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RESEARCH ARTICLE

Quality of abstracts of randomized controlled trials on alternative and complementary therapies for anxiety: cross-sectional study

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Aim: To assess the quality of summaries of randomized controlled trials on alternative and complementary therapy for anxiety.

Methods: The quality of abstracts was assessed using the 17-item CONSORT checklist. PubMed was selected as the database for identifying relevant abstracts. The search was performed in May 2023 using the following search strategy: "anxiety"[All Fields] AND "alternative and complementary therapies"[All Fields]. Filters were applied for randomized controlled trials published between 2018 and 2022, with available abstracts and articles published in English.

Results/Findings: A selection of 303 abstracts on randomized controlled trials on alternative and complementary therapies for anxiety were analysed. The median total score on the 17-item CONSORT checklist was 7 (IQR = 6–8). The items most frequently included were the research objective, outcome measures, and research conclusion. The items that were most often missing were the source of funding for the research, which was not mentioned in any of the abstracts, adverse effects, and the method of randomization into the test and control groups. A greater proportion of studies had significant results for the primary outcome.

Conclusions: According to the CONSORT checklist, the quality of abstracts of randomized controlled trials on complementary and alternative therapies for anxiety was generally low. Reporting of funding, harms, and randomization methods was rare to absent, reducing the transparency and interpretability of the published research. These findings highlight the need for improved reporting quality in future abstracts.

Keywords: anxiety; alternative therapy; reporting guidelines; CONSORT; abstract

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Introduction

Anxiety is an emotion characterized by fear and somatic symptoms of tension, in which an individual anticipates impending danger, catastrophe, or misfortune. It manifests through various emotional, cognitive, behavioural, and physical symptoms (*1*). Anxiety becomes pathological and requires treatment when there is an overestimation of perceived threats or a misjudgement of the danger of a situation, leading to excessive and inappropriate responses that prevent the affected individual from leading a normal life (*2*). According to epidemiological studies, one-third of the population experiences some form of anxiety disorder during their lifetime (*3*).

The treatment of anxiety disorders can be carried out through pharmacotherapy and/or psychotherapy (cognitive-behavioural therapy), with both options considered equally effective. The choice of treatment should be made in light of the severity of the disorder, patient preferences, expected side effects, and the availability of specific therapies. The medications with the highest level of evidence for effectiveness in anxiety disorders include selective serotonin reuptake inhibitors (SSRIs), selective serotonin-norepinephrine reuptake inhibitors (SNRIs), and pregabalin, which is a calcium channel modulator. Benzodiazepines are used for the treatment of acute anxiety and for rapid control of panic attacks (*4*).

Since patients often hesitate to use antidepressants, the popularity of alternative and complementary medicine in the treatment of anxiety disorders has been growing. Alternative and complementary refers to a broad range of medical and health care practices, products, and interventions that are not generally considered part of conventional medicine, including interventions such as yoga, acupuncture, phytotherapy, music therapy, and mindfulness-based approaches. According to scientific literature, the most research has been conducted in the fields of physical exercise, phytotherapy, and micronutrition (specific vitamins and minerals) (*5*). Randomized controlled trials represent the standard for assessing the benefits and risks of various therapeutic interventions in medicine. The significance of these studies depends on the quality of their implementation and the thoroughness of the presented results. The abstract is an especially relevant part of a published study and must be transparent, encompassing the study design, implementation, analysis, and results (*6*).

CONSORT (Consolidated Standards of Reporting Trials) is a set of evidence-based recommendations for reporting randomized controlled trials. According to CONSORT guidelines for abstracts published in journals, the abstract must indicate that the study is a randomized controlled trial, provide author contact details, describe the study design, specify participant selection criteria and data collection sites, outline interventions for each study group, state the study objective, identify the primary outcome, explain the randomization process, include information on participant blinding, report the number of randomized participants in each group, describe the study status, present the number of participants analysed for the primary outcome, provide results for each group along with effect size and precision estimates, list adverse effects, interpret the results, and include study registration and funding sources (*7*).

The aim of the study was to analyse the quality of abstracts of published randomized controlled trials that examine the effectiveness of alternative and complementary therapies for anxiety. We analysed the quality of abstracts from randomized controlled trials on alternative and complementary therapies for anxiety, whether there has been an increase in research in this field, and whether there are differences in the frequency of various CONSORT items among studies on alternative and complementary therapies for anxiety.

Methods

The study was conducted in May 2023 as a cross-sectional assessment of the quality of available abstracts from randomized controlled trials in patients with anxiety. The MEDLINE database was searched via PubMed to identify relevant abstracts using the Boolean operator AND and the following search strategy: "anxiety"[All Fields] AND "alternative and complementary therapies"[All Fields]. The search was restricted to randomized controlled

Table 1. Operational definitions used for CONSORT Abstract assessment

Consort item	Operational definition used in the present study
Title	Considered present only if the title explicitly identified the study as a randomized controlled trial (e.g., "randomized trial", "randomized controlled trial", or "RCT").
Authors (contact details)	Considered present if at least one author contact detail (e-mail address or correspondence address) was provided in the abstract or accompanying abstract information.
Study design	Considered present if the abstract explicitly stated the trial design (e.g., parallel-group, crossover, cluster randomized, factorial, superiority, equivalence, or noninferiority).
Participants	Considered present if the eligibility criteria for participants and/or the setting of recruitment or data collection were reported.
Interventions	Considered present if the interventions in the experimental and control groups were described.
Objective	Considered present if the study objective and/or hypothesis was explicitly stated.
Outcome	Considered present if the primary outcome measure was explicitly identified.
Randomization method	Considered present only if the method of sequence generation was explicitly described (e.g., computer-generated randomization, block randomization, random number table). Merely stating that participants were "randomized" was not considered sufficient.
Blinding	Considered present only if the abstract explicitly specified whether participants, investigators, outcome assessors, or combinations thereof were blinded.
Number of participants	Considered present if the number of participants randomized or allocated to each study group was reported.
Recruitment	Considered present if the study status (ongoing, completed, or interim analysis) and/or recruitment period was reported.
Number of analysed participants	Considered present if the number of participants included in the primary outcome analysis was reported.
Primary outcome results	Considered present if the results for the primary outcome were reported for each study group, including effect estimates and/or measures of precision when available.
Adverse effects	Considered present if harms, adverse events, side effects, or unintended effects of the intervention were reported.
Conclusion	Considered present if the interpretation of the study findings and conclusions were explicitly stated.
Study registration	Considered present if the trial registration number and/or the name of the registry was reported.
Funding	Considered present only if the source of funding or a statement regarding funding support was explicitly provided.

trials published between 1 January 2018 and 31 December 2022, with available abstracts and articles published in English; all non-English publications were excluded. The five-year period (2018–2022) was selected to provide a contemporary overview of reporting practices in randomized controlled trials investigating alternative and complementary therapies for anxiety disorders.

The quality of the abstracts was assessed using the CONSORT checklist, which includes 17 items (7). All abstracts were screened and the CONSORT items were extracted by a single reviewer (K.M.). Because the assessment was performed by one reviewer, no formal calibration exercise or inter-rater agreement analysis (e.g., Cohen's κ) was conducted. To ensure consistency, predefined operational definitions were used for each CONSORT item and are presented in **Table 1**. The following data were analysed: article title and identification of the study as a randomized controlled clinical trial, author contact details, study design (parallel group, cluster randomized, crossover, factorial, superiority, equivalence, or noninferiority), participant inclusion criteria and data collection sites, intervention in each group, study objective, primary outcome, randomization method, blinding (if specified, whether the participant and/or investigator was blinded), number of participants in each group, study duration, number of participants analysed for the primary outcome, primary outcome results in each group with effect size estimation, adverse effects in any group, conclusion, study registration, and source of funding.

Additional data analysed included the number of authors, year of publication, journal name, whether the total number of participants was greater or less than 100, the country where the trial was conducted, whether the study was a pharmacological trial (i.e., evaluating the effect of a drug), multicentricity, significance of results (whether the intervention was superior to placebo), funding source (industry, university, or nonprofit organizations), whether the hospital was the research site, and whether the article was structured.

Results were reported as medians, whole numbers, and percentages. Statistical analysis and the chi-square test were performed using MedCalc for Windows (v.11.5.1.0, MedCalc Software, Ostend, Belgium). A P-value less than 0.05 was considered statistically significant.

Ethics approval was not required for this study because it involved the analysis of publicly available published abstracts and did not include human participants, identifiable personal data, or unpublished information.

Results

A search of the MEDLINE database using the specified criteria identified 509 published randomized controlled trials investigating the effects of alternative and complementary therapies on anxiety disorders between 2018 and 2022. Out of these 509 studies, only 303 were included in the final analysis, as 1 study was conducted on animal models, 15 were not designed as randomized controlled clinical trials, and 190 did not involve interventions from the field of alternative or complementary therapies. The largest share, 24.4% of studies in the field of complementary therapies for anxiety, was published in 2021, while

23.8% were published in the last year of the observed period, 2022. The five most frequently studied interventions in the analysed randomized controlled trials were in the areas of yoga, acupuncture, music therapy, phytotherapy, and psychotherapy. The greatest increase in research was observed for yoga as a complementary therapy for anxiety, while only phytotherapy saw a decrease in the number of studies during the observed period.

The median total score on the 17-item CONSORT checklist was 7 (IQR = 6–8). No statistically significant differences were found between the medians of the total scores for the five most common interventions: yoga 8 (IQR = 6–8), acupuncture 7 (IQR = 7–8), music therapy 7 (IQR = 6–9), phytotherapy 7 (IQR = 6–8), and psychotherapy 6 (IQR = 4–7), P = 0.159. The proportion of abstracts containing specific CONSORT checklist items is shown in **Table 2.** The most frequently included items in the abstracts of randomized controlled clinical trials were the study objective (96.4%), outcome measures (93.4%), and study conclusion (94.1%). The items most frequently missing from the abstracts were the source of funding, which was not mentioned in any abstract, adverse effects in the study, which were reported in only 2 studies (0.7%), and the method of randomization in the experimental and control groups, which was stated in 6.3% of abstracts.

Table 2. The proportion of abstracts that include the specified CONSORT item (n = 303)

Item	Number (%)
Title contains design	190 (62.7)
Contact authors	138 (45.5)
Study design	29 (9.6)
Participants	45 (14.9)
Intervention	192 (63.4)
Study objective	292 (96.4)
Outcome	283 (93.4)
Method of randomization	19 (6.3)
Blinding	65 (21.5)
Participant allocation	132 (43.7)
Study period	41 (13.7)
Number of analysed participants	134 (44.2)
Study outcome	167 (55.1)
Adverse effects reported	2 (0.7)
Study conclusion	285 (94.1)
Study registration	43 (14.2)
Funding	0 (0.0)

Based on the reviewed abstracts, a higher proportion of studies show significant results for the primary outcome, with 62.9% reporting significant findings, compared to 37.1% of studies that did not report significant results for the primary outcome. **Table 3** shows the differences in the representation of CONSORT items between randomized controlled trials that reported significant results for the primary outcome and those that did not show a

significant difference between the experimental and control groups for the primary outcome. Studies that achieved significant results for the primary outcome had a higher proportion of items such as the title containing the study design (65.7% vs. 52.2%, P = 0.045) and participant allocation (49.6% vs. 22.4%, P<0.001) compared with studies reporting no statistically significant differences in the primary outcome. In contrast, study registration was reported more frequently in studies with no statistically significant differences than in studies with a marginally significant findings (22.4% vs. 11.9%, P = 0.049) (**Table 3**).

Table 3. Differences in the frequency of CONSORT items between studies reporting statistically significant primary outcomes and studies reporting no statistically significant differences in the primary outcome

CONSORT items	Differences in the primary outcome (number, %)		*P**
	No statistically significant differences (n = 67)	Statistically significant differences (n = 236)	
Title includes study design	35 (52.2)	155 (65.7)	0.045
Author contact	32 (47.8)	106 (44.9)	0.813
Study design	7 (10.4)	22 (9.3)	0.975
Participants	5 (7.5)	40 (17.0)	0.012
Intervention	38 (56.7)	154 (65.3)	0.238
Study objective	59 (88.1)	233 (98.3)	<0.001
Outcome	51 (76.1)	232 (98.7)	<0.001
Randomization method	3 (4.5)	16 (6.8)	0.683
Blinding	16 (23.9)	49 (20.9)	0.716
Participant allocation	15 (22.4)	117 (49.6)	<0.001
Study period	11 (16.4)	30 (12.7)	0.573
Number of analysed participants	15 (22.4)	119 (50.4)	<0.001
Study outcome	20 (29.9)	147 (62.3)	<0.001
Adverse effects reported	0 (0)	2 (0.9)	0.923
Study conclusion	51 (76.1)	234 (99.2)	<0.001
Study registration	15 (22.4)	28 (11.9)	0.049
Funding	0 (0)	0 (0)	-

*Chi-square test.

Discussion

Our study showed that according to the CONSORT checklist, the quality of the abstracts of studies on alternative and complementary therapies for anxiety can be rated as very low. With the exception of the items related to the study's objective, outcome measures,

and conclusion, which were found in over 93% of the abstracts, all other items were included in no more than 63.6% of the abstracts. Similar results were found in the study by Kuriyama and colleagues on the quality of abstracts from randomized controlled trials published in major intensive care journals, where the frequency of appropriate reporting on the source of funding and randomization methods was suboptimal (*8*). The findings of this study align with those of Song and colleagues, who assessed the quality of abstracts of randomized controlled trials in psychiatry and reported a very low representation of items related to adverse effects, study design, blinding, and source of funding, which were mentioned in fewer than 25% of the abstracts (*9*). Furthermore, the possibility arises that some interventions, such as phytotherapy, may interact with the patient's existing pharmacological therapy. The lack of information on randomization methods and sources of funding causes difficulties in interpreting the results of research and detracts from its transparency.

An interesting finding is the increase in the number of anxiety-related studies during the observed period, especially from 2020. This phenomenon corresponds with the COVID-19 pandemic period, which, in addition to affecting physical health, likely had a significant impact on the mental health of the population (*10*). It is believed that anxiety symptoms during this period began to develop at a high rate among healthcare workers, who were under significant strain from large numbers of patients, a high risk of infection, inadequate personal protective equipment, high mortality rates among patients, and public pressure (*11*). As a result, healthcare systems around the world began conducting numerous studies suggesting that special interventions should be applied to promote the mental well-being of healthcare workers exposed to the COVID-19 pandemic (*12*).

One of the most commonly used interventions among alternative and complementary therapies for anxiety was yoga, a group of interconnected ancient Hindu physical and mental exercises originating from India (*13*). From 2012 to 2016, the practice of yoga in the United States increased by 75%, reaching 36 million people in 2016 (*13*). In a study by More and colleagues, practicing yoga reduced subjective symptoms of anxiety and their severity in patients, with no reported adverse effects (*14*).

According to the findings of this study, phytotherapy was not the most commonly researched form of complementary therapy. One possible reason for this is that, according to legal regulations, herbal products must be registered as medicines if they meet the criteria for traditional or proven medical use (*15*).

Furthermore, due to the broad concept covered by the search terms, it is possible that additional relevant studies could have been identified by using terms specific to individual interventions. The study also covered a wide range of interventions, which made comparisons between different types of therapies more challenging. For example, music therapy, based on auditory experience, and phytotherapy, often applied through aromatherapy, have different forms and mechanisms of action, making direct comparisons difficult.

Moreover, data extraction and assessment were based solely on published abstracts rather than full-text articles. Consequently, the reporting of CONSORT items may have been incomplete or misclassified. Similarly, the significance of the primary outcomes was determined exclusively from information reported in the abstracts. Because abstracts may

selectively emphasize positive findings, contain reporting bias, or inadequately describe primary outcomes, the observed proportion of studies reporting significant results should be interpreted with caution.

Finally, all abstracts were screened and assessed by a single reviewer; therefore, no duplicate data extraction, formal calibration exercise, or inter-rater agreement assessment (e.g., Cohen's κ) was performed. In addition, multiple statistical comparisons were conducted, increasing the possibility of type I error and chance findings.

Conclusions

According to the CONSORT checklist, the quality of abstracts of randomized controlled trials on alternative and complementary therapies for anxiety was generally low. Reporting of funding, harms, and randomization methods was rare to absent, reducing the transparency and interpretability of published research. Authors should adhere more closely to the CONSORT for Abstracts (CONSORT-A) guidelines, and journal editors should encourage or require the reporting of key methodological and safety information, particularly funding sources, adverse effects, and randomization methods, in trial abstracts.

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