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Effectiveness of Internet-based self-help intervenions on PTSD: a systematic review and meta-analysis of randomized controlled trials

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ADMINISTRATIVE INFORMATION

Support - None.

Review Stage at time of this submission - Preliminary searches.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202420099

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 23 February 2024 and was last updated on 23 February 2024.

INTRODUCTION

Review question / Objective This study aimed to evaluate the effectiveness of Internet-based self-help interventions for post-traumatic stress disorder (PTSD).
Population: Subjects are screened by relevant scales (e.g., PCL, IES-R, CAPS-5, etc.) or diagnosed by a clinician using specific instruments, such as the Diagnostic and Statistical Manual of Mental Disorders, Fourth (DSM-IV) or Fifth (DSM-V) editions, or the International Classification of Diseases, Tenth Edition (ICD-10)Intervention.
Intervention: Internet-based self-help interventions (interventions that use multimedia content on the Internet to carry out activities such as reading written materials, listening to audio materials, watching videos, completing games, etc., to help with issues related to personal development or treatment).
Comparison: Treated as usual, waiting list group (negative control), placebo group (negative control).
Outcome: Changes in PTSD symptoms measured by validated scales (pre-intervention, post-intervention, follow-up).
Study design: Randomized controlled trials (RCT).

Rationale The use of the Internet as a medium for delivering psychological interventions may help to overcome these barriers compared to traditional face-to-face interventions, and Internet- and mobile-based interventions have now been found to be effective for psychiatric disorders in general, in addition to the fact that the interventions provided by these technologies may be readily available, less costly, and provide patients with the opportunity to flexibly integrate psychological treatments into their daily lives.

Condition being studied Post-traumatic stress disorder (PTSD) is a delayed onset and long-term persistence of mental disorders in individuals caused by abnormally threatening or catastrophic psychological trauma. Previous studies have estimated that 60% of men and 50% of women

have experienced at least one traumatic event in their lifetime, and that the prevalence of PTSD in the general population has a demographic range of 6.4-6.8%. The lifetime prevalence in the general population is 7.8%-9.8% . It is estimated that approximately 25%-30% of the population develops symptoms of PTSD after experiencing a traumatic event, and there is a significant correlation between PTSD symptoms and the patient's post-traumatic growth, quality of life, psychological state (anxiety, depression, distress), and cancer-caused fatigue.

METHODS

Search strategy (1) English databases: PubMed, Embase, Cochrane Review, Scopus, PsycoINFO.
(2) Chinese databases: China Knowledge Network Institution (CNKI), Wanfang Database, Weipu Database, China Biomedical Literature Database (CBM).
(3) Gray literature sources: International Clinical Trials Registry Platform (ICTRP), Clinical Trials.gov, PsycEXTRA, PQDT Dissertation Library.
In addition to this, after the articles were screened, the reference list of each included article was tracked to identify other articles related to the topic of this study. The timeframe for the search was from the creation of each database to 2nd February 2024.
For the search strategy, PubMed was presented as an example:
#1:"Computer Communication Networks [MeSH]" OR "Internet-based intervention[MeSH]" OR "Internet[MeSH]" OR “cell phone[MeSH]” OR “Telemedicine[MeSH]” OR “electronic mail[MeSH]" OR “Mobile applications” [MeSH] OR "digital health"[MeSH]
#2:"Internet*" OR "web" OR "webs" OR "website*" OR "online*" OR "app" OR "apps" OR "mobile*" OR "smartphone*" OR "computer*" OR "tele*" OR "Portable Electronic Application" OR "remote" OR "social media" OR "email*" OR "e-mail*" OR "electronic mail*" OR "digital*" OR "e-mental*" OR "e-psycho*" OR "mhealth" OR "eHealth" OR "m-health" OR "e-Health"(note: all terms in [title/abstract])
#3:#1 OR #2

#4:"Self Care [MeSH]" OR "Self-Management[MeSH]"
#5:"self-help*" OR "self-management*" OR "self-car*" OR "self-guid*" OR "self-serv*" OR "self-treatment*" OR "self-therap*" OR "self-support*" OR "self-assist*"(note: all terms in [title/abstract])
#6：#4 OR #5

#7:“Stress Disorders, Post-Traumatic[MeSH]" OR “Stress Disorders, Traumatic[MeSH]" OR “Stress Disorders, Traumatic, Acute[MeSH]" OR “Trauma and Stressor Related Disorders [MeSH]" OR “Combat Disorders[MeSH]" OR “Psychological Trauma[MeSH]"
#8:PTSD OR “posttrauma*” OR “post-trauma*” OR “post trauma*” OR “stress disorder*” OR “combat disorder*” OR “war neuros*” OR “trauma and stressor related disorder*” (note: all terms in [title/abstract])
#9：#7 OR #8

#10:randomized controlled trial [publication type]
#11: controlled clinical trial [publication type]
#12: "randomized controlled trial [MeSH]" OR clinical trials as topic [MeSH: noexp]
#13:"randomi*"[title/abstract] OR "RCT"[title/abstract]
#14: placebo [title/abstract]
#15: trial*[title]
#16: animals [mesh] NOT humans [mesh]
#17:(#10 OR #11 OR #12 OR #13 OR #14 OR #15) NOT #16

#18:#3 and #6 and #9 and #17.

Participant or population It has been described in "Review question/ objective--Population".

Intervention It has been described in “ Review question/ objective--intervention”.

Comparator It has been described in “ Review question/ objective--Comparison”.

Study designs to be included RCT.

Eligibility criteria Inclusion Criteria:(1) Subjects are screened by relevant scales (e.g., PCL, IES-R, CAPS-5, etc.) or diagnosed by a clinician using a specific tool, such as the Diagnostic and Statistical Manual of Mental Disorders (DSM) or the International Classification of Diseases (ICD). (2) Intervention: Provide an Internet-based self-help intervention for the trial, such as a web-based platform (website, email, etc.), mobile application, or use of an online course or online module to provide active treatment. (3) Control type: regular treatment, waiting for treatment, no treatment, and symptom monitoring only. (4) PTSD symptoms were measured by validated scales and reported for the trial and control groups (e.g. baseline information, post-intervention). (5) Only randomized controlled trials (RCTs) will be included.Exclusion criteria: (1) Literature written in languages neither Chinese nor English. (2) Duplicate publications were excluded (e.g. if there

was a revised version of the literature, the latest version was included) (3) If multiple articles reported data from the same sample, the most recent and complete article was included in our systematic evaluation. (4) When the full text was not available or detailed data could not be obtained, related information of these references would be recorded in the Appendix for readers to assess potential bias. (5) Clinical professional-related staff-led online treatments will be excluded, such as specialized physician-led videoconference consultations.

Information sources Please see "Search Strategy".

Main outcome(s) Changes in the severity of PTSD symptoms indicated by scale scores (e.g. Pre-intervention, just after the intervention, and at post-intervention follow-up) . Scales should be widely used and have good reliability and authority, such as the PDS, PCL-C, and CAPS.

Data management Data management: two trained researchers will extract information independently. The two researchers will import the literature from the search into NoteExpress 3.2 software, screen out duplicates and irrelevant literature, perform an initial screening based on the inclusion and exclusion criteria, read the title and abstract, and screen again by reading the full text to obtain the final included literature.

Quality assessment / Risk of bias analysis Quality assessment/risk of bias analysis: the Cochrane Randomized Trials Risk of Bias Tool (ROB 2.0) will be used. Egger's test will be used to detect publication bias ($\alpha = 0.10$).

Strategy of data synthesis The combined SMD and 95% confidence interval (CI) will be calculated using Comprehensive Meta-Analysis software (CMA 3.0), and $P < 0.05$ was considered statistically significant. In this study, the random effects model was chosen to merge the results ($\alpha = 0.05$), and the merged results were demonstrated by forest plots.

Subgroup analysis
(1) Type of intervention: computer-based, mobile-based.
(2) Duration of intervention: ≤3 months, >3 months to 6 months;
(3) Level of instruction: 0-no instruction provided and included a simple mail-in intervention, 1-intervention with some level of instruction including initial contact with a healthcare professional, 2-intervention with contact time and some form of follow-up;
(4) Reminders for subjects to complete the intervention: yes, no;
(5) Intervention provider: no description, healthcare professional, researcher, other, none;
(6) Duration of follow-up: ≤6 months, >6 months;
(7) Recruitment: school, clinical, community, mixed sources/not mentioned;
(8) Risk of bias: high, moderate, low;
(9) Inclusion of severe patients: yes, no;
(10) Regular feedback from subjects: yes, no;
(11) Financial incentives: yes, no;
(12) Specific psychological interventions: CBT, non-CBT;
(13) a pilot study or not: yes, no;
(14) Mindfulness-based treatment or not: yes, no
(15) Self-monitoring or not: yes, no
(16)Sample type: clinician diagnosed (e.g. with DSM or ICD), scale screened;
(17)Types of Scales.

Sensitivity analysis In this study, sensitivity analysis will be performed using CMA 3.0 software. The sensitivity analysis will be performed by excluding the included study case-by-case.

Language restriction English references or Chinese references.

Country(ies) involved P.R. China.

Other relevant information (1) Variables for meta-regression analysis:
1) Percentage of gender (%);
2) Mean age of intervened subjects (years);
3) Attrition rate (%);
4) Number of modules (number of subjects in the intervention content);
5) Duration of intervention (weeks);
6) Sample size;
7) Year of publication.

Alpha was 0.10 for one-way meta-regression analysis and 0.05 for multifactor meta-regression analysis.
(2) Evaluation of quality of evidence: GRADE was used to evaluate the quality of evidence.
(3) Heterogeneity: I2 will be used to reflect the heterogeneity (I2 over 50% is considered high heterogeneity). Possible sources of heterogeneity will be explored through subgroup analysis and Meta-regression.
The study is currently self-financed. All authors participated in designing this study.

Keywords Internet-based; self-help; mobile; Post traumatic; PTSD; randomized controlled trial; RCT.

Contributions of each author

Author 1 - Yan B designed the study in detail and will draft the manuscript.
Email: yb2023@gzhmu.edu.cn
Author 2 - He GM contributed to the development of search strategy, inclusion/exclusion criteria, subgroup analysis, and revised this protocol.
Author 3 - Wang HX contributed to the development of inclusion criteria, subgroup analysis, and search strategy.
Author 4 - Lin YQ contributed to forming the search strategy, exclusion criteria, and subgroup analysis.
Author 5 - Xie Y participated in modifying the search strategy and meta-regression analysis.
Author 6 - Liu JY participated in modifying the search strategy, and exclusion criteria.
Author 7 - Xu M participated in designing the study and revised this protocol.
Author 8 - Lu Y provided statistical expertise and revised this protocol in detail.