



A checklist to assess the quality of reports on spa therapy and balneotherapy trials was developed using the Delphi consensus method: The SPAC checklist

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KEYWORDS

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Interventional trials;
Health enhancement;
Curative effect

Summary

Objective: The purpose of this study was to develop a checklist of items that describes and measures the quality of reports of interventional trials assessing spa therapy.

Methods: The Delphi consensus method was used to select the number of items in the checklist. A total of eight individuals participated, including an epidemiologist, a clinical research methodologist, clinical researchers, a medical journalist, and a health fitness programmer. Participants ranked on a 9-point Likert scale whether an item should be included in the checklist.

Results: Three rounds of the Delphi method were conducted to achieve consensus. The final checklist contained 19 items, with items related to title, place of implementation (specificity of spa), care provider influence, and additional measures to minimize the potential bias from withdrawals, loss to follow-up, and low treatment adherence.

Conclusion: This checklist is simple and quick to complete, and should help clinicians and researchers critically appraise the medical and healthcare literature, reviewers assess the quality of reports included in systematic reviews, and researchers plan interventional trials of spa therapy.

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Introduction

Balneotherapy or spa therapy has been frequently used as an alternative to medicine for the treatment of disease. Spa therapy is a very popular form of treatment for all types of arthritis in many European countries, as well as in Israel and Japan.^{1,2} In addition, some reports have demonstrated that comprehensive health education, which includes lifestyle education and exercise in combination with spa bathing, has positive effects for male white-collar workers³ and middle-aged and elderly people.^{4,5}

In a recent study, there was a randomized controlled trials (RCTs) which clarified the effects of treatment and QOL for psoriasis patients using sulphurous water.⁶ In addition, well planned RCTs for atopic dermatitis in children⁷ and osteoarthritis of the hands⁸ were carried out using balneotherapy. RCTs are widely accepted as the most reliable method to assess the efficacy of treatments. Assessing the effectiveness of nonpharmacological treatments (NPTs) such as psychotherapy, behavioral therapy, surgery, or acupuncture presents specific methodological issues.^{9–11} In NPT trials, it is often difficult to perform sham intervention, and blinding of participants and care providers is frequently impossible.^{9–13} Intervention with spa therapy also has the same issues. Moreover, unlike pharmacological treatment, the success of spa therapy treatment and health enhancement often depends on environmental and other specific factors such as chemical and thermal character, water temperature, ambient temperature, type of bath, nature, and combined intervention such as walking and stretching exercise.

Assessing the quality of study reports is particularly important for researchers' and clinicians' critical appraisal of healthcare literature, and for systematic reviews.^{14,15} The AMSTAR¹⁶ and PRISMA statement¹⁷ specifies that "the criteria and process used for validity assessment" should be reported.

Several checklist tools^{13,18} take into account specific methodological issues in assessing NPTs, such as influence of care providers, standardization, feasibility of blinding, and the risk of bias in unblinded trials. Moreover, specific and unique tools were developed for acupuncture¹¹ or traditional Chinese medicine.¹⁹ However, as one type of NPT, spa therapy and its effectiveness cannot be assessed appropriately regardless of the increased number of reports. If the raw material for these reports is flawed, then the conclusions of systematic reviews are more likely to compound these biases. It therefore seems important to develop a specific tool to assess the quality of these study reports. The purpose of this study was to develop a checklist of items that describe and measure the quality of reports of interventional trials that assess spa therapy.

Methods

We applied the general methods for instrument development used by others.^{18,20–23} This process consists of three main steps: definition of the purpose of the tool, generating items, and selecting items.

Steering author

A steering author (H.K.) was in charge of determining the purpose of the instrument, generating items, and selecting participants for the Delphi consensus method to select and reduce the number of items. The steering author also analyzed and discussed participants' qualitative and quantitative answers after each round, and decided on the format of the feedback.

Definition of the purpose of the tool

The purpose of the tool was to recommend the description and assess the quality of reports of interventional trials that assessed the effectiveness of spa therapy on cure and health enhancement. In this study, quality was defined as internal validity, which implies that the differences observed between groups of participants are linked to the treatment and bias is avoided. We focused on special and methodological items particularly relevant to spa therapy; we did not include the general items already covered in the CONSORT of NPTs,¹⁸ the CONSORT 2010,²² and the TREND statement²³ such as method of randomization and intention-to-treat analysis in the selection process. We did not consider other aspects of quality such as reporting, clinical relevance, precision of outcomes, statistical analysis, ethical issues, and the appropriateness of the conclusions.

The definition of spa therapy varies according to a country and an area, and there is not the clear consensus. For the definition of spa therapy in this study, we used spa bathing for health enhancement and care prevention in community-dwelling people, as well as cure. The definition included comprehensive health education such as exercise, meal, and other healthcare activities. Moreover, this definition specified that spa therapy included visits to spa facilities, but did not include extended stays in spa hotels.²⁴

Generating items

Development of the initial pool of items was performed in two stages. First, we collected and confirmed items from existing quality tools of interventional trials.^{18,22,23} We decided to focus on special and methodological items based on the definition of the purpose of the tool. Specifically, we decided to build a checklist with the title, background, methods, and results.

Second, we enumerated items specific to spa therapy that were identified in reference to systematic reviews based on RCTs.^{25–29} These items were categorized under the following headings: standardization and quality of the treatments, characteristics of spa, care providers, and treatment adherence. Twenty-seven potential items were identified. Each item was reported with a clear definition of what it meant and with examples, when necessary. For example, the item "Setting" had the following definition: "Clear descriptions of spa with right condition for intervention of health enhancement and cure."

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