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Dropout from randomized controlled trials of Internet-based self-help interventions for anxiety in adolescents and young adults: a systematic review and meta-analysis

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ADMINISTRATIVE INFORMATION

Support - None.

Review Stage at time of this submission - The review has not yet started.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY2023120096

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 24 December 2023 and was last updated on 24 December 2023.

INTRODUCTION

Review question / Objective The purpose of this study was to analyze the dropout rate of Internet-based self-help interventions for anxiety in adolescents and young adults and to explore the factors that may influence the dropout rate.

Population: (1) The subject population is adolescents and young adults, ages 10-24 years old. (2) Subjects with symptoms of anxiety should be screened by relevant scales (e.g., SAS-A, GAD-7, etc.) or diagnosed by a clinician using a validated tool (e.g., DSM-5).

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: information on the control group is not required for this study unless the control group

is also associated with an Internet-based self-help intervention.

Outcome: dropout rate for the Internet-based self-help intervention group. In this study, we defined the dropout rate as (number of subjects at baseline - number of subjects at the end of the intervention)/number of subjects at baseline*100%. **Study design:** Randomized controlled trial (RCT).

Rationale In recent years, with the wide use of Internet technology in healthcare, more and more RCTs have introduced Internet-based self-help interventions for anxiety in adolescents and young adults. However, the dropout rate is usually high, which may affect the intervention effects.

Condition being studied It is estimated that 4% of the global population suffers from anxiety. As of 2019, 301 million people worldwide suffer from anxiety, making it one of the most common mental disorders. Symptoms of anxiety disorders usually begin during adolescence and continue into adulthood. However, in previous studies, patients

who failed to complete the study protocol affected statistical analyses, findings, and interpretation of results.

METHODS

Search strategy (1) English databases: PubMed, Embase, Cochrane Review, Scopus, PsycINFO, PsycNET.

(2) Chinese databases: China Knowledge Network (CNKI, Journal Database), Wanfang Database (Journal Database), Weipu Chinese Science and Technology Journal Database, and China Biomedical Literature Database (CBM).

(3) Gray literature sources: International Clinical Trials Registry Platform (ICTRP), ClinicalTrials.gov, PsycEXTRA, ProQuest Dissertations & Theses Global.

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. The timeframe for the search was from the creation of each database to January 17, 2024. Where possible, searches will be conducted using a combination of subject headings and free words.

The search strategy for Pubmed is presented as an example:

#1: "Computer Communication Networks [MeSH]" OR "Internet-based intervention [MeSH]" OR "Internet[MeSH]"

#2: "Internet*" OR "web" OR "webs" OR "online*" OR "app" OR "apps" OR "mobile*" OR "smartphone*" OR "computer*" OR "tele*" 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: "Anxiety [MeSH]" OR "Anxiety Disorders[MeSH]" OR "Panic Disorder [MeSH]" OR "agoraphobia [MeSH]" OR "Mutism [MeSH]"

#8: "anxi*" OR "Anxiety Disorders" OR "generalized anxiety disorder" OR "GAD" OR "social anxiety disorder" OR "SAD" OR "panic disorder" OR "PD" OR "Panic Attack" OR "agoraphobia" OR "separation anxiety disorder" OR "specific phobias" OR "selective mutism" OR

"worr*" OR "phobi*" OR "panic*" OR "low mood"(note: all terms in [title/abstract])

#9:#7 OR #8

#10: "Adolescent [MeSH]" OR "Young Adult[MeSH]" OR "Child[MeSH]" OR "Students[MeSH]"

#11: "adolescent*" OR "teenager*" OR "young" OR "youth*" OR "child" OR "student*" OR "juvenile*" (note: all terms in [title/abstract])

#12:#10 OR #11

#13: Randomized Controlled Trial[publication type]

#14:controlled clinical trail[publication type]

#15:"Randomized Controlled Trial[Mesh]" OR clinical trails as topic[Mesh:noexp]

#16: "RCT"[title/abstract] OR "randomi*" [title/abstract]

#17: placebo[title/abstract]

#18: trial*[title]

#19: animals[Mesh] NOT humans[Mesh]

#20: (#13 OR #14 OR #15 OR #16 OR #17 OR #18) NOT #19

#21: #3 AND #6 AND #9 AND #12 AND #20

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

Intervention It was described in "Review question/ objective-Intervention".

Comparator No applicable.

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

Eligibility criteria Inclusion criteria:(1) Subjects were aged 10-24 years; those diagnosed with anxiety at baseline either by a clinician (e.g., Diagnostic and Statistical Manual of Mental Disorders (DSM) criteria) or using a validated self-report instrument (e.g., SAS-A, GAD-7, etc.);(2) Only the WHO-described type of anxiety was included in this study. (3) The self-help intervention was supposed to be delivered by the Internet, such as web-based platforms (websites, email addresses, etc.), mobile applications, or the use of online courses, or online modules.(4) In the same randomized controlled trial, if there is more than one group that meets the inclusion/exclusion criteria, each group will be included. (5) The number of subjects before and after the intervention will be reported in the included articles or provided by the authors.(6) The study design should be an RCT. Exclusion criteria:(1) Outcome data were not available even after trying to contact corresponding authors or use other means;(2) Duplicate publications were excluded. Studies

identified only as protocols, abstracts, or reviews were flagged to check for RCTs that might have been missed;(3) Non-Chinese or non-English literature (recorded in the Annex if published in other languages).

Information sources This is described in the "Search strategy". In addition, the authors of the included studies will be contacted for further information if necessary (e.g., by e-mail). For each included study, the reference list will be tracked to identify more possible literature.

Main outcome(s) The dropout rate for the Internet-based self-help intervention group. The formula for the attrition rate is (number of subjects at baseline - number of subjects at the end of the intervention)/number of subjects at baseline*100%.

Data management Two trained researchers will extract the information independently. The two researchers will import the literature 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.

Quality assessment / Risk of bias analysis The Cochrane Randomized Trial Risk of Bias Tool (Rob 2.0) will be used to assess the quality of each included study. The 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 displayed by forest plots.

Subgroup analysis We will explore sources of heterogeneity through subgroup analyses.

(1) Population: 10-19 years old (adolescents) / 20-24 years old (young adulthood).

(2) Type of anxiety:

1) Generalized anxiety disorder;

2) social anxiety disorder;

3) panic disorder;

4) agoraphobia;

5) Separation anxiety disorder;

6) specific phobias;

7) selective mutism;

8) Mixed anxiety or not mentioned

(3) Type of anxiety scale;

(4) Type of intervention: computer-based, use of mobile devices;

(5) Duration of intervention(months): ≤ 3 , more than 3 and less than 6 months, >6 ;

(6) Level of guidance: 0-no guidance provided and included a simple mail-in intervention, 1-intervention with some level of guidance including initial contact with a healthcare professional, 2-intervention with contact time and some form of follow-up;

(7) Reminders for subjects to complete the intervention: yes, no;

(8) Intervention provider: no description, healthcare professional, researcher, other, none;

(9) Duration of follow-up: ≤ 6 months, >6 months;

(10) Source of subjects: school, clinical, community, mixed sources/not mentioned;

(11) Risk of bias: high, moderate, low;

(12) Inclusion of severe patients: yes, no;

(13) Regular feedback from subjects: yes, no;

(14) Financial incentives: yes, no;

(15) Specific psychological interventions: CBT, non-CBT;

(16) Pilot study: yes, no;

(17) Mood monitoring: yes, no;

(18) MBCT-based: yes, no.

CMA 3.0 was used to calculate p-values between groups ($\alpha=0.05$).

Sensitivity analysis Sensitivity analysis was performed, using Comprehensive Meta-Analysis 3.0 software, by excluding the literature one by one and observing the stability of the results.

Language restriction References written in English and Chinese will be included. References in other languages will be recorded in an attached file.

Country(ies) involved P. R.China.

Other relevant information (1) Meta-regression: We will explore the sources of heterogeneity through meta-regression.

1) Percentage of gender(%);

2) Mean age (years);

3) Number of modules;

4) Duration of intervention (weeks)

5) Sample size (n);

6) Year of publication.

Alpha was set at 0.10 for one-way regression and 0.05 for multivariable meta-regression.

(2) Heterogeneity: I^2 will be used to reflect the heterogeneity (more than 50% is considered high heterogeneity). Possible sources of heterogeneity will be explored through subgroup analysis and Meta-regression.

(3) The study is currently self-financed by the authors.

All authors participated in the design of this study and will help revise the manuscript.

Keywords Internet; self-help; anxiety; dropout rate; Randomized controlled trial (RCT); adolescents; young adults; meta-analysis.

Contributions of each author

Author 1 - Yan Bo designed the study and will contribute to the quality assessment, data analysis, and manuscript drafting.

Author 2 - Xie Y mainly contributed to the development of the search strategy, exclusion criteria, and subgroup analysis and will help analyze the data and draft the manuscript.

Author 3 - Wang HX mainly contributed to the development of the search strategy, inclusion/exclusion criteria, and subgroup analysis strategy.

Author 4 - Lin YQ mainly contributed to developing the search strategy and inclusion/exclusion criteria.

Author 5 - Hu J helped with the development of inclusion/exclusion criteria and subgroup analysis.

Author 6 - Zheng XH helped with modifying the search strategy and inclusion criteria.

Author 7 - Luo SY contributed to modifying the search strategy and subgroup analysis.

Author 8 - Liu JY contributed to modifying the subgroup analysis.

Author 9 - Xu M provided help with quality assessment, as well as forming inclusion criteria and modifying subgroup analysis.

Author 10 - Lu Y contributed to reviewing the protocol and provided statistical expertise. The protocol was revised in detail by Lu Y.