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Efficacy of an internet-based guided trauma-focused intervention in reducing ICD-11 posttraumatic stress disorder symptoms: study protocol of a randomized controlled trial

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Abstract

Background Posttraumatic stress disorder (PTSD) is a common mental disorder. However, many cases of PTSD remain untreated because of limited healthcare resources and other treatment-seeking barriers. Effective internet-based interventions could help to improve access to PTSD treatments. Therefore, the main objective of the planned randomized controlled trial is to evaluate the efficacy of the Lithuanian version of the guided internet-based self-help programme (Spring) in reducing ICD-11 PTSD symptoms.

Methods The planned sample size is 50 participants exposed to different traumatic experiences. Participants eligible for the study will be randomized into two study groups: the immediate treatment group and the delayed treatment control group. Both groups will receive guided trauma-focused ICBT intervention, but the delayed treatment group will receive access to the programme five months after randomization. The International Trauma Interview (ITI) will be used for the assessment of ICD-11 PTSD symptoms at pre-treatment, post-treatment, and at a 3-month follow-up. Changes in disturbances in self-organization, depression and anxiety levels, as well as posttraumatic cognitions and trauma-related shame, will also be evaluated. In addition, associations between changes in symptoms of PTSD and readiness for treatment, treatment expectations and working alliance will be explored. Changes in treatment outcomes will be evaluated using multiple Latent Change Models.

Discussion This study is expected to contribute to valuable knowledge on the efficacy of internet-based interventions for posttraumatic stress disorder.

Trial registration ClinicalTrials.gov NCT06475716. Registered on 25 June 2024.

Keywords Posttraumatic stress disorder, PTSD, Internet-based intervention, Treatment, Guided self-help, Trauma-focused CBT, ICBT

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Background

Research shows that most people experience potentially traumatic events during their lifetime. In a study of general population surveys from 24 countries, exposure to at least one traumatic event was reported by 70% of participants. In some countries, the prevalence of lifetime trauma exposure reached 85% [1]. Although for many people, the clinical consequences of trauma are absent or mild, for some, they lead to the development of post-traumatic stress disorder (PTSD). Research shows that around 18% of people exposed to traumatic events have PTSD symptoms at 3 months post-trauma. This PTSD prevalence rate remains relatively stable, measured two years after trauma, demonstrating the potential chronic course of PTSD that is not likely to diminish without clinical intervention [2]. Untreated PTSD can have serious long-term consequences not only for the individual but also at social and economic levels [3, 4].

There is considerable evidence for effective face-to-face PTSD therapies recommended in various treatment guidelines across the world [5]. Unfortunately, many PTSD cases remain untreated because of limited healthcare resources and other barriers, such as logistics, distance or stigma [3]. Internet-based interventions could help to reduce these barriers and improve access to PTSD treatments. Such interventions are mainly delivered via the Internet, with specific therapeutic tasks delegated to an app or website [6], so therapist time is reduced compared to face-to-face therapy. They can also be more accessible and convenient to users [7].

Various Internet-Based Cognitive Behavioral Therapy (ICBT) programmes have demonstrated significant improvement in symptoms of mental health problems, such as anxiety and depression [8]. In a meta-analysis Hedman-Lagerlöf et al. [9] found that therapist-supported ICBT for psychiatric and somatic disorders yielded similar effects as face-to-face CBT. Although the majority of trials have focused on depression and anxiety disorders, an increasing number of studies have also been examining the outcomes of such programmes developed for the treatment of PTSD.

Despite the increased interest in ICBT for PTSD, a recent Cochrane review concluded that the current evidence was limited due to a scarcity of trials that could be included in the review [10]. However, recent results from several large-scale RCTs on ICBT for PTSD published since the Cochrane review provide additional support for the efficacy of such treatments. A guided internet-based trauma-focused CBT (CBT-TF) intervention 'Spring' for mild to moderate PTSD was developed by researchers at Cardiff University in the UK. The Spring programme includes more therapeutic guidance than previous ICBT programmes, strict adherence to the CBT principles, and more interaction with the patient than earlier ICBT programmes for PTSD. A recent RCT study demonstrated the efficacy of the programme in the treatment of PTSD, indicating that Spring was non-inferior to individual face-to-face CBT-TF [11]. It was also found to be acceptable, and treatment satisfaction of programme users was high [12]. In another RCT study, the importance of exposure to trauma as a treatment component was demonstrated in the internet-based cognitive therapy for PTSD which was superior to an internet-delivered non-trauma-focused stress management therapy for PTSD [13].

It is important to note that the aforementioned studies were carried out by the researcher groups who developed the interventions, which may introduce bias. Both recent large-scale RCTs were conducted in the UK, and it is premature to assume the same effects would be found in other countries. It is important to evaluate ICBT programmes in different study sites, countries, and cultures. Also, previous studies have concentrated on the DSM (The Diagnostic and Statistical Manual of Mental Disorders) conceptualization of PTSD. The latest versions of the DSM-5 and the 11th International Classification of Diseases (ICD-11) show a discordance in their conceptualization of PTSD [14]. Research demonstrated that more PTSD cases are recognized in the same samples if DSM-5 criteria are used [14, 15]. Also, a new distinct diagnosis of complex posttraumatic stress disorder (CPTSD) has been introduced in the ICD-11 [16]. For complex PTSD, in addition to all PTSD symptoms, a person should also experience clinical levels of disturbance in self-organization (emotion dysregulation, negative beliefs about oneself and disturbed relationships) [16]. Therefore, a study with assessments based on ICD-11 diagnostic criteria for PTSD and complex PTSD would help determine treatment efficacy in the context of this classification system specifically.

In the current study, we also plan to evaluate changes in trauma-related shame after the treatment. Post-traumatic shame can contribute to the maintenance of PTSD symptoms and reduce the effects of treatment [17, 18]. Little research exists on whether and how trauma-focused therapies reduce shame [19]. It has been argued that trauma-related shame should be an important specific clinical target [20]. However, in their systematic review, Serfioti et al. [19] concluded that cognitive-based treatments were effective in reducing trauma-related guilt and anger, while exposure-based treatments were effective for post-trauma guilt, shame and anger. So, it is unclear whether specific treatment components targeting shame are needed to reduce trauma-related shame. Digital delivery of therapy adds further confusion as users usually have little or no contact with a therapist whose nonjudgemental stance can be seen as an important component in reducing shame [21]. The Spring programme

has not been developed to target shame specifically, so the results on its effect on trauma-related shame scores may contribute to the knowledge about whether trauma-focused ICBT for PTSD can contribute to a reduction in post-trauma shame levels.

In addition to disorder-specific treatment components, it is crucial to explore common factors that may contribute to the effectiveness of therapies. There is evidence that readiness for treatment, treatment expectations and working alliance are associated with the outcomes in face-to-face therapies [22, 23]. However, there is a lack of knowledge on how the importance of these aspects manifests in internet-based interventions. Matthews et al. [24] found that clients' higher treatment expectations were associated with greater reductions in PTSD symptoms after trauma-focused CBT. Nonetheless, it is also noted that people see therapist-guided internet interventions as not as equally helpful as face-to-face therapies [25]. So, it is unclear whether expectations in internet-based therapies are related to outcomes in the same way as in face-to-face treatments. Pontén et al. [26] found that treatment expectations predicted clinical outcomes at the end of psychological interventions, with higher expectations associated with more significant symptom reduction, and no moderating effect was found on whether the treatment was delivered face-to-face or online. However, no PTSD treatment studies have been included in this analysis.

Research also suggests that it is possible to establish a therapeutic alliance in technology-based interventions [27]. It was found that alliance and outcome were significantly correlated in internet-based therapy [28]. In their meta-analysis, Howard et al. [29] concluded that the strength of the alliance in PTSD therapies was not different for face-to-face versus remote therapies. The association between alliance and outcome was also similar. However, Norwood et al. [30] found that working alliance in videoconferencing psychotherapy was inferior to face-to-face delivery. It has been noted that the components of the therapeutic alliance in digital interventions may differ from those in face-to-face treatments. For example, Jasper et al. [31] discovered that more time was needed to build a strong alliance in ICBT for tinnitus compared to the face-to-face intervention. These questions are difficult to untangle, as online interventions vary considerably in how they present their content, the dose or form of therapists' guidance and other aspects [7], all of which can influence the therapeutic alliance and how it interacts with prior readiness for treatment and expectations. Dropout rates from therapies with a trauma focus are high [32], so it is essential to analyze the correlates of positive outcomes and withdrawal from treatments.

Therefore, ***the primary objective*** of the current study is to conduct an RCT to evaluate the efficacy of the Lithuanian version of the guided internet-based trauma-focused CBT programme Spring in reducing ICD-11 PTSD symptoms post-treatment.

The key secondary objectives are

1) To evaluate the outcomes of the Spring programme in changes of ICD-11 PTSD symptoms at 22 weeks post-randomization and DSO (disturbance in self-organization) symptoms at 10 and 22 weeks post-randomization;
2) To measure the efficacy of the Spring programme in reducing depression and anxiety symptoms, as well as improving general well-being as measured at 10 and 22 weeks post-randomization;
3) To measure whether the Spring programme can be efficacious in reducing the severity of posttraumatic cognitions and trauma-related shame evaluated at 10 and 22 weeks post-randomization.

Other secondary objectives are

1) To evaluate how the change in the ICD-11 PTSD symptoms after using the Spring programme is associated with readiness for treatment, treatment expectations and working alliance.

We hypothesize that the programme will significantly reduce ICD-11 PTSD symptoms, as well as ICD-11 DSO symptoms, posttraumatic cognitions, trauma-related shame, depression and anxiety levels at post-treatment, with the effects remaining significant at a follow-up. We also hypothesize that the change in PTSD symptoms after using the programme will be associated with higher readiness for treatment, more positive treatment expectations, and greater working alliance.

Methods

Study setting

The RCT will be conducted remotely and participants from all regions of Lithuania, both rural and urban, will be invited to take part. The intervention will be delivered online via the Spring web app, and guidance sessions with psychologists will be held online.

Eligibility criteria

A three-step screening procedure will evaluate eligibility. Inclusion and exclusion criteria will initially be assessed through self-report measures. Subsequently, telephone interviews will be conducted to ensure a more thorough eligibility check. Finally, the ICD-11 International Trauma Interview (ITI) will be administered to evaluate symptoms of PTSD.

Inclusion criteria

Individuals eligible for the trial must comply with all the following at randomization:

1) aged 18 or over;
2) ability to read and write fluently in Lithuanian;
3) have regular access to a device with an internet connection to use the programme;
4) provide informed consent for participation;
5) experience PTSD symptoms (including full diagnostic and subthreshold levels) following a non-prolonged and non-repetitive traumatic experience as measured by the ITI.

Exclusion criteria

A person is not eligible to enter the trial if any of the following apply:

1) regularly seeing a therapist or counsellor for mental health issues;
2) change in psychotropic medication in the last month;
3) meeting full criteria for ICD-11 complex PTSD diagnosis;
4) psychosis;
5) severe suicide risk;
6) substance dependence;
7) experiencing ongoing threat.

Intervention

Intervention

Spring is an internet-based guided programme for PTSD developed by Cardiff University research team in the UK [11]. It was developed based on trauma-focused cognitive behavioral therapy (CBT-TF) principles and seeks to reduce the time spent with a therapist by making certain therapy content and activities available online in a self-help format [33]. Spring is an 8-week online programme comprising 8 steps: (1) psychoeducation, (2) grounding, (3) management of anxiety, (4) behavioral activation, (5) imaginal exposure, (6) cognitive restructuring, (7) in vivo exposure, and (8) relapse prevention. The usual sequence involves completing all eight online steps, where certain later steps depend on mastering techniques taught in earlier ones. Every Spring step includes psychoeducation presented in the form of text and audio narrative aimed at explaining the reasoning behind specific treatment components. The programme also includes video excerpts where five characters present their traumatic experiences, PTSD symptoms and ways of using the techniques presented in the programme. Users can access the programme via computers or smart devices with an internet connection.

The participants use the programme in their own time, but therapists guide them through the process. Before using the programme, there is a one-hour online meeting with the therapist to develop a rapport, learn about the participant's trauma, present the programme, and further use of it. Later, 4 online meetings with the therapist lasting no longer than 30 min and 4 short contacts by phone or email between sessions are held in order to follow the progress, support the participant and recognize any emerging issues.

The Spring programme was systematically developed following Medical Research Council (MRC) guidance, incorporating systematic reviews of the existing evidence and qualitative work by experts with lived and professional experience. The original version of Spring has been tested in a feasibility randomized controlled trial [34] and in a large scale randomized controlled non-inferiority trial conducted by Cardiff University [11]. Afterwards, the programme design and some technical solutions have been updated, as well as an additional character with traumatic experiences related to the COVID-19 pandemic has been added. In the current study, this second version of the Spring programme, translated and fully adapted to the Lithuanian population, will be used. All the programme material was translated into Lithuanian by a team of three researchers who have experience in clinical practice with trauma clients. The Lithuanian version of the programme was tested and reviewed by 10 clinical psychologists during the Spring training process. The acceptability of the Lithuanian version of the programme will also be pilot-tested in a study including at least 10 clients with PTSD symptoms.

Programme therapists

The Spring programme will be delivered by practising clinical psychologists who do not have prior training in CBT or trauma-focused CBT. However, therapists will undergo four hours of online training delivered by one of the originators of Spring. Additionally, the programme therapists will receive continuous group supervision of cases being treated until they are regarded as qualified to deliver the intervention. While working with clients, therapists will follow the Spring Therapist manual. Therapists will also be required to report regularly to the researchers on the progress of their work with clients. This will ensure that the intervention is delivered according to the protocol.

Recruitment

The invitation to participate in the study will be disseminated via media (press releases), social media (e.g., Facebook adverts), and various organizations or professionals who encounter traumatized clients in their everyday practice (e.g., Crisis Intervention Centre, Mental

Health Centers). Information about Spring and participation in the RCT will be provided on a study specific website. Anyone interested in participating in the study will be able to register and fill out screening measures on the secure data collection platform. Informed consent will be obtained before filling out the screening measures. Participants will also be asked to provide their contact information. The responses of each registered participant to the survey questionnaires will be checked by the research team for compliance with the eligibility criteria. Those not meeting the inclusion criteria will be referred to other mental health services by sending out an e-mail with a list of contacts of relevant institutions and professionals. People meeting the inclusion criteria after the initial screening will be contacted by phone for an interview to check their compliance with the eligibility criteria further, to provide information about the study and the intervention, and to answer any questions that potential participants may have. Participants who meet the eligibility criteria in online screening and interview by phone, as well as demonstrate interest in participation in the randomized controlled trial, will be referred to a clinical assessment of ICD-11 PTSD and complex PTSD symptoms by a trained interviewer. Participants who meet all inclusion criteria and do not meet any exclusion criteria will be randomized to one of the study arms.

After randomization, participants assigned to the immediate treatment group will start using the intervention. Participants in the delayed treatment control group will receive the intervention 22 weeks after randomization. The control group will be able to access social support in the community but will be informed that if they enter trauma-focused psychotherapy or counselling, they will be excluded from participation in the trial. Participants randomized to the immediate treatment group who have not started using the programme won't be asked to take post-treatment assessments. Based on the reports from previous studies [11], it is planned that around one hundred participants will have to be evaluated for PTSD symptoms with the International Trauma Interview (ITI) in order to have the planned target sample size.

Recruitment is planned to start in September 2024, and enrolment is planned for 12 months, or until the target sample size is reached. The final decision to terminate the trial will be taken by the principal investigator of the study. Participants will not receive financial remuneration for their participation in the study. However, a lottery will be held to encourage participants to participate in the follow-up assessments so that some participants who completed the evaluations can receive low-value Vilnius University souvenirs (e.g. cups, bags, t-shirts).

Participants will have the option to withdraw from the study at any time, for reasons either specified or unspecified. In addition, the therapists and researchers have the authority to discontinue the treatment of any participant in case of adverse events, such as acute suicide risk, that may hinder treatment or jeopardize the participant's health. In such cases, participants will be referred to relevant mental health services depending on their mental health condition. All Spring therapists will be familiarized with the crisis management plan on how they should deal with such situations. Therapists will have to inform the research team of such situations immediately. Information about withdrawn participants and reasons for discontinuing the intervention and participation in the study (if available) will be recorded and reported with the study outcomes.

Allocation and blinding

After the baseline assessment, a participant who is eligible for the study will be randomly assigned to either immediate treatment or delayed treatment control group. A computer program will be used to generate randomization codes with a 1:1 allocation ratio with a blocked randomization option. All details of randomization scheme cannot be fully disclosed in this paper in order not to undermine randomization process, but it will be documented in a separate document with restricted access and disclosed with the results of the study. An investigator not involved in the enrolment process will seal the generated codes in numbered envelopes. A researcher involved in enrolment will open the envelopes consecutively and inform the participant of the study arm to which they have been allocated.

Blinding of the outcome assessors will be implemented. Interviewers administering the ITI interviews will not be informed which study group the interviewee belongs to. Self-report data will be collected via a secure online platform, so it will help avoid ascertainment bias in the measurement of outcomes.

Trial participants and therapists cannot be fully blinded because the delayed treatment group will start the treatment 22 weeks after randomization.

Outcomes

Primary outcome measure

PTSD The primary outcome will be the severity of PTSD symptoms as measured with the International Trauma Interview (ITI) [35] at baseline and 10 weeks after randomization (post-treatment). The ITI is a semi-structured clinical interview that includes the description of the primary traumatic event followed by two sections for evaluating symptoms related to ICD-11 PTSD and DSO symptoms [35]. The first part is for evaluating PTSD symptoms (re-experiencing, avoidance and sense of current threat) and in the second part, three clusters of DSO symptoms are assessed (affective dysregulation, negative self-concept and disturbances in relationships). The Lithuanian

version of the ITI has been tested in the previous study, showing that it is a valid and reliable tool for assessing ICD-11 PTSD and complex PTSD [36].

Secondary outcome measures

PTSD and complex PTSD The secondary outcome will be the severity of PTSD symptoms as measured with the ITI at 22 weeks post-randomization (three-month follow-up). The disturbance in self-organization (DSO) symptoms measured by the ITI at post-treatment and at a three-month follow-up will be considered a secondary outcome.

The International Trauma Questionnaire (ITQ) will also be used to measure self-reported symptoms of PTSD and DSO at baseline, 10 weeks, 22 weeks and 32 weeks (only for the control group) after randomization. The ITQ is a 12-item measure of ICD-11 PTSD and complex PTSD and accordingly consists of two sections for PTSD and DSO symptoms [37]. Each item is measured using 5-point Likert scale ranging from 0 (=not at all) to 4 (=extremely). The overall ITQ score ranges from 0 to 24, higher score suggesting more severe symptoms of PTSD and DSO. The ITQ demonstrated sufficient factorial validity and good psychometric characteristics in a previous study with Lithuanian sample [38].

Depression and anxiety

The International Depression Questionnaire (IDQ) will be used to assess depression symptoms. The IDQ aligns with the ICD-11 description of depressive episode [39]. It consists of 9 items referring to an individual's feelings, thoughts, and behaviors over the last 2 weeks. Each item is assessed on a 5-point Likert scale ranging from 0 (=never) to 4 (=every day). The total IDQ scores range from 0 to 36, a higher score indicates more severe depression symptoms.

The International Anxiety Questionnaire (IAQ) will be used to measure anxiety symptoms. The IAQ corresponds to the ICD-11 description of Generalized Anxiety Disorder [39]. The IAQ is an 8-item questionnaire for measuring anxiety symptoms over the last several months. Every item is evaluated on a 5-point Likert scale ranging from 0 (=never) to 4 (=every day). The overall IAQ score ranges from 0 to 32 with a higher score indicating more severe anxiety symptoms.

The IDQ and the IAQ will be measured at baseline, 10 weeks, 22 weeks and 32 weeks (only for the control group) after randomization.

Psychological well-being

The World Health Organization Well-Being Index (WHO-5) will be used to assess psychological well-being [40]. The WHO-5 is a self-report scale comprising of 5 items, regarding well-being during the last 2 weeks. The WHO-5 items are assessed on a 6-point Likert scale ranging from 0 (indicating "at no time") to 5 (indicating "all the time"). The final percentage score (ranging from 0 to 100) is calculated by multiplying the raw sum score by 4. A higher WHO-5 score signifies higher psychological well-being. The WHO-5 has been widely used in research [40]. The scale will be used at baseline, 10 weeks, 22 weeks and 32 weeks (only for the control group) after randomization.

Trauma-related cognitions and shame

The Posttraumatic Cognitions Inventory – 9 (PTCI-9) will be used to measure trauma-related cognitions. The PTCI-9 is a brief version of the PTCI [41] and consists of 9 of the original PTCI items, which are rated on a 7-point Likert scale ranging from 1 (=totally disagree) to 7 (=totally agree) [42]. The PTCI-9 includes 3 subscales: negative beliefs about the self, negative beliefs about the world, and self-blame. The scores for each subscale and the total score are calculated as the mean. The overall PTCI-9 score ranges from 1 to 7. Research demonstrated that the brief version of PTCI is a reliable and valid measure of posttraumatic cognitions [42].

The Trauma-Related Shame Inventory – Short Form (TRSI-SF) will be used to assess trauma-related shame. The TRSI-SF is a short version of the TRSI [17] and is scored on a 4-point Likert scale ranging from 0 (=not true of me) to 3 (=completely true of me), with higher scores reflecting increased levels of trauma-related shame [43]. It includes 2 subscales: internal and external shame. Research demonstrated that the short form of TRSI can serve as a valid measurement of shame associated with trauma [43].

Trauma-related cognitions and shame will be assessed at baseline, 10 weeks, 22 weeks and 32 weeks (only for the control group) after randomization.

User satisfaction

The Patient satisfaction questionnaire (ZUF-8) [44] will be used to assess participants' satisfaction with treatment. It is an 8-item self-report measure, with each item rated on a 4-point Likert scale ranging from 1 to 4. The ZUF-8 will be used after 9 weeks since the start of the programme.

Further secondary outcome measures

Working alliance The Working Alliance Inventory for Guided Internet Interventions (WAI-I) [45] will be used to assess working alliance. It has been specifically adapted to assess the working alliance in the context of guided Internet interventions. This 12-item self-report measure consists of two subscales: "bond", which refers

to the therapist, and "goals and tasks", which refers to the programme. Each WAI-I subscale comprises four items, assessed with a 5-point Likert scale ranging from 1 (=rarely) to 5 (=always). The overall WAI-I score ranges from 12 to 60. The assessment will take place after using the intervention programme for 1 month (mid-treatment) and after 9 weeks since the start of the programme.

Treatment expectations and readiness for treatment The Treatment Expectation Questionnaire (TEX-Q) [22] will be used to measure the expectations for the treatment. The TEX-Q consists of 6 subscales: treatment benefit, positive impact, adverse events, negative impact, process, behavior control. Each item of the TEX-Q subscales is measured on an 11-point Likert scale from 0 to 10. The overall score of TEX-Q is determined by calculating the mean with a reversal of the harm expectation subscales; higher values indicate more positive treatment expectations.

The Readiness for Therapy Questionnaire (RTQ) [46] will be used to assess readiness to change. It consists of 6 items evaluated on 5-point Likert scale, ranging from 0 (=strongly disagree) to 4 (=strongly agree). The total RTQ score is the overall sum of the items, with Q2, Q3 and Q6 reversed. It varies from 0 to 24, with a higher RTQ score indicating greater readiness for therapy.

Both the TEX-Q and the RTQ will be administrated before the participant starts using the programme.

Sample size

A statistical power analysis was carried out in order to estimate the necessary sample size for the planned study. It is assumed that PTSD treatment response could be measured on a clinician- or self-report scale as a reduction in the symptomatology of ≥30–50% [47]. The sample size of 40 was found to be sufficient to detect significant differences between RCT groups (significance level 0.05, power 80%). The comparable trial to this study by Bisson et al. [11] showed that 10% of the participants dropped out of the internet-based CBT-TF. As this drop-out rate is rather low compared to other studies, we chose a more conservative number of 80% retention rates. Therefore, the sample size adjusted to the dropout rate of 20% is 50 [48]. Considering the experience of Bisson et al. [11], it is expected that around 50% of those who expressed an interest in taking part in the intervention after the clinician-administered interview may not meet the eligibility criteria (e.g., symptoms will be under-represented). Hence, a sample size of around 100 individuals assessed with the ITI at baseline is planned as the optimal minimum sample size, given the complexity of the planned trial procedures and design. The CONSORT flow chart for the planned trial is presented in Fig. 1.

Data collection methods and data management

Self-report data will be collected using a secure online survey and questionnaire software. All personal data collected will be managed in compliance with the Vilnius University guidelines and the laws of the Republic of Lithuania. Participants will be briefed on the data protection policy upon registration and will be asked to provide contact information, including name, email address, and telephone number. These details will solely serve study-related communication and will be accessible only to the main research team members and study administrators. To maintain anonymity, participants will be assigned identification codes during the assessment and participation in the intervention and data analysis, with only the main research team having access to the complete dataset. Therapists will get access to the contact information of the assigned participant, such as an email and phone number. Usage data of the programme, such as the number of programme steps completed, will also be collected and accessible solely to the main research team and the programme users' therapist. Upon study completion, participant contact details will be stored for 5 years and removed after the expiration of this term, and the remaining data will be securely stored in the University's storage facilities. Anonymized data may be released upon request in accordance with the open-access research data policy.

Statistical methods

To assess the efficacy of the programme (primary and secondary key objectives), changes in primary (PTSD) and secondary outcome measures (PTSD, DSO, depression, anxiety, psychological well-being, trauma-related cognitions, and shame) will be analyzed by comparing changes in the immediate intervention group with the delayed treatment control group. Changes in outcomes will be evaluated using multiple Latent Change Models (LCM) [49], regressing the RCT group (0=delayed treatment control group, 1=immediate treatment group) on the change in outcome from baseline to 10 weeks after randomization and from baseline to 22 weeks after randomization. Analyses will be carried out with Mplus 8.8 [50], and the Full Information Maximum Likelihood (FIML) algorithm will be used to process missing data. Effect sizes, both within and between groups, will be calculated in accordance with the guidelines for calculating effect sizes in growth models [51] and interpreted following Cohen's [52] recommendations.

Additionally, to evaluate the association between changes in outcomes and readiness for treatment, treatment expectations, and working alliance (other secondary objectives), regression analyses within a series of Latent Change Models will be conducted. This involves

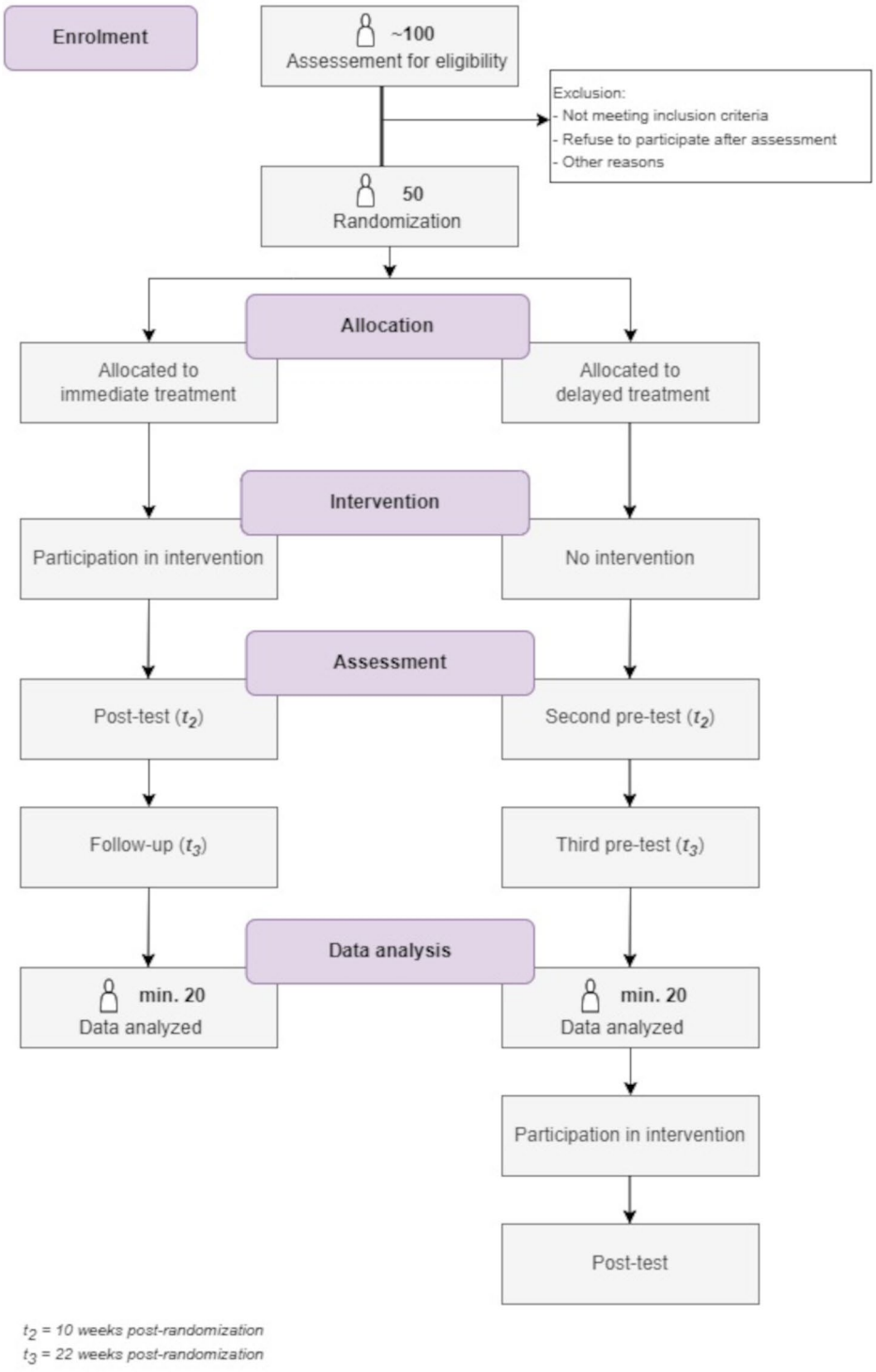

Fig. 1 Flow chart for the planned trial

regressing secondary measures onto the change in outcome as measured before and after using the programme.

Dissemination

The results of the trial will be published in peer-reviewed journals. It will also be presented at the national and international scientific conferences. Furthermore, information about the results will be made available to the broader public by press releases and public events. In case of any important protocol modifications, they will be disclosed and justified with reported study outcomes.

Discussion

The aim of the current study is to contribute to research-based evidence on the efficacy of the guided trauma-focused ICBT programme Spring for the reduction of posttraumatic stress disorder symptoms. Although the efficacy of the original Spring programme in English has already been tested in a large scale RCT study in the UK [11], outcomes of the Spring in other countries have not yet been investigated. Therefore, we are aiming to evaluate the efficacy of the Spring in reducing ICD-11 PTSD symptoms in Lithuania, adding relevant knowledge on the outcomes of the intervention in the RCT trial. A clinician-administered interview, ITI, based on the ICD-11 criteria for PTSD, will be used to assess traumatic symptoms. To our knowledge, there are no published RCT studies that would use a reference standard – clinical diagnostic interview [53] – for the assessment of ICD-11 PTSD symptoms as an outcome measure in treatment studies. Contrary to Bisson et al. [11] study, Spring therapists in our RCT won't have a previous training background in CBT or CBT-TF. The demonstration that Spring users can be guided effectively by therapists without a specific background in formal CBT training would allow easier and less expensive programme implementation into practice [54]. We also aim to explore if the change in symptoms of PTSD after using the programme will be associated with common therapeutic factors such as higher readiness for treatment, more positive treatment expectations and greater working alliance.

Posttraumatic stress disorder is a common mental disorder [55], so it is important to improve access to effective treatments. Effective guided self-help interventions can become an important part of stepped care – an approach aiming at increasing the accessibility of treatment [56]. Here, users can be matched to an intervention level that best suits their needs, which could be an economically and resource-efficient option. The level of development in psycho-trauma care varies in different countries [57]. Research shows that in Lithuania, PTSD recognition is poor, and the trauma care system is underdeveloped [58] with low access to specialized PTSD treatments. In such countries where effective face-to-face treatment options are very limited, internet-based interventions could ensure faster development and access to the care system for people who are suffering from the consequences of traumatic experiences. We expect this study to contribute to valuable knowledge on the efficacy of internet-based PTSD interventions.

Abbreviations

PTSD	Posttraumatic Stress Disorder
DSO	Symptoms of Disturbance in Self–Organization
ICBT	Internet–Based Cognitive Behavioral Therapy
CBT-	TFTrauma–Focused Cognitive Behavioral Therapy
DSM	The Diagnostic and Statistical Manual of Mental Disorders
ICD	International Classification of Diseases

Acknowledgements

Not applicable.

Author contributions

OG is the principal investigator of the study. OG, GG and AN are the main researchers in the trial. JB has been involved in training and supervising Spring therapists. JB and CL have been consulting the research team about the aspects associated with the adaptation and delivery of the Spring intervention in Lithuania. EK has been consulting the research team on the RCT methodology. OG, GG and AN wrote the first draft of the paper. All authors reviewed the first draft and contributed to the final manuscript.

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Data availability

No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate

The study was approved by the Vilnius University Committee for Ethics in Psychology Research (16 / (1.13 E) 250000-KT-33). All study participants will be informed in detail about the trial and will have to give their informed consent before participation.

Consent for publication

Not applicable.

Competing interests

JB and CL are co-authors of the intervention programme that will be investigated. The other authors declare that they have no competing interests.

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