

## 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

#### Keywords:

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  $10.8 \pm 2.3$  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.

<b>1. MEDLINE via PubMed</b>
#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
<b>2. CINHAL</b>
#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
<b>3. Web of Science</b>
#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
<b>4. Ichushi Web</b>
#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)
<b>5. Global Health Library</b>
(Balneology OR balneotherapy OR “spa therapy”) AND “Randomized Controlled Trial”
<b>6. WPRIM</b>
#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
<b>7. PsycINFO</b>
ti(Balneology OR balneotherapy OR “spa therapy”) OR ab(Balneology OR balneotherapy OR “spa therapy”)
<b>8. Cochrane Reviews</b>
#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.

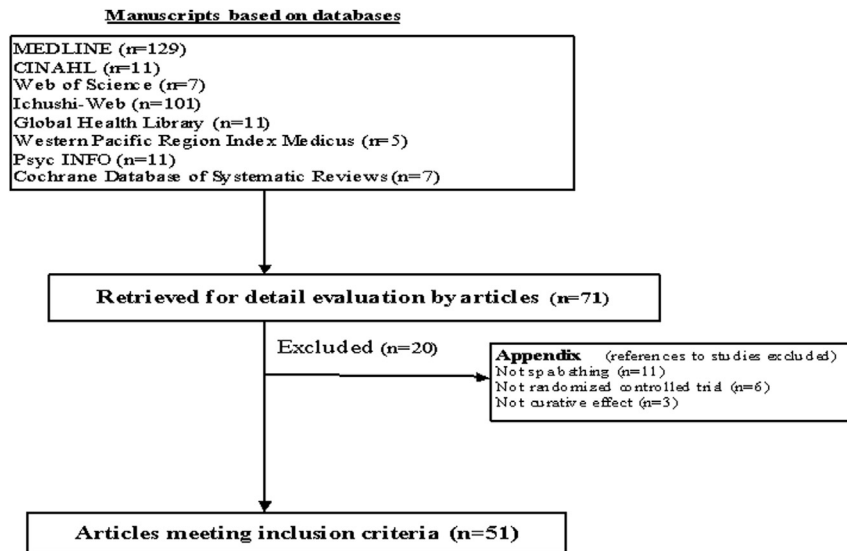


Fig. 1. Flowchart of trial process.

### 3.4. Types of outcome measures

We focused on all cure, rehabilitation, and health enhancement effects using the International Classification of Diseases-10 (ICD-10).

## 4. Search methods for study identification

### 4.1. Bibliographic database

We searched the following databases from 1990 up to September 30, 2013: MEDLINE via PubMed, CINAHL, Web of Science, Ichushi Web (in Japanese), Global Health Library, the Western Pacific Region Index Medicus (WPRIM), and the PsycINFO. The International Committee of Medical Journal Editors (ICMJE) recommended uniform requirements for manuscripts submitted to biomedical journals in 1993. We selected articles published (that included a protocol) since 1990, because it appeared that the ICMJE recommendation had been adopted by the relevant researchers and had strengthened the quality of reports. We also searched the Cochrane Database of Systematic Reviews up to September 30, 2013.

All searches were performed by a specific searcher (hospital librarian) who was qualified in medical information handling, and who was sophisticated in searches of clinical trials.

### 4.2. Search strategies

The special search strategies contained the elements and terms for MEDLINE, CINAHL, Web of Science, Ichushi Web, Global Health Library, WPRIM, PsycINFO, and Cochrane Reviews (Table 1). Only keywords about intervention were used for the searches. First, titles and abstracts of identified published articles were reviewed in order to determine the relevance of the articles. Next, references in relevant studies and identified RCTs were screened.

### 4.3. Handsearching

We handsearched original articles in the Journal of Japanese Society of Balneology, Climatology, and Physical Medicine published from 1990 up to September 30, 2013.

## 5. Review methods

### 5.1. Selection of trials

In order to make the final selection of studies for the review, all criteria were applied independently by two authors (JK, TA) to the full text of articles that had passed the first eligibility screening (Fig. 1). Disagreements and uncertainties were resolved by discussion with other authors (HK).

Studies were selected when (i) the design was an RCT and (ii) one of the interventions was a form of spa bathing. Cure, rehabilitation, and health enhancement effects were used as a primary outcome measure. Trials that were excluded are presented with reasons for exclusion (Appendix).

The literature searches based on databases included potentially relevant articles (Fig. 1). Abstracts from those articles were assessed, and 71 papers were retrieved for further evaluation (checks for relevant literature). Twenty publications were excluded because they did not meet the eligibility criteria (see Appendix). Fifty-one studies [4,5,26–74] met all inclusion criteria (Table 1).

### 5.2. Quality assessment of included studies

A review author (HK) and two research methodologists (HA and AL) who could scrutinize French and Italian articles independently assessed the quality of such articles. A full quality appraisal of these papers was made using the SPAC [19].

Each item was scored as “yes” (y), “no” or “do not know or unclear” (n), or “not applicable” (n/a). Depending on the study results, some items were not applicable. We counted the “n/a” as “y” and calculated for quality assessment. We displayed the percentage of present description on all 19 check items for the quality assessment of articles. For each article, a 19-point scale was used as the SPAC score.

Then, based on the percentage of risk of poor description and methodology or bias, each item was assigned to the following categories: good description (80–100%), poor description (50–79%), or very poor description (0–49%).

We also assessed the association between English and non-English article score as well as the relevance of SPAC score and publication period for each article. In addition, we assessed the

**Table 2**

Brief summary of articles based on structured abstracts and additional elements.

No.	Author	Published year	Title	Aim/objective	ICD code <sup>a</sup>	Conclusion
26	Gremeaux V, et al.	2013	Evaluation of the benefits of low back pain patients' education workshops during spa therapy	To evaluate the medium-term impact of education workshops on low back pain (LBP) in the setting of a thermal spa on: fear-avoidance beliefs, disability, pain, and satisfaction.	M54.5	Standardized education workshops have a beneficial impact on LBP and contribute to an improvement in the medical services provided during spa therapy by reducing the effect of fear-avoidance beliefs as well as relieving pain. Extending the use of such workshops could contribute to enhance the positive impact of spa therapy in the management of chronic disabling diseases.
27	Ciprian L, et al.	2013	The effects of combined spa therapy and rehabilitation on patients with ankylosing spondylitis being treated with TNF inhibitors	To evaluate the effects and tolerability of combined spa therapy and rehabilitation in a group of ankylosing spondylitis patients being treated with TNF inhibitors.	M08.1	Combined spa therapy and rehabilitation caused a clear, long-term clinical improvement in ankylosing spondylitis patients being treated with TNF inhibitors. Thermal treatment was found to be well tolerated and none of the patients had disease relapse.
28	Kovács C, et al.	2012	The effect of sulfurous water in patients with osteoarthritis of the hand. double-blind, randomized, controlled follow-up study	To demonstrate the effectiveness of sulfurous water in patients with osteoarthritis of the hand.	M15–19	Balneotherapy and within this the sulfurous spa water alone may be effective for the attenuation of pain in patients with hand osteoarthritis.
29	Kesiktaş N, et al.	2012	Balneotherapy for chronic low back pain: a randomized, controlled study	To determine the effectiveness of balneotherapy versus physical therapy in patients with chronic low back pain.	M54.5	Balneotherapy combined with exercise therapy had advantages over therapy with physical modalities plus exercise in improving quality of life and flexibility of patients with chronic low back pain.
30	Tefner IK, et al.	2012	The effect of spa therapy in chronic low back pain: a randomized controlled, single blind, follow-up study	To evaluate the beneficial effect of balneotherapy with thermal mineral versus tap water on clinical parameters, along with improvements in quality of life.	M54.5	Our study demonstrated—in comparison with treatment with tap water—the beneficial effect of balneotherapy on clinical parameters in chronic low back pain. Additionally, it had a clearly positive impact on the patients' quality of life, as well as on their analgesic and NSAID requirements.
31	Fioravanti A, et al.	2012	Efficacy of balneotherapy on pain, function and quality of life in patients with osteoarthritis of the knee	To evaluate whether balneotherapy with mineral sulphate–bicarbonate–calcium water could determine substantial symptomatic improvement, and to detect any changes in the quality of life (QoL) of patients with symptomatic knee osteoarthritis (OA).	M15–19	Our results show the beneficial effects of a cycle of sulphate–bicarbonate–calcium mineral water baths on the pain management, functional capacity and quality of life parameters in patients with knee osteoarthritis. This therapy also proved to have long-lasting effects during the follow-up period (3 months). Our results confirm that balneotherapy may therefore be a useful aid, alongside the usual pharmacological and physio-kinesiotherapies, and may represent an alternative treatment in patients with osteoarthritis with a high risk of drug-related side effects.

32	Ozkurt S, et al.	2012	Balneotherapy in fibromyalgia: a single blind randomized controlled clinical study	To evaluate the effectiveness of balneotherapy in fibromyalgia management.	M79.7	Balneotherapy is found to be effective in treating patients with fibromyalgia. Beneficial effects are observed both in short and long terms. There is a need for further randomized controlled studies to verify these results and to identify whether balneotherapy is cost effective in fibromyalgia treatment.
33	Horváth K, et al.	2012	Evaluation of the effect of balneotherapy in patients with osteoarthritis of the hands: a randomized controlled single blind follow-up study.	To evaluate the effectiveness of thermal mineral water compared with magnetotherapy without balneotherapy as control, in the treatment of hand osteoarthritis.	M15–19	Balneotherapy combined with magnetotherapy improved the pain and function as well as the quality of life in patients with hand osteoarthritis.
34	Farina S, et al.	2011	Balneotherapy for atopic dermatitis in children at Comano spa in Trentino, Italy	To investigate the efficacy and safety of balneotherapy performed at Comano spa (Trentino, Italy) compared to topical corticosteroids (TCS) in the treatment of atopic dermatitis (AD).	L20	Balneotherapy at Comano spa appears to be beneficial in children with mild to moderate AD.
35	Oláh M, et al.	2011	The effect of balneotherapy on antioxidant, inflammatory, and metabolic indices in patients with cardiovascular risk factors (hypertension and obesity)—a randomized, controlled, follow-up study	To explore the changes of antioxidant, inflammatory, and metabolic parameters in obese and hypertension patients during balneotherapy and to evaluate the safety of balneotherapy in these participants.	I10–15, E66	This study contributes important information regarding the safety of balneotherapy in hypertensive and obese diabetics by showing no alterations of antioxidant, inflammatory, or metabolic indices. The findings of this study confirm that balneotherapy is not contraindicated for hypertensive or obese patients.
36	Kesiktas N, et al.	2011	The efficacy of balneotherapy and physical modalities on the pulmonary system of patients with fibromyalgia	To assess the effects of balneotherapy + physical therapy modalities (PTM) on respiratory systems of patients with fibromyalgia syndrome (FMS) with a prospective controlled design.	M79.7	Balneotherapy is found to be effective in FMS patients' spirometric measurements and some symptoms. Beneficial effects are observed both at the end of therapy and six months follow-up.
4	Sakurai R, et al.	2011	A randomized controlled trial of the effects of a comprehensive intervention program for community-dwelling older adults	To evaluate the effects of a comprehensive intervention program named SPRING, which utilizes a hot spring facility, in community-dwelling older adults in a randomized controlled trial.	Z72 <sup>b</sup>	The comprehensive intervention program SPRING may improve physical function among community-dwelling older adults. In addition, SPRING may have long-term beneficial effects for older adults.
37	Forestier R, et al.	2010	Spa therapy in the treatment of knee osteoarthritis: a large randomized multicentre trial	To determine whether spa therapy, plus home exercises and usual medical treatment provides any benefit over exercise and usual treatment, in the management of knee osteoarthritis.	M15–19	For patients with knee osteoarthritis a 3-week course of spa therapy together with home exercise and usual pharmacological treatments offers benefit after 6 months compared with exercise and usual treatment alone, and is well tolerated.
38	Fioravanti A, et al.	2010	Short- and long-term effects of spa therapy in knee osteoarthritis	To assess both the short- and long-term effectiveness of spa therapy in patients with primary knee osteoarthritis in a prospective, randomized, single blinded, controlled trial.	M15–19	The beneficial effects of spa therapy in patients with knee osteoarthritis lasts over time, with positive effects on the painful symptomatology and a significant improvement on functional capacities. Spa

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Table 2 (continued)

No.	Author	Published year	Title	Aim/objective	ICD code <sup>a</sup>	Conclusion
39	Dubois O, et al.	2010	Balneotherapy versus paroxetine in the treatment of generalized anxiety disorder	To assess the efficacy of Balneotherapy (BT) in generalized anxiety disorder (GAD).	F40–42	therapy can represent a useful backup to pharmacologic treatment of knee osteoarthritis or a valid alternative for patients who do not tolerate pharmacologic treatments. Balneotherapy (at least for the predominantly female population included in our study) appears to be an effective and well tolerated alternative for subjects with GAD who otherwise mainly rely on psychotropic drugs.
40	Sherman G, et al.	2009	Intermittent Balneotherapy at the Dead Sea area for patients with knee osteoarthritis	To evaluate the effectiveness of an intermittent regimen of balneotherapy at the Dead Sea for patients with knee osteoarthritis.	M15–19	Intermittent balneotherapy appears to be effective for patients with knee osteoarthritis.
41	Carpentier PH, et al.	2009	Randomized trial of balneotherapy associated with patient education in patients with advanced chronic venous insufficiency	To assess the efficacy of balneotherapy associated with patient education, as performed in the spa resort of La Lechère, in patients with advanced chronic venous insufficiency (CEAP clinical classes C4/C5).	I87.2	Spa therapy, associating balneotherapy and patient education, is able to improve significantly the skin trophic changes of the CVD patients and their CVD related quality of life and symptoms. This effect is of large magnitude and remains significant one-year after the treatment course.
5	Kamioka H, et al.	2009	Effectiveness of comprehensive health education combining lifestyle education and hot spa bathing for male white-collar employees: a randomized controlled trial with 1-year follow-up	To clarify the effectiveness of a comprehensive health education and hot spa bathing for male white-collar employees.	Z72 <sup>b</sup>	Participants who attended classes and/or performed the supplementary individualized programs tended to maintain their immunological function and to experience a decrease in body fat percentage. However, few effects were noted in participants with poor adherence, even in the intervention group.
42	Zámbó L, et al.	2008	The efficacy of alum-containing ferrous thermal water in the management of chronic inflammatory gynaecological disorders—a randomized controlled study	To investigate potential differences between the clinical symptoms, pelvic blood flow and specific laboratory parameters of patients undergoing balneotherapy with two different types of immersion: alum-containing and tap water.	O20–29	As demonstrated by our results, 3-week balneotherapy is a potentially useful adjunct for the management of chronic pelvic inflammatory disease, but further, long-term studies are notwithstanding necessary.
43	Karagülle M, et al.	2008	A 10-day course of SPA therapy is beneficial for people with severe knee osteoarthritis. A 24-week randomized, controlled pilot study	To test if spa therapy can play a role in the management of severe knee osteoarthritis (OA).	M15–19	A 10-day traditional spa therapy may have a role in the management of severe knee osteoarthritis (OA) and might be an effective alternative to drug therapy in countries, like Turkey, where it is affordable and widely used by patients and is partly reimbursed by health insurance systems as well.

44	Leibetseder V, et al.	2007	Does aerobic training enhance effects of spa therapy in back pain patients? A randomized, controlled clinical trial	To evaluate the effects of 3 weeks of individualized aerobic exercise training combined with conventional spa therapy on patients' assessment of chronic pain and quality of life.	M54.5	Individualized aerobic training does not seem to enhance beneficial effects of a 3-week spa therapy on chronic pain and quality of life.
45	Bálint GP, et al.	2006	The effect of the thermal mineral water of Nagybaracska on patients with knee joint osteoarthritis-a double-blind study	To study the effect of thermal mineral water of Nagybaracska (Hungary) on patients with primary knee osteoarthritis in a randomized, double-blind clinical trial, 64 patients with nonsurgical knee joint osteoarthritis were randomly selected either into the thermal mineral water or into the tap water group in a non-spa resort village.	M15–19	Thermal mineral water provides significant pain relief in nonsurgical osteoarthritis of the knee, and this was greater than that of tap water at the same temperature.
46	Franke A, et al.	2007	Long-term benefit of radon spa therapy in the rehabilitation of rheumatoid arthritis: a randomized, double-blinded trial	To investigate the effects of radon (plus CO <sub>2</sub> ) baths on RA in contrast to artificial CO <sub>2</sub> baths in RA rehabilitation using a double-blinded trial enrolling 134 randomized patients of an inpatient rehabilitative program (further 73 consecutive non-randomized patients are not reported here).	M05–06	Beneficial long-term effects of radon baths as adjunct to a multimodal rehabilitative treatment of RA.
47	Schiener R, et al.	2007	Bath PUVA and saltwater baths followed by UV-B phototherapy as treatments for psoriasis: a randomized controlled trial	To evaluate the efficacy of psoralens dissolved in a warm-water bath followed by exposure to UV-A irradiation (bath PUVA) or saltwater phototherapy (SW UV-B) or UV-B irradiation alone in psoriasis.	L40	Bath PUVA and SW UV-B are comparably effective treatments in psoriasis and superior to UV-B and TW UV-B.
48	Forestier R, et al.	2007	Are SPA therapy and pulsed electromagnetic field therapy effective for chronic neck pain? Randomized clinical trial first part: clinical evaluation	To compare SPA therapy (ST) with pulsed electromagnetic field (PEMF) therapy in chronic neck pain.	M15–19	PEMF seems to be superior to standard ST without massage in control of neck pain. The difference between groups, although perhaps biased, seems to suggest importance of our conclusions.
49	Forestier R, et al.	2007	Are SPA therapy and pulsed electromagnetic field therapy effective for chronic neck pain? Randomized clinical trial. Second part: medicoeconomic approach	To report the results of a cost-effectiveness evaluation of pulsed electromagnetic field (PEMF) therapy and spa therapy (ST) versus usual care (control) for chronic neck pain.	M15–19	A potential cost-effectiveness for ST and particularly PEMF as compared to usual care in chronic cervical pain. Our results perhaps lack significance probably because of lack of statistical power and do not distinguish sodts [What does the term "sodts" mean?] related or not to chronic cervical pain.
50	Cantarini L, et al.	2007	Therapeutic effect of spa therapy and short wave therapy in knee osteoarthritis: a randomized, single blind, controlled trial	To assess their efficacy in comparison to conventional therapy in patients with osteoarthritis of the knee in a single blind, randomized, controlled trial.	M15–19	The superiority of arsenical-ferruginous spa therapy compared to short wave therapy, and it confirmed the symptomatic efficacy of spa therapy, already shown by other authors, in the treatment of gonarthrosis.
51	Ardıç F, et al.	2007	Effects of balneotherapy on serum IL-1, PGE2 and LTB4 levels in fibromyalgia patients	To investigate the clinical effects of balneotherapy in the treatment of Fibromyalgia Syndrome (FMS) and to determine if balneotherapy influences serum levels of inflammation markers, IL-1, PGE2, and LTB4.	M79.7	Balneotherapy is an effective choice of treatment in patients with FMS relieving the clinical symptoms, and possibly influencing the inflammatory mediators.
52	Yurtkuran M, et al.	2006	Balneotherapy and tap water therapy in the treatment of knee osteoarthritis	To investigate if spa water is superior to tap water (TW) in relieving the symptoms of pain, joint motion, life	M15–19	The results of our placebo-controlled study including the assessment of the clinical-physical functions and quality of life have led us to suggest

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Table 2 (continued)

No.	Author	Published year	Title	Aim/objective	ICD code <sup>a</sup>	Conclusion
				quality in knee osteoarthritis KOA) patients.		that BT may be more effective immediately after treatment and in the long-term than heated TW in reducing only pain and tenderness in KOA patients. The changes in the physical function, quality of life, and other clinical variables were similar. These results may stimulate further research with longer follow-up period and larger patient groups.
53	Altan L, et al.	2006	The effect of balneotherapy on patients with ankylosing spondylitis	To compare the effect of balneotherapy on physical activity and quality of life as well as the symptoms of pain and stiffness with exercise alone in ankylosing spondylitis patients.	M08.1	Balneotherapy has a supplementary effect on improvement in disease activity and functional parameters in ankylosing spondylitis patients immediately after the treatment period. However, in the light of our medium-term evaluation results, we suggest that further research is needed to assess the role of balneotherapy applied for longer durations in ankylosing spondylitis patients
54	Kamioka H, et al.	2006	Comprehensive health education combining hot spa bathing and lifestyle education in middle-aged and elderly women: one-year follow-up on randomized controlled trial of three- and six-month interventions	To clarify the duration of effects of 3- and 6-month comprehensive health education programs based on hot spa bathing, lifestyle education and physical exercise for women at 1-year follow-up.	Z72 <sup>b</sup>	Beneficial effects of 6-month intervention on hemoglobin A1c, aerobic capacity, pains in the back, vigor, fatigue and depression remained significant at the 1-year follow-up. Duration of effects was longer in the 6-month intervention than in the 3-month intervention.
55	Donmez A, et al.	2005	Spa therapy in fibromyalgia: a randomized controlled clinic study	To evaluate the effectiveness of spa therapy in the management of fibromyalgia.	M79.7	Spa therapy is found to be effective in Fibromyalgia patients. Beneficial effects are observed both in the short and the long-term. There is a need for further randomized and controlled studies to verify these results, and to identify whether spa therapy is cost effective in Fibromyalgia.
56	Balogh Z, et al.	2005	Effectiveness of balneotherapy in chronic low back pain – a randomized single-blind controlled follow-up study	Undertaken to compare the effects of hydrotherapy with mineral water vs. tap water on low back pain.	M54.5	Balneotherapy in itself can alleviate low back pain. As demonstrated by this study, the analgesic efficacy and improvement of mobility accomplished by the use of mineral water is significantly superior to that afforded by hydrotherapy with tap water. Our results clearly establish the beneficial effects of mineral water. Moreover, it is a valuable adjunct to other forms of physical treatment as well as to pharmacotherapy.



57	Condish S, et al.	2005	Spa therapy for ankylosing spondylitis at the Dead sea	To study the efficacy of balneotherapy and climatictherapy (climatotherapy) at the Dead Sea area in patients with ankylosing spondylitis.	M08.1	Climatotherapy at the Dead Sea area can improve the condition of patients suffering from long-standing ankylosing spondylitis.
58	Yurtkuran M, et al.	2005	Improvement of the clinical outcome in ankylosing spondylitis by balneotherapy	To show the efficacy of balneotherapy and balneotherapy + nonsteroid antiinflammatory drug use in ankylosing spondylitis patients.	M08.1	We concluded that balneotherapy and balneotherapy + nonsteroid antiinflammatory drug use can be suggested as an effective symptomatic treatment modality in patients with ankylosing spondylitis. Furthermore, sufficient improvement in clinical parameters can be obtained by balneotherapy + nonsteroid antiinflammatory drug use and balneotherapy alone.
59	Leibetseder V, et al.	2004	Improving homocysteine levels through balneotherapy: effects of sulfur baths	To analyze whether balneotherapeutic sulfur baths can influence the level of tHcy and/or the status of oxidative stress.	M15–19	Sulfur baths exert beneficial effects on plasma tHcyt whereas effects on 8-OHdG seem to be unlikely.
60	Delfino M, et al.	2003	Studio sperimentale sull'efficacia dei fanghi termali dell'isola di Ischia associati a balneoterapia nella cura della psoriasi volgare a placche <sup>a</sup>	To evaluate the clinical efficacy of thermal bath plus mudsin patients affected by psoriasis.	L40	Results obtained can be considered useful, considering that thermal treatment was used alone in the treatment of all patients.
61	Brefel-Courbon C, et al.	2003	Clinical and economic analysis of spa therapy in Parkinson's disease	To clarify the effectiveness of spa therapy in the management of patients with Parkinson's disease (PD)	G20	Spa therapy is more effective and less expensive than conventional treatment alone and could be beneficial in the management of PD.
62	Kovács I, et al.	2002	The therapeutic effects of Cserkeszölő thermal water in osteoarthritis of the knee: a double-blind, controlled, follow-up study	To evaluate the therapeutic effects of the famous thermal water from Cserkeszo lo in osteoarthritis of the knee.	M15–19	Balneotherapy has the potential to become a major nonpharmacologic modality in the therapy of musculoskeletal disease.
63	Tubergen AV, et al.	2002	Cost-effectiveness of combined spa-exercise therapy in ankylosing spondylitis: a randomized controlled trial	To evaluate the cost-effectiveness and cost-utility of a 3-week course of combined spa therapy and exercise therapy in addition to standard treatment consisting of antiinflammatory drugs and weekly group physical therapy in ankylosing spondylitis (AS) patients.	M08.1	Combined spa-exercise therapy besides standard treatment with drugs and weekly group physical therapy is more effective and shows favorable cost-effectiveness and cost-utility ratios compared with standard treatment alone in patients with AS.
64	Ekmekcioglu C, et al.	2002	Effect of sulfur baths on antioxidative defense systems, peroxide concentrations and lipid levels in patients with degenerative osteoarthritis	To investigate the effect of 3-week therapy with sulfur baths on antioxidative defense system, peroxide concentrations, and lipid levels in patients with degenerative osteoarthritis.	M15–19	A sulfur bath therapy could cause a reduction in oxidative stress, alterations of superoxide dismutase (SOD) activities, and a tendency towards improvement of lipid levels.
65	Buskila D, et al.	2001	Balneotherapy for fibromyalgia at the Dead sea	To evaluate the effectiveness of balneotherapy on patients with fibromyalgia at the Dead sea.	M79.7	Treatment of fibromyalgia at the Dead Sea is effective and safe and may become an additional therapeutic modality in fibromyalgia.
66	Neumann L, et al.	2001	The effect of balneotherapy at the Dead Sea on the quality of life of patients with fibromyalgia syndrome	To assess the possible effects of balneotherapy at the Dead Sea on the quality of life (QoL) of patients with Fibromyalgia.	M79.7	Staying at a Dead Sea spa, and especially the addition of balneotherapy, can transiently improve the QoL of patients with Fibromyalgia. Other controlled studies, with longer follow-up periods, are needed to strengthen our findings.

(continued on next page)

Table 2 (continued)

No.	Author	Published year	Title	Aim/objective	ICD code <sup>a</sup>	Conclusion
67	Tubergen AV, et al.	2001	Combined spa-exercise therapy is effective in patients with ankylosing spondylitis: a randomized controlled trial	To determine the efficacy of combined spa-exercise therapy in addition to standard treatment with drugs and weekly group physical therapy in patients with ankylosing spondylitis (AS).	M08.1	In patients with AS, a 3-week course of combined spa-exercise therapy, in addition to drug treatment and weekly group physical therapy alone, provides beneficial effects. These beneficial effects may last for at least 40 weeks.
68	Consrant F, et al.	1998	Use of spa therapy to improve the quality of life of chronic low back pain patients	To assess the effectiveness of adding spa therapy to usual drug treatment in chronic low back pain patients.	M54.5	Spa therapy is an effective treatment for chronic low back pain patients.
69	Nguyen M, et al.	1997	Prolonged effects of 3-week therapy in a spa resort on lumbar spine, knee and hip osteoarthritis: following-up after 6 months. A randomized controlled trial	To assess the carry-over symptomatic effect of spa therapy in osteoarthritis patients.	M15–19	Spa therapy of 3 weeks duration has a prolonged, beneficial, symptomatic effect in osteoarthritis.
70	Sukenik S, et al.	1995	Balneotherapy for rheumatoid arthritis at the Dead Sea	To evaluate the effectiveness and safety of sulfur baths and bathing in the Dead Sea water, alone or in combination, in patients with severe, active rheumatoid arthritis (RA).	M05–06	Bathing in Dead Sea water and sulfur baths, alone or in combination, is safe and effective, for up to 3 months, in the treatment of active RA.
71	Wifler I, et al.	1995	Spa therapy for gonarthrosis: a prospective study	To evaluate the effect of spa therapy on clinical parameters of patients with gonarthrosis.	M15–19	Mud packs and mineral baths are safe and effective for the short- and medium-term treatment of osteoarthritis (OA) of the knee. The beneficial effect is in part due to rest and local heat, but it seems that balneotherapy in itself has a positive effect on OA patients.
72	Constant F, et al.	1995	Effectiveness of spa therapy in chronic low back pain: a randomized clinical trial	To assess the overall effectiveness of spa therapy compared with usual routine drug therapy in chronic low back pain (LBP).	M54.5	Both immediate and 6-month effectiveness of spa therapy in chronic LBP. Spa therapy may be beneficial in the management of chronic LBP.
73	Guillemin F, et al.	1994	Short and long-term effect of spa therapy in chronic low back pain	To assess both the short-term and the long-term effectiveness of spa therapy on chronic low back pain (LBP).	M54.5	Spa therapy has a positive short-term and a moderate long-term effectiveness on chronic LBP.
74	Elkayam O, et al.	1991	Effect of spa therapy in Tiberias on patients with rheumatoid arthritis and osteoarthritis	To evaluate the effectiveness of mud packs and mineral baths from Tiberias' springs on patients with rheumatoid arthritis (RA) and osteoarthritis (OA) of the knee.	M05–06	Mud packs and mineral baths are relatively safe and could be partially beneficial in the treatment of RA.

<sup>a</sup> Details of ICD-10.<sup>b</sup> Z72; Positive health enhancement for healthy people.

**Table 3**  
International Classification of target diseases in each article.

Chapter	ICD code	Classification	Reference no.	Total no. and rate (%)
1	A00–B99	Certain infectious and parasitic diseases		0(0)
2	C00–D48	Neoplasms		0(0)
3	D50–D89	Diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism		0(0)
4	E00–E90	Endocrine, nutritional and metabolic diseases	[35] <sup>a</sup>	1(2%)
5	F00–F99	Mental and behavioral disorders	[39]	1(2%)
6	G00–G99	Diseases of the nervous system	[61]	1(2%)
7	H00–H59	Diseases of the eye and adnexa		0(0)
8	H60–H95	Diseases of the ear and mastoid process		0(0)
9	I00–I99	Diseases of the circulatory system	[35] <sup>a</sup> , [41]	2(4%)
10	J00–J99	Diseases of the respiratory system		0(0%)
11	K00–K93	Diseases of the digestive system		0(0)
12	L00–L99	Diseases of the skin and subcutaneous tissue	[34,47,60]	3(6%)
13	M00–M99	Diseases of the musculoskeletal system and connective tissue	[26–33,36–38,40,43–46,48–53,55–59,62–74]	40(78%)
14	N00–N99	Diseases of the genitourinary system		0(0)
15	O00–O99	Pregnancy, childbirth and the puerperium	[42]	1(2%)
16	P00–P96	Certain conditions originating in the perinatal period		0(0)
17	Q00–Q99	Congenital malformations, deformations and chromosomal abnormalities		0(0)
18	R00–R99	Symptoms, signs and abnormal clinical and laboratory finding not elsewhere classified		0(0)
19	S00–T98	Injury, positioning and certain other consequences of external causes		0(0)
20	V00–Y98	External causes of morbidity and mortality		0(0)
21	Z00–Z99	Factors influencing health status and contact with health services	[4,5,54]	3(6%)
22	U00–U99	Code for special purpose		0(0)
				51(100%)

<sup>a</sup> Duplication.

association between SPAC score and impact factor (IF) for the 2011 journals in which the articles had been published. We assessed the IF according to the Thomson Reuters guidelines (i.e. <http://admin-apps.webofknowledge.com/JCR/JCR?PointOfEntry=Home&SID=Q1x7vC9sRPoITm3uwu3>).

### 5.3. Summary of studies and data extraction

We fully reviewed and understood the recommended structured abstracts [24,25], but because the volume of abstracts was so large, we summarized only the purpose, the ICD-10 number, and the conclusion for each abstract.

### 5.4. Analysis

Parametric comparisons used analysis of variance (ANOVA) to assess the difference in SPAC score between the periods of publish year. The significance of individual differences was evaluated by using the Bonferroni test if ANOVA was significant. The Mann–Whitney test was performed with discrete variable to the difference in SPAC score between English and non-English publications. Pearson correlation was performed to determine the association between the IF and the SPAC score. Differences within and among groups and association were judged significant when the significance levels were 5% or less. SPSS 15.0J for Windows was used for the statistical analysis.

## 6. Results

### 6.1. Study characteristics

Fifty-one studies [4,5,26–74] met all inclusion criteria (Table 2). The languages of eligible publications were English [5,26–47,50–59,61–74], French [48,49], Italian [60], and Japanese [4]. Target diseases and/or symptoms (Table 2) were osteoarthritis (knee, hip, hand, and neck) [28,31,33,

37,38,40,43,45,48–50,52,59,62,64,69,71], low back pain [26,29,30,44,56,68,72,73], fibromyalgia [32,36,51,55,65,66], ankylosing spondylitis [27,53,57,58,63,67], rheumatoid arthritis [46,70,74], psoriasis [47,60], atopic dermatitis [34], hypertension and obesity [35], venous insufficiency [41], anxiety disorder [39], Parkinson's disease [61], gynecological disorder [42], and health enhancement in healthy people [4,5,54].

Based on ICD-10, we identified a disease targeted in each article (Table 3). Among 51 studies, 40 studies (78%) were about “(Diseases of the musculoskeletal system and connective)”. There were three studies each in “Diseases of the skin and subcutaneous tissue” and “Factors influencing health status and contact with health services (health enhancement)”.

### 6.2. Quality assessment

We evaluated 19 items from the SPAC in more detail (Table 4). This assessment evaluated the quality of how the main finding of the study was summarized in the written report. The items for which the description was lacking (very poor; <50%) in many studies were as follows (present ratio; %): “locations of spa facility where the data were collected (location and surrounding environment)” (45%); “pH” (27%); “scale of bathtub” (8%); “presence of facility (if any, the property; e.g., comfortable resting room)” (8%); “existence of other exposure than bathing (sauna, steam bath, etc.)” (25%); “qualification of care provider (specialist in balneotherapy, related experts and health fitness programmer, etc.)” (33%); “experience of care provider” (0%); “Instructions about daily life (the same as usual, increase the step number a day as much as possible, etc.)” (43%); and “adherence (the frequency and rate of actual implementation)” (33%). The SPAC score (full-mark; 19 pts) was  $10.8 \pm 2.3$  pts and the rate was  $56.6\% \pm 12.2\%$  (mean  $\pm$  SD) in total.

Fig. 2 shows result for the SPAC score among the period of published year. There was no significant difference between 1988 and 2004 ( $10.1 \pm 1.9$  pts), 2005 to 2008 ( $11.5 \pm 3.0$  pts), and 2009 to

**Table 4**

Evaluation of the quality of methodology based on the SPAC for each article.

No	The issues which should be included (descriptor)																												
		26	27	28	29	30	31	32	33	34	35	36	4	37	38	39	40	41	5	42	43	44	45	46	47	48			
	Published year	2013	2013	2012	2012	2012	2012	2012	2012	2011	2011	2011	2011	2010	2010	2010	2009	2009	2009	2008	2007	2007	2007	2007	2007	2007	2007		
1	Identification as a spa intervention in the title	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y		
2	Description of why do spa intervention	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y		
3	Explanation of spa suitable for intervention as health enhancement	n	y	n	y	y	n	n	n	y	n	n	n	n	n	y	y	n	n	y	y	y	y	y	y	y	y		
4	Locations of spa facility where the data were collected (location and surrounding environment)	n	n	n	y	y	n	y	y	n	n	n	y	n	n	n	y	y	y	y	y	n	y	y	y	n	y		
5	Bathtub temperature	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	n	y	y	y	y	y		
6	pH	n	n	n	n	n	y	n	y	y	n	y	y	n	y	n	n	n	n	y	y	n	n	n	n	n	n		
7	Chemical and thermal characteristics of spa	n	y	y	y	y	y	n	y	y	y	y	y	n	y	n	n	n	y	y	y	n	y	y	y	y	n		
8	Scale of bathtub	n	n	n	n	n	n	n	n	n	n	n	n	n	n	n	n	y	n	n	n	n	n	n	n	n	n		
9	Presence of facilities (if any, the property; e.g., comfortable resting room, etc.)	n	n	n	n	n	n	n	n	n	n	n	n	n	n	n	n	n	n	n	y	y	n	y	n	n	n		
10	(When applicable) existence of other exposure than bathing (sauna, steam bath, etc.)	n	n	n	n	n	n	n	n	n	n	n	n	n	y	n	n	n	n	n	y	y	n	y	n	y	y		
11	Qualification of care provider (specialist in balneotherapy, related experts and health fitness programmer, etc.)	y	y	y	y	y	n	n	y	n	n	n	y	y	n	n	n	y	y	n	y	n	n	y	n	y	y		
12	Experience of care provider	n	n	n	n	n	n	n	n	n	n	n	n	n	n	n	n	n	y	n	n	n	y	n	n	n	n		
13	Information about the intervention subject (e.g., public health service of administration, research group, etc.)	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y		
14	Details of the contents of bathing instruction (including bath time, frequency in use and period)	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y		
15	When combined with a method other than bathing (exercise, meals, or drinkable spa, etc.), detail of the contents	y	y	y	y	n	n	n	y	n	y	n	n	n	y	n	n	y	y	y	y	n	n	y	n	n	n		
16	Instructions about daily life (the same as usual, increase the step number a day as much as possible, etc.)	y	n	n	y	n	y	n	n	n	n	n	y	n	n	n	n	y	y	n	y	n	n	y	n	n	n		
17	Details of how to deal with the control group	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y		
18	Number and detail reason of dropout	n	n/a	y	y	y	n/a	y	n/a	y	n/a	y	y	y	y	y	y	y	y	y	y	n	y	y	y	y	n/a		
19	Adherence (the frequency and rate of actual implementation)	n	n/a	y	n	n	n	n	y	y	n	n	y	y	n	y	n	n	y	n	y	n	y	y	y	y	n		
	Present description no/19 (pts)	9	12	11	13	11	10	8	13	11	9	9	13	9	11	9	9	12	14	12	17	8	12	16	10	11			
	Rate (%)	47	63	58	68	58	53	42	68	58	47	47	68	47	58	47	47	63	74	63	89	42	63	84	53	58			
	Impact factor (2011) of the journal	2.748	2.214	2.037	2.214	2.214	2.590	2.214	2.191	1.504	1.597	0.613	0	9.111	1.731	2.093	0	2.879	2.113	1.843	2.037	1.652	2.037	2.214	4.792	0			

Yes; y, no or unclear; n, not applicable; n/a.

2013 ( $10.7 \pm 1.8$  pts). Fig. 3 shows results of the SPAC score between English and non-English publications. There was no significant difference between English ( $10.8 \pm 2.3$  pts) and non-English ( $10.8 \pm 3.3$  pts). Fig. 4 shows the correlation between the IF and the SPAC score. A significant correlation was not found with a Pearson product–moment correlation coefficient,  $r = -0.044$  ( $p = 0.761$ ).

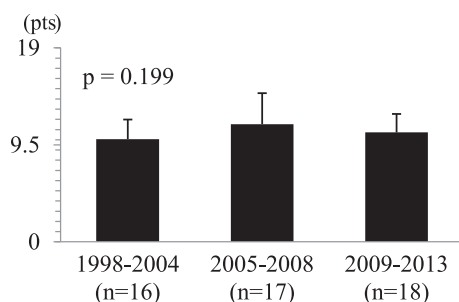
## 7. Discussion

This is the first quality assessment by SPAC on studies of spa therapy based on RCT. Our study summarized each target disease according to ICD-10 classification. We originally did not plan to evaluate the “effect of spa intervention”, but it was meaningful to identify the main target diseases (“Diseases of the musculoskeletal

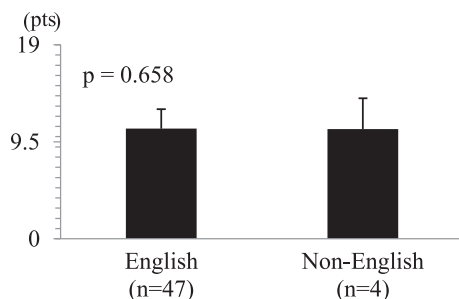
																								Present description				
49	50	51	52	53	54	55	56	57	58	59	60	61	62	63	64	65	66	67	68	69	70	71	72	73	74	No/51 articles	Rate (%)	
2007	2007	2007	2006	2006	2006	2005	2005	2005	2005	2004	2003	2003	2002	2002	2002	2001	2001	2001	1998	1997	1995	1995	1995	1994	1991	—	—	
y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	51	100%	
y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	51	100%	
y	y	y	n	n	y	y	n	y	n	y	y	n	n	n	n	y	y	n	y	n	y	n	n	n	y	26	51%	
	y	y	y	n	n	n	n	n	n	n	y	n	y	n	n	y	n	n	y	n	y	n	y	y	n	23	45%	
	n	y	y	y	y	y	y	y	y	n	y	n	y	n	n	y	y	y	y	n	y	y	y	y	y	44	86%	
	n	n	y	y	n	n	n	n	n	y	y	n	n	n	y	n	n	n	n	n	n	n	n	n	n	14	27%	
	n	y	y	y	y	y	y	y	n	y	y	n	y	n	y	y	y	n	y	n	y	n	y	y	y	36	71%	
n	n	y	y	n	n	n	n	n	n	n	y	n	n	n	n	n	n	n	n	n	n	n	n	n	n	4	8%	
n	y	n	n	n	n	n	n	n	n	n	n	n	n	n	n	n	n	n	n	n	n	n	n	n	n	4	8%	
	n	y	n	n	n	n	y	n	n	n	n	y	Y	n	n	y	n	n	n	y	n	n	y	y	n	n	13	25%
	n	y	n	y	n	y	n	n	n	n	n	n	n	n	n	n	n	y	n	n	n	n	y	y	n	17	33%	
	n	n	n	n	n	n	n	n	n	n	n	n	n	n	n	n	n	n	n	n	n	n	n	n	n	0	0%	
	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	51	100%	
	n	y	y	y	y	y	y	y	y	n	y	y	y	y	y	y	y	y	y	n	y	y	y	y	y	48	94%	
	n	y	y	n	y	y	y	y	y	n	y	y	y	y	y	n	n	y	y	y	y	y	y	n	y	31	61%	
	n	y	y	y	y	y	n	n	y	n	n	y	y	n	n	n	n	y	y	y	n	y	y	n	y	22	43%	
	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	y	51	100%	
n	y	y	y	y	y	y	y	n/a	n/a	n/a	n	n	y	y	n	n	n/a	y	y	y	n/a	n/a	y	y	n/a	44	86%	
n	y	n	n	y	y	n	n	n	n	n	n	n	n	n	n	n	n	y	n	n	n	n	n	n	n	17	33%	
6	16	14	12	11	13	11	9	10	8	10	13	8	10	7	9	9	9	11	13	7	11	10	13	10	11	10.8 ± 2.3 pts (mean ± SD)		
32	84	74	58	58	68	58	47	53	42	53	68	42	53	37	47	47	47	58	68	37	58	53	68	53	58	56.5 ± 12.2% (mean ± SD)		
0	2.21	2.21	2.21	2.22	2.11	2.21	0	0	2.75	2.850	0.33	4.56	2.21	7.48	0	2.21	2.04	7.48	3.23	0	0	2.21	3.26	0	3.26	—		

system and connective)”; (78%) in all RCTs. Moreover, we clarified the relationship between publish period, language, and the IF for SPAC score. We assume that this study will be helpful to researchers who want to understand the effect of balneotherapy comprehensively, and it could provide indispensable information for researchers who are going to design a research protocol according to each disease.

A clear description of the intervention is necessary to evaluate the treatment administered and consider whether two interventions are similar enough to be grouped in a meta-analysis. For instance, it would seem unacceptable to have no details about the bathing program (content) and an additional intervention (comprehensive education for participants) of administration of spa therapy, both of which are complex and difficult to standardize.



**Fig. 2.** SPAC score on the period of published year all values were presented as means  $\pm$  standard deviation. *P* value was tested by analysis of variance.



**Fig. 3.** The difference of SPAC score between English and non-English publication All values were presented as means  $\pm$  standard deviation. *P* value was tested by Mann–Whitney *U* test.

This review found serious problems with the conduct and reporting of the target studies. It especially detected omissions of the following descriptions: location of spa facility, intervention method and facility (pH, scale of bath, other exposure than bathing), information on care provider, instructions about daily life, and adherence. Descriptions of these items were lacking (very poor; <50%) in many studies. Because readers and reviewers obtain information on interventional trials without exceptions, these items are indispensable for meta-analysis. The individual spas had various characteristics, but minimum information was available for these characteristics.

In particular, the experience of care providers was very poorly described. Care providers (*balneo-therapist*, *balneo-doctor*, etc.) can have some influence on the treatment effect, whether pharmacological or not; however, this influence is more important for spa therapy, in which the care provider may be considered part of the treatment. For pragmatic trials, it is more suitable to provide background information about care providers, such as experience, frequency of performing a procedure, years of practice, qualifications, and certification.

Adherence to treatment, such as frequency and rate of actual implementation was also not well described. SPAC highlighted that adherence can also be linked to treatment failure, and could be

used as outcomes. It could be difficult to conclude that a trial had low quality based on this item.

We focused on and evaluated methodological items particularly relevant to spa therapy. We did not consider general aspects of quality such as reporting, clinical relevance, randomization, blinding, precision of outcomes, statistical analysis, ethical issues, and the appropriateness of the conclusions. SPAC improve the quality of article evaluation when combined with other appropriate checklist such as the CONSORT of NPTs [15], the CONSORT 2010 [22], and the TREND statement [23] as prompted by the EQUATOR network [75].

We clarified that there was no relationship between publish period, language, and the IF for SPAC score. Based on our interpretation of these results, we assume that regardless of the language or journals character, SPAC is required in the planning, implementation, and paper description by the researcher.

We excluded interventions such as mud-pack, drinking, nasal irrigation, radon oxidative exposure, aerosol spray, and partial body soaking without whole body bathing (see Appendix; not spa bathing). Current SPAC cannot cover these interventions based on spa. It is required that some specific checklists be developed for treatment with these various spa interventions. We propose to develop a SPAC extension version that is similar to other well known extensions for assessing trials [16,17,76].

There were several limitations to the present study. Selection criteria were common across studies, as described above; however, bias remained due to differences in eligibility for participation in each study. Publication bias was a factor. Although there was no linguistic restriction in the eligibility criteria, we searched studies with only English and Japanese keywords. Furthermore, the use of the IF for the 2011 annual is somewhat difficult to understand.

## 8. Conclusion

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

### Ethical approval

Not required.

### Funding

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### Contributors

HK, KT, MM, SH, HO, and SO developed the SPAC. HK (steering author) conceived the study. JK, TA and HK selected articles. HK, HA, and AL take responsibility for the quality assessment and summary of included studies and data extraction. HK performed the statistical analysis. KT, MM, SH, YG, HO, SO confirmed medical and balneological items. KT was the guarantor. All authors read and approved the manuscript.

### Conflict of interest

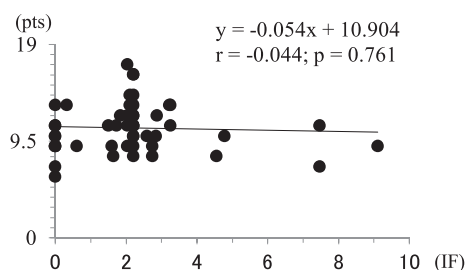
None declared.

### Data sharing

No additional data available.

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**Fig. 4.** Correlation between impact factors and SPAC score correlation was calculated by Pearson's product–moment correlation coefficient.

## Appendix

References to studies excluded in this review.

Excursion no.	Author, journal (year)	Title	Reason for exclusion
1	Ottaviano G, et al. Am J Otolaryngol (2012)	Smoking and chronic rhinitis: effects of nasal irrigations with sulfurous-arsenical-ferruginous thermal water. A prospective, randomized, double-blind study	Not spa bathing
2	Miraglia Del Giudice M, et al. Int J Immunopathol Pharmacol (2011)	Effectiveness of Ischia thermal water nasal aerosol in children with seasonal allergic rhinitis: a randomized and controlled study	Not spa bathing
3	Dogan M, et al. Southern Med J (2011)	Additional therapeutic effect of balneotherapy in low back pain	Not randomized controlled trial
4	Terhorst L, et al. J Manipulative Physiol Ther (2011)	Complementary and alternative medicine in the treatment of pain in fibromyalgia: a systematic review of randomized controlled trials.	Not randomized controlled trial
5	Ottaviano G, et al. Am J Otolaryngol (2011)	Effects of sulfurous, salty, bromic, iodine thermal water nasal irrigations in nonallergic chronic rhinosinusitis: a prospective, randomized, double-blind, clinical, and cytological study	Not spa bathing
6	Fioravanti A, et al. Rheumatol Int (2011)	Effects of spa therapy on serum leptin and adiponectin levels in patients with knee osteoarthritis	Not randomized controlled trial
7	Kendrick D, et al. Arch Dis Child (2011)	Randomized controlled trial of thermostatic mixer valves in reducing bath hot tap water temperature in families with young children in social housing	Not curative effect
8	Wynn E, et al. Bone (2009)	Alkaline mineral water lowers bone resorption even in calcium sufficiency: alkaline mineral water and bone metabolism	Not spa bathing
9	Salami A, et al. Int J Pediatr Otorhinolaryngol (2008)	Sulfurous water inhalations in the prophylaxis of recurrent upper respiratory tract infections	Not randomized controlled trial
10	Alp A, et al. Am J Phys Med Rehabil (2007)	Efficacy of a self-management program for osteoporotic subjects	Not spa bathing
11	Goldman MP, et al. J Cosmetic Dermatol (2007)	Comparative benefit of two thermal spring waters after photodynamic therapy procedure	Not spa bathing
12	Hoeffner B, et al. The Gerontologist (2006)	Assisting cognitively impaired nursing home residents with bathing: effects of two bathing interventions on caregiving	Not spa bathing
13	Ay A, et al. Am J Med Rehabil (2005)	Influence of aquatic and weight-bearing exercises on quantitative ultrasound variables in postmenopausal women	Not spa bathing
14	Lopalco M, et al. Clin Ter (2004)	Effetto terapeutico dell'associazione ventilazione polmonare e aerosol-inalazione con acqua minerale solfurea nelle broncopneumopatie cronico-ostruttive (BCPO)	Not spa bathing
15	Mancini S, et al. VASA (2003)	Clinical, functional and quality of life changes after balneokinesis with sulfurous water in patients with varicose veins	Not randomized controlled trial
16	Halevy S, et al. IMAJ (2001)	The role of trace elements in psoriatic patients undergoing balneotherapy with Dead Sea bath salt	Not curative effect
17	Gambichler T, et al. Photodermatol Photoimmunol Photomed (2001)	Balneophototherapy of psoriasis: highly concentrated saltwater versus tap water – a randomized, one-blind, right/left comparative study	Not spa bathing
18	Guillemin F, et al. Joint Bone Spine (2001)	Effect on osteoarthritis of spa therapy at Bourbonne-les-Bains	Not randomized controlled trial
19	Franke A, et al. Rheumatol (2000)	Long-term efficacy of radon spa therapy in rheumatoid arthritis-a randomized, sham-controlled study and follow-up	Not spa bathing
20	Allard P, et al. Rev Rhum (1998)	Is spa therapy cost-effective in rheumatic disorders?	Not curative effect

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