCT).

interview to assess study eligibility. During the initial interview, participants are informed about the study protocol neglecting the hypotheses of the trial. If the initial interview suggests participants' study eligibility (suspected diagnosis of PTSD and depressive symptoms), participants are asked to provide informed consent and are invited to participate in detailed psychological and medical diagnostic sessions. Participants, who show signs of clinical distress, but are not eligible for study participation also receive a treatment offer at the Psychotherapeutic Outpatient Clinic of Saarland University.

5.5.3. Psychological assessment

The psychological assessment includes the Clinician-Administered PTSD Scale (CAPS-5; Weathers et al., 2013), the Hamilton Depression Scale (HAM-D; Hamilton, 1960; 1967) and the Structured Clinical Interview for DSM-5 Clinician Version (SCID-5-CV; First et al., 2016), the War and Adversity Exposure Checklist (WAEC; Ibrahim et al., 2018) and self-report questionnaires assessing general mental distress (Brief Symptom Checklist (BSCL); Franke, 2017), sleep quality (Pittsburgh Sleep Quality Index (PSQI); Buysse et al., 1989) and agoraphobic symptoms and somatoform symptoms (Fragebogen zu körperbezogenen Ängsten, Kognitionen und Vermeidung AKV; Ehlers et al., 2001). All measures (except of the SCID-5-CV) will also be assessed after the completion of treatment (T1) and at six-month follow-up (T2).

5.5.4. Medical assessment

To assess participants' physical eligibility a detailed medical diagnostic is performed (including evaluation of medical history, resting and stress Electrocardiogram (ECG), spiroergometry, Complete Blood Count (CBC)).

5.5.5. Randomization

Participants are assigned to the NET⁺ and NET-group via computer-assisted randomization using Mersenne Twister in IBM SPSS Statistics version 22.0 (IBM Corp, 2013). After completion of the diagnostic sessions, participants receive a closed envelope containing group assignment.

5.5.6. NET and NET⁺

Participants are randomly assigned to the NET vs. NET⁺-group. All participants receive 10 NET sessions. The NET+-group additionally receive MAET. The total duration of the treatment is estimated to range from 10-15 weeks.

5.6. Language mediation and translation

All sessions are accompanied by interpreters who are fluent in the participants' native speech and in

Table 2. Treatment overview.

Session no.	Therapeutic content				
1	Exploratory sessions	Relationship-oriented			
		Assess of medication, suicidal behavior, risk of dissociation			
		Development of the emergency plan			
		Review of psychosocial problems			
2		Psychoeducation on trauma, PTSD, and memory			
		Rationale and basic principles of NET and trauma-focused therapy			
		Preparing for the following NET sessions			
3	Narrative exposure therapy	Lifeline			
4		Starting the narration at birth			
		In-sensu exposure of the first traumatic life event			
5–11		Rereading of the previous narration to add further details if necessary			
		Continuing the in-sensu exposure of further traumatic events following the narration			
12		Rereading of the whole written narration/ relaying of the lifeline			
		Appreciating and signing the written narration			
		Optimistic perspective on future considered in a positive light			

Note: MAET starts in the third session together with the beginning of NET.

German. Each interpreter is informed about the rationale and procedure of NET prior to the start of the first diagnostic session. During therapeutic sessions, interpreters are instructed to take a neutral role and solely translate everything the participant and psychotherapist are saying. NET sessions are transcribed by students who passively participate in the psychotherapeutic sessions.

5.7. Mental hygiene

Every fourth therapy session, language mediators and co-writing students receive group supervision led by the head of the Psychotherapeutic Outpatient Clinic of Saarland University to prevent psychological distress (through the refugees' narratives). In addition, there is the possibility of individual supervision if required.

5.8. Treatment fidelity

NET is conducted by licensed psychotherapists and psychotherapists in initial training. Participating psychotherapists were trained in NET in a two-day online workshop and receive supervision after every session. Additionally, all psychotherapeutic sessions are audiorecorded.

5.9. Intervention

5.9.1. Exploratory sessions and psychoeducation

Participants first undergo two exploratory sessions aiming at developing a therapeutic alliance (participant, psychotherapist, interpreter, co-writing students) and providing psychoeducation about PTSD and NET. Details on the content of the exploratory sessions can be found in Table 2.

5.9.2. Narrative exposure therapy

In the present trial NET consists of 10 weekly sessions (each with a duration of 100 min). The therapy takes

place at the Psychotherapeutic Outpatient Clinic of Saarland University and is conducted by licensed psychotherapists or psychotherapists in initial training. In order to minimize the exclusion of individuals due to financial constraints that prevent them from travelling to therapy, the study will provide coverage for travel costs when necessary. The psychotherapists receive a professional NET coaching before starting the therapy and receive supervision by an experienced psychotherapist after every second double session.

During the first NET session the participant's lifeline - with traumatic events symbolized by stones, situations of grief symbolized by candles and positive events symbolized by flowers - is laid (Elbert et al., 2015).

The following sessions consist of the in-sensu exposure for each traumatic event. To ensure an effective exposure the psychotherapist encourages participants to recall the traumatic events in emotion, sensation, cognition and physiological details. The exposure of a maximum of two traumatic events must be completed in one session. In the final session the events are reviewed as a holistic narration. The participant, the psychotherapist, the co-writing student, and the interpreter sign the narrative which is subsequently handed to the participant.

5.9.3. Narrative

Written transcripts of each session are provided by the co-writing students. The traumatic events are documented in the past tense and submitted weekly to the psychotherapist for revision. The participants are encouraged to revise and add to the narrative in each follow-up session and in the final NET session.

5.9.4. Moderate-intensity aerobic exercise

Moderate-intensity aerobic exercise training (MAET) in the present study is adapted to the national recommendation for the treatment of depression recommended by WHO for health of adults aged between 18 and 64 (DGPPN, 2017; WHO, 2022). The NET⁺-group receives three weekly outdoor sessions of MAET consisting of 45 min of jogging at 60% heart rate reserve (±5 bpm) (e.g. Stanton and Reaburn (2014)) with one MAET group session of no more than three participants supervised by a medical and psychological supervisor and two unsupervised exercise sessions per week. The route will be chosen to be close to participants' place of residence and with only a slight incline. Depending on individuals' baseline fitness levels, the intensity of MAET varies along a continuum from walking to jogging. Walking is typically assumed to occur at low baseline fitness levels, while jogging is associated with elevated baseline fitness levels.

To be included in the final analysis participants must complete 70% of MAET (Hecksteden et al., 2013). Each participant of the NET+-group receives a mobile heart rate monitor with integrated memory function (Sigma ID.Free) and a compatible heart rate belt (Sigma R1 ANT+/BLE + COMFORTEX) to control and record parameters such as duration (in min), route (in m), speed (in min/km), altitude (in m) and average heart rate (in bpm) during MAET. To ensure an aerobic exercise training with moderate intensity, the heart rate monitor is programmed to display a green light when participant's heart rate was in the individually predefined heart rate zone. In addition to the digital recording of the MAET, participants document the completed MAET session and their mood before and after MAET training in a diary.

5.10. Primary outcomes

5.10.1. Posttraumatic stress disorder

PTSD symptoms are assessed with the PTSD Checklist for DSM-5 (PCL-5), the Clinician-Administered PTSD-Scale for DSM-5 (CAPS-5), and the War and Adversity Exposure Checklist (WAEC). All three measures are assessed before the start of the treatment (T0), post-treatment (T1) and at six-month follow-up (T2).

5.10.2. Depression

Depressive symptoms are assessed with the Hopkins Symptom Checklist-25 (HSCL-25) and the HAM-D. Depressive symptoms are assessed before treatment (T0), post-treatment (T1) and at six-month followup (T2).

5.11. Secondary outcomes

Secondary outcomes are also assessed at T0, T1 and T2.

5.11.1. General mental distress

General mental distress is measured using the BSCL, the German version of the Brief Symptom Inventory (BSI; Derogatis, 1993).

5.11.2. Agoraphobia and somatoform complaints

Agoraphobic symptoms and somatoform complaints are assessed with the Questionnaire on Body-Related Anxieties, Cognitions and Avoidance, AKV (Ehlers et al., 2001), a self-report measure, which is a compilation of the Body Sensations Questionnaire (BSQ; Chambless et al., 1984), the Agoraphobic Cognitions Questionnaire (ACQ; Chambless et al., 1984) and the Mobility Inventory (MI; Chambless et al., 1985). Somatoform complaints are physical complaints for which no physical cause has been found that would sufficiently explain the extent of the complaints.

5.11.3. Sleep quality

The PSQI (Buysse et al., 1989) is a self-report measure assessing sleep quality and sleep disturbances over the past month.

5.12. Physical assessments

The physical assessments include a resting ECG, stress ECG, CBC and spiroergometry.

5.13. Additional measures

5.13.1. Socio-demographic information

Participants' age, sex, region of origin, native speech, further languages, medication, family status and duration of living in Germany are assessed once prior to study inclusion.

5.13.2. Comorbidities

The SCID-5-CV (First et al., 2016) is conducted to assess further comorbid psychological disorders in a semi-structured interview at T0.

5.13.3. Motivation in moderate-intensity aerobic exercise training

Participants are interviewed concerning their motivation during MAET at T1. Questions on motivational factors are answered for supervised group training and unsupervised training separately (see supplementary material SM4).

5.14. Measurements

Table 3 gives a comprehensive summary of employed physical and psychological assessments and outcomes. Details can be found in the supplementary material SM1; SM2.

5.15. Data management

5.15.1. Statistical methods

All statistical analyses will be conducted by a member of the research team, who was not involved in the data collection process and the study interventions, using R

Table 3. Assessments' characteristics and schedule.

Assessments and		Schedule of assessment			
measures	Evaluation	T0	T1	T2	Outcome
Sociodemographic details	Self-report	х			Additional
PCL-5	Self-report	Х	Х	Х	2nd
HSCL-25	Self-report	х	Х	Х	2nd
CAPS	Interview	х	Х	Х	1st
WAEC	Interview	х	Х	Х	1st
HAM-D	Interview	х	Х	Х	1st
BSCL	Self-report	х	Х	Х	2nd
AKV	Self-report	х	Х	Х	2nd
PSQI	Self-report	х	Х	Х	2nd
SCID-5-CV	Interview	х			Additional
Medical history	Self-report, Interview	Х			Explorative
CBC		х	Х	Х	Explorative
Spiroergometry		х	Х	Х	Explorative
Submaximal parameters		х	Х	Х	Explorative
Resting ECG		х	Х	Х	Explorative
Stress ECG		х	Х	Х	Explorative
Motivation in MAET	Interview		Х		Explorative

Notes: T0 = Baseline assessment before randomization and treatment; T1 = assessment after treatment completion: T2 = assessment at sixmonth follow-up: PCL-5 = PTSD Checklist for DSM-5: HSCL-25 = Hopkins Symptom Checklist-25; CAPS = Clinician-Administered PTSD Scale; WAEC = War and Adversity Exposure Checklist; HAMD-D = Hamilton Depression Scale; BSCL = Brief Symptom Checklist; AKV = Questionnaire on Body-Related Anxieties, Cognitions and Avoidance (Fragebogen zu körperbezogenen Ängsten, Kognitionen und Vermeidung); PSQI = Pittsburgh Sleep Quality Index; SCID-5-CV = Structured Clinical Interview for DSM-5 Clinician Version; CBC = Complete Blood Count; ECG = Electrocardiogram; MAET = Moderate-intensity Aerobic Exercise Training.

version 4.1.2 (R Core Team, 2021). Alpha level for the main analyses is set to .025 due to multiple primary outcomes. Multiple 2×3 mixed ANOVA's (group: NET+ vs. NET; time: pre vs. post vs. six-month follow-up) will be conducted to examine symptom severity in primary outcomes (PTSD and depression) and secondary outcomes. Contrasts will be conducted to separately examine the group-specific development of symptom severity over time (T0 vs T1; T0 vs T2; T1 vs T2).

5.15.2. Dealing with missing data

The statistical analyses will include the whole sample data of the RCT. Dropping out of trial will not exclude participants from final analyses. In this case the missing data will be imputed using Fully Conditional Specification (FCS; Sterne et al., 2009).

6. Discussion

NET reduces PTSD symptoms in refugees, but many keep PTSD diagnostic status. Further, there is insufficient evidence that NET improves depressive symptoms. Endurance exercise has been shown to improve depressive symptoms and there is some evidence that it may also impact on PTSD symptomatology. Thus, physical exercise as an adjunct to NET seems a promising option to improve both PTSD and depression symptoms. However, up to date, no studies exist investigating the combination of NET and exercise in a

sample of refugees with PTSD and depressive symptoms in a RCT. The present RCT aims to close this gap in research and aims to clarify whether the effectiveness of NET can be enhanced by MAET.

The results of the current RCT will be crucial to improve mental health care for refugees. If NET+ proves to be superior to NET alone, future trials should investigate the combination of other traumafocused therapies with MAET. Importantly, MAET may not only impact on PTSD and depression symptoms, but may also enhance patients' physical health, which has been shown to be poor in refugees.

6.1. Challenges of the trial

First, the recruitment of the sample might prove to be difficult due to the strict psychological and physical exclusion criteria.

Recent studies have highlighted the underrepresentation and neglect of women's participation, especially of traumatized female refugees, in health-promoting exercise programmes and clinical trials (e.g. Pebole et al., 2021). Potential imbalance in gender distribution within a sample of traumatized refugees might be a potential challenge for the current RCT due to several reasons. Exclusion of female participants is justified based on physiological factors, such as a higher probability of experiencing extreme variations in ferritin levels. Additionally, social considerations, such as childcare responsibilities, may hinder female participation. Furthermore, cultural- and trauma-related factors, such as difficulties associated with mixed-gender group training in public settings, further contribute to the exclusion of females from the study. In response, the RCT addresses these issues for example by incorporating trauma-informed considerations in exercise and psychotherapy, such as providing childcare services to promote equal opportunities for participation.

Furthermore, dropout rates might be high. Trauma-focus in psychotherapy is associated with high dropout rates, and in our trial treatment is combined with a very thorough psychological and physiological diagnostic, which may lead to high dropout rates in both groups, which might be even higher in the NET+ group due to the higher rate of weekly appointments.

Gender specific dropout rates due to cultural and trauma-associated barriers for refugee women to participate in public, group-based MAET may require special attention, as they have a significant impact on feasibility. Nonetheless, the implementation of individualized treatment approaches, such as matching gender in MAET, undermines the quality criteria of a RCT. However, considering the importance of evaluating these factors, further research should contemplate to specifically examine the acceptability and feasibility aspects in general.

It is also important to acknowledge that the participants did not have free choice in the type of sport intervention. Allowing free choice of sport could potentially enhance participant engagement, reduce dropout rates, and potentially amplify the intervention's effectiveness. However, offering a wide range of sports activities would compromise the feasibility of conducting a randomized controlled trial (RCT).

Furthermore, language and cultural barriers might affect therapy by interfering with a solid therapeutic alliance. We will work with language and cultural interpreters to minimize this challenge.

6.2. Limitations

The limitations of our trial are those typical for empirical assessment of psychological therapy such that it is impossible to conduct double-blind trials. Participants are randomly assigned to NET⁺ vs. NET group. However, participants in the NET+ group know that they receive a more comprehensive treatment, which might be part of the reason that patients in the NET⁺ group perform systematically better than participants in NET group. Also, a systematic underperformance of participants in the NET⁺ group is conceivable, as the combined treatment requires a higher level of motivation and compliance. However, all outcome measures will be assessed blinded to the intervention group and independent of the leading researchers and therapists.

Finally, we do not examine the mechanisms of action that underlie our hypothesis. It has been posited that the interaction of neurobiological processes and psychological factors achieve the beneficial effect of endurance exercise on psychological symptoms. Anticipating the findings that confirm our hypotheses, future studies should explore the underlying mechanisms of action.

Overall, the present RCT shows high external validity while adhering to scientific standards. The RCT is the first trial assessing whether the efficacy of NET can be augmented by endurance exercise. The results of the current RCT may boost clinical treatment approaches to improve the mental healthcare of traumatized refugees.

6.3. Trial status

The study was pre-registered in DRKS on July 29, 2020 (DRKS ID: DRKS00022145). At the time of submission of this manuscript, the data collection is in progress. The date of inclusion of the first subject was in October 2020. Due to the health policy situation of the global COVID-19 pandemic, the implementation of the trial is delayed. The completion of the data collection was initially scheduled for 2023. Due to the impact of the COVID-19 pandemic, a oneyear delay is expected, moving the prospective completion of data collection to 2024.

6.4. Ethics approval and consent to participate

The Ethics Committee of the Faculty of Empirical Human Sciences and Economics of Saarland University approved the ethics committee application from 13 September 2017 to 10 October 2017 (Ethics committee number: 1713). Respectively, all methods are conducted in accordance with the ethical standards of the Declaration of Helsinki. All participants will have to provide written informed consent before being included in the study (see supplementary material SM3).

Note

1. In this studyprotocol the term 'refugees' is used interchangeably with 'refugees and asylum seekers'. Therefore, the term 'refugees' refers to both individuals who have been granted refugee status and those who are seeking asylum.

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Disclosure statement

No potential conflict of interest was reported by the author(s).

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Authors' contributions

CCL: conceptualization, project administration and implementation, resources, methodology, formal analysis, data curation, writing (original, final draft), visualization. TM: conceptualization, project administration, methodology, resources, supervision, writing (review and editing). JL: resources, writing (review and editing). CGS: conceptualization, resources, methodology. AV: implementation, resources, methodology, writing (review and editing). TMe: implementation, resources, methodology, supervision, writing (review and editing). ME: conceptualization, project administration, methodology, resources, supervision, writing (original draft, review and editing).

Data availability statement

Availability of data is not applicable yet.

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