QUALITY OF RANDOMIZED CLINICAL TRIAL REPORTS ON VIRTUAL REALITY DURING PERIPHERAL INTRAVENOUS CATHETERIZATION/VENIPUNCTURE

QUALIDADE DOS RELATOS DE ENSAIOS CLÍNICOS RANDOMIZADOS SOBRE REALIDADE VIRTUAL DURANTE PUNÇÃO/CATETERISMO INTRAVENOSO PERIFÉRICO

CALIDAD DE LOS INFORMES DE ENSAYOS CLÍNICOS ALEATORIZADOS SOBRE REALIDAD VIRTUAL DURANTE PUNCIÓN/CATETERISMO INTRAVENOSO PERIFÉRICO

ABSTRACT
Objective: to evaluate the quality of reports of randomized clinical trials on virtual reality during peripheral venous catheterization. Method: an evaluative study, conducted in two stages: scoping review, to identify randomized clinical trials on the subject, published in Cochrane, Cumulative Index to Nursing and Allied Health Literature, Embase, PubMed® and Latin American and Caribbean Health Sciences Literature databases; and quality assessment of the reports of randomized clinical trials, using the Consolidated Standards of Reporting Trials. Data were analyzed using descriptive and inferential statistics, and the Kappa Test was applied. Results: a total of 291 studies were found, eight of which were included. Of these, 75% showed good quality reporting, partially meeting the items previously defined as necessary. Conclusion: the articles presented good quality reports, but there is a need for improvement in the description of the items.
Descriptors: Virtual Reality; Catheterization, Peripheral; Blood Specimen Collection; Clinical Trial; Nursing

RESUMO
Objetivo: avaliar a qualidade dos relatos de ensaios clínicos randômicos sobre realidade virtual durante a punção/cateterismo venoso periférico. Método: estudo avaliativo, realizado em duas etapas: revisão de escopo, no intuito de identificar ensaios clínicos randômicos sobre a temática, publicados nas bases de dados Cochrane, Cumulative Index to Nursing and Allied Health Literature, Embase, PubMed® e Literatura Latino-Americana e do Caribe em Ciências da Saúde; e avaliação do qualidade dos relatos dos ensaios clínicos randômicos, utilizando-se do Consolidated Standards of Reporting Trials. Os dados foram analisados por meio de estatística descritiva e inferencial, sendo aplicado o Teste Kappa. Resultados: o total de estudos encontrados foram 291, sendo incluídos oito; destes, 75% apresentaram boa qualidade do relato, atendendo parcialmente os itens previamente definidos como necessários. Conclusão: os artigos apresentaram boa qualidade no relato, porém há necessidade de melhora na descrição dos itens.
Descritores: Realidade Virtual; Cateterismo Periférico; Coleta de Amostras Sanguíneas; Ensaio Clínico, Enfermagem.
RESUMEN

**Objetivo:** evaluar la calidad de los informes de ensayos clínicos aleatorizados sobre realidad virtual durante la punción/cateterismo venoso periférico. **Método:** estudio evaluativo, realizado en dos etapas: scoping review, con el fin de identificar ensayos clínicos aleatorizados sobre el tema, publicados en las bases de datos Cochrane, Cumulative Index to Nursing and Allied Health Literature, Embase, PubMed® y Literatura Latinoamericana y del Caribe en Ciencias de la Salud; y evaluación de la calidad de los informes de ensayos clínicos aleatorios, utilizando los Consolidated Standards of Reporting Trials. Los datos fueron analizados mediante estadística descriptiva e inferencial, utilizando la prueba de Kappa. **Resultados:** el total de estudios encontrados fue de 291, de los cuales se incluyeron ocho; de estos, el 75% presentó buena calidad del informe, cumpliendo parcialmente con los ítems previamente definidos como necesarios. **Conclusión:** los artículos presentaron buena calidad en el informe, pero hay necesidad de mejora en la descripción de los ítems.

**Descripores:** Cateterismo Periférico; Recolección de Muestras de Sangre; Ensayo Clínico; Enfermería

---

1.4.6.7 Universidad Federal de Santa Catarina/UFSC. Florianópolis (SC), Brasil. 2 Universidade Estadual de Feira de Santana. Feira de Santana (BA), Brasil. 3 Instituto Federal de Santa Catarina/IFSC. Joinville (SC), Brasil. 4 Universidade Federal de São Paulo/UNIFESP. São Paulo (SP), Brasil.

---

**How to cite this article**


---

**INTRODUCTION**

Virtual reality is an image and sound technology that provides auditory and visual experiences, creating the sensation of being present in another place, enabling immersive and multisensory experience that can be used as a distraction\(^1\). It is simple to use and easily accessible, as it can be adapted and used with smartphones\(^2\).

Distraction can be used during invasive procedures that generate pain or anxiety, such as peripheral intravenous catheterization and peripheral venipuncture. These procedures are common in the nursing routine, being used for medication infusion and blood collection for laboratory tests. Even with a short time of hospitalization or in brief care in the emergency room, patients are subject to these procedures\(^3\)^4\(^5\).

However, the procedures often provide negative experiences, since procedures involving skin punctures are painful\(^6\)^5\(^7\). Thus, blood collection or intravenous medication administration can become traumatizing events, especially in children or people with phobia of needles\(^5\). Thus, distraction interventions for pain management are recommended, and virtual reality is a viable and low-cost alternative for this purpose\(^1\). Therefore, to verify the effects of virtual reality
in reducing pain and anxiety during peripheral intravenous catheterization procedures, clinical studies have been conducted\textsuperscript{1-2,4-5}.

Clinical trials evaluate the effectiveness of new treatments and have consolidated importance as a scientific method. They are carried out systematically and must present carefully elaborated protocols and methods that guarantee the feasibility and possible reproducibility of the study. They also test the effect of an intervention, whether therapeutic, prophylactic, or diagnostic. Due to their methodological rigor, they are considered the standard of excellence among clinical research methods\textsuperscript{6}.

However, this type of study has a serious risk of bias. Bias can occur from sample selection, difficulties in controlling for variables or other factors, and in the final analysis\textsuperscript{6}. The Consolidated Standards of Reporting Trials (CONSORT) is a tool used to reduce bias and ensure quality in the reporting of randomized clinical trials.

CONSORT is a checklist to guide the writing, conduct, and analysis of clinical trial reports. Thus, it presents recommendations for reports of randomized clinical trials, including items for title, abstract, methods, randomization, blinding, results and discussion\textsuperscript{7}. Based on this instrument, it is possible to systematize and evaluate the quality of published study reports, verifying their methodological rigor and reliability\textsuperscript{8}. It is emphasized that the quality of a clinical trial consists of the list of information presented in the article that indicate adequate description of the study and the items for reliability should be contemplated\textsuperscript{8}.

It is noteworthy that CONSORT is the tool used to evaluate the reports of randomized clinical trials, as referenced. And, for the analysis of the quality of evidence, the appropriate tool is the Grading of Recommendations Assessment, Development, and Evaluation (GRADE)\textsuperscript{9} and, for the analysis of the risk of bias, the Cochrane Risk of Bias Tool (RoB 2.0)\textsuperscript{10} can be used.

Therefore, the evaluation of clinical trial reports regarding the use of virtual reality ensures the possibility of quality evidence-based care, since they are research that support the decision making of professionals regarding new interventions and individualized care. Furthermore, it is noteworthy that the results of these studies support care protocols and changes in nursing professional practice\textsuperscript{6}.

Thus, the assessment of the rigor of the reports of these studies, by means of a validated and recommended instrument, such as the CONSORT\textsuperscript{7}, which brings reliability to it and, consequently, applicability in clinical practice, emphasizing that there are no studies on this subject. In addition to providing an overview of the evolution of the construction of knowledge and methodological rigor in the development of studies on the subject\textsuperscript{7}.

Therefore, the objective of this study was to evaluate the quality of randomized clinical trial reports on virtual reality during peripheral intravenous catheterization using CONSORT\textsuperscript{7}.

**METHOD**

Evaluative research, developed in two stages, the first being a scope review to identify randomized clinical trials on virtual reality during peripheral intravenous catheterization/puncture; the second stage consisted in the evaluation of the articles found regarding the quality of the reports of randomized clinical trials using CONSORT\textsuperscript{7,8}, developed between July 2020 and
November 2021. The guiding question was: what is the quality of the reports of randomized clinical trials on virtual reality during peripheral intravenous catheterization using CONSORT?

In the first stage of this study, a protocol based on the quality parameters of Prisma-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols)\textsuperscript{11} was developed. This protocol included the guiding question, search strategy, databases used, and other methodological steps, and was registered in the Open Science Framework Platform (OSF), according to the protocol (https://osf.io/ayhxn/), DOI 10.17605/OSF.IO/AYHXN.

The scope review in this study was used because this method allows the selection of articles in a systematic way, its reproducibility, and it is a consolidated scientific method. Still, it is important to emphasize that the protocol was designed to also evaluate quasi-experimental studies, however, at the time of the selection of articles, it was verified that only one study of this nature was published and, from this, by consensus among the researchers, it was decided to exclude these studies and use only randomized clinical trials.

The first stage of the study consisted of a search in the national and international databases Cochrane Library, Cumulative Index to Nursing and Allied Health Literature (CINAHL), Embase, Medical Literature Analysis and Retrieval System Online (MEDLINE) via PubMed and Latin American and Caribbean Health Sciences Literature (LILACS), using the controlled descriptors Medical Subject Headings (Mesh) and Health Sciences Descriptors (DeCS), and similar terms in Portuguese, English and Spanish: virtual reality, peripheral catheterization, blood sample collection, and clinical trial. The Boolean operators AND and OR were also used.

The search strategies were developed by a librarian with experience in the health area, following the Peer Review of Electronic Search Strategies (PRESS)\textsuperscript{12} recommendation, which consists of a set of recommendations for search strategy development. For retrieval of randomized clinical trials, a filter developed by the BMJ Knowledge Center of the InterTASC Information Specialists' Sub-Group (ISSG)\textsuperscript{13} was applied.

The studies were selected according to the search strategy, being established as inclusion criteria randomized clinical studies on virtual reality during peripheral intravenous catheterization or peripheral venipuncture, in Portuguese, English and Spanish languages, with accessible full text. Those that tested central venous catheterization together with peripheral catheterization were excluded. The selection process was divided into two stages; the first consisted of independent, blinded reading of titles and abstracts by two reviewers. The selection was performed using the online reference manager RAYYAN®.

In the second step, the main reviewer separated the pre-selected abstracts, searching for the full studies and sent them to the reviewers for independent analysis. Subsequently, the articles were paired for analysis. There was no divergence among reviewers.

In the second stage of the research, the quality of the reports of randomized clinical trials was verified. The items used as criteria for evaluation were based on the CONSORT, which includes 25 items, including title and abstract, methods, results, and discussion\textsuperscript{7,8}. The abstracts were evaluated according to the criteria of the CONSORT checklist extension for abstracts\textsuperscript{7}.

Thus, this stage was also divided into two moments, where the first moment was to train the reviewers on CONSORT, with the aim of reducing the risk of study bias as much as possible. This was done through an online synchronous class on the Meet® Platform, with specific
explanations of the instruments and exercises on them. Then, a randomized clinical trial article was sent to the reviewers, external to the study sample, performing the pairing of criteria among reviewers to reduce the risk of bias in the study. This moment was supervised by a third researcher due to his expertise in the area.

In the second moment, the main evaluator distributed the selected articles among the reviewers, which were coded, since the article evaluation process was blind.

To record the evaluation of the article reports, two instruments were prepared: the first contained the CONSORT questions and the second the identification data of the study, such as year of publication, journal in which the study was published, place of study development, and study population.

The article reports were evaluated according to the number of items that met the CONSORT criteria. To guide the evaluation, we used the basis of available publications\(^7\) together with the checklist that guided this study.

The abstracts were evaluated by the extension for abstracts, which is the subdivision of the checklist, containing the criteria: authors’ contact details, study design, participants, interventions, objectives, outcomes, randomization, blinding, results, recruitment, numbers analyzed, harms, conclusions, study registration and financing.

In performing this assessment, the articles were described according to the percentage of items presented in the randomized clinical trials in relation to the total number of items predicted by CONSORT. Items 3b, 6b, and 14b were not considered because they refer to possible changes during the research process, in other words, they are items that do not necessarily need to be described. Also, item 17b was not considered, as it refers to binary outcomes, which were not used in the studies in question. Item 25 was removed because not all studies received funding for execution, thus not being reported in the studies, being evaluated, therefore, 32 items.

In performing this assessment, scores adapted from Manouchehri E, Alirezaei S, and Roudsari RL (2020)\(^{14}\) were adopted, in which articles were classified into four categories: poor (≤ 8), average (9-16), good (17-24), and excellent (25-32).

After the articles were checked by the two evaluators, a consensus meeting was held to analyze the data and verify their agreement or disagreement regarding the analysis of the items that met the CONSORT criteria\(^7\).

To assess this agreement, descriptive and inferential statistical analysis was used, applying the Kappa Test\(^{15}\) through the IBM SPSS Statistics 22 program.

**RESULTS**

The results found were 291 articles, 35 of which were duplicates. After reading the titles and abstracts, 238 articles were excluded. Then, 18 abstracts were included for full-text search and eligibility analysis. One was excluded because it was a quasi-experimental study; two because they analyzed central and peripheral venous catheterization together; one because it was an extended abstract; and six because they were protocols (Figure 1).
Figure 1. Flowchart of study identification, selection, and inclusion prepared based on the PRISMA recommendation. Florianópolis (SC), Brasil, 2022.

Based on this, an analysis was made of the agreement between the evaluators regarding the CONSORT items, which resulted in 1 (100%) of agreement, both for the analysis of the articles and the abstracts. Thus, the Kappa index was calculated and obtained a value of one for all items, demonstrating excellent agreement with a high reliability index.

Next, the quality of the articles was verified, and first they were characterized. All were published in English, and the year 2019 presented the highest number of publications. Turkey was the country with the largest number of publications on the subject, with five published articles, followed by the USA, with two published articles, and Canada, with one published article. As for the study population, seven were conducted with children and adolescents, with the majority being under the age of 12. Seven were published between 2018 and 2020, with the only one dating from 2006.

Regarding the analysis of the items included in the reports of the randomized clinical trials, we analyzed their frequency. Items 3b, 6b, 14b, and 17b were not counted for frequency analysis, as well as for discussion in this article, as stated in the method (Table 1).

Table 1. Quality assessment of randomized clinical trial reports on virtual reality during peripheral intravenous catheterization according to the frequency analysis of the CONSORT items. Florianópolis (SC), Brazil, 2022.

<table>
<thead>
<tr>
<th>Section/Topics</th>
<th>Items</th>
<th>N°</th>
<th>Items on the List</th>
<th>N (%)</th>
<th>Articles - References</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title and abstract</td>
<td>1a</td>
<td></td>
<td>Identification as a randomised trial in the title</td>
<td>5 (62,5)</td>
<td>2-4-16-17-18</td>
</tr>
</tbody>
</table>
### Introduction

**Background and objectives**
- **Scientific background and explanation of rationale**
  - 7 (87,5)
  - 2-4-16-17-18-19-20
- **Specific objectives or hypotheses**
  - 8 (100)
  - 2-4-16-17-18-19-20-21

### Methods

**Trial design**
- **Description of trial design**
  - 6 (75)
  - 4-16-17-18-19-20
- **Important changes to methods**
  - 0 (0)

**Participants**
- **Eligibility criteria for participants**
  - 8 (100)
  - 2-4-16-17-18-19-20-21
- **Settings and locations where the data were collected**
  - 8 (100)
  - 2-4-16-17-18-19-20-21

**Interventions**
- **The interventions for each group with sufficient details to allow replication**
  - 8 (100)
  - 2-4-16-17-18-19-20-21

**Outcomes**
- **Completely defined pre-specified primary and secondary outcome measures**
  - 7 (87,5)
  - 2-4-16-18-19-20-21
- **Any changes to trial outcomes**
  - 0 (0)

**Sample size**
- **How sample size was determined**
  - 6 (75)
  - 2-4-17-18-19-20
- **Explanation of any interim analyses and stopping guidelines**
  - 4 (50)
  - 4-17-18-19

**Randomisation**
- **Method used to generate the random allocation sequence**
  - 7 (87,5)
  - 2-4-16-17-18-19-20
- **Type of randomisation; details of any restriction**
  - 5 (62,5)
  - 2-4-17-18-19

**Allocation concealment mechanism**
- **Mechanism used to implement the random allocation sequence**
  - 5 (62,5)
  - 2-16-17-18-19

**Implementation**
- **Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions**
  - 3 (37,5)
  - 4-16-17

**Blinding**
- **If done, who was blinded after assignment to interventions**
  - 5 (62,5)
  - 2-4-16-17-18
<table>
<thead>
<tr>
<th>Page</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>11</td>
<td>If relevant, description of the similarity of interventions</td>
</tr>
<tr>
<td>12</td>
<td>Statistical methods used to compare groups for primary and secondary outcomes</td>
</tr>
<tr>
<td>12</td>
<td>Methods for additional analyses</td>
</tr>
<tr>
<td>13</td>
<td>Participant flow (a diagram is strongly recommended)</td>
</tr>
<tr>
<td>13</td>
<td>For each group, losses and exclusions after randomisation, together with reasons</td>
</tr>
<tr>
<td>14</td>
<td>Dates defining the periods of recruitment and follow-up</td>
</tr>
<tr>
<td>14</td>
<td>Why the trial ended or was stopped</td>
</tr>
<tr>
<td>15</td>
<td>A table showing baseline demographic and clinical characteristics for each group</td>
</tr>
<tr>
<td>16</td>
<td>Numbers analysed</td>
</tr>
<tr>
<td>17</td>
<td>For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)</td>
</tr>
<tr>
<td>17</td>
<td>For binary outcomes, presentation of both absolute and relative effect sizes is recommended</td>
</tr>
<tr>
<td>18</td>
<td>Results of any other analyses performed</td>
</tr>
<tr>
<td>19</td>
<td>All important harms or unintended effects in each group</td>
</tr>
<tr>
<td>20</td>
<td>Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses</td>
</tr>
<tr>
<td>21</td>
<td>Generalisability of the trial findings</td>
</tr>
<tr>
<td>22</td>
<td>Interpretation consistent with results, balancing benefits and harms, and</td>
</tr>
</tbody>
</table>
considering other relevant evidence

<table>
<thead>
<tr>
<th>Other information</th>
<th>Registration</th>
<th>23</th>
<th>Registration number and name of trial registry</th>
<th>3 (37.5)</th>
<th>2-4-19</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protocol</td>
<td>24</td>
<td></td>
<td>Where the full trial protocol can be accessed</td>
<td>2 (25)</td>
<td>4-18</td>
</tr>
<tr>
<td>Funding</td>
<td>25</td>
<td></td>
<td>Sources of funding and other support (such as supply of drugs), role of funders</td>
<td>4 (50)</td>
<td>2-16-17-21</td>
</tr>
</tbody>
</table>

It is worth noting that item 1b was not considered to meet 100% of the CONSORT evaluation criteria because it did not present all the criteria requested in the abstract writing extension. Thus, no abstract completely met this criterion: one article had 14 (74%) of the items, three had 13 (68%), two had 12 (63%), and one had 11 (58%). The details of the items of the CONSORT extension for abstracts are in Table 2.

Table 2. CONSORT summary items. Florianópolis (SC), Brazil, 2022.

<table>
<thead>
<tr>
<th>CONSORT items abstracts</th>
<th>n (%)</th>
<th>Articles - References</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title</td>
<td>8 (100.0)</td>
<td>2-4-16-17-18-19-20-21</td>
</tr>
<tr>
<td>Authors - with contact details</td>
<td>6 (75.0)</td>
<td>2-4-17-18-19-20</td>
</tr>
<tr>
<td>Trial design</td>
<td>7 (87.5)</td>
<td>2-4-16-17-18-19-20-21</td>
</tr>
<tr>
<td>Methods</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Participants</td>
<td>8 (100.0)</td>
<td>2-4-16-17-18-19-20-21</td>
</tr>
<tr>
<td>Interventions</td>
<td>8 (100.0)</td>
<td>2-4-16-17-18-19-20-21</td>
</tr>
<tr>
<td>Objective</td>
<td>8 (100.0)</td>
<td>2-4-16-17-18-19-20-21</td>
</tr>
<tr>
<td>Outcome</td>
<td>8 (100.0)</td>
<td>2-4-16-17-18-19-20-21</td>
</tr>
<tr>
<td>Randomization</td>
<td>4 (50.0)</td>
<td>16-17-18-21</td>
</tr>
<tr>
<td>Blinding (masking)</td>
<td>1 (12.5)</td>
<td>6</td>
</tr>
<tr>
<td>Results</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Numbers randomized</td>
<td>3 (37.5)</td>
<td>18-19-20</td>
</tr>
<tr>
<td>Recruitment</td>
<td>4 (50.0)</td>
<td>4-5-6-8</td>
</tr>
<tr>
<td>Numbers analysed</td>
<td>3 (37.5)</td>
<td>4-18-20</td>
</tr>
<tr>
<td>Outcome</td>
<td>7 (87.5)</td>
<td>2-4-16-17-18-19-21</td>
</tr>
<tr>
<td>Harms</td>
<td>0 (0)</td>
<td></td>
</tr>
<tr>
<td>Conclusions</td>
<td>8 (100.0)</td>
<td>2-4-16-17-18-19-20-21</td>
</tr>
<tr>
<td>Trial registration</td>
<td>2 (62.5)</td>
<td>4-18</td>
</tr>
<tr>
<td>Funding</td>
<td>1 (12.5)</td>
<td>17</td>
</tr>
</tbody>
</table>

After analysis, the articles were rated according to scores adapted from Manouchehri E, Alirezaei S, and Roudsari RL (2020), in which six (75%) of the articles were rated good, one (12.5%) average, one (12.5%) excellent, and none were rated poor (Table 3).

Table 3. Classification of articles regarding methodological quality. Florianópolis (SC), Brazil, 2022.
In the evaluation of the articles in relation to the CONSORT items, seven (87.5%) articles received excellent or good ratings, data similar to another study\(^7\), in which the overall quality was rated as medium to good. However, essential items for adequate understanding of the clinical trial need to be clearly reported in the article, with a need for improvement in the description of the items.

The title, which corresponds to item 1a, did not present the term "randomized clinical trial" in three articles\(^{19-21}\). This recommendation is based on the need to adequately identify and index these studies in electronic databases, preventing them from being inappropriately classified\(^7,8,22\), a finding also found in two other studies on the evaluation of CONSORT items\(^7,14,24\), in which less than 50% correctly identified the title. However, identification of the type of study in the title may be suppressed due to the number of words required by journal formation rules. Thus, authors often record in the title only the intervention and the outcome.

Regarding item 1b, analyzed by the CONSORT extension for abstracts, it was evident that no study contemplated all the requested items, and essential items were missing\(^7,8,22\), such as contact details of the author, blinding, number of randomized participants, and possible harms of the study.

The abstracts of the articles are essential, because it is from the abstract that the reader evaluates if he/she will read the full text, and it is through the abstract that the first selections of articles to be included in review studies are made. It is also noteworthy that health professionals may base their decision making solely on the abstract, supporting the need for the abstract to contain the main details of the study, as suggested by the CONSORT extension for abstracts\(^7\).

This systematized structure allows an abstract to be adequately detailed and transparent, since it is responsible for promoting the complete reading of the article and sometimes represents the only source of access to the information contained therein, which may be used to support evidence-based clinical decisions. On the other hand, it is known that there are journals that limit the number of characters for abstracts of studies, which makes it difficult for authors to insert details, as recommended by CONSORT\(^7\).

Regarding the items 2a, scientific rationale and explanation of the reasoning, and 2b, specific objectives or hypotheses, item 2a was not present in only one study\(^21\), while all studies met item 2b. Corroborating the findings, a study\(^22\) on CONSORT recommendations for reporting randomized clinical trials states that the scientific rationale is essential, especially in these studies, as it is used to justify the study and the exposure of participants, as well as to point out the possible benefits of the intervention and explain the reasons for its execution.

Some items were not present in any study, but they should be analyzed with caution, because their absence does not necessarily reflect the quality of the publications. Items 3b, 6b,
and 14b refer to possible changes during the research process, i.e., they are items that do not need to be described, if there is no change\textsuperscript{22}. It is noteworthy that, for an adequate evaluation of these items, it would be necessary to assess the protocol of each study, indicating the need or not of describing these items\textsuperscript{24}.

In item 3a, which provides the description of the clinical trial, including the allocation rate, two studies\textsuperscript{2,21} did not fully address this item, thus compromising its internal validity. However, as a potentiality of the studies, all of them contemplated the items 4a and 4b, referring to the eligibility criteria for participants and information, places where the data found were collected, and demographic data of the participants\textsuperscript{22}.

Item 5, which refers to the interventions of each group with details that allow replication, including how and when the intervention was performed, was described in all studies, but sometimes lacked detail. For example, one of the studies\textsuperscript{4} described peripheral intravenous catheterization, but there was not the same detailing regarding the virtual reality intervention, especially regarding the time of use and end of the intervention. Making this item available in a clear and complete way, describing all procedures performed in the intervention, is recommended to facilitate comparison\textsuperscript{22}.

Regarding the outcome, item 6a, in only one study\textsuperscript{17}, there was no description of it. In item 7a, six (75\%) studies\textsuperscript{2,4,17-20} detailed the sample size determination and in item 7b, sample closure guidelines, only four (50\%) studies\textsuperscript{4,17-19} presented this item. Sample determination should be planned and should have a minimum number to detect statistically and clinically significant differences\textsuperscript{7,22}.

Sometimes, the planned sample size in the clinical trial is not the actual sample, due to the need of an early interruption, either for ethical reasons, redesign of the sample size, and difficulty in recruitment, therefore, it is necessary to describe the sample closure guidelines\textsuperscript{7,22}.

Randomization, item 8, is primordial for this type of study, and its essential items are randomization, masking, and allocation secrecy, to mask the sequence, preventing researchers involved in recruiting individuals from biasing the individuals to the groups\textsuperscript{22-23}.

Randomization is performed by distributing the individuals in the control group and the intervention group, using randomization methods, . In this way, it creates the ideal means to determine whether the efficacy of the intervention is a consequence of the dependent variables and not by chance or covariates\textsuperscript{7,22-23}.

Thus, it is necessary that the authors describe the method used to generate this sequence\textsuperscript{7,22-23}. Related to this are items 8a, present in seven (87.5\%) studies\textsuperscript{2,4,16-20}; 8b, presented in five (62.5\%) studies\textsuperscript{2,4,17-19}; and item 9, corresponding to the allocation, in five (62.5\%) studies\textsuperscript{2,16-19}. It is noteworthy that, despite presenting the items, in one of the studies evaluated\textsuperscript{4}, randomization was performed on a first-come, first-served basis, which is not recommended because it impairs randomization.

Item 10 presents the implementation of the study and requires careful planning and prior definition of who will generate the randomization sequence, who will register the individuals and distribute them into groups\textsuperscript{7,22-23}. This information should be respected and detailed in the studies\textsuperscript{7,22-23}; however, in the articles analyzed, only three (37.5\%)\textsuperscript{4,16-17} had detailed implementation.
Regarding items 11a, blinding, and 11b, similarity between interventions, no study fully addressed this item, due to the impossibility of blinding using virtual reality, because it is necessary to use a device, such as a virtual reality goggle for the intervention. Thus, both the participant and the researcher can visualize which group the participant was participating in. Therefore, it would be possible to blind only the data evaluator, and this occurred in five (62.5%) of the studies evaluated. One article reported no blinding and four others described blinding. Blinding the evaluator is an important factor to avoid confirmation bias, characterized by the researcher’s attempts to prove the hypothesis of his investigation.

Regarding statistical methods, item 12a was present in seven (87.5%) studies, and item 12b, additional analyses, was present in one (12.5%) study. The description of the statistical procedures used during all stages of the studies, and whether they were previously planned or suggested from the findings, is recommended. In general, in clinical trials, the analyses result in estimates regarding the efficacy of the tested intervention. However, in the studies evaluated, item 17b, binary outcomes, was not presented, limiting the analysis by seeking statistical differences between groups.

As for the items that meet the results, items 13 to 19, only demographic data (item 15) were present in all studies. We emphasize the importance of item 13a, regarding the construction of a flowchart of the participants, where all data on recruitment and follow-up of individuals for each group are highlighted, in addition to reporting cases of protocol deviation and exclusion of participants after randomization.

Item 19 requires researchers to detail the occurrence of adverse events or side effects that, although unintentional, when present may impair the applicability of findings in future studies.

Regarding the discussion, these meet items 20 to 25. Item 20, which deals with limitations, was not presented in only one study, but this is prior to CONSORT. Generalization, item 21, refers to the need for the author to suggest whether the study results are applicable to other samples or to the study population. Two studies reported having the potential for generalizability, one reported limited generalizability and one reported that generalizability was not possible.

Item 22 requires the authors to adopt an expanded interpretation of the results, based on current scientific evidence, so they should confront the findings with the existing literature on the subject, and it is recommended that similar randomized clinical trials be included. Items 23, 24, and 25 require the authors to present the registry, the study protocol, and the presence of funding agencies, and are partially presented in the studies.

Recording the protocol for this type of study is important, as it specifies the methods that will be used during the conduct of the experiments. Providing the protocol allows replication of the study in other settings, but it was available in two studies.

Thus, from an expanded analysis of the studies investigated, it was found that only one of the articles was from before the publication of CONSORT, dated 2006, and even then, only two reported having followed this checklist for study design.

Randomized clinical trials are considered the gold standard, because from them, it is possible to evaluate and identify the cause-and-effect relationship between a series of independent and dependent variables. However, for this to occur, it is necessary to evaluate the
quality of the reports, that is, the way they were conducted. CONSORT is an important tool for this purpose. Thus, it is recommended to use CONSORT since the design of the randomized clinical trial, taking care to include all items indicated.

Compliance with guidelines ensures that studies are conducted with methodological rigor, guiding the researcher to conduct the study and its subsequent report, to ensure the quality of these investigations, which in turn serve as input for decision making by nursing professionals and implementation of interventions.

It is important to emphasize that this study assessed the quality of the reports, which does not necessarily indicate that the study was poorly conducted in the face of unidentified items. Therefore, this study contributes to the analysis of other studies that have been developed for the use of virtual reality in peripheral intravenous catheterization, so that readers can critically reflect before implementing the results in clinical practice, to base care on quality scientific evidence.

**CONCLUSION**

The limitation of this research is that the CONSORT items that need to be checked in the study protocol were not addressed, since they were not described, as well as possible modifications that occurred during the process. This is because we did not have access to the protocols and that we did not ask the authors. Also, regarding the initial stage of the literature search, due to its size, not all available databases were consulted, and some publications may have been lost with the search strategy used. Furthermore, we can highlight the limitation of the language of publication, being researched only in Portuguese, Spanish, and English.

This study allowed us to evaluate that the reports of randomized clinical trials published on virtual reality and peripheral intravenous puncture/catheterization have good quality, although the articles need to improve the description of the items mentioned by CONSORT. Thus, it is corroborated that the use of CONSORT to guide the writing of clinical trials should be encouraged to ensure the quality of the reports and the decision making for the use of new technologies in health care.

**CONTRIBUTIONS**

All authors contributed equally to the conception of the research project, the collection, analysis, and discussion of the data, as well as the writing and critical review of the content, with intellectual contribution, and the approval of the final version of the study.

**CONFLICT OF INTERESTS**

Nothing to declare.

**FUNDING**
This work was carried out with the support of the Coordenação de Aperfeiçoamento de Pessoal de Nível Superior - Brazil (CAPES) (“Coordination for the Improvement of Higher Education Personnel”) - Funding Code 001.

REFERENCES


24. Devos F, Ibrahim N, Foissac F, Bouazza N, Ancel PY, Chappuy H, Elie CE, Tréluyer JM. Comparison of the Quality of Pediatric Randomized Controlled Trials Published in Both...

Correspondence
Patrícia Fernandes Albeirice da Rocha
E-mail: patricia.albeirice@gmail.com

Submission: 05/30/2022
Accepted: 12/19/2022
Published: 04/13/2023

Section Editor: Vânia Pinheiro Ramos
Scientific Editor: Tatiane Gomes Guedes
Manager Editor: Maria Wanderleya de Lavor Coriolano Marinus

Copyright© 2023 Revista de Enfermagem UFPE on line/REUOL.
Este é um artigo de acesso aberto distribuído sob a Atribuição CC BY 4.0 Creative Commons Attribution-ShareAlike 4.0 International License, a qual permite que outros distribuam, remixem, adaptem e criem a partir do seu trabalho, mesmo para fins comerciais, desde que lhe atribuam o devido crédito pela criação original. É recomendada para maximizar a disseminação e uso dos materiais licenciados.