STUDY PROTOCOL



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Nature videos for PTSD: protocol for a mixed-methods feasibility study

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ABSTRACT

Background: Given the prevalence of post-traumatic stress disorder (PTSD), particularly among military personnel, new treatment approaches are needed. One may be virtual relaxation interventions, especially 360-degree nature videos, since studies have demonstrated their relaxation effects for healthy participants. If these relaxation effects can be reproduced in patients with PTSD, they may offer a viable tool to reduce distress and hyperarousal.

Objective: This research protocol describes a planned study that will examine the relaxation effects of 360-degree nature videos for patients with PTSD. It will also investigate whether these relaxation effects differ depending on the hardware immersion level (head-mounted display [HMD] vs. PC screen) in comparison to a control condition in which patients only listen to natural sounds and do not view a video. Finally, the effect of each intervention's dose duration (five vs. ten minutes) will be explored.

Method: A counterbalanced, randomised, controlled, within-subject experiment will be conducted (sample size N = 36). Only soldiers aged 18 years or older with a primary diagnosis of PTSD will be included. Those with psychosis, substance dependence, a change in psychiatric medication within the last month, suicidal intent, and motion sickness will be excluded. All patients will experience the HMD, PC, and control conditions once for five or ten minutes. Self-reported relaxation measures will be collected before and after, and patients' skin conductance level, heart rate, and heart rate variability will be assessed during each condition. Semi-structured interviews will be conducted to examine the patients' experiences in detail.

Conclusions: This feasibility study will provide initial evidence of whether viewing 360-degree nature videos via HMD or PC screen is relaxing for patients with PTSD and whether the effects are greater compared with the control condition. The study will also validate the dose duration and thereby informing a subsequent confirmatory interventional trial.

Trial registration: DRKS00020277.

Videos de la naturaleza para el TEPT: un protocolo para un estudio de factibilidad de métodos mixtos

Introducción: Dada la prevalencia del trastorno de estrés postraumático (TEPT), particularmente entre militares, se necesitan nuevos enfoques de tratamiento. Uno podría ser intervenciones de relajación virtual, especialmente videos de naturaleza de 360-grados, ya que los estudios han demostrado sus efectos de relajación para participantes sanos. Si estos efectos de relajación pueden reproducirse en pacientes con TEPT, podrían ofrecer una herramienta viable para reducir la angustia y la hiperalerta.

Objetivo: Este protocolo de investigación describe un estudio planificado que examinará los efectos de relajación con videos de naturaleza de 360-grados, para pacientes con TEPT. También investigará de qué manera estos efectos de relajación difieren dependiendo del nivel de inmersión del hardware (pantalla montada en la cabeza [HMD] vs. pantalla de PC) en comparación con una condición de control en la que los pacientes solo escuchan los sonidos de la naturaleza y no ven un video. Finalmente, el efecto de la duración de la dosis de cada intervención (cinco vs diez minutos) será explorados.

Método: Se llevará a cabo un experimento contrabalanceado, aleatorizado, controlado e intrasujeto (tamaño de muestra N = 36). Solo serán incluidos los soldados de 18 años o más con un diagnóstico primario de TEPT. Serán excluidos aquellos con psicosis, dependencia de

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Trastorno de estrés postraumático; potenciación del tratamiento; relajación virtual; inmersión; videos monoscópicos de naturaleza en 360°; pacientes militares

关键词

创伤后应激障碍;治疗增 强;虚拟放松;沉浸感;单视 场 360°自然视频;军人患 者

HIGHLIGHTS

 This randomised controlled feasibility study will examine whether 360degree nature videos are a suitable relaxation intervention for military personnel with posttraumatic stress disorder.

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sustancias, un cambio en la medicación psiquiátrica en el último mes y quienes presenten ideación suicida o cinetosis (mareo de movimiento). Todos los pacientes experimentarán las condiciones de HMD, PC y control una vez durante cinco o diez minutos. Las mediciones de relajación autoreportadas se recopilarán antes y después y el nivel de conductancia de la piel de los pacientes, la frecuencia cardíaca y la variabilidad de la frecuencia cardíaca se evaluarán durante cada condición. Se realizarán entrevistas semiestructuradas para examinar las experiencias de los pacientes en detalle.

Conclusiones: Este estudio de factibilidad proporcionará evidencia inicial de si visualizar videos de naturaleza de 360-grados a través de HMD o la pantalla de la PC es relajante para los pacientes con TEPT, y si los efectos son mayores comparados con la condición de control. El estudio también validará la duración de la dosis y operacionalización de los puntos de termino, informando así un ensayo interventivo confirmatorio posterior.

PTSD的自然视频:一项混合方法可行性研究的方案

背景: 鉴于创伤后应激障碍 (PTSD) 的普遍性,特别是在军事人员中,需要新的治疗方法。 一种方法可能是虚拟放松干预,尤其是 360 度自然视频,因为研究已经证明了它们对健康 参与者的放松效果。如果这些放松效果可以在 PTSD 患者中重现,它们可能会提供一种可 行的工具来减少痛苦和高唤起。

目的: 本研究方案描述了一项计划中的考查 360 度自然视频对 PTSD 患者放松效果的研究。与患者只听自然声音而不看视频的控制条件相比,它还将考查这些放松效果是否因硬件沉浸程度(头戴式显示器 [HMD] 与 PC 屏幕)而有所不同。最后,将探讨每种干预措施的剂量持续时间(五分钟对十分钟)的影响。

方法:将进行一项平衡的随机对照被试间实验(样本量 N=36)。仅纳入18 岁或以上具有 PTSD初步诊断的士兵。排除了患有精神病、物质依赖、最近一个月内更换精神科药物、有 自杀意图和晕动的被试。所有患者将体验一次5 或 10 分钟的 HMD、PC 和控制条件。将在 前后收集对自我报告放松的测量,并在每种情况下评估患者的皮肤电导水平、心率和心率 变异性。将进行半结构化访谈,以详细考查患者的经历。

结论:本可行性研究将提供初步证据,证明通过 HMD 或 PC 屏幕观看 360 度自然视频是否 能让 PTSD 患者放松,以及与对照条件相比效果是否更大。该研究还将验证终点的剂量持 续时间和可操作性,从而为随后的验证性干预试验提供信息。

1. Background

1.1. Introduction and explanation of rationale

Post-traumatic stress disorder (PTSD) is a highly prevalent mental disorder and of particular challenge to military personnel (Doody et al., 2021). Although most soldiers do well after the end of service, the number of military personnel with PTSD is consistently high (Van Gelderen, Nijdam, Haagen, & Vermetten, 2020). Military personnel are also at a higher risk of receiving a PTSD diagnosis than the general population (Doody et al., 2021; Bisson et al., 2020).

Several trauma-focused psychotherapies recommended by international guidelines are currently available for the treatment of PTSD (Jericho, Luo, & Berle, 2021). These include exposure-focused interventions such as prolonged exposure (PE) (Foa, Hembree, Rothbaum, & Rauch, 2019), written exposure therapy (WET) (Sloan & Marx, 2019), and narrative exposure therapy (NET) (Schauer, Neuner, & Elbert, 2005); cognitive-focused interventions, such as cognitive processing therapy (CPT) (Resick, Monson, & Chard, 2017) or trauma-focused cognitive behavioural therapy (TF-CBT) (Cohen, Deblinger, & Mannarino, 2017); and eye movement desensitisation and reprocessing (EMDR) (Shapiro, 2018). Though these approaches have shown to be effective for some populations, clinical and empirical evidence demonstrates that not all patients can adhere to or benefit from

them (Kitchiner, Lewis, Roberts, & Bisson, 2019; Knaust et al., 2020; Lewis, Roberts, Gibson, & Bisson, 2020; Varker et al., 2021). For instance, systematic reviews have reported mean dropout rates of 22-28% for PE, 30-34% for CPT, and 14-18% for EMDR (Lewis et al., 2020; Varker et al., 2021). Further, the average dropout rate across all guideline treatments is significantly higher in military samples than in civilian samples (Varker et al., 2021). Yet there is also no established standard for the definition of dropout. Varker et al. (2021) found that only 7% of the included studies (included studies: k = 85) clearly operationalised the dropout rate. Meta-analytic summaries may have subsumed non-attendance after randomisation and before treatment commencement, dropout without symptom improvement, and early completion with symptom improvement. Thus, the results should be interpreted with caution. More recent randomised control trials (RCT) differentiate between dropout and early completion (Schnurr et al., 2022). For instance, Schnurr et al. (2022) (N =916) examined the effectiveness of PE vs. CPT for treating veterans with PTSD. The authors reported a dropout rate of 55.8% for PE and 46.6% for CPT, as well as an early completion rate of 12.1% for PE and 5.1% for CPT. Systematic reviews also revealed that not all patients experience substantial symptom reduction in terms of remission and response rate (Knaust et al., 2020). However, these results should also be interpreted cautiously, since there is no

generally accepted definition of response and remission rate (Varker et al., 2019).

The reasons for dropout, response, and remission rates are multifactorial. Besides young age (Niles et al., 2018), one explanation might be found in patients' distress that is experienced during trauma exposure, especially during initial sessions (Foa, Zoellner, Feeny, Hembree, & Alvarez-Conrad, 2002) that may continue afterwards (Alpert, Hayes, Barnes, & Sloan, 2020). Another reason may be hyperarousal, which is a key symptom in PTSD: patients who report hyperarousal to be their most bothersome symptom at the baseline measurement experience less reduction in overall distress than other patients (Schell, Marshall, & Jaycox, 2004).

Owing to the dropout, response, and remission rates, interest in additional treatments (Van Gelderen et al., 2020; Williston, Grossman, Mori, & Niles, 2021) and augmentation approaches (Metcalf et al., 2019) have grown. Augmentation approaches aim to enhance the therapy outcomes of recommended for PTSD. first-line treatments Considering exposure-focused recommended treatments, augmentation approaches can be used before (pre) and/or after (post) an exposure session (Metcalf et al., 2019). Pre-exposure augmentations aim to improve the accessibility to trauma-related thoughts and emotions during exposure sessions. According to the emotional processing theory (EPT) (Foa & Kozak, 1986), pre-exposure augmentations should facilitate the ability to activate the pathological fear structure and increase the probability of embedding new and corrective information. Therefore, it is reasonable to assume that pre-exposure augmentations may speed up the with-session habituation process (Foa & Kozak, 1986; Metcalf et al., 2019). Meanwhile, postexposure augmentations, for example, relaxation methods aimed at reducing hyperarousal and/or assisting as a functional coping behaviour to mitigate trauma-related distress, can be expected to help patients engage in first-line treatments (Metcalf et al., 2019). Post-exposure relaxation interventions could also help patients regulate their emotions and shift attention from stressful trauma-related memories or ruminations to something more pleasant and nonarousing. This disconfirming experience might be helpful to modify the trauma-related fear structure. Relaxation interventions can also be used as a preexposure treatment augmentation. Based on the results of Borkovec and Sides (1979), EPT suggests that relaxed patients have an increased voluntary attention capacity (Foa & Kozak, 1986). Accordingly, they might be able to encode trauma-relevant information more fully, which increases the accessibility to the trauma-related memory and thereby the modification probability of the trauma-related fear structure. Despite the increasing interest in augmentation

approaches, the actual therapy-enhancing effect of augmentation approaches has been scarcely examined. Empirical evidence and clear conclusions regarding the efficacy of augmentation approaches for PTSD are lacking (Metcalf et al., 2019).

Previous studies have demonstrated that military populations in general (Rizzo & Koenig, 2017; Wilson, Onorati, Mishkind, Reger, & Gahm, 2008), and military personnel with therapy-resistant PTSD in particular (Bisson et al., 2020; Van Gelderen et al., 2020), are receptive to technological treatment approaches in psychological care. Therefore, it is conceivable that virtual reality (VR) relaxation interventions (Riches, Azevedo, Bird, Pisani, & Valmaggia, 2021), such as an immersive presentation of a natural environment via a head-mounted display (HMD) (Veling, Lestestuiver, Jongma, Hoenders, & van Driel, 2021), could be a useful relaxation method for patients with PTSD.

Well-established relaxation interventions such as breathing exercises, progressive muscle relaxation (PMR), mental imagery, and mindfulness interventions already exist (Metcalf et al., 2019; Williston et al., 2021). However, they demand patients' voluntary attention capacity, concentration, and imagination skills as well as intrinsic motivation to practice these relaxation interventions (Nijland, Veling, Lestestuiver, & van Driel, 2021; Veling et al., 2021). This can be challenging for some patients, especially after resource-taxing trauma exposure sessions (Metcalf et al., 2019). Immersive relaxation interventions might be a viable alternative. They benefit from involuntary attention allocation to relaxing, non-arousing, and mood-enhancing virtual environments, which require far fewer cognitive and emotional resources than traditional relaxation interventions (Nijland et al., 2021; Veling et al., 2021).

The relaxing effect of immersive natural environments has already been demonstrated in healthy participants who were exposed to an acute stressor (Knaust et al., 2021; Mostajeran, Krzikawski, Steinicke, & Kühn, 2021) and in psychiatric samples (Veling et al., 2021). We are unaware of any empirical evidence on the relaxation effects of immersive natural environments for patients with PTSD. It is also unclear which hardware should be used and for how long immersive natural environments should be presented. We propose a mixed-method feasibility study to address these fundamental questions. According to the typology of feasibility studies, this type of investigation is well suited to examine the details of a future intervention study. In contrast, a pilot study 'tries out the operation of all pieces as they will be implemented in the planned RCT' (Tickle-Degnen, 2013, p. 172). Based on the results of the proposed mixed-method feasibility study, future intervention studies can then examine the efficacy of immersive natural environments as well as post-exposure relaxation augmentation.

Next, we provide an overview of immersive natural environments. Based on this overview, we derive the specific aims of our proposed mixed-method feasibility study.

1.2. Immersive virtual nature

Immersion is defined as a technical continuum that comprises the interaction between hardware and software and can be systematically described according to the following criteria: (1) inclusiveness, (2) extensiveness, (3) surrounding, and (4) vividness (Slater & Sanchez-Vives, 2016; Slater & Wilbur, 1997). Inclusiveness describes the degree to which external, real-world stimuli are shut out by technology. Extensiveness is related to the range of sensory modalities that are addressed by the technology. Surrounding is operationalised by the field of view. Finally, other technological features such as the resolution, accuracy, and degree of head and hand tracking (three-degrees-of-freedom tracking, 3DoF; six-degrees-of-freedom, 6DoF) are summarised under the term vividness (Slater & Sanchez-Vives, 2016; Slater & Wilbur, 1997).

The immersion levels of virtual natural environments are determined by hardware and software elements like 360-degree nature videos or a computer-programmed 3D natural environment. The latter comprehensively uses the immersive features of contemporary HMDs to create a stereoscopic full 6DoF interactive virtual natural environment; however, they are relatively high in cost and require expertise to make them deceptively realistic (Knaust et al., 2021; Ritter & Chambers, 2021). In contrast, the immersion levels of monoscopic 360-degree nature videos are limited since they lack stereoscopy, and 6DoF head and hand tracking is reduced to 3DoF; however, they are gaining popularity, likely due to their ease of use, low cost, and photorealistic footage, especially when compared with 3D computer-programmed or stereoscopic 360-degree nature recordings (Knaust et al., 2021; Ritter & Chambers, 2021).

The theoretical foundations for immersive natural environments are grounded in the attention restoration (ART) (Kaplan, 1995) and/or stress reduction theories (SRT) (Ulrich et al., 1991), which were originally conceptualised for real natural environments. According to ART, natural environments that meet four criteria (extent, being away, soft fascination, and compatibility) can encourage involuntary attention capabilities and, thereby, restore voluntary attention capabilities. This redirection of attention can reduce stress and improve mood (Kaplan, 1995). SRT takes an evolutionary perspective, contending that exposure to an unthreatening natural environment rapidly activates psychophysiological responses via parasympathetic activation, reduces stress, and induces positive emotions (Ulrich et al., 1991).

Though some questions regarding the efficacy factors of both theories remain to be addressed, (Corazon, Sidenius, Poulsen, Gramkow, & Stigsdotter, 2019; Ohly et al., 2016) the relaxation and stress-reducing effects of nature on mental and physical well-being are well-established (World Health Organisation, 2016).

A key assumption for virtual natural environments is that if they are presented with immersive technology, they can create a deceptively genuine illusion of a real environment; therefore, comparable relaxation effects are expected. Nevertheless, the results of previous studies are unclear. For example, a recent meta-analysis emphasised that real natural environments are significantly superior to virtual ones in terms of changes in positive affect (Browning et al., 2020), operationalised by the positive and negative affect schedule (PANAS) (Watson, Clark, & Tellegen, 1988). Furthermore, the authors found no significant difference in changes in negative affect. However, the meta-analysis also indicated that the results are yet to be sufficiently confirmed statistically due to the small sample sizes of the included studies. Moreover, the immersion level varied across the studies. If only those studies that used an HMD are considered, the results are less conclusive and often show non-significant differences (Knaust et al., 2021). Another systematic review was also undertaken that only included virtual natural environments presented on immersive hardware (HMD, or Cave Automatic Virtual Environment) (Frost et al., 2022). Both reviews concluded that, based on the predominantly non-significant results, better powered and designed research trials are needed to draw clear conclusions regarding the efficacy of monoscopic 360-degree nature videos compared with real nature experiences (Browning et al., 2020; Frost et al., 2022).

Access to real natural environments is limited, particularly during inpatient care in metropolitan hospitals (Browning et al., 2020; Mostajeran et al., 2021). 360-degree nature videos might overcome this limitation. They offer a wide variety of natural environments that can be used flexibly in terms of time (e.g., during intrusive re-experiencing at night), dose, and patient demand, which seems especially promising for inpatient care. Furthermore, they are considered to be a user-friendly relaxation tool: after an introduction to the technology, patients can use it autonomously (Veling et al., 2021). Furthermore, the low acquisition and production costs offer good cost-effectiveness.

Nevertheless, the immersion level offered by monoscopic 360-degree nature videos is limited (Knaust et al., 2021). Accordingly, it remains unclear whether the relaxation effect is influenced by the hardware's immersion level or is equally achievable with less immersive technology such as PCs or TV screens (Knaust et al., 2021; Yeo et al., 2020). Yeo et al. (2020) examined whether there was a significant difference between a 3D computer-programmed underwater environment presented via 6DoF HMD (3D condition), a monoscopic 360-degree underwater recording presented via 6DoF HMD (360-degree condition), and a normal underwater recording shown on a TV screen (TV condition) in terms of patients' selfreported mood states. The results revealed that positive mood states were significantly higher after the 3D condition than after the 360-degree and TV conditions, although the authors found no significant difference between the 360-degree and TV conditions. Furthermore, the results showed no significant differences between the three conditions in terms of postmeasurement negative mood states and boredom scores. Nonetheless, the outcome measures demonstrated medium to large pre-post effect sizes across all conditions. The authors concluded that all presentation types had a relaxing effect, and the 360-degree condition had only low added value in comparison with the TV condition, and the 3D condition '[appeared] to offer a qualitatively different experience.' (Yeo et al., 2020, p. 11).

It is still not known whether the relaxation effect of monoscopic 360-degree nature videos is generalisable to patients with mental illnesses. Veling et al. (2021) compared the adjunct relaxation effects of monoscopic 360-degree nature videos presented via 3DoF HMD (360-degree condition) with those of audio recordings for mediation and progressive muscle relaxation (control condition) in patients with different mental disorders. Positive and negative affect significantly improved immediately after the interventions, and reported negative affect was significantly more reduced in the 360-degree than in the control condition. Thus, the authors concluded that monoscopic 360-degree nature videos can be used as a treatment augmentation for mental disorders (Veling et al., 2021).

Research is yet to address whether monoscopic 360-degree nature videos presented with more or less immersive hardware lead to different relaxation effects for patients with mental disorders and whether the results are generalisable to patients with PTSD. Besides a single-case report (Jensen, Andersen, Petersen, & Nyboe, 2021), no other empirical studies have examined the relaxation effect of such videos for patients with PTSD.

Finally, it is unclear whether the relaxation effects of virtual natural environments presented with more or less immersive technologies evoke different levels of spatial presence (Mostajeran et al., 2021; Yeo et al., 2020). It is assumed that immersive technology enables the recipient to experience spatial presence (the sense of being there), which is considered to be a key efficiency factor for virtual environments (Hartmann et al., 2016; Wirth et al., 2007). Yeo et al. (2020) found initial evidence that greater improvements in positive mood in the 3D condition might be mediated through higher levels of spatial presence. However, less is known about spatial presence among patients with PTSD (Knaust et al., 2020) and, thus, whether previous findings can be replicated.

1.3. Specific research aims of the current feasibility study

The planned study will investigate the relaxation effects of a monoscopic 360-degree nature video presented on an HMD and PC screen in comparison with a control condition in which patients will be exposed only to nature sounds and see no video at all. Thereby, we will explore the extent to which immersion levels of the hardware are sufficient for 360-degree nature videos to enable beneficial relaxation levels in patients with PTSD.

We will also investigate the optimal dose-duration of 360-degree nature videos for the most beneficial relaxation response. Previous studies have used approximately five minutes to examine the relaxation effect (Knaust et al., 2021; Mostajeran et al., 2021; Yeo et al., 2020), although Veling et al. (2021) used approximately ten minutes. The length will be varied in the proposed study; half the patients will be exposed for five minutes and the other half for ten.

Furthermore, we will examine whether monoscopic 360-degree videos presented with different immersion levels facilitate different levels of spatial presence, which might be associated with different relaxation levels. Although this reasoning has been reported in previous studies (Yeo et al., 2020), it is yet to be empirically confirmed for patients with PTSD.

Finally, we will conduct semi-structured interviews after each condition to qualitatively assess the perceived safety, prospective acceptability and usability, satisfaction, dropout reasons (if applicable; otherwise, we will ask for hypothetical reasons), and side-effects of the interventions, as well as suggest improvements. Following the last condition, we will ask patients which intervention they preferred and why. We will extend the semi-structured interviews to patients who report prior experience with trauma-focused imaginal exposure therapy to ask how they feel about using each intervention after imaginal trauma exposure.

2. Methods

The ethics committee of the local chamber of physicians (PV7270) approved this randomised mixedmethods feasibility study, which was commissioned by the Bundeswehr Medical Service Headquarters (40K2-S-32 2124).

2.1. Design

This feasibility study will feature a monocentric, unblinded, randomised, controlled, within-subject experiment that follows a mixed-method analytic approach, as well as the current CONSORT guidelines for pilot and feasibility research (see Supplementary File 1 for the CONSORT checklist) (Eldridge et al., 2016). Pre-registration can be found at www.drks.de (registration number: 00020277; registration date: June 29, 2020).

2.2. Participants

2.2.1. Sample eligibility

Recruitment will follow a clinical ad-hoc convenience sampling procedure, including only soldiers aged 18 or older with a primary diagnosis of PTSD (according to the ICD-10; F43.1), who will be treated at Bundeswehr Hospital Hamburg. Those with psychosis, substance dependence, a change in psychiatric medication within the last month, suicidal intent, and motion sickness will be excluded. No further inclusion or exclusion criteria will be defined. Eligibility will be assessed through unstructured clinical interviews performed by an experienced psychiatrist or licensed psychotherapist at treatment intake.

2.2.2. Sample size

Viechtbauer et al. (2015) proposed a specific formula for calculating sample sizes in pilot and feasibility studies (Viechtbauer et al., 2015). This method is based on the probability of an 'unforeseen problem' (Viechtbauer et al., 2015, p. 1375) that compromises the quality of a larger, more comprehensive, but also more expensive and timeconsuming, investigation.

The long-term aim is to use the relaxation effect of monoscopic 360-degree nature videos presented via HMDs as a post-exposure treatment augmentation. Therefore, a significant problem in the future RCT would be if patients were unable to engage with the video or drop out prematurely due to simulation sickness, which is a form of motion sickness linked to interaction with a simulated environment or loss-of-control fears induced by the immersiveness of the HMD. Veling et al. (2021) reported that two (4%) patients stopped using the VRelax (monoscopic 360-degree nature videos presented via an HMD) intervention due to nausea and dizziness. Several patients also reported relatively high simulator sickness scores (Veling et al., 2021). Therefore, it can be assumed that a 4% dropout rate during the first exposure to virtual nature experiences might be a conservative occurrence probability estimation. Nevertheless, it is unclear whether this 4% is generalisable to

patients with PTSD or could be higher. There is currently no valid empirical evidence demonstrating the dropout rate for monoscopic 360-degree nature videos presented via HMDs among patients with PTSD. However, several studies have examined the efficiency of virtual reality exposure therapy (VRET) with older HMDs for the treatment of PTSD. Recent reviews (Knaust et al., 2020) and meta-analyses (Eshuis et al., 2020) have reported a dropout range of 0-52%; the pooled average dropout rate is 21.9% (Eshuis et al., 2020), although specific reasons for this rate have not been reported (Eshuis et al., 2020; Knaust et al., 2020). Consequently, it can only be speculated to what extent the dropout rate was caused by the immersiveness of the HMD. In addition, the comparability of the virtual environments (trauma-associated vs. natural environment) is highly limited.

In short, we expect that some patients with PTSD will prematurely remove the HMD and drop out. A valid probability of the *unforeseen problem* cannot be derived from previous studies; however, based on the increased simulator sickness scores found by Veling et al. (2021) and the different samples, we conservatively assume a dropout rate of 8%. Thus, applying a 8% dropout probability combined with a 95% confidence interval, determines a total required sample size of N = 36 (https://www.crutzen.net/n.htm) (Viechtbauer et al., 2015).

2.2.3. Recruitment

Patients will be recruited from the clinical-psychotraumatological routine at Bundeswehr Hospital Hamburg, which offers trauma therapy, diagnostics, assessments, and other psychiatric expertise procedures. Each treatment intake begins with an unstructured clinical interview performed by licensed psychotherapists or psychiatrists in which the patient's therapy procedures are determined. During these interviews, patients will be asked to participate in the proposed study and informed that participation is voluntary and that non-participation will have no negative consequences.

2.3. Measures

2.3.1. Self-rated measures

2.3.1.1 PTSD checklist for DSM-5 (PCL-5). The German version of the PCL-5 will be used to assess patients' PTSD symptoms (items: k = 20). In general, the PCL-5 is well-established; the German version has good psychometric properties and takes approximately 5–10 minutes to complete (Krüger-Gottschalk et al., 2017). It will be administered once during the administration session (see Section 2.4.1).

We will use the PCL-5 to support the diagnosis of PTSD, which will be assessed within several

unstructured clinical interviews performed by experienced licensed psychotherapists or psychiatrists and supervised by the clinical director of the Center for Mental Health of the Bundeswehr Hospital Hamburg. Our aim is not to rigorously track symptom changes, so we chose the PCL-5 over the Clinician-Administered Posttraumatic Stress Disorder Scale (CAPS-5) (Weathers et al., 2018) because it is less time- and resource-intensive. Recent evidence suggests that both measurements are highly concordant, although not identical, in assessing the presence of PTSD symptoms and tracking the symptoms over time (Lee, Weathers, Thompson-Hollands, Sloan, & Marx, 2022).

2.3.1.2. Positive and negative Affect schedule (PANAS). The PANAS is a well-established standardised measure that assesses positive and negative affect (items: k = 20) (Browning et al., 2020; Watson et al., 1988). The psychometric properties of the German version are adequately established (Breyer & Bluemke, 2016). The PANAS will be administered before and after each condition.

2.3.1.3. Relaxation state Questionnaire (RSQ). The RSQ is a short (items: k = 10), self-report measure that assesses short-term relaxation effects (Steghaus & Poth, 2021). Although the psychometric validation results are adequate, they were published in preprint and should be interpreted cautiously. Nevertheless, there is currently no other scale-based relaxation questionnaire available to assess short-term relaxation effects; therefore, we will assess RSQ scores before and after each condition.

2.3.1.4. Visual analogue Scale (VAS). The PANAS and RSQ will be supplemented with VAS items (Boer et al., 2004) to measure the patients' current distress, overall relaxation levels, and situational emotional state. Following Chirico and Gaggioli (2019) we will apply the VAS to eight discrete emotions: anger, awe, amusement, disgust, fear, pride, sadness, and joy. The VAS items will be administered before and after each condition.

2.3.1.5. Spatial presence Experience scale (SPES). The SPES (Hartmann et al., 2016) was deductively-nomologically derived from the two-level model of spatial presence (Wirth et al., 2007). The short version measures spatial presence and has adequate psychometric properties on two dimensions and six associated spatial presence determinants (Hartmann et al., 2016). Each construct will be assessed with four items (total items: k = 32). The SPES will be administered after each condition.

2.3.2. Psychophysiological measures

The NeXus Mark II (Mind Media B. V., The Netherlands) and its Biotrace+ software (v. 20.13) will be used to record patients' skin conductance level (SCL), heart rate (HR), and heart rate variability (HRV). To measure SCL, two Ag/AgCI finger electrodes will be attached to the index and ring fingers of the patient's non-dominant hand, and a blood volume pulse sensor will be attached to the index finger of their dominant hand to record their HR and HRV. Biotrace+ measures the time between heartbeats (inter-beat interval [IBI]) in milliseconds. These raw IBI data will be exported and analyzed using the open-source HRVTool (Vollmer, 2019) software.

SCL predominantly reflects sympathetic activation. It is associated with emotional arousal and will be recorded in microsiemens (µS) (Boucsein, 2012). HR and HRV represent parasympathetic and sympathetic activation and are associated with psychophysiological relaxation responses (Malik et al., 1996). HR will be measured in beats per minute (bpm). According to Malik et al. (1996) the root mean square of successive differences (RMSSD) is a variability measure of HRV that is particularly associated with parasympathetic activity. To complement the SCL, the RMSSD represents the primary outcome variable of the HRV. Other variability measures, such as the average and median RR, standard deviation of the NN interval (SDNN), the percentage of pairs of RR intervals (pNN50), low frequency (LF), and high frequency (HF), will also be calculated and reported.

It is relatively well-established that patients with PTSD compared to healthy controls have a lower HRV resting state, which is associated with higher HR and interpreted as a physiological stress response (Sadeghi, Sasangohar, & McDonald, 2020). Sadeghi et al. (2020) reported that the RMSSD was approximately seven milliseconds lower for patients with PTSD, compared to healthy controls. Similar results were found for HF and SDNN. Coherently, the resting HR was about five bpm higher in patients with PTSD than in healthy individuals (Sadeghi et al., 2020).

A pilot study found preliminary evidence that respiratory sinus arrhythmia (RSA) biofeedback training compared to PMR increases HRV (operationalised by SDNN) in patients with PTSD (Zucker, Samuelson, Muench, Greenberg, & Gevirtz, 2009). The authors conducted two physiological assessment sessions (pre to post) to evaluate the impact of RSA and PMR on HRV. However, they did not report physiological data while the patients practiced RSA or PMR (Zucker et al., 2009). Another pilot study found preliminary evidence for an adjunctive therapy-enhancing effect of RSA biofeedback compared to TAU (Tan, Dao, Farmer, Sutherland, & Gevirtz, 2011). The results of both pilot studies must be interpreted cautiously due to their small sample sizes.

2.3.3. Qualitative interviews

Following Dicicco-Bloom and Crabtree (2006), we will conduct semi-structured interviews after each condition using predetermined questions aligned with the study's aims (see Supplementary File 2).

2.4. Procedure

The study will be comprised of three conditions (PC, HMD, and nature sounds only), which the patients will complete in a randomised order on three separate dates. A third party, who is not involved in the study's enrolment or implementation, will generate the randomisation sequence by following a block randomisation procedure with randomly varying block sizes. Time (five vs. ten minutes) will be the block factor. The block randomisation will be valid for all conditions. If patients are randomised to the five-minute category, they will be exposed to each condition (HMD, PC, control) for five minutes. Enrolment will be performed by psychiatrists or licensed psychologists who are not involved in the sequence randomisation process or implementation. Finally, the experimenter, who is not involved in the generation of the randomisation sequence or the enrolment, will implement the interventions.

In total, the procedure will include four sessions (administration and HMD, PC, and control conditions). Sessions will be arranged individually with at least one day in between. The exact date of the sessions will be recorded to assess a potential confounding time effect. Each session is described in detail below (for a schematic overview, see Figures 1–3).

2.4.1. Session 1: Administration

If patients declare interest in participating, an administration appointment will be arranged during which they will receive standardised instructions and be informed about the research and procedures. The participant information and an informed consent form will be distributed. The patients will have sufficient time to read all documents and ask questions if necessary. If they agree to participate, they will be required to sign the informed consent form. Thereafter, they will create a pseudonymization code (according to the guidelines of the German Psychological Society) under which all research data will be stored. Then, they will complete a socio-demographic questionnaire, which also explores clinical aspects (e.g., previous psychological treatment experience, pharmacological treatment, type of trauma, comorbidities, and initial diagnosis of PTSD), their experiwith HMDs, the PCL-5. ence and The administration session will end with making arrangements for an appointment for the first condition.

2.4.2. Session 2: HMD, PC, or natural sounds only (depending on randomisation)

The treatment program at the Bundeswehr Hospital Hamburg is multi-modally conceptualised. Patients can choose to participate in group training such as social skills or problem-solving skills, or they can use occupational and physical therapy. Furthermore, patients will discuss different themes with their licensed psychotherapists or psychiatrists (e.g. trauma-focused vs. non-trauma-focused content). This type of treatment heterogeneity is institutionally rooted. Correspondingly, patients will receive a brief inventory at the beginning of sessions two through four to assess if inpatient services were received and, if so, what kinds of services were provided. Since we cannot rule out this type of heterogeneity, we will be collecting data on these potentially confounding effects for exploratory analyses among subsamples of participants with different therapeutic modality combinations. Thereafter, patients will complete the self-reported pre-measures (PANAS, RSQ, and VAS). They will then be connected to the NeXus Mark II and a three-minute connection check will be conducted, followed by a five-minute baseline. Patients will be instructed to sit quietly with their eyes open and to place their hands on the chair's arms or their thighs. After finding the most comfortable position, they will be further instructed to reduce their arm and hand movements as much as possible to avoid motion artifacts. Thereafter, they will either view the monoscopic 360-degree nature video via HMD while listening to nature sounds, see the 360-degree nature video via PC screen while listening to nature sounds, or listen only to nature sounds without any video for five or ten minutes (depending on randomisation). The HMD will then be removed, or the PC screen will be switched off, and/or the headphones will be removed (again, depending on randomisation), and the post-intervention phase will be measured. The instructions for the post-intervention will be the same as for the baseline. After the post-intervention phase, the psychophysiological recordings will end, and the post-measurements (PANAS, RSQ, VAS, and MEC-SPES) will be collected. The first semi-structured interview will be conducted, and an appointment for the third session will be made.

2.4.3. Session 3: HMD, PC, or natural sounds only (depending on randomisation)

The Session 3 procedure will be identical to that of Session 2 except for the intervention. For example, if patients watch the monoscopic 360-degree video via HMD in Session 1, they will experience the PC or control condition in this session.

2.4.4. Session 4: HMD, PC, or natural sounds only (depending on randomisation)

The Session 4 procedure will be identical to that of Session 3 except for two changes. The patients will

experience the remaining intervention and will be asked during the qualitative interview to compare the three conditions and describe which intervention they preferred and why.

2.5. Technological equipment

The HMD will be operationalised with an HTC Vive, which will be connected to a computer. We will use a normal PC screen (EV2750), which will be connected to the same computer. In addition, on-ear headphones (JBL JR300) will be connected to either the PC screen or the HMD, depending on the randomisation, to ensure that the sound quality and auditory substitution are the same for each condition.

Following Knaust et al. (2021) we will show a monoscopic 360-degree beach video (link: https:// www.sphaeresvr.com/experience/vr-nature/dreambeach-mallorca). In the PC condition, patients can change their viewing angle at the beginning with the computer mouse. Interactions with the mouse during the video will be disabled to prevent artifacts. In the HMD condition, the viewing angle can be changed with head movements throughout the video.

2.6. Analysis

The CONSORT guidelines for feasibility and pilot studies do not recommend formal hypothesis testing because such studies are usually under-powered to achieve this (Eldridge et al., 2016). Therefore, the feasibility data will be analyzed descriptively (means, medians, standard deviations, and IQR; Cohen's d, following Morris, 2008) with IBM SPSS Version 28 (SPSS Inc. Chicago, USA). Outliers will be detected with boxplots. All analyses will be performed with and without outliers; both sets of results will be reported.

2.6.1. Self-reported measures

Regarding the PANAS, RSQ, and VAS, we will calculate pre-post effect sizes (Cohen's d) for each condition. To compare the three conditions, we will calculate pre-post mean differences and use them to calculate between-condition effect sizes (Cohen's d). Furthermore, we will calculate between-condition Cohen's d for spatial presence and construct a correlation matrix with all self-reported and psychophysiological measures using the rmcorr package in R (Bakdash & Marusich, 2017).

2.6.2. Psychophysiological data

It is expected that the HMD condition will lead to stronger psychophysiological relaxation responses than the PC and control conditions. This reasoning is rooted in the assumption that virtual nature presented with more immersive technology will create a more genuine simulation of reality than less immersive technologies. In line with the ART (Kaplan, 1995) and/or SRT (Ulrich et al., 1991), this difference will lead to stronger relaxation responses in the HMD condition.

Anderson et al. (2017) showed that healthy participants who were experimentally stressed and watched a monoscopic 360-degree nature video in a HMD experienced lower states of physiological arousal than before the stressor took place. Based on the higher resting states of physiological arousal among patients with PTSD (Sadeghi et al., 2020), one could speculate that exposure to virtual natural environments could also produce psychophysiological recordings that are lower than at baseline. However, since there is little empirical evidence on whether and to what extent monoscopic 360-degree nature videos in HMDs or on PC screens lead to a psychophysiological relaxation response among patients with PTSD, we can only speculate whether such a response occurs and/or what the dose-response curve looks like.

Therefore, we will descriptively explore psychophysiological responses to monoscopic 360-degree nature videos among patients with PTSD. The raw 32 SPS SCL data will be averaged to one data point per second. Thereafter, intervals that do not directly belong to the intervention, for example, the patient putting on the HMD, will be deleted. Subsequently, we calculated 30-second intervals by averaging the 30 data points to one. The raw IBI data will be exported to the HRVTool (Vollmer, 2019), which will be used to pre-process the HR and HRV data. Thereafter, the same 30-second intervals will be calculated. The pre-processed SCL, HR, and HRV raw data sets will be z-standardised to minimise inter-individual differences. Finally, we will perform descriptive analyses. The results will be reported and visualised with line graphs for both the z-transformed and untransformed pre-processed raw data sets.

2.6.3. Analysis of the semi-structured interviews

The transcription and subsequent categorisation of the audio-recorded semi-structured interviews will be performed with MAXQDA (Kuckartz & Rädiker, 2019).

2.6.3.1. *Transcription.* We will use transcription software (https://otter.ai) to generate the first draft of the audio-recorded interviews. The first drafts will be corrected after listening to the recordings. The transcription will follow a semantic-content systematization that does not transcribe, for example, word breaks or dialectal expressions, thus ensuring that the focus is on the reported content (Dresing & Pehl, 2017). The specific transcription rules that will be followed are presented in Kuckartz and Rädiker (2019, p. 42). We will transcribe the audio-recorded data as soon as

Begin	General assessment	Closing		
Patient information, data policy, informed consent, creation of patient code	SES (age, gender, education, rank) + clinical factors (first time PTSD was diagnosed, duration of the disturbance, type of trauma, comorbidities, pharmacological treatment, experience with psychotherapeutically treatment + duration, experience with in-sensu trauma exposure) + experience with HMDs + PCL-5	Patients' questions, if required + appointment for session 2		
Approx. 15 Min	Approx. 30 Min	Approx. 5 Min		

Figure 1. Session 1 – Administration.

Begin	Pre	SCL, HR and HRV recordings				Post	Interview	Closing
Patient code, Questionnaire about received inpatient services	PANAS, RSQ, VAS	Connection with the NeXus Mark II and connection check	Baseline (sit quietly with their eyes open)	Intervention: HMD, PC, control (nature sounds only) (depending on randomization)	Post- treatment (sit quietly with their eyes open)	PANAS, RSQ, VAS, MEC-SPES	Semi-structured interview (see Supplementary 1)	Patients' questions if required + appointment for next session
Approx. 5 Min	Approx. 10 Min	Approx. 3 Min	5 Min	5 vs. 10 Min (depending on randomization	5 Min	Approx. 20 Min	Approx. 20 Min	Approx. 10 Min

Figure 2. Session 2 & 3 – Monoscopic 360-degree nature video via HMD, PC or control condition with nature sounds only (the patients will receive each intervention once. The order of intervention as well as the duration will be randomised).

Begin	Pre	SCL, HR and HRV recordings				SCL, HR and HRV recordings Post	Post	Interview	Closing
Patient code, Questionnaire about received inpatient services	PANAS, RSQ, VAS	Connection with the NeXus Mark II and connection check	Baseline (sit quietly with their eyes open)	Intervention: HMD, PC, control (nature sounds only) (depending on randomization)	Post- treatment (sit quietly with their eyes open)	PANAS, RSQ, VAS, MEC-SPES	Semi-structured interview (see Supplementary 1)	Patients' questions if required + debriefing	
Approx. 5 Min	Approx. 10 Min	Approx. 3 Min	5 Min	5 vs. 10 Min (depending on randomization	5 Min	Approx. 20 Min	Approx. 40 Min	Approx. 10 Min	

Figure 3. Session 4 – Monoscopic 360-degree nature video via HMD, PC or control condition with nature sounds only (the patients will receive each intervention once. The order of intervention as well as the duration will be randomised).

possible and delete the recordings immediately after transcription.

2.6.3.2. Coding frame. The qualitative data analysis will be subjected to a content-structured procedure. The transcribed data will be solely examined to answer the research questions, and a deductive-inductive category formation will be applied (Kuckartz & Rädiker, 2019). Accordingly, some top- and sub-level categories will be derived deductively from specific theories (e.g. attention restoration theory, Kaplan (1995) two-level-model of spatial presence Wirth et al. (2007)), while others will be driven inductively from the transcribed data.

The first step for the creation of the inductive/datadriven categories will be paraphrasing the content-relevant statements. These paraphrases will then be further generalised and, if necessary, merged with other paraphrases until the intended abstraction level is achieved. Thereafter, the generalised paraphrases will be assigned to deductive categories. If these paraphrases cannot be assigned to an existing category, new top- or sub-level categories will be created with them. Some deductive categories may be discarded if they cannot be supported by the paraphrases extracted from the transcribed material.

Thus, after an intensive review of the transcribed material, a preliminary coding system will be created, which will be iteratively revised and supplemented with descriptions and anchor examples of the top- and sub-level categories until the saturation of codes is reached and the final coding frame is constructed. This process will be performed by two independent coders and visualised with creative coding software.

2.6.3.3. Segmentation of the Transcribed material. Formal segmentation will be applied: patients' answers will be analyzed separately according to the interview questions (Schreier, 2012).

3. Outlook

Previous studies have demonstrated that monoscopic 360-degree nature videos have a relaxation effect on healthy participants (Browning et al., 2020; Knaust et al., 2021) and individuals with mental disorders (Veling et al., 2021). Nonetheless, it remains unclear whether this relaxation effect can be generalised to patients with PTSD and, if so, which presentation method leads to greater relaxation, how long the virtual nature exposure should be, and which presentation type and dose duration patients prefer. Before a future RCT examines the efficacy of monoscopic 360-degree nature videos for post-exposure relaxation augmentation, we consider a feasibility study (Tickle-Degnen, 2013) to be the most appropriate first step to close these research gaps.

If the results demonstrate which presentation type has the greatest relaxation effect and which hardware and dose duration patients prefer, we will conduct a pilot RCT. This pilot RCT will examine whether the relaxation effect of a monoscopic 360-degree nature video is, in principle, a suitable post-exposure treatment augmentation. We also examine whether imaginal trauma will exposure therapy combined with monoscopic 360degree videos can lead to greater symptom reduction compared with imaginal trauma exposure therapy and treatment as usual, or imaginal trauma exposure therapy combined with an active control condition. Further, we will investigate whether a future large-scale RCT is realisable.

Typically for feasibility studies, the internal and external validity will be limited. However, based on this feasibility study, it can be empirically decided whether monoscopic 360-degree nature videos should be further pursued as a post-exposure treatment augmentation.

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TK designed the study in cooperation with all authors of this protocol. TK, AF, OK, MR, MB, HH, and HS drafted the manuscript of the study protocol. All authors revised sections of the manuscript and approved the final version.

Disclosure statement

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

Data availability statement

The data that support the study's findings, as well as its material, will be openly available in the Open Science Framework (https://osf.io/f4zkp/), after data collection is completed.

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