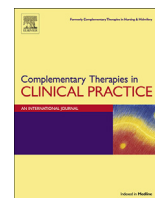




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Assessing the quality of study reports on spa therapy based on randomized controlled trials by the spa therapy checklist (SPAC)



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A B S T R A C T

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Spa therapy
Balneotherapy
Randomized controlled trials
Curative effect
Health enhancement

The purpose of this study was to assess the quality of study reports on spa therapy based on randomized controlled trials by the spa therapy and balneotherapy checklist (SPAC), and to show the relationship between SPAC score and the characteristics of publication.

We searched the following databases from 1990 up to September 30, 2013: MEDLINE via PubMed, CINAHL, Web of Science, Ichushi Web, Global Health Library, the Western Pacific Region Index Medicus, PsycINFO, and the Cochrane Database of Systematic Reviews. We used the SPAC to assess the quality of reports on spa therapy and balneotherapy trials (SPAC) that was developed using the Delphi consensus method.

Fifty-one studies met all inclusion criteria. Forty studies (78%) were about “Diseases of the musculo-skeletal system and connective). The total SPAC score (full-mark; 19 pts) was 10.8 ± 2.3 pts (mean \pm SD). The items for which a description was lacking (very poor; <50%) in many studies were as follows: “locations of spa facility where the data were collected”; “pH”; “scale of bathtub”; “presence of other facility and exposure than bathing (sauna, steam bath, etc.)”; “qualification and experience of care provider”; “Instructions about daily life” and “adherence”. We clarified that there was no relationship between the publish period, languages, and the impact factor (IF) for the SPAC score.

In order to prevent flawed description, SPAC could provide indispensable information for researchers who are going to design a research protocol according to each disease.

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1. Introduction

Balneotherapy or spa therapy has been frequently used as an alternative to medicine for the treatment of disease [1–3]. Recent reports have demonstrated that comprehensive health education, which includes lifestyle education and exercise in combination with spa bathing [4–6].

Randomized controlled trials (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 [7–9]. In NPT trials, it is often difficult to perform sham intervention, and blinding of participants and care providers is frequently impossible [7–11]. Intervention with spa therapy also has the same issues. Moreover, unlike pharmacological treatment, the success of spa therapy and health enhancement often depends on environmental and other specific factors such as chemical and thermal characteristics, water temperature, ambient temperature, type of bath, nature, and combined intervention like walking and stretching exercise.

Assessing the quality of study reports is particularly important for researchers' and clinicians' critical appraisal of healthcare

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literature, and for systematic reviews [12,13]. The AMSTAR [14] and PRISMA statement [15] specifies that “the criteria and process used for validity assessment” should be reported.

Several checklist tools [11,16] 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 heterogeneous tools were developed for acupuncture [9], herbal interventions [17], and traditional Chinese medicine [18]. 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 flaws. It therefore seems important to develop a specific tool to assess the quality of these study reports. Recently a checklist to assess the quality of reports on spa therapy and balneotherapy trials (SPAC) was developed using the Delphi consensus method [19]. The purpose of the present study was to assess the quality of study reports on spa therapy based on RCTs by using the SPAC, to show the relationship between SPAC score and the characteristics of publication, and to present a future research agenda.

2. Methods

2.1. Assessment tool

To develop a checklist of items the Delphi consensus method was used to select the number of items in the checklist [20,21]. A total of eight individuals participated in the development process, 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. Three rounds of the Delphi method were conducted to achieve consensus. The final checklist contained 19 items, including items related to title, place of implementation (specificity of spa), and care provider influence, and additional measures to minimize the potential bias from withdrawals, loss to follow-up, and low treatment adherence. This checklist is simple and quick (i.e., about 3 min to complete the checklist) to complete, and should help clinicians and researchers to critically appraise the medical and healthcare literature, reviewers to assess the quality of reports included in systematic reviews, and researchers to plan interventional trials of spa therapy.

2.1.1. Definition of the purpose of the tool

The purpose of the SPAC was to recommend a 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 [15], the CONSORT 2010 [22], and the TREND statement [23], 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 analyses, ethical issues, and the appropriateness of the conclusions.

For the definition of spa therapy, 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. We excluded the interventions of mud-pack, drinking, nasal irrigation,

Table 1
The special search strategies.

1. MEDLINE via PubMed
#1 Search ((“Balneology/therapeutic use”[Mesh] OR “Balneology/therapy”[Mesh]) OR (“Mineral Waters/therapeutic use”[Mesh] OR “Mineral Waters/therapy”[Mesh]))
#2 Search balneotherapy[TIAB] OR balneology[TIAB] OR “spa therapy”[TIAB]
#3 Search (“1990/01/01”[Date – Publication]: “2013/08/20”[Date – Publication])
#4 Search Randomized Controlled Trial[Publication Type] OR “Randomized Controlled Trial”[TIAB]
#5 Search (#1 OR#2) AND#3 AND#4
2. CINHAL
#1 (MH “Balneology”)
#2 TI balneotherapy OR AB balneotherapy OR TI balneology OR AB balneology OR TI “spa therapy” OR AB “spa therapy”
#3 TI Randomized OR AB Randomized
#4 TI Controlled OR AB Controlled
#5 (#3 AND#4)
#6#1 OR#2
#7#5 AND#6
3. Web of Science
#1 トピック = (Balneology OR balneotherapy OR “spa therapy”)
絞り込み: ドキュメントタイプ = (ARTICLE)
データベース = SCI-EXPANDED タイムスパン = 1990–2013
#2 トピック = (“Randomized Controlled Trial”)
データベース = SCI-EXPANDED タイムスパン = 1990–2013
#3#1 AND#2
データベース = SCI-EXPANDED タイムスパン = 1990–2013
4. Ichushi Web
#1 “Spa therapy”/AL or (温泉学/TH or balneotherapy/AL) or (温泉学/TH or balneology/AL) or (温泉学/TH or 温泉/AL)
#2(#1) and (DT = 1990:2013 PT = 会議録除く RD = ランダム化比較試験)
5. Global Health Library
(Balneology OR balneotherapy OR “spa therapy”) AND “Randomized Controlled Trial”
6. WPRIM
#1 All: Randomized and All: Controlled
#2 Title: balneotherapy or Abstract: balneotherapy or Keywords: balneotherapy
#3 Title: balneology or Abstract: balneology or Keywords: balneology or MeSH: balneology
#4 Title: “spa therapy” or Abstract: “spa therapy” or Keywords: “spa therapy”
#5#4 or#3 or#2
#6#5 and#1
7. PsycINFO
ti(Balneology OR balneotherapy OR “spa therapy”) OR ab(Balneology OR balneotherapy OR “spa therapy”)
8. Cochrane Reviews
#1 MeSH descriptor: [balneology] explode all trees
#2 balneotherapy or “spa therapy”: ti,ab,kw (Word variations have been searched)
#3#1 OR#2

radon oxidative exposure, aerosol spray, and partial body soaking (e.g., only elbow) without spa water bathing (whole body).

3. Criteria for considering studies included in this review

3.1. Types of studies

Studies were eligible if they were RCTs.

3.2. Types of participants

There was no restriction on type of patients.

3.3. Types of intervention and language

Studies included at least one treatment group in which spa therapy with bathing was applied. There was no restriction on the basis of language.

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