

# INPLASY PROTOCOL

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**Support:** None.

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

## Quality of Abstracts in Randomized Controlled Trials Published in Leading Critical Care Nursing Journals

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**Review question / Objective:** This review aims to evaluate the methodological quality of RCT-abstracts in leading critical care nursing journals. A methodological quality review with the Consolidated Standards of Reporting Trials (CONSORT) criteria will be performed in RCT-abstracts published between 2011-2021 in the first Scopus-ranking (2021) nursing journals.

**Eligibility criteria:** Abstracts of scientific articles will be included if they fulfil the following inclusion criteria: 1) they report the results of parallel and/or cross-over group RCTs, 2) they are written in English, 3) they refer to the care of adult patients with acute/critical illness or conducted in adult ICUs. Manuscripts reporting results of pilot or feasibility studies, cluster trials, observational or cohort studies, interim analyses, economic analyses of RCTs, post-trial follow-up studies, subgroup and secondary analyses of previously published RCTs, editorials and RCTs without an abstract such as RCTs published as letters to the editor, single-subject clinical trials will be excluded.

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 09 June 2022 and was last updated on 09 June 2022 (registration number INPLASY202260039).

### INTRODUCTION

**Review question / Objective:** This review aims to evaluate the methodological quality of RCT-abstracts in leading critical care nursing journals. A methodological quality review with the Consolidated Standards of Reporting Trials (CONSORT) criteria will be performed in RCT-abstracts published

between 2011-2021 in the first Scopus-ranking (2021) nursing journals.

**Rationale:** Randomised controlled trials (RCTs) are the methodologically most powerful designs for testing cause-effect hypotheses. They represent the gold-standard for treatment studies and for evaluating the effectiveness of a nursing

intervention. RCTs generate high-quality evidence available to clinicians to evaluate the effectiveness of nursing interventions. However, RCTs that lack methodological rigor and adequate reporting lead to biased estimates of treatment effectiveness. In the absence of clear reporting, clinicians may misinterpret the results and misapply the study interventions to their clinical practice. Following the increased interest in quality reporting, an international group in 2010 updated the Consolidated Standards of Reporting Trials (CONSORT) Statement, i.e. the set of reporting guidelines, identifying the most important elements that should be reported by authors when an RCT is published. Its use is strongly promoted by most scientific journals and has been associated with better quality reporting. A section on abstracts, consisting of 17-items (CONSORT-A) and developed in 2008, was integrated into the 2010 statement with the aim of promoting clear, transparent and sufficiently detailed abstracts. The abstract is a fundamental element of scientific reporting. It is a brief, selective summary of the research and is often the initial source on which the decision is made whether or not to read the full paper. It should include the key information of the study so that readers can adequately assess the validity and generalisability of the results and possibly apply them in their own clinical context. Furthermore, access to the abstract is free of charge. Many trials published in nursing and other journals provide insufficient information and do not report the key points for quality reporting. It has also been shown that the reporting of abstracts of RCTs in nursing and other discipline journals, even of high scientific value, is sometimes inadequate. The production and use of research is considered to be of paramount importance for nurses in ICUs, as the possibility of providing high quality, cost-effective and up-to-date nursing care also depends very much on the use of scientific research results in clinical practice, as was also shown in the recent SARS-CoV-2 pandemic. The absence of quality reporting of abstracts in the field of critical care nursing research could therefore lead to

misleading interpretations of the results, with negative implications for nurses' clinical decisions. To the best of our knowledge, there is still no information available regarding the volume and quality of reporting of abstracts of RCTs in this specific subject area.

**Condition being studied:** This study will be a methodological and descriptive review aimed at analysing the abstracts of published studies reporting the results of RCTs in intensive care nursing journals.

## METHODS

**Search strategy:** An in-depth search in MEDLINE via PubMed of RCTs published in the years between 1 January 2011 and 1 January 2022 in the journals listed above will be conducted. The search will be performed by two authors who are experts in literature search via PubMed using the Cochrane Highly Sensitive Search Strategy for identifying randomised trials adapted for MEDLINE using a temporal filter. To improve the sensitivity of the search, an additional search will also be performed on the web page of each journal by searching through Advanced Search mode, when available, for the term 'randomised controlled trial' in the title field. Any duplicate abstracts after merging the results of the two searches were removed with the appropriate functionality of the EndNote 20 software (Clarivate Analytics).

**Participant or population:** The abstracts of the RCTs will be searched in intensive care nursing journals according to the ranking published by Scopus for the year 2021 and which are indexed in Medline. In order of ranking they are: Nursing in Critical Care, Intensive and Critical Care Nursing, Australian Critical Care, American Journal of Critical Care, Critical Care Nurse, Dimensions of Critical Care Nursing, Critical Care Nursing Clinics of North America, Journal of Trauma Nursing, Enfermeria Intensiva, AACN Advanced Critical Care, and Critical Care Nursing Quarterly. As AACN Advanced Critical Care replaced the journal AACN Clinical Issues

in 2013, the search string will also include the name of the former journal.

**Intervention:** Not applicable.

**Comparator:** Not applicable.

**Study designs to be included:** Randomised controlled trials.

**Eligibility criteria:** Abstracts of scientific articles will be included if they fulfil the following inclusion criteria: 1) they report the results of parallel and/or cross-over group RCTs, 2) they are written in English, 3) they refer to the care of adult patients with acute/critical illness or conducted in adult ICUs. Manuscripts reporting results of pilot or feasibility studies, cluster trials, observational or cohort studies, interim analyses, economic analyses of RCTs, post-trial follow-up studies, subgroup and secondary analyses of previously published RCTs, editorials and RCTs without an abstract such as RCTs published as letters to the editor, single-subject clinical trials will be excluded.

**Information sources:** In order to include only abstracts meeting the inclusion and exclusion criteria in the analysis, the bibliographic records identified by the search string were examined independently by two authors. When the title or abstract were insufficient to determine eligibility, the full text was evaluated. Disagreements were resolved through discussion with a third author until consensus was reached.

**Main outcome(s):** The aim of the present work is to assess the quality of reporting of abstracts of randomised controlled trials published in the last ten years in the leading journals of intensive care nursing by checking for the presence of the items on the CONSORT-A checklist. Possible factors associated with the quality of abstract reporting will also be explored.

**Additional outcome(s):** Not applicable.

**Data management:** Identified abstracts were archived in EndNote X20 and

subsequently imported into a dataset in Excel.

**Quality assessment / Risk of bias analysis:** Not applicable.

**Strategy of data synthesis:** The quality of the reporting of the abstracts was assessed by verifying that the 17 items of the CONSORT-A statement are adequately reported in the text of the abstract. Each individual item was assigned a score of 1 if the item is adequately reported, otherwise 0 if deemed inadequate. For each abstract, the Overall Score of CONSORT-A (OSCA) was calculated by summing the result of the evaluation of the 17 items. Items (#4) Participants, (#8) Randomization, (#9) Blinding, (#13) Outcome results will receive the full score (1 pt.) only if the criteria were completely fulfilled, otherwise if only one criterion was fulfilled the score will be 0.5 pt.

**Subgroup analysis:** Not applicable.

**Sensitivity analysis:** Not applicable.

**Language:** English.

**Country(ies) involved:** Switzerland and Italy.

**Other relevant information:** Not applicable.

**Keywords:** Abstract; CONSORT; Randomized Controlled Trial; Reporting Quality; Nursing Research.

**Contributions of each author:**

**Author 1 - Michele Villa -** Conducting the study selection process; formal screening of research results against eligibility criteria; data extraction; analysis and evaluation of abstracts; drafting the research protocol.

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**Author 3 - Michela Bottega -** Supervision of the research and data extraction process,

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**Resolution of disagreements in the abstract inclusion and evaluation.**

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**Conflicts of interest:** All authors declare that they have no known competing financial interests or personal relationships with industry or organization that could have influenced the work reported in this paper.