

Through nightmare eyes: Nightmare disorder and Eye Movement Desensitization and Reprocessing (EMDR) therapy in Portuguese adults

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Registration date 09/08/2024	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 09/08/2024	Condition category Nervous System Diseases	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

This study investigates the effectiveness of an adapted eye movement desensitization and reprocessing (EMDR) therapy protocol for treating nightmare disorder. Frequent nightmares can significantly impact an individual's quality of life and mental well-being. However, there's a lack of understanding among healthcare professionals regarding the severity of this issue and the appropriate treatment approaches. By evaluating the efficacy of EMDR therapy, this study seeks to address these gaps in knowledge and provide evidence-based interventions for individuals suffering from nightmare disorder. EMDR therapy was developed by Francine Shapiro, an American psychologist, in 1987. It is a psychological treatment aimed at disturbing memories /experiences and uses eye movements similar to those that happen naturally in a phase of sleep called REM or rapid eye movement. During therapy, the therapist asks the person to focus on a particular experience/memory, while promoting the movement of the person's eyes from side to side, through visual, auditory, or tactile methods. EMDR therapy aims to modify the way these experiences/memories are stored in the brain, reducing symptoms and/or altering the emotions, sensations and thoughts associated with them. This intervention program is based on the standard EMDR therapy protocol and a specific EMDR protocol for traumatic nightmares. This research project consists of three substudies, which aim to adapt and translate nightmare assessment questionnaires into Portuguese (Study I); investigate whether there are chronic nightmares and nightmare disorder in Portuguese adults (Study II); and, test whether EMDR therapy could be a treatment for nightmare disorder (Study III).

Who can participate?

Adults aged 18 to 64 years old diagnosed with nightmare disorder, preferably with chronic nightmares, irrespective of the presence or absence of nocturnal awakenings

What does the study involve?

Participation in Study III is voluntary and open to Portuguese adults experiencing distressing nightmares that cause them suffering and/or impair their daily functioning. Study III entails

conducting EMDR therapy sessions to treat nightmares. The intervention consists of up to 8 sessions of individual therapy, lasting between 30 to 120 minutes each. The therapy sessions will be tailored to the participant's needs and conducted by a qualified therapist under supervision. In the first phase, a clinical evaluation will be carried out to define the topics to be worked on in the sessions and ensure that this study is suitable. In the second phase, the therapist and participant will discuss various aspects related to nightmares and EMDR therapy. Finally, in the third phase and until the end of the intervention, the EMDR therapy protocol under study is applied.

What are the possible benefits and risks of participating?

Potential benefits:

It is intended that this research will contribute to the advancement of scientific knowledge in this area and to raise awareness among the population and health professionals of situations in which nightmares can be a mental health problem. Participating in the study and having access to therapy is free and at no direct cost to participants. However, participating may incur indirect costs, such as travel, for which there is no compensation.

In several studies, the treatment of nightmares has shown improvements in sleep quality, less sleep during the day and greater ease in falling asleep. This specific intervention is hypothesized to reduce the occurrence of nightmares and the suffering associated with them.

Potential drawbacks, risks or side effects:

As it is an experimental treatment, there are no known disadvantages, risks or side effects. Associated with EMDR therapy, side effects (withdrawals) may occur, such as intense agitation or dissociation (i.e. feeling disconnected from oneself). If participants experience any kind of emotional or psychological reaction as a result of the intervention, they should contact the research team or, in case of emergency/psychological crisis (e.g. thoughts of suicide), the European emergency number (112), the SNS 24 line (808 24 24 24) or one of the following psychological crisis helplines*:

Where is the study run from?

The host institutions of the project are the Faculty of Psychology and Educational Sciences of the University of Coimbra (FPCEUC) and the Centre for Research in Neuropsychology and Cognitive-Behavioural Intervention (CINEICC).

When is the study starting and how long is it expected to run for?

November 2022 to November 2026

Who is funding the study?

The project "Nightmares in Portuguese adults and EMDR therapy" is funded by a PhD scholarship from the Foundation for Science and Technology (FCT) (reference: 2022. 13382.BD), a government entity that evaluates and funds scientific research activities.

Who is the main contact?

The research team is made up of two members of these institutions:

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Study website

<https://pesadelos-e-terapia-emdr.my.canva.site>

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Additional identifiers

EudraCT/CTIS number

Nil Known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title

Nightmare disorder in the Portuguese adult population: Frequency and feasibility study of Eye Movement Desensitization and Reprocessing (EMDR) therapy

Acronym

EMDR and Nightmare disorder

Study objectives

Nightmares can be defined as dysphoric and intense dreams, which typically occur during REM sleep and are vividly recalled. Nightmare disorder (ND) is a parasomnia characterized by the persistent occurrence of extremely dysphoric nightmares, associated with significant distress and/or impairment in functioning.

There is a significant underreporting, underdiagnosis, and undertreatment of nightmares as an independent clinical problem, despite their significant impact on sleep and everyday functioning. Adequate and specific therapeutic responses to nightmares have been proven to reduce nightmares and improve sleep quality, daytime sleepiness, and insomnia symptoms. Research conducted recently, however, has called into question the effectiveness of current treatment approaches. While some empirical evidence supports eye movement and desensitization therapy (EMDR) as a treatment for nightmares and ND, the evidence is insufficient, especially when compared to imagery rehearsal therapy (IRT), which has received the most empirical support.

As nightmares and nightmare disorder can negatively impact mental and physical health, and new and promising interventions (such as EMDR) need to be empirically evaluated, this study intends to examine the feasibility of EMDR as a treatment for nightmare disorder and chronic nightmares in a sample of Portuguese adults.

Three studies are proposed to address this issue. In Study I, three nightmare assessment instruments (i.e., Disturbing Dream and Nightmare Severity Index (DDNSI), Nightmare Effect Survey (NES), and Nightmare Disorder Index (NDI)) will be adapted. Study II will use quota sampling via social media and mailing lists to estimate the prevalence of nightmare disorder and chronic nightmare symptoms among Portuguese adults. Study III will examine whether the EMDR standard protocol and the Luber protocol for trauma nightmares can be adapted for treating chronic idiopathic nightmares and nightmare disorder.

This research project will explore EMDR as an intervention for ND, particularly in adults experiencing chronic idiopathic nightmares since most studies on EMDR have focused on traumatic nightmares and children.

To sum up, this research is primarily focused on:

1. Adapting nightmare assessment instruments for Portuguese adults (Study I) - specifically:
 - 1.1. Disturbing Dream and Nightmare Severity Index (DDNSI), to assess nightmare frequency, severity, and intensity;
 - 1.2. Nightmare Effect Survey (NES), to assess functional impairment;
 - 1.3. Nightmare Disorder Index (NDI), for ND screening (ongoing).

2. Determining the presence of clinically significant symptoms of ND and chronic nightmares (i.e., 1 time per week, for at least 6 months) * in a sample of Portuguese adults obtained through quota sampling (Study II);

3. Analyzing the feasibility of a standardized protocol of Eye Movement Desensitization and Reprocessing (EMDR) therapy for intervention in clinical symptoms of PP and in the experience of chronic nightmares in adults (Study III).

In Study I, the adapted instruments are expected to exhibit good psychometric properties, such as internal consistency, discriminant, and convergent validity.

In study II, the aim is to better understand the presence of chronic nightmares and ND among Portuguese adults, since research that addresses adults who frequently experience nightmares may result in better risk assessment and intervention. Similar frequency rates are expected compared to other studies.

In Study III, the results will contribute to the existing but very scarce literature that supports EMDR as a potentially useful intervention to treat chronic nightmares and ND. It is important to mention that for this study the primary outcome is nightmare distress, as measured by the Nightmare Distress Questionnaire (NDQ). Secondary outcomes include the frequency, severity and intensity of nightmares, the degree of impairment in functioning, sleep quality and symptoms of insomnia, also measured through self-response questionnaires. Thus, specifically, reductions in nightmare distress, nightmare frequency, intensity, degree of impairment, insomnia symptoms and sleep quality improvement are expected. Nonetheless, this is a preliminary quasi-experimental study with no control group, so no cause-effect relationships can be established between treatment and these positive outcomes. However, given the lack of research on the topic, the results could stimulate future research about EMDR as a treatment for nightmares and serve as a starting point for more highly controlled studies (i.e., randomized clinical trials (RCT)) that compare EMDR against the gold standard (i.e., IRT) to be developed in the future.

*Note: Although the DSM-V-TR and the ICSD-3 do not define a minimum frequency for the diagnosis of ND, there is consensus in the literature that a frequency of at least 1 nightmare per week is indicative of clinically significant psychopathology and that a minimum frequency of 1 nightmare per month is relevant for confirming the diagnosis. In addition, chronic/persistent nightmares (characterized by a duration of at least 6 months and a minimum frequency of 1 nightmare per week) have been the focus of most clinical studies in this field.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 21/06/2023, Research Ethics and Deontology Committee of the Faculty of Psychology and Educational Sciences of the University of Coimbra (FPCEUC) (Rua do Colégio Novo, Coimbra, 3000-115, Portugal; +351 239 851 450; dir@fpce.uc.pt), ref: CEDI/FPCEUC:77/7

Study design

Single-center interventional feasibility study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

University/medical school/dental school

Study type(s)

Screening, Treatment, Efficacy

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Treatment of nightmare disorder

Interventions

Study I: Cross-cultural adaptation of psychometric instruments

Study II: Descriptive epidemiological study using quota sampling

Study III: Single-center interventional feasibility study (i.e., two groups (potentially four): nightmare disorder with or without comorbid disorders VS online or in-person intervention, no control group; several measures before, during and after treatment)

Nightmares are typically assessed in terms of their frequency, intensity, and distress. There are few validated instruments available in Portuguese, so the research began by adapting psychological instruments that would allow for a complete assessment of the experience of nightmares (Study I).

The first instrument being adapted and validated is the DDNSI/NES. This instrument measures nightmare frequency, severity, and functional impairment. As part of Study I, the NDI is also being adapted as it provides a DSM-5-compliant screening of nightmare disorder (ND) symptoms. The authors' permission was obtained to adapt these instruments (cf. Ethical Issues). The adaptation process comprises six distinct phases: translation, synthesis, expert review, cognitive interviewing, backward translation, and proofreading/finalization.

The final versions of these instruments will be used in Study II, which aims to assess the frequency of chronic nightmares and ND in a sample of Portuguese adults. A research protocol that includes the validated instruments (i.e., DDNSI/NES and NDI) and self-report measures of sleep quality, anxiety, depression, and post-traumatic stress symptoms will be developed for this study. These variables are relevant to clinically describe the sample's nightmare experience.

The samples of Studies I and II will be recruited online (e.g., social networks, and mailing lists). Using the data from the Portuguese census of 2021, the sampling process will consider four variables: sex, area of residence (i.e., 7 NUTS 2 geographic regions), age, [age groups (18-34, 35-54, and 55-64 years)] and level of education (i.e., basic, secondary, and higher education). Participants who cannot understand the Portuguese language (orally or in writing) and those aged < 18 and >64 are excluded from Studies I and II.

Those with ND symptoms (i.e., score over 10 on the DDNSI/NES and probable diagnosis of ND on the NDI), preferably with chronic/persistent nightmares, and who express their interest will be invited to participate in Study III. As mentioned, this study aims to evaluate the feasibility of an EMDR clinical protocol for treating chronic nightmares and ND.

The intervention protocol will be adapted from the standard EMDR therapy protocol and the Luber protocol for traumatic nightmares. The sessions (maximum=8) will take place weekly, last between 30 and 120 minutes and be administered by Dr. Almeida under supervision.

Study III will be conducted online and in person. In an individual clarification session, those interested in participating will be told about the study's purpose, ethics, how the sessions function, and how data will be processed. An informed consent form will be provided to those still interested.

The EMDR-based intervention will be preceded by a structured clinical interview, adapted from the Portuguese version of the Structured Clinical Interview for Disorders of the DSM-V (SCID-5-CV). This clinical interview ensures compliance with the inclusion/exclusion criteria of Study III and allows the characterization of the participants' data in four groups (i.e., individuals with ND with or without comorbid psychological disorder(s)-except for those included in the exclusion criteria, who will receive the intervention either online or in person).

Prior clinical interviews ensure compliance with Study III's inclusion/exclusion criteria and allow us to categorize the participants into four groups (i.e., individuals with ND with or without comorbid psychological disorder(s), who will receive the intervention online or in person).

Following a repeated measures design (i.e., interrupted time series), part of the research protocol used in Studies I and II will be completed again at the beginning of the first intervention session (pre-test-T2), in the middle of the intervention (during-T3), in the last intervention session (post-test-T4), and four weeks afterwards (Follow-up-T5), to obtain five repeated measurements.

The completion of these instruments at these different moments (T2-T5) is intended to evaluate the potential influence of the intervention on nightmare symptomatology. Additionally, a daily checklist of nightmare frequency and intensity, along with a sleep diary, will be given to participants as homework in the first and last weeks of the intervention, since "prospective daily records are considered measure of reference of nightmare frequency.

The intervention can be concluded before the eighth session if the following conditions are met:

1. Presence of 0 subjective units of distress (USD) in relation to the nightmare(s) processed and a score of 7 for the validity of positive cognition (VOC) and/or
2. Absence of clinically significant symptoms of ND (i.e., considering clinical evaluation and NDI score).

In terms of statistical analyses, in Study I, a confirmatory factor analysis will be performed to analyze the factor structure of the validated instruments. An analysis of internal consistency will be conducted using McDonald's omega. To assess the convergent and discriminant validity of nightmare scales, the matrix of correlations between different scales' scores will be used.

In Study II, the frequency of individuals with chronic nightmares or ND, globally and by sex, age, area of residence, and educational level, will be estimated and the confidence intervals associated with these values will be determined.

It is estimated that Study III will have 50 participants (based on other intervention studies on nightmares). Hierarchical linear models will be utilized to analyze the differences in frequency, distress and impairment related to nightmares between and within groups, at each of the five assessment points (T1, T2, T3, T4, T5).

The methodological procedures to be adopted in this investigation were based on previous studies on the subject and the CONSORT guidelines (2010) for each type of study, when applicable.

Intervention Type

Behavioural

Primary outcome measure

Study III: Nightmare distress measured using the Nightmare Distress Questionnaire (NDQ) at baseline (T1) and the beginning of the first intervention session (pre-test-T2), in the middle of the intervention (during-T3), in the last intervention session (post-test-T4), and four weeks afterwards (Follow-up-T5)

Secondary outcome measures

Study III: Frequency, severity and intensity of nightmares, the degree of impairment in functioning, sleep quality and symptoms of insomnia measured through self-response questionnaires at baseline (T1) and the beginning of the first intervention session (pre-test-T2), in the middle of the intervention (during-T3), in the last intervention session (post-test-T4), and four weeks afterwards (Follow-up-T5)

Overall study start date

01/11/2022

Completion date

01/11/2026

Eligibility

Key inclusion criteria

Inclusion criteria for Study III will be as follows:

1. A diagnosis of ND based on the DSM-V-TR and ICSD-3, preferably with chronic nightmares, irrespective of the presence or absence of nocturnal awakenings
2. Minimum frequency: 1 nightmare/month.

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

64 Years

Sex

Both

Target number of participants

50

Key exclusion criteria

1. Exposure to significant and/or traumatic life events (e.g., pregnancy, death) in the last 6 months
2. Clinically significant symptoms of comorbid disorders incompatible with the implementation of the intervention program and/or study objectives (i.e., PTSD, Substance-related disorders, Psychotic Spectrum Disorders, Night Terrors, Sleepwalking, Narcolepsy, dissociation symptoms, severe depressive symptomatology and/or suicidal ideation), assessed by clinical interview and questionnaires)
3. Consumption/abstinence of medication/substances, which influence sleep architecture (e.g., alcohol) and/or the occurrence of nightmares
4. Psychological and/or psychiatric treatment in the last 6 months, particularly if directed to nightmares

Date of first enrolment

20/04/2024

Date of final enrolment

20/04/2025

Locations**Countries of recruitment**

Portugal

Study participating centre

Center for Research in Neuropsychology and Cognitive Behavioral Intervention (CINEICC)

Aculdade de Psicologia e de Ciências da Educação da Universidade de Coimbra, Rua do Colégio

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Sponsor information**Organisation**

Fundação para a Ciência e Tecnologia

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Sponsor type

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Funder(s)

Funder type

Government

Funder Name

Fundação para a Ciência e a Tecnologia

Alternative Name(s)

Foundation for Science and Technology, Portuguese Science and Technology Foundation,
Fundacao para a Ciencia e a Tecnologia, FCT

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Portugal

Funder Name

International Association for the Study of Dreams

Alternative Name(s)

IASD

Funding Body Type

Private sector organisation

Funding Body Subtype

Associations and societies (private and public)

Location

United States of America

Funder Name

DreamScience Foundation

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal

Intention to publish date

01/11/2027

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to the sensitive nature of the data collected (i.e., data regarding mental health)

IPD sharing plan summary

Not expected to be made available