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The dropout rate of Internet-based self-help intervention for post-traumatic stress disorder (PTSD): a protocol of systematic review and meta-analysis

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ADMINISTRATIVE INFORMATION

Support - Self-supported.

Review Stage at time of this submission - Preliminary searches.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202380020

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 04 August 2023 and was last updated on 04 August 2023.

INTRODUCTION

Review question / Objective To figure out the pooled drop-out rate of Internet-based self-help intervention and explore the factors that may impact the drop-out rate.

Population: Subjects with symptoms of PTSD. Subjects should be screened by a related scale or diagnosed by a clinician with specific tools, including the Diagnostic and Statistical Manual of Mental Disorders (DSM).

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). Information on the control group is not necessary for this study unless the control groups are also relevant to internet-based self-help intervention.

Outcome: The dropout rate in Internet-based selfhelp intervention group. In this study, we define dropout rate as: (The number of subjects at baseline - The number of subjects when the Intervention was just finished) / The number of subjects at baseline *100%.

Study design: Randomized controlled trials (RCT).

Rationale In recent years, with the development of Internet technology, more RCTs have applied Internet-based self-help interventions to PTSD, which provided an opportunity to explore the dropout rate. In this study, we aim to explore the pooled dropout rate of Internet-based self-help interventions for PTSD and tend to identify influential factors. It can help to reduce the dropout rate and improve the quality of RCTs.

Condition being studied PTSD is a mental disorder caused by exposure to significant psychological trauma. Diagnostic symptoms of PTSD include re-experiencing the trauma as upsetting thoughts, nightmares, or flashbacks; and avoiding thoughts about the trauma or reminders of it. Approximately 60% of men and 50% of women experience at least one traumatic event in their lifetime, and the prevalence of PTSD in the general population ranges from 6.4% to 6.8%. PTSD is associated with significant functional

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impairment, compromised health, early mortality, and substantial economic costs. Dropout represents an essential barrier to the achievement of successful treatments. Subjects who drop out generally experience worse clinical outcomes. Dropout from RCTs is a significant concern, associated with a greater risk of rehospitalization and greater resource utilization. In research, patients who fail to complete study protocols can affect statistical analyses, study outcomes, and interpretation of results.

METHODS

Search strategy (1) Chinese databases: China National Knowledge Infrastructure (CNKI), Wanfang, VIP, China Biology Medicine (CBM).

(2) English databases: Pubmed, Web of Science, Embase, Cochrane Review, Scopus, PsycInfo.

(3) Grey literature sources: Clinical Trials.gov, Open Grey, Google Scholar, ProQuest Dissertations, and Theses Global (PQDT global). Besides, for each included article, the list of references will be traced. The search timeframe is from the establishment of each database to August 4th, 2023. If possible, a combination of subject headings and free words will be used to retrieve, and Pubmed is an example.

#1: Computer Communication Networks [MeSH Terms] OR internet-based intervention [MeSH Terms]

#2: Internet* OR web OR online* OR app OR mobile* OR smartphone* OR computer* OR tele* OR email* OR e-mail* OR "electronic mail*" OR digital* OR e-mental* OR e-psycho* (note: all terms in [title/abstract])

#3: #1 OR #2

#4: Stress Disorders, Post-Traumatic [MeSH Terms]

#5: PTSD OR "post traumatic stress" OR "post-traumatic stress" OR "stress disorder*" (note: all terms in [title/abstract])

#6: #4 OR #5

#7: Self Care [MeSH Terms]

#8: self-management* OR self-help* OR self-care* OR self-guid* OR self-serv* OR self-treatment* OR self-therap*(note: all terms in [title/abstract])

#9: #7 OR #8

#10 Filter: randomized controlled trial #11: #3 AND #6 AND #9 AND #10.

Participant or population Subjects with symptoms of PTSD screened by a scale (such PCL-5, CAPS-5, etc.) or diagnosed by a clinician (using DSM-4, DSM-5, or other tools).

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 address issues related to personal development or treatment of illnesses).

Comparator No applicable.

Study designs to be included Randomized controlled trial (RCT).

Eligibility criteria (1) Inclusion criteria: 1 Subjects with symptoms of PTSD screened by the PTSD Scale or diagnosed by a clinician (usually with the DSM criteria). 2 The screening scales should be fully validated and repeatable, such as PCL-5, CAPS-5, etc. 3 The intervention type is Internet-based self-help intervention. 4 The number of subjects at pre- and at post-intervention are reported or can be provided by the authors. (5) If more than one group is involved in Internetbased self-help intervention in the same RCT, each group will be included as long as it can meet the eligibility criteria. 6 Study design should be RCT. (7) References written in English/Chinese. References published in other languages will be listed in supplementary materials. (2) Exclusion criteria: 1 Excluding duplicate publications. 2 If studies are conducted among the same populations, only the study with a larger sample size will be kept. 3 Practitioner-led online therapy, e.g. practitioner-led video-conference-based counseling.

Information sources (1) Chinese Database: CNKI、wanfang、VIP、CBM.

- (2) English database: Pubmed, Web of Science, Embase, Cochrane Review, Scopus, PsycInfo.
- (3) Grey literature database: Clinical Trials.gov, Open Grey, Google Scholar, PQDT global. For each included study, the list of references will be traced to find out omitted documents.

Main outcome(s) The dropout rate is calculated as follows: (The number of subjects at the beginning of intervention - The number of subjects when the Intervention was just finished) / The number of subjects at the beginning of intervention *100%.

Data management Two trained researchers will independently extract information and import the literature into NoteExpress3.7 to exclude duplicate literature. The researchers will exclude irrelevant literature after reading the title, abstract, and full

text of the literature. We will use Excel 2016 to extract the following data: title, year of publication, regions, types of intervention, first author, gender, age, number of dropouts, and the number of subjects at the beginning of the intervention. Other information considered for subgroup analysis and meta-regression will also be collected (see Subgroup analysis). In this study, information will be extracted separately if both groups are intervention groups. We will seek additional information from the authors if necessary. We will resolve disagreements through discussion and invite the corresponding author to settle the disagreements.

Quality assessment / Risk of bias analysis The Cochrane risk-of-bias tool for randomized trials (RoB 2.0) will be used. Egger's test will be used to detect publication bias (α =0.10).

Strategy of data synthesis The pooled dropout rate and 95% confidence interval (CI) will be calculated by Comprehensive Meta Analysis software (CMA 3.0), and a random effects model will be selected in this study (α =0.05).

Subgroup analysis We will explore the sources of heterogeneity through subgroup analyses and meta-regression.

Subgroup analyses: (1) Intervention type (computer-based/ mobile-phone-based). (2) Duration of intervention (\leq 6 weeks/ >6 weeks). (3) Be reminded to complete the intervention (yes/ no). (4) Therapist support status (self-help and therapist-supported / self-help only). (5) Risk of bias (high/ some or low). (6) Types of PTSD scales. (7) Severe subjects inclusion (yes/ no). (8) Regular feedback from participants (yes/ no). (9) Financial incentives (yes/ no). (10) Recruitment (Non-clinical/ clinical). (11) Specific psychological intervention (CBT/ not CBT). (12) Pilot studies or not (yes/ no). We used CMA 3.0 to calculate P-values between subgroups (α =0.05) .

Meta-regression: (1) Mean age of intervened participants (years). (2) Percent of females (%). (3) Sample size (n). (4) Publication year. And $\alpha{=}0.10$ for univariate meta-regression and $\alpha{=}0.05$ for multivariate meta-regression.

Sensitivity analysis We used Comprehensive Meta-Analysis 3.0 software to conduct sensitivity analyses and observe whether the results were robust by excluding literature one by one.

Language restriction English or Chinese.

Country(ies) involved P.R.China.

Keywords Internet; self-help; PTSD; dropout rate; meta-analysis.

Contributions of each author

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