ΠΑΝΕΠΙΣΤΗΜΙΟ ΘΕΣΣΑΛΙΑΣ

ΣΧΟΛΗ ΕΠΙΣΤΗΜΩΝ ΥΓΕΙΑΣ

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ΠΡΟΓΡΑΜΜΑ ΜΕΤΑΠΤΥΧΙΑΚΩΝ ΣΠΟΥΔΩΝ

Η ΔΙΑΤΡΟΦΗ ΣΤΗΝ ΥΓΕΙΑ ΚΑΙ ΣΤΗ ΝΟΣΟ

ΔΙΠΛΩΜΑΤΙΚΗ ΕΡΓΑΣΙΑ

Αξιολόγηση της ποιότητας της αναφοράς των τυχαιοποιημένων κλινικών μελετών που ερευνούν την αποτελεσματικότητα της κουρκουμίνης στη θεραπεία της κατάθλιψης

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UNIVERSITY OF THESSALY
SCHOOL OF HEALTH SCIENCES
FACULTY OF MEDICINE
POSTGRADUATE STUDIES PROGRAM
NUTRITION IN HEALTH AND DISEASE

Assessment of the reporting quality of randomized controlled trials that investigate the efficacy of curcumin for treating depression

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1 Abstract

1.1 Background - Purpose

The gold standard of evidence-based medicine is randomized controlled trials (RCTs), however sometimes their reporting is subpar. A set of evidence-based suggestions to raise the standard of RCTs is found in the Consolidated Standards of Reporting Trials (CONSORT) statement.

The purpose of the present study was the evaluation of the compliance of RCTs with the CONSORT Statement to investigate the efficacy of curcumin for treating depression.

1.2 Methods

We looked through medical databases for randomized controlled trials (RCTs) where individuals were treated with curcumin for depression. An updated CONSORT 2010 guidelines-based 37-item checklist was used to evaluate the reporting quality, with compliance levels of ≥ 75% being considered optimal-adequate. The estimation of compliance for each CONSORT item and the univariate and multivariate analysis of potential determinants were the secondary goals. A compliance rate of more than 75% on the items was deemed sufficient. ideal.

1.3 Results

Ten eligible trials were found. The mean CONSORT compliance was 47.03% ± 16.23%. Among retrieved studies, none of them (100%) achieved a good reporting quality (≥75%). Items in respect to randomization and blinding were principally underreported. Univariate analysis revealed no statistically significant association with reporting quality: IF of journal and sample size (p-value=1.00, OR=1.00, 95% CI: 0.80-12.56). Logistic regression could not be applied due to the lack of significant predictors. An additional exploratory analysis indicated non-significant linear correlation between IF and reporting quality (Spearman's ρ=0.01, p-value=0.97) and publication year and reporting quality (Spearman's ρ=0.56, p-value=0.09).

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1.4 Discussion

The average CONSORT adherence of RCTs looking into curcumin for depression disorders is at a low level, according to this analysis. Adhering to the CONSORT statement can substantially improve reporting quality, thereby enhancing the overall validity of research.

Keywords: CONSORT, Randomized controlled trials, curcumin, curcuma, depression

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2 Περίληψη

2.1 Ιστορικό – Σκοπός

Οι τυχαιοποιημένες ελεγχόμενες κλινικές δοκιμές αποτελούν βασικό εργαλείο στην ιατρική που βασίζεται σε στοιχεία, αλλά η αναφορά τους πρέπει να γίνεται με προσοχή. Η έκθεση CONSORT αναπτύχθηκε ως ένα σύνολο συστάσεων για τη βελτίωση της ποιότητας των αναφορών των τυχαιοποιημένων κλινικών δοκιμών. Σκοπός της παρούσας μελέτης ήταν να αξιολογήσει την ποιότητα αυτών των δοκιμών σε σχέση με τη χρήση της κουρκουμίνης για τη θεραπεία της κατάθλιψης. Τα αποτελέσματα δείχνουν ότι η ποιότητα της αναφοράς των τυχαιοποιημένων κλινικών δοκιμών για την κουρκουμίνη είναι ανεπαρκής, υπογραμμίζοντας την ανάγκη για βελτιωμένες πρακτικές αναφοράς και συμμόρφωσης προς τις συστάσεις της CONSORT.

2.2 Μέθοδοι

Οι ιατρικές βάσεις δεδομένων αναζητήθηκαν για τυχαιοποιημένες ελεγχόμενες κλινικές δοκιμές που αφορούσαν ασθενείς που λάμβαναν κουρκουμίνη για τη θεραπεία της κατάθλιψης. Η ποιότητα των αναφορών αξιολογήθηκε χρησιμοποιώντας μια λίστα ελέγχου 37 στοιχείων που βασίζεται στις ενημερωμένες οδηγίες CONSORT 2010, με ποσοστό συμμόρφωσης ≥75% που ορίζεται ως βέλτιστο-επαρκές. Ο πρωταρχικός στόχος ήταν να υπολογιστεί η μέση συμμόρφωση με βάση την αναφορά CONSORT των τυχαιοποιημένων κλινικών μελετών που περιλάμβανε κουρκουμίνη στη θεραπεία της κατάθλιψης. Δευτερεύοντες στόχοι ήταν η αξιολόγηση της συμμόρφωσης με τις απαιτήσεις της έκθεσης CONSORT και η μελέτη πιθανών τροποποιητικών παραγόντων μέσω μεθόδων μονομεταβλητής και πολυμεταβλητής ανάλυσης. Η συμμόρφωση άνω του 75% των απαιτήσεων ορίζεται ως επαρκής – βέλτιστη.

2.3 Αποτέλεσματα

Δέκα (10) κλινικές δοκιμές βρέθηκαν να πληρούν τα κριτήρια επιλογής. Σύμφωνα με την έκθεση CONSORT, η μέση συμμόρφωση ήταν 47.03% ± 16.23%. Μεταξύ των ανακτημένων μελετών καμία δεν (0%) πέτυχε καλή ποιότητα αναφοράς (≥75%). Τα στοιχεία που αφορούν την τυχαιοποίηση και την τυφλότητα αναφέρθηκαν στο ελάχιστο. Η μονομεταβλητή ανάλυση δεν έδειξε στατιστικά σημαντική συσχέτιση με την ποιότητα της αναφοράς: δείκτης απήχησης του περιοδικού και μέγεθος του δείγματος (p-τιμή=1.00, OR=1.00, 95% CI: 0.80-12.56). Η λογαριθμική παλινδρόμηση δεν μπορούσε να εκτελεστεί λόγω έλλειψης στατιστικά σημαντικών προγνωστικών παραγότων. Μια πρόσθετη ανάλυση έδειξε μη στατιστικά σημαντική γραμμική συσχέτιση μεταξύ του δείκτη απήχησης και της ποιότητας αναφοράς

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(Spearman's ρ=0.01, p-value=0.97) καθώς και του έτους δημοσίευσης και της ποιότητας αναφοράς (Spearman's ρ=0.56, p-value=0.09).

2.4 Συμπέρασμα

Αυτή η μελέτη αποκαλύπτει ότι η μέση συμμόρφωση με τη έκθεση CONSORT στις τυχαιοποιημένες κλινικές δοκιμές που εξετάζουν την κουρκουμίνη για την καταθλιπτική διαταραχή βρίσκεται σε χαμηλό επίπεδο. Η συμμόρφωση με την έκθεση CONSORT μπορεί να βελτιώσει σημαντικά την ποιότητα της αναφοράς, βελτιώνοντας έτσι τη συνολική εγκυρότητα της έρευνας.

Λέξεις-κλειδιά: CONSORT, Τυχαιοποιημένες κλινικές δοκιμές, κουρκουμίνη, κατάθλιψη

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3 Introduction

Depression, also known as major depressive disorder, is a common and serious medical illness that negatively impacts feelings, ideas, and behavior. Depression is frequently accompanied by a variety of health issues, including anxiety, melancholy, overeating or loss of appetite, and loss of interest in routine tasks. Although many antidepressants (e.g. selective serotonin reuptake inhibitors) have been proven to be effective, many patients with depression failed to achieve an adequate response [18]. Therefore, people are currently searching for complementary and alternative medicines that are safer and more effective. Since curcumin (diferuloylmethane) can alter neuronal substrates closely linked to depression, it may aid in the recovery process for depression. Curcuma longa is a plant of the Zingiberoide family. Numerous clinical trials have been conducted to examine curcumin's potential as an antidepressant for treating depression or its associated symptoms.

So far there is no published study evaluating the quality of RCTs focusing on the use of curcumin for treating depression and depression symptoms.

Randomized controlled trials (RCTs) and particularly double-blind trials are regarded as the gold standard of evidence-based medicine, and the development of therapeutic guidelines heavily relies on the findings of these trials [19]. The quality of randomized controlled trials (RCTs) is still crucial because it better captures the overall strategy and philosophy of the research, even though meta-analyses offer more valid input [20].

A number of challenges have been brought about by the overabundance of information available in biomedical journals, including publication or selection bias and the retraction of invalid literature [21][22]. In order to evaluate the benefits and drawbacks of the RCTs that serve as the foundation for clinical practice and treatment guidelines, readers must be aware of the perceived quality of the methods being employed [22].

The CONSORT (Consolidated Standards of Reporting Trials) Statement was developed in 1996 by an international group of experts with the goal of improving the reporting's purity [14]. There were two more revisions in 2001 and 2010, each with a comprehensive set of justification and elaboration documents [15][16]. This statement is a set of evidence-based recommendations that includes a flow diagram with reporting that prevents the omission of crucial information and a checklist with 37 items [16]. Because of this, a growing number of journals recommend that readers adhere to the CONSORT statement in order to raise the bar for reporting standards [17].

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Therefore, the goal of the current study was to determine whether RCTs complied with the CONSORT Statement, thereby evaluating the quality of data reporting that impacts clinical practice by informing current treatment guidelines.

4 Methods

The goal of the current study is to evaluate the quality of data reporting that informs current treatment guidelines and, in turn, impacts clinical practice. Specifically, it will evaluate the compliance of RCTs with the CONSORT Statement. Currently, there is no knowledge regarding the quality of reporting of RCTs that investigate the efficacy of curcumin for treating depression.

4.1 Data sources and search strategies

The Cochrane Library and PubMed databases were used to organize an electronic structured literature search. Our aim was to locate relevant randomized controlled trials that were released between 1996 and 2019.

The following terms have been replicated in the implemented combination:

((curcumin) OR (curcuma)) AND (depression)

The Randomized Controlled Trial article type, the English language, and the human species filter restricted our PubMed search.

4.2 Eligibility of studies

First, the study title will be visually inspected, then the abstract, and finally the entire document will be examined to ascertain the study's eligibility.

Eligible studies will be those that

- include patients diagnosed with depression or have depressive symptoms.
- Studies that included patients with other physical illnesses or not diagnosed with depression will not be excluded since we focused on the overall effect of curcumin treatment on depressive symptoms.
- Depression was diagnosed according to standard diagnostic criteria, such as ICD-10. Depressive symptoms will be measured according to standardized scales.

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- Curcumin will be performed at any dosage in the intervention group and placebo plus standard care or standard care alone in the comparison group.

Exclusion criteria will be:

- animal studies
- reviews, and systematic reviews
- meta-analyses
- non- randomized s t u d i e s
- follow-up studies of previously published trials
- economic analyses
- safety analyses
- dose-comparison studies
- small pilot studies
- abstracts
- protocols
- editorials

4.3 Report assessment tool

We made use of the 37-item CONSORT checklist, which has been revised. Our process was guided by the CONSORT explanation and elaboration document. [1]. CONSORT covers every facet of a properly conducted clinical trial and offers instructions for each section of an RCT article, including the title, introduction, methods, results, and funding.

4.4 Methodological evaluation

Using the updated CONSORT version from 2010, we examined each of the chosen articles individually throughout the evaluation process. Every item received one of the following scores: "yes," which is worth one point when reported accurately; "no," or "unclear." 0 points for incomplete or nonexistent reporting. An item was regarded as a positive response if it was reported in a different trial section. Items with statements like "When applicable" (7b), "If done" (11a), or "If relevant" (11b) on the CONSORT checklist were marked as "non-applicable" if the response was unambiguously yes or no; the answers to these items were then analyzed accordingly. As a result, a score between 0 and 37 was generated.

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Publication year, journal ranking (5-year Journal Impact Factor -IF- published in 2020 by Clarivate Analytics via Journal Citation Reports), first author's name, and sample were among the extra details provided.

4.5 Outcome measures and statistical analysis

The mean CONSORT adherence of RCTs using curcumin to treat depression served as the main outcome measure. The cutoff was defined as compliance with the CONSORT items of more than 75% [2][3]. The determination of potential contributing factors to the reporting quality of RCTs and the computation of adherence per CONSORT item were secondary objectives.

Every parameter was examined as a categorical variable: sample size (≤58, >58 based on our sample median), IF (≤4.75, >4.75 based on our sample median). Pearson's chi squared test was employed for the univariate analysis (Fisher's exact test was used if any of the cell expected values were less than 5). A cut-off value of 0.20 was arbitrarily selected as the relaxed p-value to enter the binary logistic regression. The criterion for significance was set at the significance level of 0.05. Displayed are the odds ratios (ORs), p-value, and 95% confidence intervals (95% Cls). To investigate a potential linear relationship between IF and sample size and reporting quality, Spearman's rank correlation was used. Version 29 of IBM SPSS Statistics Software released

4.6 Ethical view

Since this study did not involve human subjects and the included RCT abstracts could be obtained from databases, ethics committee approval was not warranted.

5 Results

723 studies were first retrieved using the chosen databases (Pubmed and Cochrane library). After eliminating duplicates, 335 records were left.

After a review of the abstract and title, thirteen papers were determined to be potentially qualified. Ultimately, these studies' entire texts were reviewed, and ten of them were picked for additional evaluation. The search strategy's five steps are shown in a CONSORT flow diagram in Figure 1.

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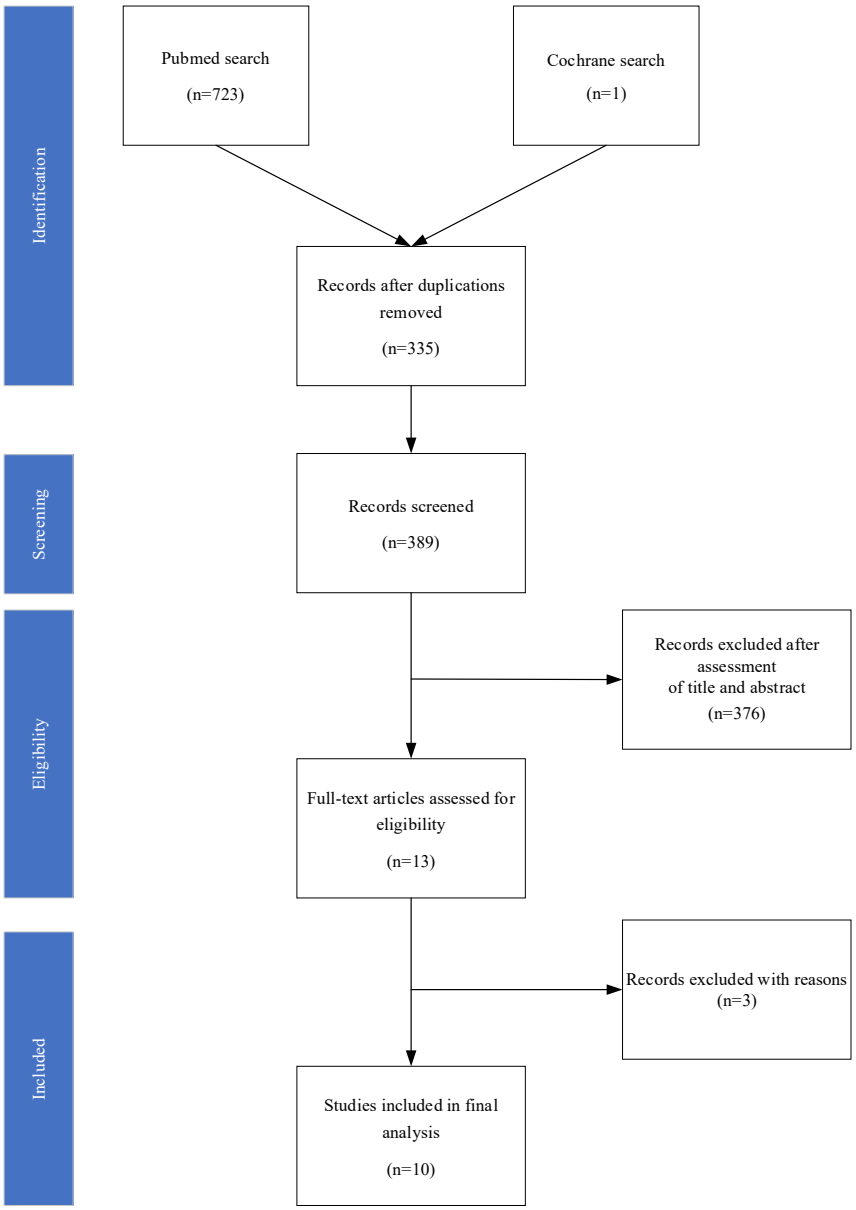
Figure 1: CONSORT flow diagram



5.1 CONSORT adherence

According to the CONSORT statement, the mean compliance for RCTs was determined to be 47.03% with SD = 16.23% (Median = 51.35%; the minimum and maximum adherence were 18.92% and 64.86%,

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respectively). Less than 75% of the items in all ten trials (100%) had insufficient reporting. The mean proportion of adherence to the CONSORT statement for each study are presented in Table 1 and Figure 2.

Table 1: List of RCTs along with the CONSORT score

Article	Medical Journal	Year	Mean compliance score (%)
Jing-Jie Yu et. al [4]	Journal of Clinical Psychopharmacology	2015	32.43
Chanoch Miodownik et. al [5]	Clinical Neuropharmacology	2019	64.86
Joseph Bergman et. al [6]	Clinical Neuropharmacology	2013	59.46
Habibollah Esmaily et. al [7]	Chinese Journal of Integrative Medicine	2015	29.73
Adrian L. Lopresti et. al [8]	Journal of Affective Disorders	2014	51.35
Adrian L. Lopresti et. al [9]	Journal of Affective Disorders	2016	59.46
Jayesh Sanmukhani et. al [10]	PHYTOTHERAPY RESEARCH	2013	51.35
Sara Asadi et. al [11]	Phytotherapy Research	2019	64.86
A. J. RUSH et. al [12]	Psychological Medicine	1996	18.92
Maria Caecilia N. Setiawati et. al [13]	Indonesian Journal of Pharmacy	2018	37.84

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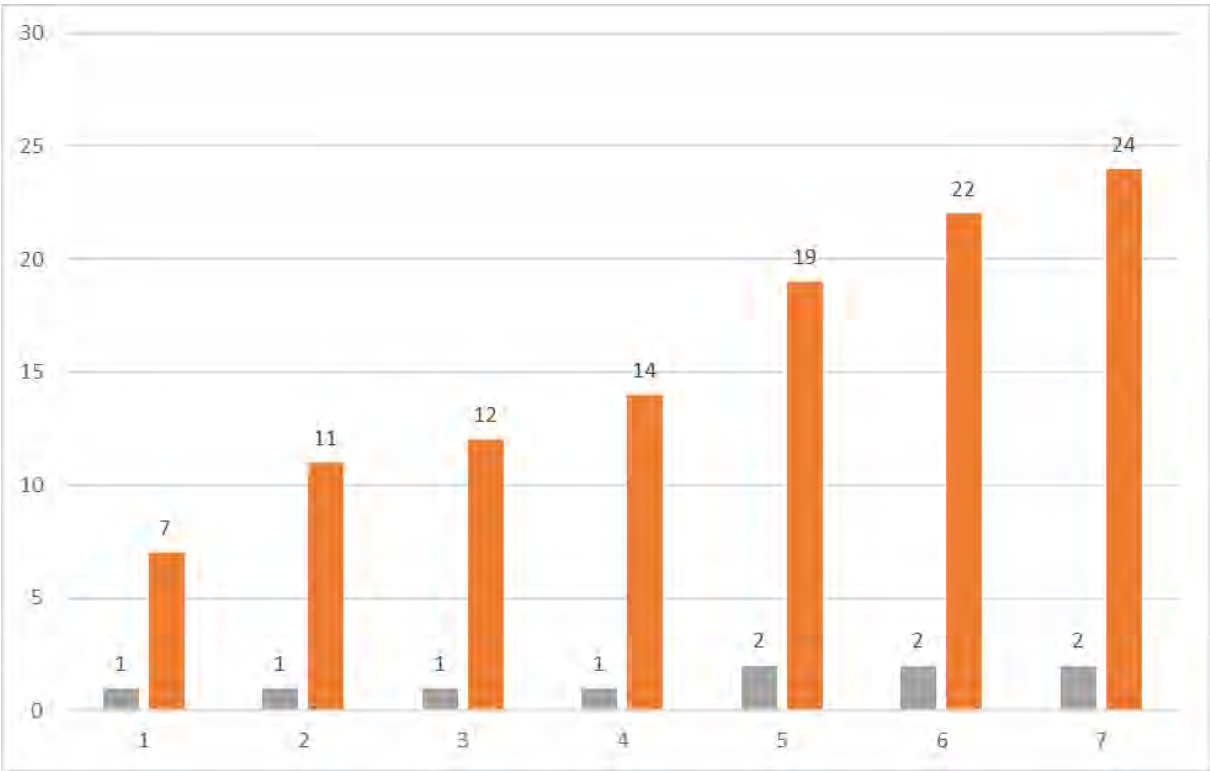
Figure 2: Distribution of the total CONSORT scores of the 10 studies



An estimate of adherence was made for each CONSORT item (Table 2, Figure 3). In particular, only 11 of the 37 checklist items (29.73%) were reported by 75% or more of the studies, whereas 6 of the 37 items (16.22%) were recorded in all (100%) of the publications.

The compliance scores, as reflected in the Table 2, offer an insightful overview of reporting quality within ten evaluated Randomized Controlled Trials (RCTs), and they underscore notable strengths and areas for improvement across specific checklist items. For instance, items related to the scientific background and rationale (Item 2a) and eligibility criteria for participants (Item 4a) demonstrate robust compliance at 100%. However, aspects like explaining changes to trial outcomes (Item 6b) and describing the similarity of interventions (Item 11b) show limited compliance at 0%. This variability highlights the imperative need for standardized reporting guidelines and ongoing efforts to bolster the transparency and comprehensiveness of research reporting in clinical trials. It further emphasizes the importance of addressing specific items, such as providing rationale for sample size determination (Item 7a) and justifying trial termination (Item 14b), to ensure that research findings maintain their credibility and reliability within the clinical trial domain.

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Table 2: Adherence per CONSORT item

	Item No	Checklist item	Complianc (%)
Title and abstract	1a	Identification as a randomized trial in the title	80%
	1b	Structured summary of trial design, methods, results, and conclusions	80%
Introduction	2a	Scientific background and explanation of the rationale	100%
	2b	Specific objectives or hypotheses	70%
Methods	3a	Description of trial design (such as parallel, factorial) including allocation ratio	60%
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	10%
	4a	Eligibility criteria for participants	100%
	4b	Settings and locations where the data were collected	100%
	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	80%
	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	100%
	6b	Any changes to trial outcomes after the trial commenced, with reasons	0%
	7a	How sample size was determined?	10%
	7b	When applicable, explanation of any interim analyses and stopping guidelines	10%
	8a	The method used to generate the random allocation sequence	30%
	8b	Type of randomization; details of any restriction (such as blocking and block size)	30%
	9	The mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	40%
	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	10%

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	11a	If done, who was blinded after assignment to interventions (e.g., participants, care providers, those assessing outcomes) and how	20%
	11b	If relevant, description of the similarity of interventions	0%
	12a	Statistical methods used to compare groups for primary and secondary outcomes	100%
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	10%
Results	13a	For each group, the numbers of participants who were randomly assigned received intended treatment and were analyzed for the primary outcome	80%
	13b	For each group, losses and exclusions after randomization, together with reasons	60%
	14a	Dates defining the periods of recruitment and follow-up	20%
	14b	Why the trial ended or was stopped	0%
	15	A table showing the baseline demographic and clinical	100%
	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	60%
	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	40%
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	10%
	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	10%
	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	70%
Discussion	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, the multiplicity of analyses	80%
	21	Generalizability (external validity, applicability) of the trial findings	10%
	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	60%
Other information	23	Registration number and name of trial registry	50%
	24	Where the full trial protocol can be accessed, if available	0%

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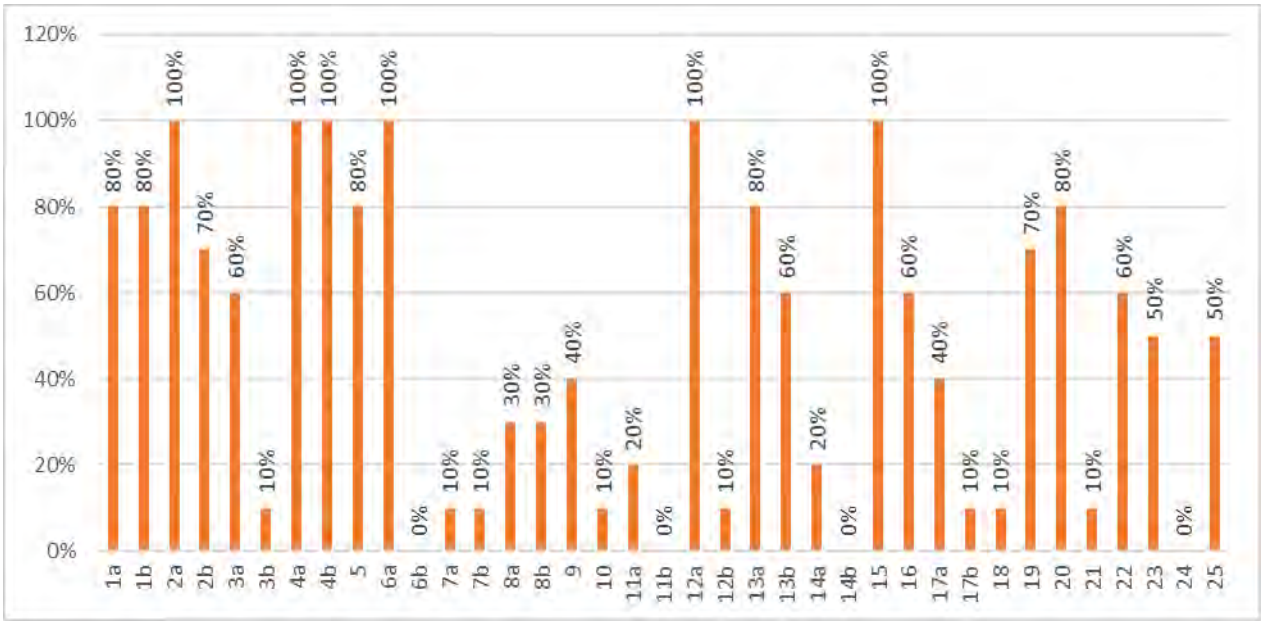
	25	Sources of funding and other support (such as the supply of drugs), the role of funders	50%

Figure 3: Graphical presentation of adherence per CONSORT item



5.2 Determinants of reporting quality

Ten RCTs were identified for the assessment of reporting quality using the CONSORT statement. None of these studies achieved a reporting quality score exceeding 75%. The percentage scores for individual studies ranged from 18.92% to 64.86%, indicating substantial gaps in reporting various key aspects of the trials.

The associations between sample size and impact factor, were analyzed using Pearson's chi-square test to investigate their potential influence on reporting quality. The results for both analyses revealed non-statistically significant associations ($p>0.05$), indicating that there were no significant relationships between these variables and CONSORT percent scores.

The odds ratios calculated for both sample size (OR=1.00, 95% CI: 0.80-12.56) and impact factor (OR=1.00, 95% CI: 0.80-12.56) further supported these findings by showing no significant relationships with reporting quality. Results are summarized at Table 3.

Given that both sample size and impact factor did not exhibit any significant association ($p<0.20$) with reporting quality when assessed individually, they are not considered meaningful predictors in our logistic regression model.

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Table 3: Univariate analysis of possible determinants of reporting quality

Parameter	OR	95 CI	p-value
Sample size (>58=median)	1.00	0.80-12.56	1.00
Impact Factor (>4.75=median)	1.00	0.80-12.56	1.00

OR odds ratio, 95% CI 95% confidence interval, IF impact factor

In our analysis, we additionally considered the impact factors as a scale variable, allowing us to assess any potential linear relationships between impact factors and reporting quality (Table 4). We observed a spectrum of impact factors among the selected journals, ranging from 0.18-7.20.

To explore the potential relationship between journal impact factors and reporting quality, we conducted a Spearman's rank correlation analysis. However, the analysis did not reveal a statistically significant correlation (Figure 4) between journal impact factors and the reporting quality scores of the RCTs (Spearman's ρ=0.01, p-value=0.97).

The non-significant correlation coefficient (ρ) suggests that, in this specific context, there may not be a strong linear relationship between the journals' impact factors and the reporting quality of the RCTs. This finding, while not statistically significant, still provides valuable insight into the complex interplay of factors influencing research reporting.

The following summary provides an overview of the journals' impact factors alongside the corresponding reporting quality scores:

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Table 4: Impact factors of the journals in which these RCTs were published

Journal Name	Impact Factor	Mean compliance score (%)
Journal of Clinical Psychopharmacology	1.38	32.43
Clinical Neuropharmacology	1.00	64.86
Clinical Neuropharmacology	1.00	59.46
Chinese Journal of Integrative Medicine	2.90	29.73
Journal of Affective Disorders	6.60	51.35
Journal of Affective Disorders	6.60	59.46
PHYTOTHERAPY RESEARCH	7.20	51.35
Phytotherapy Research	7.20	64.86
Psychological Medicine	6.90	18.92
Indonesian Journal of Pharmacy	0.176	37.84

This dual analysis underscores the potential impact of the choice of journal on the reporting quality of RCTs, offering a valuable perspective on the relationship between publication venue and research rigor.

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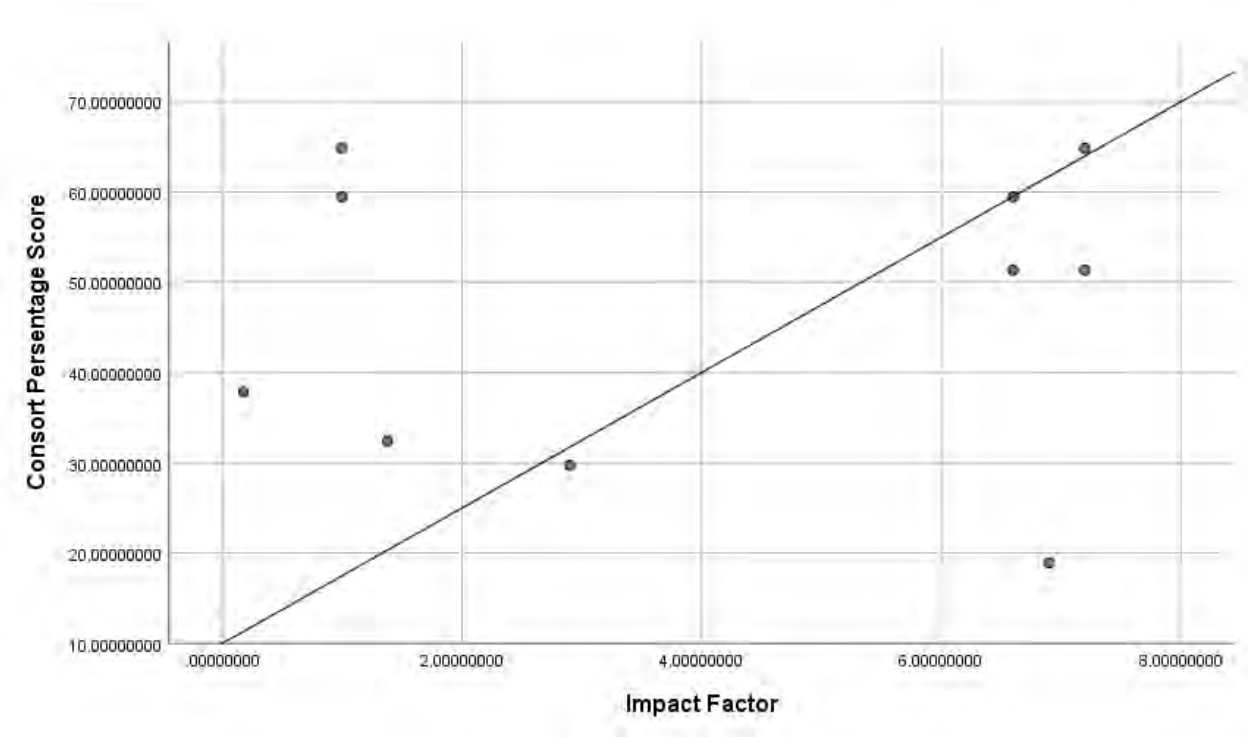
Figure 4: Scatterplot showing the relationship between reporting quality and Impact Factor



Additionally, we examined the relationship between the publication year of the RCTs and the CONSORT scores to investigate potential trends in reporting quality over time. However, our findings revealed that there was no statistically significant relationship between publication year and CONSORT scores (Spearman's ρ=0.56, p-value=0.09).

This result signifies that there was no clear and consistent trend in the reporting quality over time. It implies that, within the parameters of our analysis, reporting quality, as determined by CONSORT scores, has neither appreciably increased or decreased over time.

The absence of a noteworthy chronological pattern is consistent with our previous examination of the association between journal impact factors and CONSORT scores, which likewise failed to produce a statistically significant correlation ($p>0.05$). All of these findings demonstrate how complicated the variables affecting reporting quality are and how important it is to use a variety of methods to evaluate and improve study adherence to CONSORT recommendations.

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CONSORT 2010 checklist		
Section/topic	**Item number**	**Checklist item**
Title and abstract	1a	Identification as a randomized trial in the title
	1b	Structured summary of trial design, methods, results, and conclusions
Introduction		
Background and objectives	2a	Scientific background and explanation of the rationale
	2b	Specific objectives or hypotheses
Methods		
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons
Participants	4a	Eligibility criteria for participants
	4b	Settings and locations where the data were collected
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed
	6b	Any changes to trial outcomes after the trial commenced, with reasons
Sample size	7a	How sample size was determined?
	7b	When applicable, explanation of any interim analyses and stopping guidelines
Randomization		
Sequence generation	8a	The method used to generate the random allocation sequence
	8b	Type of randomization; details of any restriction (such as blocking and block size)
Allocation concealment mechanism	9	The mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned

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CONSORT 2010 checklist		
Section/topic	**Item number**	**Checklist item**
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions
Blinding	11a	If done, who was blinded after assignment to interventions (e.g., participants, care providers, those assessing outcomes) and how
	11b	If relevant, description of the similarity of interventions
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses
Results		
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned received intended treatment and were analyzed for the primary outcome
	13b	For each group, losses and exclusions after randomization, together with reasons
Recruitment	14a	Dates defining the periods of recruitment and follow-up
	14b	Why the trial ended or was stopped
Baseline data	15	A table showing the baseline demographic and clinical characteristics for each group
Numbers analyzed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)
Discussion		
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, the multiplicity of analyses

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CONSORT 2010 checklist		
Section/topic	**Item number**	**Checklist item**
Generalizability	21	Generalizability (external validity, applicability) of the trial findings
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence
Other information		
Registration	23	Registration number and name of trial registry
Protocol	24	Where the full trial protocol can be accessed, if available
Funding	25	Sources of funding and other support (such as the supply of drugs), the role of funders

6 Discussion

Using the CONSORT statement, we evaluated the reporting quality of the ten identified Randomized Controlled Trials (RCTs) and found a worrying pattern. A reporting quality score of more than 75% was attained by none of the studies (100%) with individual percentage values ranging from 18.92% to 64.86%. This large range highlights the significant gaps in the reporting of several important trial components, highlighting the pressing need for better reporting guidelines in this field of study.

In an attempt to gain a deeper understanding of the variables influencing reporting quality, we looked at the possible contributions of sample size (OR=1.00, 95% CI: 0.80-12.56) and journal impact factor (OR=1.00, 95% CI: 0.80-12.56). However, the results of these analyses indicated that no associations were statistically significant ($p>0.05$). Whenever we looked at journal impact factor or sample size, the odds ratios that were computed and the Pearson's chi-square tests never showed any significant correlations with reporting quality. These results imply that, within the parameters of our study, neither journal prestige nor sample size were significant predictors of reporting quality in the RCTs that were included.

We also took into account journal impact factors as a scale variable in an effort to gain a more thorough understanding. This allowed us to look at possible linear links between impact factors and reporting quality. This method revealed a wide range of impact factors, from 0.18 to 7.20, in the chosen journals.

A statistically significant association between journal impact factors and the reporting quality scores of the RCTs was not shown by our Spearman's rank correlation analysis, despite this wide range (Spearman's $\rho=0.01$, p-value=0.97). The non-significant correlation coefficient (ρ) indicates that there might not be a

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strong linear association between the impact factors of the journals and the RCTs' reporting quality in this particular context. Even though this discovery was not statistically significant, it nonetheless offers important insights into the complex interactions between several factors that affect study reporting.

In addition, we investigated the temporal dimension of reporting quality and looked at possible trends over time. Nevertheless, there was no statistically significant temporal trend found in our examination of the association between the CONSORT scores and the RCTs' publication year (Spearman's $\rho=0.56$, p-value=0.09). This suggests that, within the parameters of our research, reporting quality, as determined by CONSORT scores, did not show a clear and consistent pattern of progress or deterioration over time.

Together, our findings highlight the complex interplay between several factors that affect reporting quality in randomized controlled trials. It is important to recognize the possible impact of unanalyzed variables and the larger contextual factors that may affect reporting quality, even if neither sample size nor journal impact factor showed up as major predictors in this research. Our results highlight the need for a systematic strategy to improve research adherence to CONSORT principles, taking into account both the quantitative and wider components of study reporting.

7 Conclusion

In our assessment of reporting quality within ten Randomized Controlled Trials (RCTs) employing the CONSORT statement, we observed a consistent deficiency in reporting standards, with none of the studies achieving a score above 75%. The analyses of sample size and journal impact factor did not reveal statistically significant associations with reporting quality. Furthermore, our exploration of temporal trends found no discernible pattern.

These findings emphasize the imperative need for improved adherence to CONSORT guidelines and a more comprehensive approach to enhancing research reporting. The study underscores the significance of meticulous reporting for the credibility and transparency of research, particularly in the context of curcumin's efficacy for depression disorders.

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8 References

[1]. Hopewell S, Clarke M, Moher D, Wager E, Middleton P, Altman DG, et al. CONSORT for Reporting Randomized Controlled Trials in Journal and Conference Abstracts: Explanation and Elaboration. PLoS Medicine. 2008 Jan22;5(1):e20.

[2]. Rikos D, Dardiotis E, Aloizou A-M, Siokas V, Zintzaras E, Hadjigeorgiou GM. Reporting Quality of Randomized Controlled Trials in Restless Legs Syndrome 17 Based on the CONSORT Statement. Tremor and other hyperkinetic movements (New York, NY). 2019;9.

[3]. Beneki E, Vrysis C, Zintzaras E, Doxani C. Analysis of the quality of reporting of randomized controlled trials in anticoagulant versus antiplatelet medication for venous thromboembolism prophylaxis as governed by the CONSORT statement. Journal of Thrombosis and Thrombolysis. 2021 Jul 17;52(1):138–47.

[4]. Yu JJ, Pei LB, Zhang Y, Wen ZY, Yang JL. Chronic Supplementation of Curcumin Enhances the Efficacy of Antidepressants in Major Depressive Disorder: A Randomized, Double-Blind, Placebo-Controlled Pilot Study. J Clin Psychopharmacol. 2015 Aug;35(4):406-10. doi: 10.1097/JCP.0000000000000352. PMID: 26066335.

[5]. Miodownik C, Lerner V, Kudkaeva N, Lerner PP, Pashinian A, Bersudsky Y, Eliyahu R, Kreinin A, Bergman J. Curcumin as Add-On to Antipsychotic Treatment in Patients With Chronic Schizophrenia: A Randomized, Double-Blind, Placebo-Controlled Study. Clin Neuropharmacol. 2019 Jul/Aug;42(4):117-122. doi: 10.1097/WNF.0000000000000344. PMID: 31045590.

[6]. Bergman J, Miodownik C, Bersudsky Y, Sokolik S, Lerner PP, Kreinin A, Polakiewicz J, Lerner V. Curcumin as an add-on to antidepressive treatment: a randomized, double-blind, placebo-controlled, pilot clinical study. Clin Neuropharmacol. 2013 May-Jun;36(3):73-7. doi: 10.1097/WNF.0b013e31828ef969. PMID: 23673908.

[7]. Esmaily H, Sahebkar A, Iranshahi M, Ganjali S, Mohammadi A, Ferns G, Ghayour-Mobarhan M. An investigation of the effects of curcumin on anxiety and depression in obese individuals: A randomized controlled trial. Chin J Integr Med. 2015 May;21(5):332-8. doi: 10.1007/s11655-015-2160-z. Epub 2015 Mar 17. PMID: 25776839.

[8]. Lopresti AL, Maes M, Maker GL, Hood SD, Drummond PD. Curcumin for the treatment of major depression: a randomised, double-blind, placebo controlled study. J Affect Disord. 2014;167:368-75. doi: 10.1016/j.jad.2014.06.001. Epub 2014 Jun 11. PMID: 25046624.

Institutional Repository - Library & Information Centre - University of Thessaly
01/09/2026 01:41:00 EEST - 216.73.216.156

[9]. Lopresti AL, Drummond PD. Efficacy of curcumin, and a saffron/curcumin combination for the treatment of major depression: A randomised, double-blind, placebo-controlled study. J Affect Disord. 2017 Jan 1;207:188-196. doi: 10.1016/j.jad.2016.09.047. Epub 2016 Oct 1. PMID: 27723543.

[10]. Sanmukhani J, Satodia V, Trivedi J, Patel T, Tiwari D, Panchal B, Goel A, Tripathi CB. Efficacy and safety of curcumin in major depressive disorder: a randomized controlled trial. Phytother Res. 2014 Apr;28(4):579-85. doi: 10.1002/ptr.5025. Epub 2013 Jul 6. PMID: 23832433.

[11]. Asadi S, Gholami MS, Siassi F, Qorbani M, Sotoudeh G. Beneficial effects of nano-curcumin supplement on depression and anxiety in diabetic patients with peripheral neuropathy: A randomized, double-blind, placebo-controlled clinical trial. Phytother Res. 2020 Apr;34(4):896-903. doi: 10.1002/ptr.6571. Epub 2019 Dec 1. PMID: 31788880.

[12]. Rush AJ, Gullion CM, Basco MR, Jarrett RB, Trivedi MH. The Inventory of Depressive Symptomatology (IDS): psychometric properties. Psychol Med. 1996 May;26(3):477-86. doi: 10.1017/s0033291700035558. PMID: 8733206.

[13]. Setiawati, Mia et al. "EFFECT OF Curcuma xanthorrhiza Roxb . EXTRACT ON TNF α CONCENTRATION AND DEPRESSION ' S SCORE IN PATIENT WITH SYSTEMIC LUPUS ERYTHEMATOSUS." (2018).

[14]. Begg C. Improving the Quality of Reporting of Randomized Controlled Trials. JAMA. 1996 Aug 28;276(8):637.

[15]. Moher D. The CONSORT Statement: Revised Recommendations for Improving the Quality of Reports of Parallel-Group Randomized Trials. JAMA. 2001 Apr 18;285(15):1987.

[16]. Moher D, Hopewell S, Schulz KF, Montori V, Gøtzsche PC, Devereaux PJ, et al. CONSORT 2010 explanation and elaboration: Updated guidelines for reporting parallel group randomised trials. International Journal of Surgery. 2012;10(1):28–55.

[17]. Stevens A, Shamseer L, Weinstein E, Yazdi F, Turner L, Thielman J, et al. Relation of completeness of reporting of health research to journals' endorsement of reporting guidelines: systematic review. BMJ (Clinical research ed). 2014 Jun 25;348:g3804.

[18]. Fava, M., 2003. Diagnosis and definition of treatment-resistant depression. Bioi. Psychiatry 53 (8), 649-59.

[19]. Bonadonna G, Valagussa P. Influence of clinical trials on current treatment strategy for Hodgkin's disease. International Journal of Radiation Oncology*Biology*Physics. 1990 Jul;19(1):209–18.

[20]. Stolberg HO, Norman G, Trop I. Randomized Controlled Trials. American Journal of Roentgenology. 2004 Dec;183(6):1539–44.

Institutional Repository - Library & Information Centre - University of Thessaly
01/09/2026 01:41:00 EEST - 216.73.216.156

[21]. Pfeifer MP. The Continued Use of Retracted, Invalid Scientific Literature. JAMA: The Journal of the American Medical Association. 1990 Mar 9;263(10):1420.

[22]. 23. Djulbegovic B, Loughran TP, Hornung CA, Kloecker G, Efthimiadis EN, Hadley TJ, et al. The quality of medical evidence in hematology-oncology. The American journal of medicine. 1999 Feb;106(2):198–205.

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