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Clinical effects of Kneipp hydrotherapy: a systematic review of randomised controlled trials

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ABSTRACT

Objective Hydrotherapy is a traditional prevention and treatment strategy. This study's aim is to systematically review all available randomised controlled trials (RCTs) investigating clinical effects of hydrotherapy according to Kneipp which is characterised by cold water applications.

Methods RCTs on disease therapy and prevention with Kneipp hydrotherapy were included. Study participants were patients and healthy volunteers of all age groups. MEDLINE (via PubMed), Scopus, Central, CAMbase, and opengrey.eu were systematically searched through April 2021 without language restrictions and updated by searching PubMed until April 6th 2023. Risk of bias was assessed using the Cochrane tool version 1.

Results

Twenty RCTs (N=4247) were included. Due to high heterogeneity of the RCTs, no meta-analysis was performed. Risk of bias was rated as unclear in most of the domains. Of 132 comparisons, 46 showed significant positive effects in favour of hydrotherapy on chronic venous insufficiency, menopausal symptoms, fever, cognition, emotional function and sickness absenteeism. However, 81 comparisons showed no differences between groups and 5 were in favour of the respective control group. Only half of the studies reported safety issues.

Conclusion Although RCTs on Kneipp hydrotherapy seem to show positive effects in some conditions and outcomes, it remains difficult to ascertain treatment effects due to the high risk of bias and heterogeneity of most of the considered studies. Further high-quality RCTs on Kneipp hydrotherapy are urgently warranted.

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STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This is the first comprehensive systematic review on the effects of Kneipp hydrotherapy, characterised by serial cold water applications, including grey literature.
⇒ The quality of included studies varied with overall unclear and high risk of bias.
⇒ Due to high clinical heterogeneity, results were summarised qualitatively without meta-analysis.

INTRODUCTION

Hydrotherapy according to Sebastian Kneipp (1821–1897) is the most famous of the five interlocking individual components of the therapeutic Kneipp naturopathy concept, consisting of what today would be grouped into lifestyle and mind-body interventions, healthy nutrition, exercise, phytotherapy and hydrotherapy. Kneipp's hydrotherapy (KH) distinguishes between more than 100 different water applications including washing, pouring, bathing, wrapping, steaming and packing for disease prevention and therapy. KH is characterised by the frequent use of cold water, unlike other areas of hydrotherapy.

KH is present today as part of the prevention strategies and physiotherapy treatments, mainly in rehabilitation clinics. In 2016 Kneipp therapy was awarded as an immaterial cultural heritage in Germany by UNESCO.[1] The Kneipp Association is the largest lay organisation in the field of health and prevention in Germany today.[2]

The German priest and healer Sebastian Kneipp (1821–1897) was very popular at his time and founded a sanatorium in Bavaria for any kind of patients. In accordance with his conception of illness and healing, which was influenced by the era, he assumed the healing effect of water through its dissolving, draining (of illness) and invigorating (of the body) function. In contrast to balneotherapy he considered cold water as especially effective and emphasised a hardening and health promoting effect. In case of using lukewarm or hot water or alternating temperatures, the application should be followed by a final cold exposure. In the sense of a cure he often ordered repeated water applications following a detailed and for the patient individualised schedule.[3]

Today it is scientifically shown that cold water functions as a stimulus causing a compensating and regulating reaction, on the level of the cardiovascular system and

in the area of the endocrine/and immuno system and psyche.[4–8] Repeated stimuli shall lead to adapted bodily reactions that may beneficially influence inflammation and metabolic processes.[9] By repeating cold water applications, as typical, for example, in medical Kneipp cures over several weeks, the physiological reaction adapts to the stimuli[10]; this process can be used therapeutically.[11–13] Additionally, water is an excellent solvent, for example, bath additives and can be used therapeutically in baths due to its hydrostatic pressure.[14]

The scientific evidence on KH has so far been summarised mainly in two scientific reviews. In the dissertation by Claudia Haug, a total of 89 studies from 1975 onwards were identified, of which only six randomised controlled trials (RCTs) were classified as being of high quality in terms of methodology. Based on the results of these six studies, positive effects of hydrotherapy were described for the indications of heart failure, chronic venous insufficiency and infection prophylaxis in adults.[15] Another systematic review (2020) was conducted by Marita Stier-Jarmer *et al*. The authors aimed to identify studies with different methodological designs on 'Kneipp treatments of any kind' (excluding pure phytotherapy). Of the 25 studies evaluated, a total of 13 RCTs were found, for very different applications and indications.[16]

In both above-mentioned reviews, the search was restricted to a limited period of publication time and to German and English language. In addition, the keywords in the literature search were chosen relatively narrowly, and thus, from our point of view, it was not possible to detect the available total number of studies, which we estimated to be numerically larger.

The aim of our systematic review was to investigate all available scientific evidence on KH within the framework of a systematic literature review to present its therapeutic and preventive effects as well as to identify gaps and existing research needs with regard to the question of effectiveness and overall effect.

METHODS

The systematic review was conducted and reported according to Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines[17] and registered before study conduction on PROSPERO.

Patient and public involvement

None.

Eligibility assessment

Randomised controlled, randomised crossover and cluster randomised on individuals of any age, gender and origin were eligible. Studies on therapeutic, health-promoting or preventive use of KH were included. The term 'Kneipp' did not have to be mentioned as long as hydrotherapy was carried out according to the Kneipp principles and described and regular conditions.[3] This resulted in exclusion of studies for muscle soreness and exercise training and hydrotherapy during labour. Studies investigating KH with herbal additives, group and individual settings, as well as self-applied KH and those carried out under guidance or by trained medical staff were included. Studies on water treatments with other additives that do not meet KH, studies using special devices to produce, for example, steam, studies that only investigated balneotherapy, aromatherapy and aquatic exercise without including hydrotherapy were excluded. A complete list of all included and excluded interventions is given in the online supplemental figure 1. Studies comparing KH with (1) no specific intervention, (2) functionally inert interventions or (3) another form of KH as defined above were included. Studies that investigated hydrotherapy in combination with other procedures were included only if concurrent procedures were comparable between all groups. All outcomes directly relevant to the patient (eg, symptoms, quality of life, frequency of infections) measured by validated scales were included. Studies were excluded, if only physiological parameters (eg, skin temperature) were measured.

Search strategy and selection criteria

MEDLINE (via PubMed), Scopus, the Cochrane Central Register of Controlled Trials (Central), CAMbase and opengrey.eu were searched without time and language restrictions through 6 April 2021. A search update was executed in MEDLINE (via PubMed) until 6 April 2023. The complete search strategy for PubMed is presented in the online supplemental figure 2. Search strategies for the other databases were identical in content. Further, we manually searched the reference lists of previous reviews and the Deutsches Register Klinischer Studien (DRKS) study registry for unpublished studies. Search results were checked for duplicates using Covidence software. Two authors independently screened abstracts and full texts for eligibility. Disagreements were resolved in discussion with a third author.

Data extraction and management

Data on medical condition, demographics, (control) interventions and outcomes were extracted using a predeveloped data extraction form independently by two authors.

Two authors independently assessed the risk of selection bias, performance bias, detection bias, attrition bias, reporting bias and other bias using the Cochrane risk of bias tool V.1.[18]

Data synthesis

Pairwise meta-analyses were intended but not carried out because of high clinical heterogeneity of the identified studies. Instead results were pooled qualitatively by type of outcomes using vote counts.[19] Because of weak reporting of individual studies, extracting or calculating effect sizes were not possible.

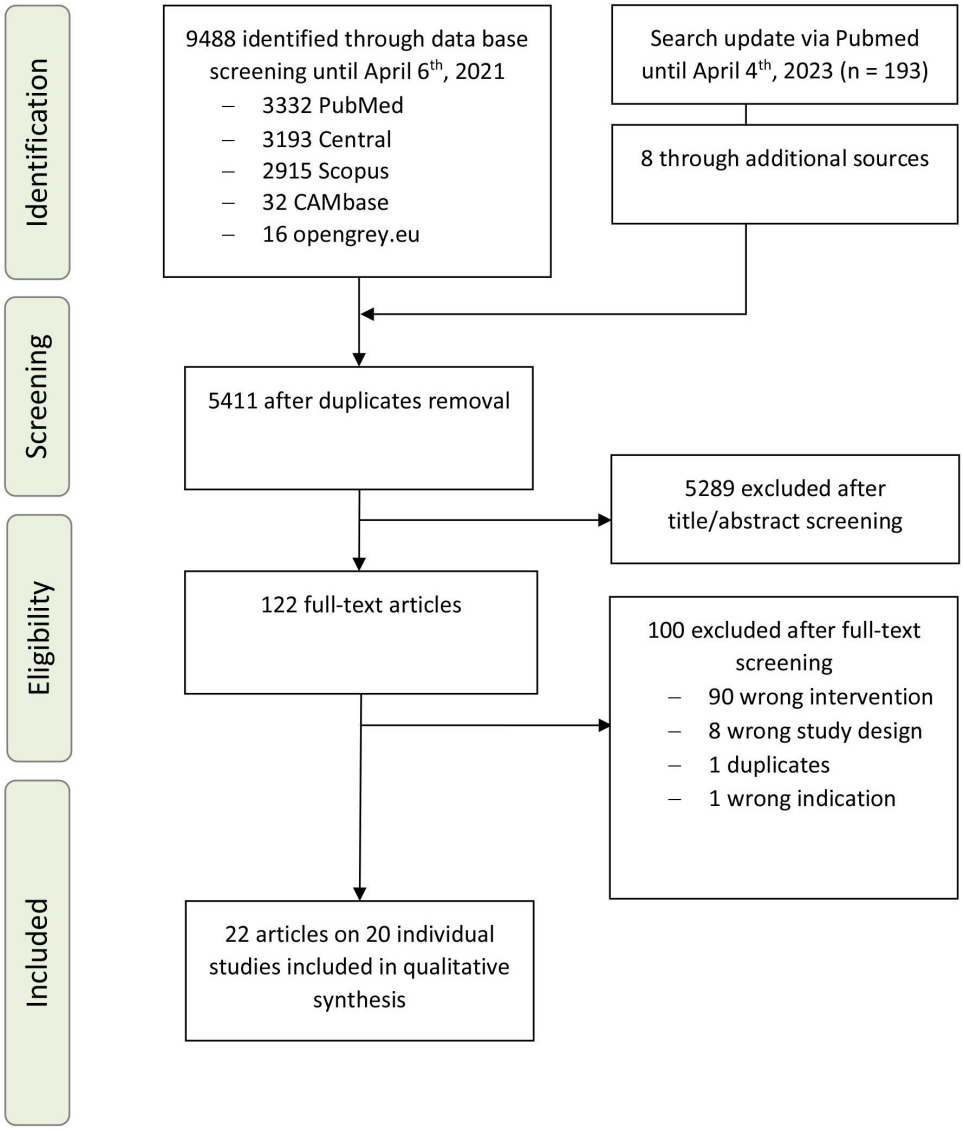


Figure 1 Flow chart.

RESULTS

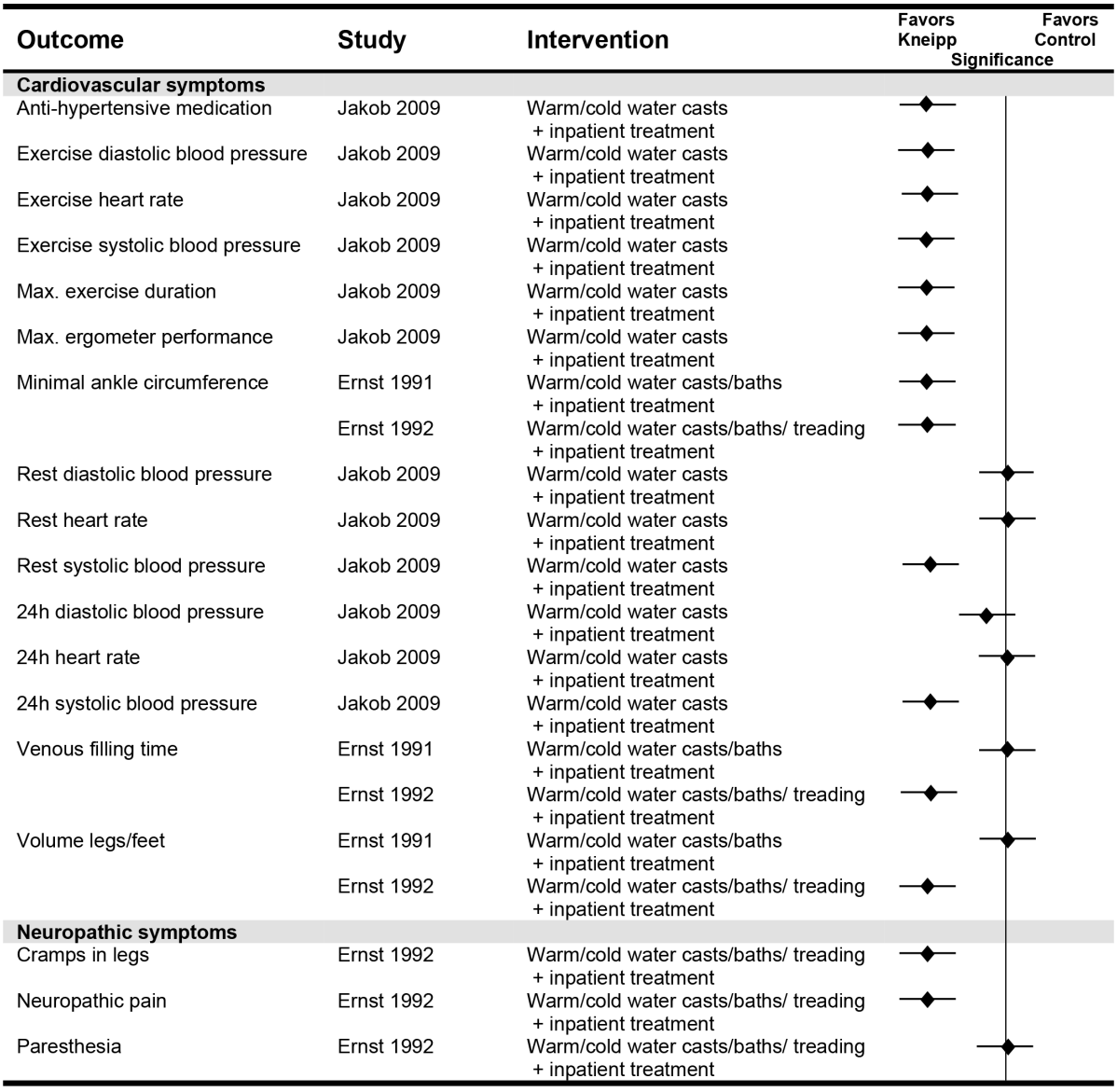
The initial literature search revealed 5218 records, the MEDLINE (via PubMed) update yielded additional 193 records (figure 1). After carefully excluding duplicates and irrelevant abstracts, 117 full texts were assessed for eligibility. Furthermore, 85 had to be excluded as studies did not investigate hydrotherapeutic interventions according to Kneipp, 8 were no RCTs, 1 was a duplicate publication and 1 investigated a condition that did not match the inclusion criteria. Twenty-two articles on 20 RCTs (N=4247) were included.[20–41] The references of not included studies after full-text screening can be found in online supplemental table 1.

Study characteristics

Study characteristics are presented in detail in online supplemental table 2, an overview of outcomes and risk of bias can be found in the online supplemental table 3. Fourteen RCTs were published in peer-reviewed journals[20 23–27 29 32 33 35–38 41] including one study that has been published as a thesis as well.[30 41] Seven RCTs were conducted within eight doctoral theses that have not been published.[21 22 28 30 31 34 39 40] Almost all of the RCTs were carried out in Germany,[21 22 24 25 27–31 33 34 36 37 39–41] one study each in Spain,[32] in the USA[38] and in Turkey.[20] The conditions varied from healthy adults[21 23 24 36] to children with a recurrent common cold infections or fever,[20 27 38] varicosis,[25 26 29] cardiovascular diseases,[30 33 39] breast cancer and menopausal issues,[22] post-polio syndrome,[28] osteoarthritis of the hip or knee,[37] polyneuropathy,[31] acute pain due to haemorrhoids or anal fissures[32] and after episiotomy.[35]

Risk of bias of individual studies

Risk of selection bias was unclear for most studies (online supplemental figures 3 and 4). Only three studies were rated as having low risk of selection bias.[22 23 38] Risk of performance bias was rated low for zero studies, while three were rated as adequately blinding outcome assessors.[25 26 35] In most studies, the risk of incomplete outcome



Outcome	Study	Intervention
Cardiovascular symptoms		
Anti-hypertensive medication	Jakob 2009	Warm/cold water casts + inpatient treatment
Exercise diastolic blood pressure	Jakob 2009	Warm/cold water casts + inpatient treatment
Exercise heart rate	Jakob 2009	Warm/cold water casts + inpatient treatment
Exercise systolic blood pressure	Jakob 2009	Warm/cold water casts + inpatient treatment
Max. exercise duration	Jakob 2009	Warm/cold water casts + inpatient treatment
Max. ergometer performance	Jakob 2009	Warm/cold water casts + inpatient treatment
Minimal ankle circumference	Ernst 1991	Warm/cold water casts/baths + inpatient treatment
	Ernst 1992	Warm/cold water casts/baths/ treading + inpatient treatment
Rest diastolic blood pressure	Jakob 2009	Warm/cold water casts + inpatient treatment
Rest heart rate	Jakob 2009	Warm/cold water casts + inpatient treatment
Rest systolic blood pressure	Jakob 2009	Warm/cold water casts + inpatient treatment
24h diastolic blood pressure	Jakob 2009	Warm/cold water casts + inpatient treatment
24h heart rate	Jakob 2009	Warm/cold water casts + inpatient treatment
24h systolic blood pressure	Jakob 2009	Warm/cold water casts + inpatient treatment
Venous filling time	Ernst 1991	Warm/cold water casts/baths + inpatient treatment
	Ernst 1992	Warm/cold water casts/baths/ treading + inpatient treatment
Volume legs/feet	Ernst 1991	Warm/cold water casts/baths + inpatient treatment
	Ernst 1992	Warm/cold water casts/baths/ treading + inpatient treatment
Neuropathic symptoms		
Cramps in legs	Ernst 1992	Warm/cold water casts/baths/ treading + inpatient treatment
Neuropathic pain	Ernst 1992	Warm/cold water casts/baths/ treading + inpatient treatment
Paresthesia	Ernst 1992	Warm/cold water casts/baths/ treading + inpatient treatment

Figure 2 Kneipp therapy combined with inpatient treatment compared with inpatient treatment alone. Note. The results presented are vote counts and are not equivalent to the numerical estimators of a meta-analysis.

data was rated as low.[20–22 26–30 33 34 36–38] Risk of reporting bias could be assessed for five studies only, of which two were rated as having low risk.[30 37] Other bias was considered as low in 12 studies.[20 22 23 25–27 29–31 33 34 38]

Study findings

Cardiovascular symptoms

Eight studies included outcomes related to cardiovascular symptoms in the frame of hypertension, mild heart failure and varicosis. There were 17 different outcomes with 44 comparisons in total. Eighteen comparisons favoured KH, 1 showed a trend in favour of KH and 25 did not show any difference between groups. The most consistent beneficial results were found in patients with varicosis (figures 2–4).

Common cold symptoms

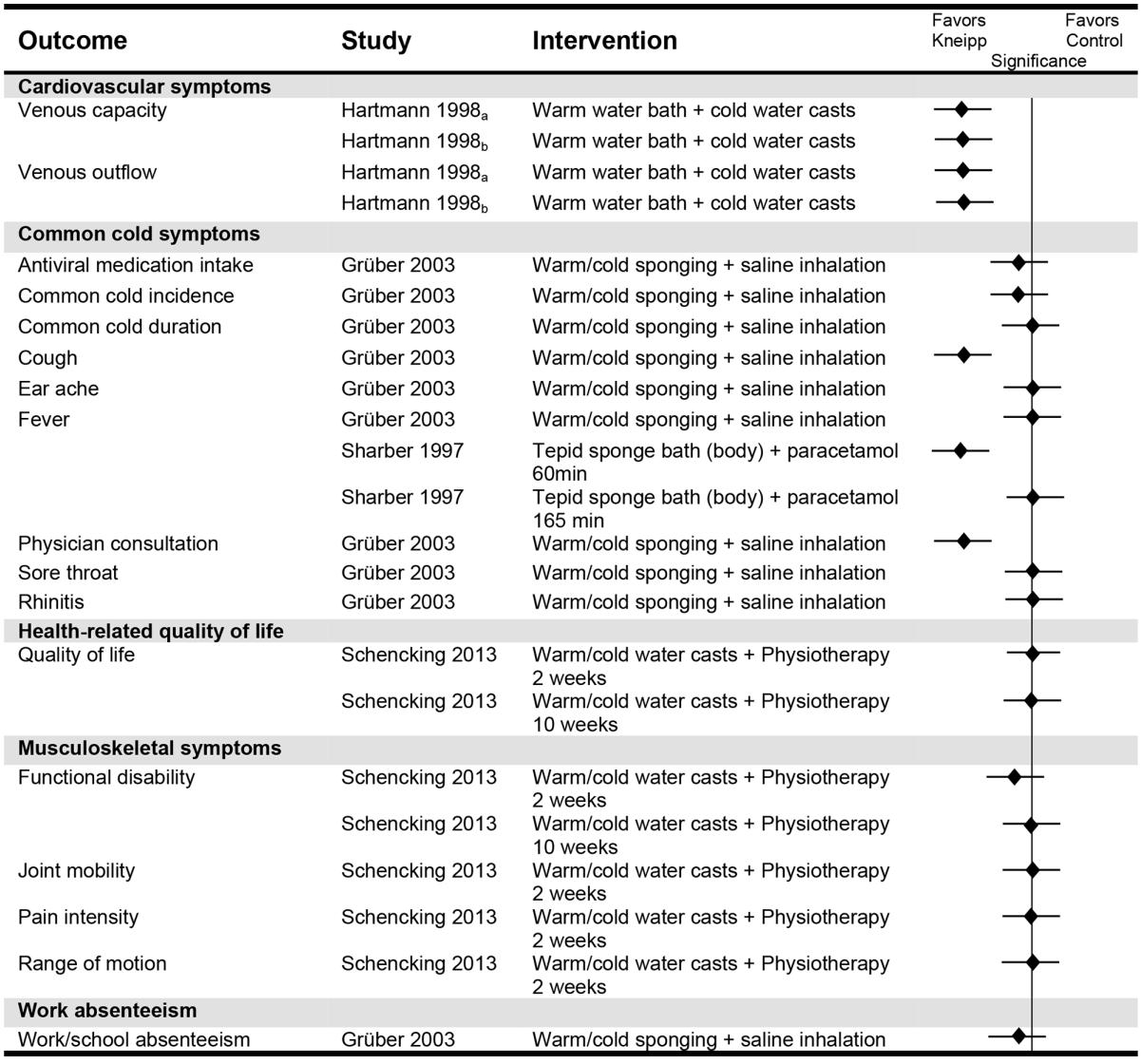
Three studies included outcomes related to upper respiratory tract infections (URTI) in children and adults. There were nine different outcomes with 17 comparisons in total. Six comparisons favoured KH, two showed a trend in favour of KH, six did not show any difference between groups and three favoured the control treatment. The best results were reached for the short time effects of sponging in children with URTI-related fever (figures 3 and 4).

Gastrointestinal symptoms

One study included outcomes related to gastrointestinal symptoms. There were four different outcomes with four comparisons in total. One comparison favoured KH and three showed a trend in favour of KH (figure 4).

Health-related quality of life

Nine studies included outcomes related to health-related quality of life. There were two different outcomes with 16 comparisons in total. Four comparisons favoured KH, 1



Outcome	Study	Intervention
Cardiovascular symptoms		
Venous capacity	Hartmann 1998$_a$	Warm water bath + cold water casts
	Hartmann 1998$_b$	Warm water bath + cold water casts
Venous outflow	Hartmann 1998$_a$	Warm water bath + cold water casts
	Hartmann 1998$_b$	Warm water bath + cold water casts
Common cold symptoms		
Antiviral medication intake	Grüber 2003	Warm/cold sponging + saline inhalation
Common cold incidence	Grüber 2003	Warm/cold sponging + saline inhalation
Common cold duration	Grüber 2003	Warm/cold sponging + saline inhalation
Cough	Grüber 2003	Warm/cold sponging + saline inhalation
Ear ache	Grüber 2003	Warm/cold sponging + saline inhalation
Fever	Grüber 2003	Warm/cold sponging + saline inhalation
	Sharber 1997	Tepid sponge bath (body) + paracetamol 60min
	Sharber 1997	Tepid sponge bath (body) + paracetamol 165 min
Physician consultation	Grüber 2003	Warm/cold sponging + saline inhalation
Sore throat	Grüber 2003	Warm/cold sponging + saline inhalation
Rhinitis	Grüber 2003	Warm/cold sponging + saline inhalation
Health-related quality of life		
Quality of life	Schencking 2013	Warm/cold water casts + Physiotherapy 2 weeks
	Schencking 2013	Warm/cold water casts + Physiotherapy 10 weeks
Musculoskeletal symptoms		
Functional disability	Schencking 2013	Warm/cold water casts + Physiotherapy 2 weeks
	Schencking 2013	Warm/cold water casts + Physiotherapy 10 weeks
Joint mobility	Schencking 2013	Warm/cold water casts + Physiotherapy 2 weeks
Pain intensity	Schencking 2013	Warm/cold water casts + Physiotherapy 2 weeks
Range of motion	Schencking 2013	Warm/cold water casts + Physiotherapy 2 weeks
Work absenteeism		
Work/school absenteeism	Grüber 2003	Warm/cold sponging + saline inhalation

Figure 3 Kneipp therapy plus add on compared with add on only. Note. The results presented are vote counts and are not equivalent to the numerical estimators of a meta-analysis.

showed a trend in favour of KH and 11 did not show any difference between groups (figures 3–5).

Menopausal symptoms

Two studies included outcomes related to menopausal symptoms in patients with cancer and patients without cancer. There were four different outcomes with eight comparisons in total. Five comparisons favoured KH, three did not show any difference between groups and three favoured the control treatment. Positive results in both studies could be shown for menopausal somato-vegetative symptoms (eg, hot flashes, sleep disturbances) (figure 4).

Mental health symptoms

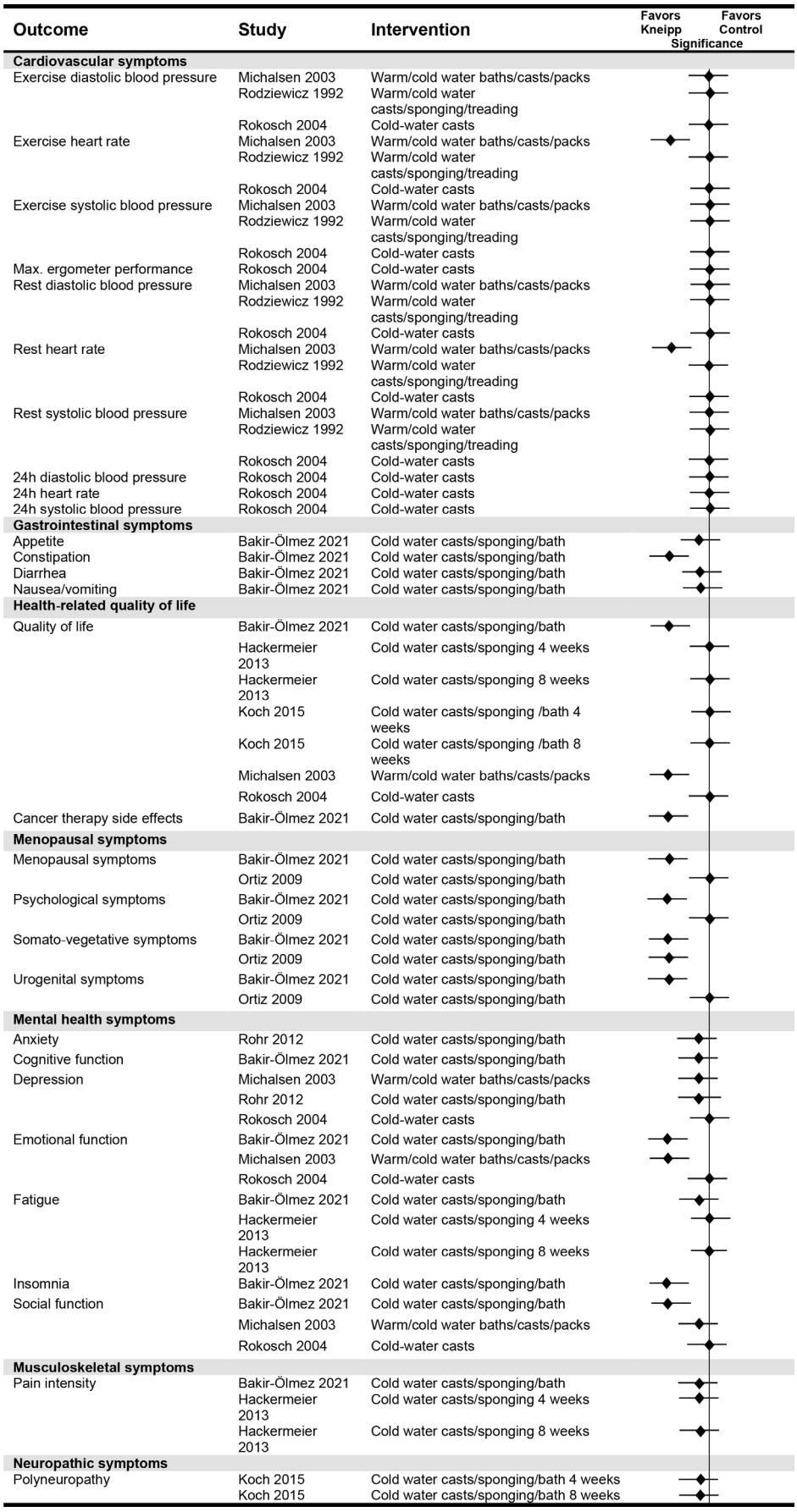
Seven studies included outcomes related to mental health symptoms including anxiety and depression. There were eight different outcomes with 21 comparisons in total. Eight comparisons favoured KH, six showed a trend in favour of KH and seven did not show any difference between groups. Emotional functioning revealed positive results in more than one study (figures 4–6).

Musculoskeletal symptoms

Three studies included outcomes related to musculoskeletal symptoms in the frame of different conditions. There were four different outcomes with 13 comparisons in total. Of six comparisons showed a trend in favour of KH, five did not show any difference between groups and two favoured the control treatment (figures 3–5).

Neuropathic symptoms

Two studies included outcomes related to neuropathic symptoms in patients with post-polio and polyneuropathy. There were four different outcomes with five comparisons in total. Two comparisons favoured KH, two showed a trend in favour of KH and one did not show any difference between groups. The comparisons in favour of KH were related to varicosis (cramps and pain) (figures 2 and 4).



Outcome	Study	Intervention
Cardiovascular symptoms		
Exercise diastolic blood pressure	Michalsen 2003	Warm/cold water baths/casts/packs
	Rodziewicz 1992	Warm/cold water casts/sponging/treading
	Rokosch 2004	Cold-water casts
Exercise heart rate	Michalsen 2003	Warm/cold water baths/casts/packs
	Rodziewicz 1992	Warm/cold water casts/sponging/treading
	Rokosch 2004	Cold-water casts
Exercise systolic blood pressure	Michalsen 2003	Warm/cold water baths/casts/packs
	Rodziewicz 1992	Warm/cold water casts/sponging/treading
	Rokosch 2004	Cold-water casts
Max. ergometer performance	Rokosch 2004	Cold-water casts
Rest diastolic blood pressure	Michalsen 2003	Warm/cold water baths/casts/packs
	Rodziewicz 1992	Warm/cold water casts/sponging/treading
	Rokosch 2004	Cold-water casts
Rest heart rate	Michalsen 2003	Warm/cold water baths/casts/packs
	Rodziewicz 1992	Warm/cold water casts/sponging/treading
	Rokosch 2004	Cold-water casts
Rest systolic blood pressure	Michalsen 2003	Warm/cold water baths/casts/packs
	Rodziewicz 1992	Warm/cold water casts/sponging/treading
	Rokosch 2004	Cold-water casts
24h diastolic blood pressure	Rokosch 2004	Cold-water casts
24h heart rate	Rokosch 2004	Cold-water casts
24h systolic blood pressure	Rokosch 2004	Cold-water casts
Gastrointestinal symptoms		
Appetite	Bakir-Ölmez 2021	Cold water casts/sponging/bath
Constipation	Bakir-Ölmez 2021	Cold water casts/sponging/bath
Diarrhea	Bakir-Ölmez 2021	Cold water casts/sponging/bath
Nausea/vomiting	Bakir-Ölmez 2021	Cold water casts/sponging/bath
Health-related quality of life		
Quality of life	Bakir-Ölmez 2021	Cold water casts/sponging/bath
	Hackermeier 2013	Cold water casts/sponging 4 weeks
	Hackermeier 2013	Cold water casts/sponging 8 weeks
	Koch 2015	Cold water casts/sponging /bath 4 weeks
	Koch 2015	Cold water casts/sponging /bath 8 weeks
	Michalsen 2003	Warm/cold water baths/casts/packs
	Rokosch 2004	Cold-water casts
Cancer therapy side effects	Bakir-Ölmez 2021	Cold water casts/sponging/bath
Menopausal symptoms		
Menopausal symptoms	Bakir-Ölmez 2021	Cold water casts/sponging/bath
	Ortiz 2009	Cold water casts/sponging/bath
Psychological symptoms	Bakir-Ölmez 2021	Cold water casts/sponging/bath
	Ortiz 2009	Cold water casts/sponging/bath
Somato-vegetative symptoms	Bakir-Ölmez 2021	Cold water casts/sponging/bath
	Ortiz 2009	Cold water casts/sponging/bath
Urogenital symptoms	Bakir-Ölmez 2021	Cold water casts/sponging/bath
	Ortiz 2009	Cold water casts/sponging/bath
Mental health symptoms		
Anxiety	Rohr 2012	Cold water casts/sponging/bath
Cognitive function	Bakir-Ölmez 2021	Cold water casts/sponging/bath
Depression	Michalsen 2003	Warm/cold water baths/casts/packs
	Rohr 2012	Cold water casts/sponging/bath
	Rokosch 2004	Cold-water casts
Emotional function	Bakir-Ölmez 2021	Cold water casts/sponging/bath
	Michalsen 2003	Warm/cold water baths/casts/packs
	Rokosch 2004	Cold-water casts
Fatigue	Bakir-Ölmez 2021	Cold water casts/sponging/bath
	Hackermeier 2013	Cold water casts/sponging 4 weeks
	Hackermeier 2013	Cold water casts/sponging 8 weeks
Insomnia	Bakir-Ölmez 2021	Cold water casts/sponging/bath
Social function	Bakir-Ölmez 2021	Cold water casts/sponging/bath
	Michalsen 2003	Warm/cold water baths/casts/packs
	Rokosch 2004	Cold-water casts
Musculoskeletal symptoms		
Pain intensity	Bakir-Ölmez 2021	Cold water casts/sponging/bath
	Hackermeier 2013	Cold water casts/sponging 4 weeks
	Hackermeier 2013	Cold water casts/sponging 8 weeks
Neuropathic symptoms		
Polyneuropathy	Koch 2015	Cold water casts/sponging/bath 4 weeks
	Koch 2015	Cold water casts/sponging/bath 8 weeks

Figure 4 Kneipp therapy compared with waiting list. Note. The results presented are vote counts and are not equivalent to the numerical estimators of a meta-analysis.

Outcome	Study	Comparison (Intervention vs. Control)
Common cold symptoms		
Fever	Aksoylar 1997	Tepid sponge bath vs. paracetamol 50 min.
	Aksoylar 1997	Tepid sponge bath vs. ibuprofen 50 min.
	Aksoylar 1997	Tepid sponge bath vs. Acetylsalicylic acid 50 min.
	Aksoylar 1997	Tepid sponge bath vs. paracetamol 200 min.
	Aksoylar 1997	Tepid sponge bath vs. ibuprofen 50 min.
	Aksoylar 1997	Tepid sponge bath vs. Acetylsalicylic acid 200 min.
Health-related quality of life		
Quality of life	Albrecht 2003$_b$	Cold water treading vs. no intervention
	Buijze 2016	Cold showering vs. no intervention 1 month
	Buijze 2016	Cold showering vs. no intervention 3 months
	Schencking 2013	Warm/cold water casts vs. physiotherapy 2 weeks
	Schencking 2013	Warm/cold water casts vs. physiotherapy 10 weeks
Mental health symptoms		
Anxiety	Buijze 2016	Cold showering (body) vs. no intervention 1 month
	Buijze 2016	Cold showering (body) vs. no intervention 3 months
Musculoskeletal symptoms		
Functional disability	Schencking 2013	Warm/cold water casts vs. physiotherapy 2 weeks
	Schencking 2013	Warm/cold water casts vs. physiotherapy 10 weeks
Joint mobility	Schencking 2013	Warm/cold water casts vs. physiotherapy
Pain intensity	Schencking 2013	Warm/cold water casts vs. physiotherapy
Range of motion	Schencking 2013	Warm/cold water casts vs. physiotherapy
Work absenteeism		
Work/school absenteeism	Buijze 2016	Cold showering vs. no intervention

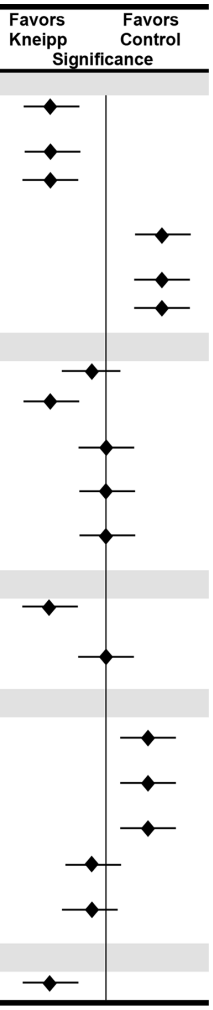


Figure 5 Kneipp therapy compared with no specific intervention, no intervention or physiotherapy alone. Note. The results presented are vote counts and are not equivalent to the numerical estimators of a meta-analysis.

Work absenteeism

Two studies included outcomes related to work absenteeism. There was one outcome with two comparisons in total. One comparison favoured KH, and one showed a trend in favour of KH (figures 3 and 5).

Pain in wound healing

Two studies included outcomes related to pain in wound healing. There was one outcome with two comparisons in total. One comparison favoured KH, and one did not show any difference between groups (figure 6).

Outcome	Study	Comparison (Intervention vs. Control)
Health-related quality of life		
Quality of life	Maestre 2010	Cold water bath + metamizole vs. warm water bath + metamizole
Mental health symptoms		
Cognitive function	Doering 1999	Cold water casts vs. warm water casts 10min
	Doering 1999	Cold water casts vs. warm water casts 30min
	Doering 1999	Cold water casts vs. warm water casts 60min
Vigilance	Doering 1999	Cold water casts vs. warm water casts 10min
Wound healing		
Pain intensity	Maestre 2010	Cold water bath + metamizole vs. warm water bath + metamizole
	Ramler 1986	Cold water bath vs. warm water bath

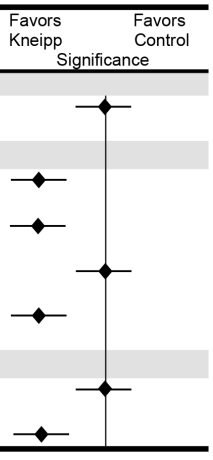


Figure 6 Kneipp therapy compared with another form of Kneipp therapy. Note. The results presented are vote counts and are not equivalent to the numerical estimators of a meta-analysis.

Safety

Eleven studies reported data on safety (online supplemental table 2).[20 22 23 26–28 31–34 38] In total, 23 serious adverse events were reported that were all considered to be not related to KH,[23 31] except for one pneumonia in the KH group, which required inpatient treatment.[28] The affected patient suffered from chronic obstructive pulmonary disease and severe hypothermia because of a URTI already at study exclusion. Thus, a causal relationship with KH is possible but not likely. Furthermore, non-serious adverse events were reported by seven studies[22 23 27 28 31 34 38] with one of these reported significantly more non-serious adverse events in the KH group compared with control.[38]

DISCUSSION

Summary and characteristics of main findings

This systematic review of RCTs on KH showed various positive effects of KH, mostly when compared with untreated controls. We found beneficial effects for the conditions varicosis, menopausal syndrome, fever in children and also for sickness absenteeism related to URTI in more than one study, and for hypertension and mild heart failure in single studies. Sleep disturbances, cognition and emotional functioning are outcomes that became better with KH under different conditions.

These results reflect the large study heterogeneity in terms of participants, outcomes, conditions and interventions. The quality of most of the studies was rather low with a high risk for bias.

It is noticeable that most of the studies we found were conducted in German-speaking countries. This could be due to the fact that cold water applications, as recommended by S Kneipp and V Prießnitz,[42] another famous hydropath of the 19th century, are still popular, especially in these countries. Although the use of cold water in therapeutic contexts has historically spread to other countries such as England and the USA,[43] it may not be as present there.

Strengths and limitations

First, to our knowledge, this is the most comprehensive systematic review on effects of KH without time or language restrictions with a broad search strategy. This included the search in clinical trial registers and the search of grey literature which was worthwhile because one-third of the studies was not published at all or not published in peer-reviewed journals. In addition, the inclusion of grey literature reduced the risk of publication bias. Second the quality of the studies was systematically assessed in this review. Third, the results of the review illustrate that there is a persisting lack of valid RCTs in this area as often in the field of non-pharmacological therapies. However, conditions where KH seem to work may be even clearer after this study and could be potential fields for research.

Limitations include the small number of trials and the large heterogeneity of participants and interventions which did not allow meta-analysis.

The impact of this review may be limited by the fact that most studies suffer from a high risk of bias concerning blinding procedures, random sequence generation or allocation concealment. While blinding in KH studies is difficult to achieve due to the nature of KH, an adequate active control should be chosen in further studies, also to balance bias coming from participants' expectations and unspecific treatment effects. Finally, some studies may lack an adequate sample size, while sample size calculation is not reported for every trial. Those study characteristics made us use vote counting to visualise the results of the studies.

Comparison to other reviews

Compared with a review by Haug,[15] KH evidence has grown in the last 20 years. Based on the results of six studies, positive effects of hydrotherapy were described for the indications of heart failure, chronic venous insufficiency and infection prophylaxis in adults. Our study was able to expand the number of conditions to include menopausal syndrome, short time relief of fever in children and also sickness absenteeism related to URTI as an objective for infections' intensity. The last point is supported by the results of a non-RCT about KH in children that was recently published. The authors found a reduction in kindergarten absenteeism for preschool children that practiced KH at home.[44]

Another recent systematic review identified 13 RCTs out of 25 included studies with different methodological designs on treatments defined as 'Kneipp treatments of any kind' (excluding phytotherapy only) from 2000 to 2019.[16] Because most of the included studies were of KH (of which eight were included also in our review), some of the results go in line with our study and potential effects were described for chronic venous insufficiency, hypertension, mild heart failure, menopausal syndrome and immune parameters related to URTI prevention.[16]

However, compared with the reviews from Stier-Jarmer and Haug we found several other RCTs on KH by our literature research, thus we could enlarge the body of evidence compared with former reviews on Kneipp therapy in general and KH especially.

Implication for clinical use

Although KH is a well-established therapeutic measure, an implication for clinical use can be drawn only with caution on the basis of this review due to the heterogeneity of studies and their quality. KH should be further explored as therapeutic options for the conditions mentioned above in larger high-quality clinical trials.

Reporting on safety of KH was overall poor, only about a half of the studies reported safety numbers. Most studies reported only serious adverse events and not adverse events. Therefore, a clear conclusion on the safety of KH cannot be drawn from our review results and should be addressed in further research. However, only one serious adverse event possibly related to KH was documented.

Implication for research

Given the high use of KH by the population, there is a high demand for further high quality RCTs on KH with adequate sample size and confirmatory design to ameliorate the quality of evidence on the effects and safety on KH. Whereas blinding of KH studies of study participants seems impossible due to its character of the intervention, three armed studies with an active and passive control group could distinguish specific from unspecific effects. Given the fact that KH is quite known as feasible, and implemented in healthcare, at least in many German speaking countries[45] also effectiveness studies seem to be sensible to enlarge the scientific body of evidence. Future research should consider, for example, Consolidated Standards of Reporting Trials guidelines and a straight publication strategy.

CONCLUSION

Although the RCTs on KH seem to show positive effects in some conditions and outcome parameters, it remains difficult to ascertain treatment effects due to the high risk of bias and heterogeneity of most of the considered studies. Therefore, further high-quality RCTs are urgently warranted to investigate HT adequately.

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