

INTERNATIONAL CONVENTION

NEW FRONTIERS OF THE EUROPEAN HEALTHCARE SYSTEM



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PROVINCIA AUTONOMA DI TRENTO

Current Situation of scientific research on Thermalism in Europe

Müfit Zeki Karagülle

19 October 2013
Palazzo delle Terme
Levico Terme (TN) - Italy



ISMH

INTERNATIONAL SOCIETY
OF MEDICAL HYDROLOGY
& CLIMATOLOGY

Thermalism/Thermal Medicine

Thermal Healthcare

Particularly in European (central, southern and eastern) countries

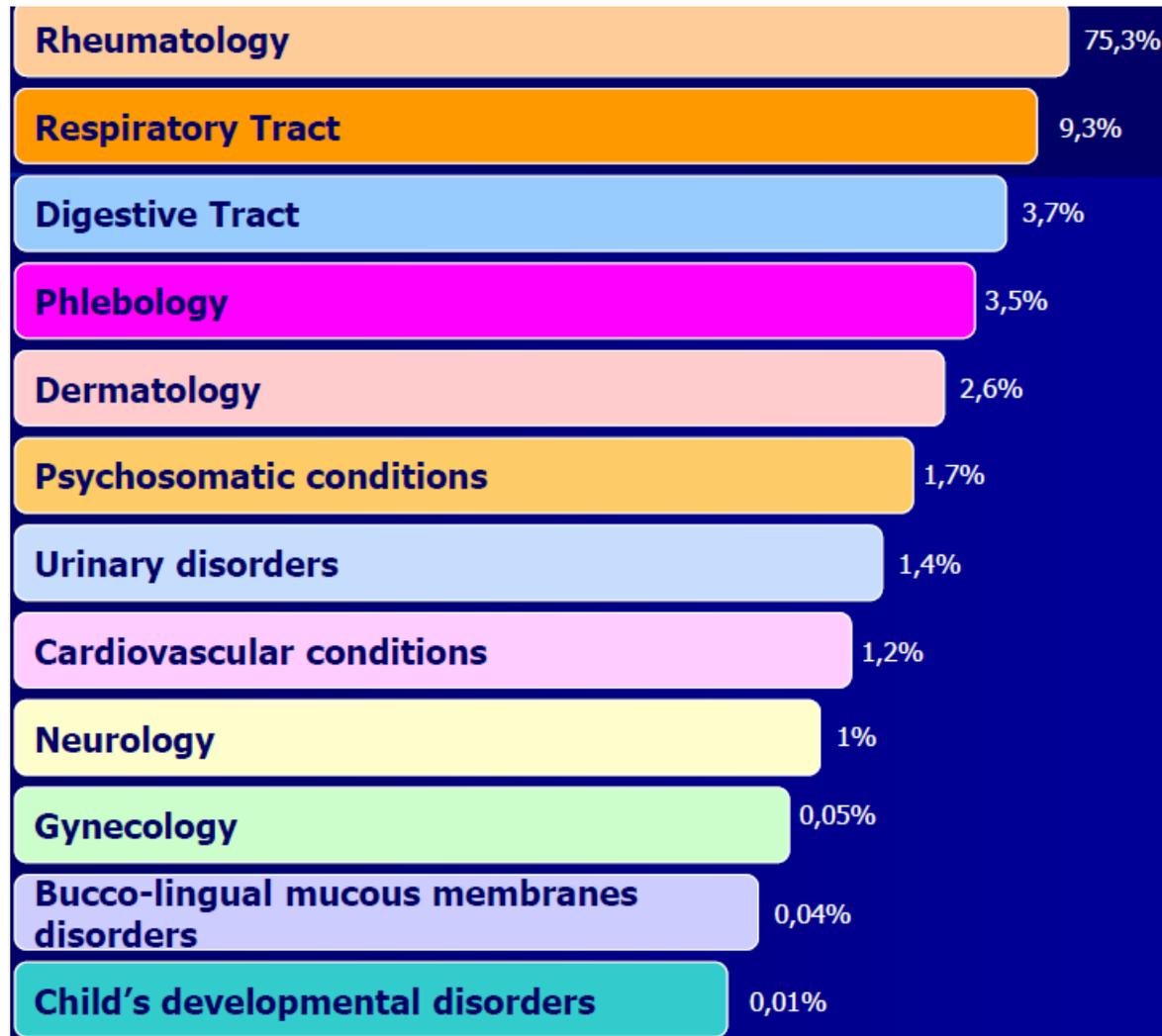
- A vivid and strong custom
- Has been considered mainstream and taught in medical schools
- Included in health care systems, reimbursed by health insurance systems (at least in part)

NEW FRONTIERS OF THE EUROPEAN HEALTHCARE SYSTEM

the EU legislation n° 2011/24 on
patients' rights for cross-border
traditional and thermal healthcare

Thermal Healthcare

frequently indicated as an effective therapy of the patients with chronic disorders



by Claude Eugène
BOUVIER

CNETH

(FRENCH PROFESSIONAL
ORGANISATION OF OPERATORS IN SPA
THERAPY)

Has time come for a re-assessment of spa therapy? The NAIADE survey in Italy

S. Coccheri • G. Gasbarrini • M. Valenti •
 G. Nappi • F. Di Orio

a cost-
 effective
 therapy of
 the patients
 with chronic
 disorders

Disease subgroup (no. patients)		No. (%) of patients with paid missed working days for appropriate sick-leave and average no. of missed working days(SD) per patient		
		At entry inquiry	At return inquiry	P ^a
Rheumatic (6,111)	Patients	525 (8.6)	313 (5.1)	0.0001
	Days	13.8 (4.1)	6.0 (2.4)	0.0001
Respiratory (3,085)	Patients	222 (7.2)	144 (4.7)	0.0001
	Days	19.2 (3.9)	15.1 (4.0)	0.0001
Dermatologic (413)	Patients	37 (8.9)	27 (6.5)	0.19
	Days	21.1 (5.0)	19.1 (4.8)	0.11
Gynecologic (827)	Patients	29 (3.5)	15 (1.8)	0.031
	Days	22.6 (3.4)	17.5 (3.7)	0.0001
ORL (6,023)	Patients	709 (11.7)	438 (7.2)	0.0001
	Days	16.0 (4.6)	11.8 (4.1)	0.0001
Urinary (490)	Patients	109 (22.2)	80 (16.3)	0.019
	Days	20.0 (2.3)	13.5 (1.2)	0.0001
Vascular (1,352)	Patients	142 (10.5)	80 (5.9)	0.0001
	Days	18.2 (3.0)	13.0 (2.8)	0.0001
Gastroenteric (5,379)				
DYS (2,868)	Patients	81 (2.6)	66 (2.3)	0.46
	Days	30.3 (6.6)	21.9 (7.0)	0.0001
IBSC (2,511)	Patients	27 (1.1)	22 (0.8)	0.25
	Days	19.8 (4.9)	18.4 (6.7)	0.45

Thermal Healthcare

Balneotherapy/Spa therapy

- one of the oldest forms of therapy for patients with arthritis
- still popular and “widely” used in particular of the musculoskeletal system
 - to soothe the pain,
 - improve joint motion
 - and as a consequence to relieve people' suffering
 - and make them feel well

Is Balneotherapy/Spa therapy effective?

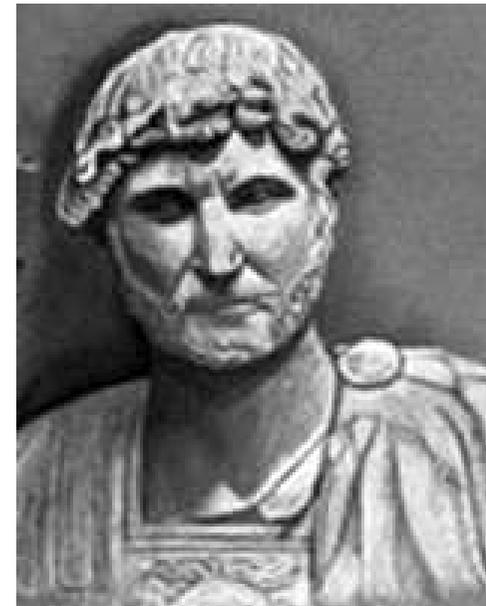
- often argued
 - the paucity of compelling data on specific effectiveness and cost-effectiveness
 - associated with considerable costs
- it is therefore reasonable to question whether it is supported by good evidence

Is there any evidence for balneotherapy in the treatment of rheumatic diseases?

“It is not every question that deserves an answer.”

Publilius Syrus (~100 BC)

Latin writer flourished in the 1st century BC.



Effectiveness

- relates to whether a 'treatment package' works in practice
- RCT (Randomized Controlled Trial)
 - The highest quality study to check this

Research Design Ratings

*	Research that is descriptive, anecdotal or authoritative;
**	Research without intervention, with results that may be used in future studies;
***	Research not involving a control group or randomization but with an evaluation;
****	Research involving a systematic study with control groups but without randomisation;
*****	Research involving a systematic study with a randomized control group.

Categories of evidence

Ann Rheum Dis 2003;62;1145-1155

adapted from the classification of the United States Agency for Health Care Policy and Research.

Category	Evidence from:
1A	Meta-analysis of RCTs
1B	At least one RCT
2A	At least one controlled study without randomisation
2B	At least one quasi-experimental study
3	Descriptive studies, such as comparative, correlation or case-control studies
4	Expert committee reports or opinions and/or clinical experience of respected

Meta-analysis of RCTs

- a quantitative statistical analysis of several RCTs in order to test the pooled data for statistical significance
- Quantitative systematic review

Categories of evidence

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Systematic reviews and Meta-analyses of RCTs of balneotherapy for rheumatic diseases

- Osteoarthritis
- Rheumatoid Arthritis
- Chronic Low Back Pain
- Fibromyalgia

Forschende
Komplementärmedizin und
Klassische Naturheilkunde

Übersichtsarbeit · Review Article

Forsch Komplementärmed Klass Naturheilkd 2004;11:33–41

Balneotherapie und Kurorttherapie rheumatischer Erkrankungen in der Türkei: Ein systematischer Review

M.Z. Karagülle M. Karagülle

Medizinische Ökologie und Hydroklimatologie, Medizinische Fakultät Istanbul der Universität Istanbul

Rheumatology 2006;45:880–884

doi:10.1093/rheumatology/kei018

Advance Access publication 31 January 2006

Spa therapy and balneotherapy for treating low back pain: meta-analysis of randomized trials

M. H. Pittler, M. Z. Karagülle¹, M. Karagülle¹ and E. Ernst

Balneotherapie und Kurorttherapie rheumatischer Erkrankungen in der Türkei: Ein systematischer Review

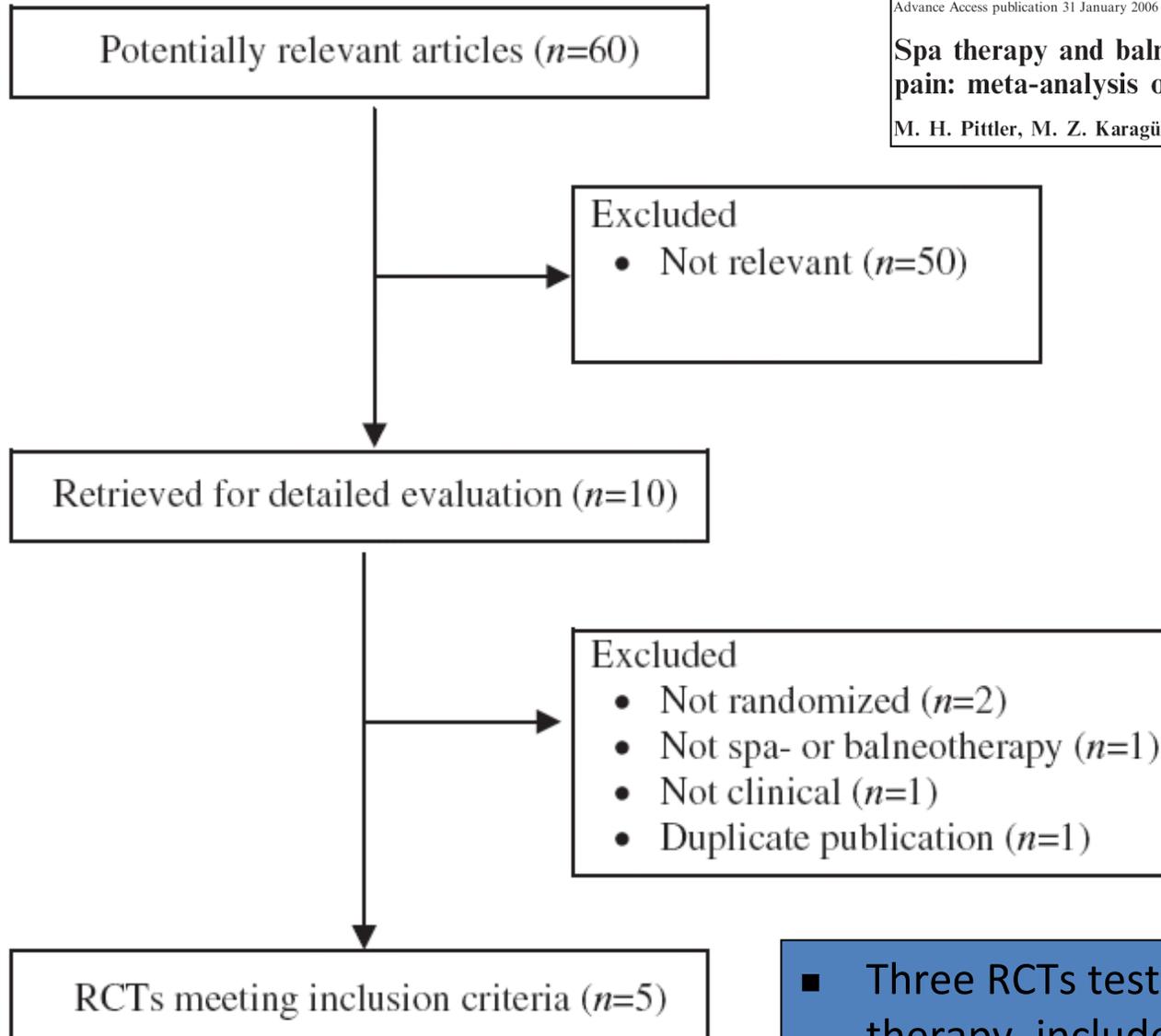
M.Z. Karagülle M. Karagülle

Medizinische Ökologie und Hydroklimatologie, Medizinische Fakultät Istanbul der Universität Istanbul

- In these studies the effectiveness and efficacy of different balneological and spa therapies on a variety of rheumatic diseases could be shown
- ***Osteoarthritis***
- ***Rheumatoid arthritis***
- ***Low back pain***
- ***Fibromyalgia***
- ***Ankylosing Spondylitis***

Spa therapy and balneotherapy for treating low back pain: meta-analysis of randomized trials

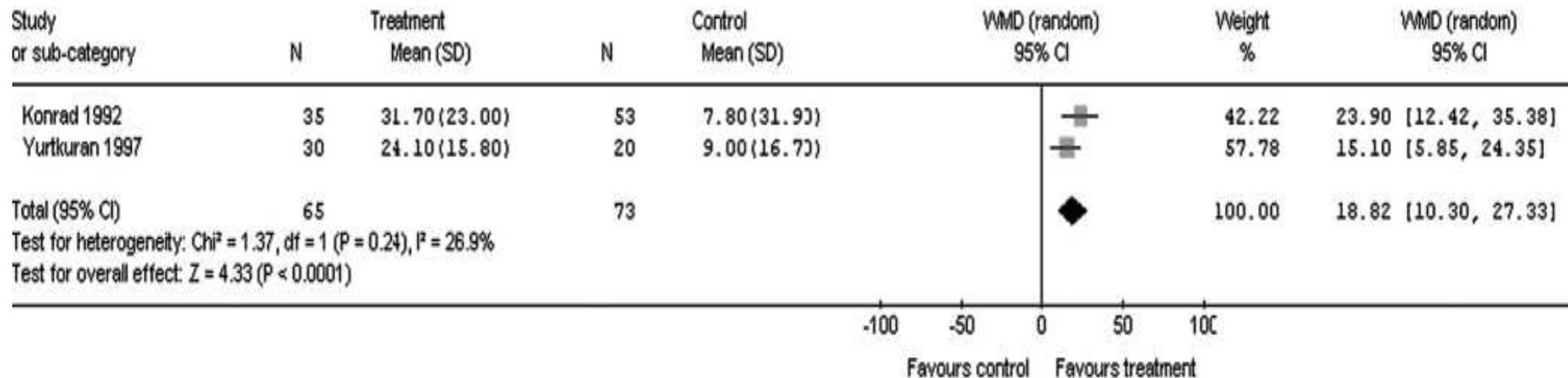
M. H. Pittler, M. Z. Karagülle¹, M. Karagülle¹ and E. Ernst



- Three RCTs tested the effectiveness of spa therapy, included 454 patients
- Two RCTs tested the effectiveness of balneotherapy, included 138 patients suffering from chronic low back pain.

Balneotherapy has an analgesic effect in chronic low back pain!!

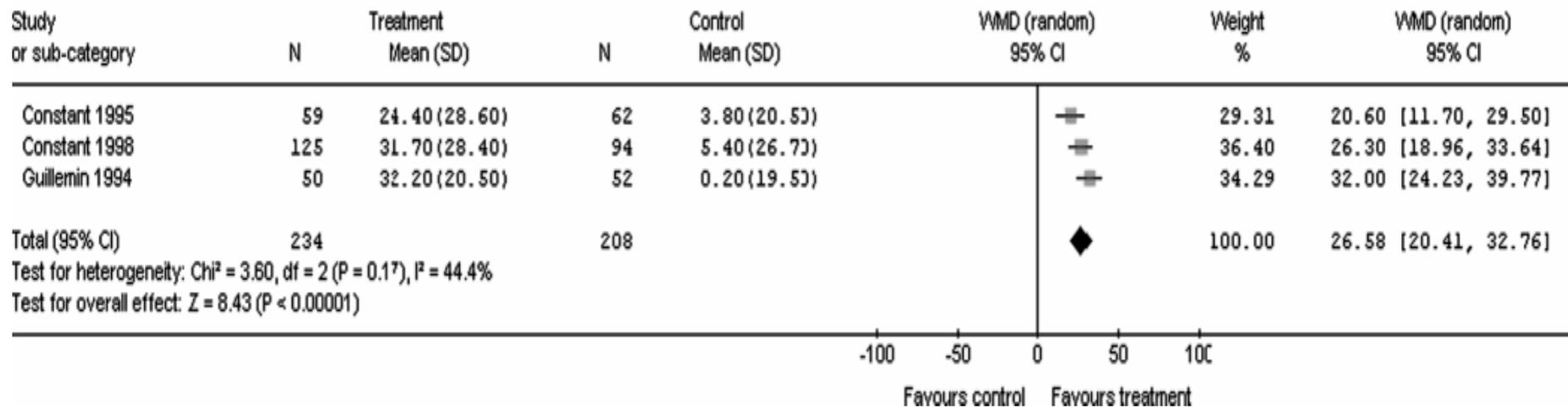
Review: Spa therapy or balneotherapy for low back pain
 Comparison: 02 Balneotherapy for low back pain
 Outcome: 01 Pain reduction (100mm VAS)



- Significant differences in favour of balneotherapy in pain reduction compared with control groups, (n=138).
- Weighted mean difference; 18.8 mm, (95% CI; 10.3–27.3), (100mm VAS)
- No visual or statistical evidence of heterogeneity ($P=0.24$, χ^2 test),

Spa therapy has an analgesic effect in chronic low back pain!!

Review: Spa therapy or balneotherapy for low back pain
 Comparison: 01 Spa therapy for chronic low back pain
 Outcome: 01 Pain reduction (100mm VAS)



- Significant differences in favour of spa therapy in pain reduction compared with waiting list control groups, (n=442).
- Weighted mean difference; 26.6 mm (95% CI; 20.4–32.8), (100mm VAS)
- No visual or statistical evidence of heterogeneity ($P=0.17$, χ^2 test).

Spa therapy and balneotherapy for treating low back pain: meta-analysis of randomized trials

M. H. Pittler, M. Z. Karagülle¹, M. Karagülle¹ and E. Ernst

- There is evidence suggesting clinically relevant pain relieving effect of thermalism (spa therapy and balneotherapy) in patients with low back pain
- However, the volume of the evidence is small and includes a total of only five RCTs assessing 674 patients.

EFFICACY OF BALNEOTHERAPY FOR OSTEOARTHRITIS OF THE KNEE: A SYSTEMATIC REVIEW

LUCIE BROSSEAU*, LYNN MACLEAY*, VIVIAN ROBINSON†, LYNN CASIMIRO*,
LUCIE PELLAND*, GEORGE WELLS, PETER TUGWELL† and JESSIE MCGOWAN†

**School of Rehabilitation Sciences, University of Ottawa, Canada*

†Institute of Population Health, University of Ottawa, Canada

‡Department of Epidemiology and Community Medicine, University of Ottawa, Canada

“Balneotherapy may have the potential to become an nonpharmacological treatment option for OA of the knee. The results of this review suggest that balneotherapy can be effective on a short-term basis for measures of pain severity and function as well as for improved ROM and timed stair climbing.”

EFFICACY OF BALNEOTHERAPY FOR RHEUMATOID ARTHRITIS: A META-ANALYSIS

LUCIE BROSSEAU*, VIVIAN ROBINSON†, GUILLAUME LÉONARD*,
LYNN CASIMIRO*, LUCIE PELLAND*, GEORGE WELLS‡ and PETER TUGWELL†

**School of Rehabilitation Sciences, †Institute of Population Health, and ‡Department of Epidemiology and
Community Medicine, University of Ottawa, Ontario, Canada*

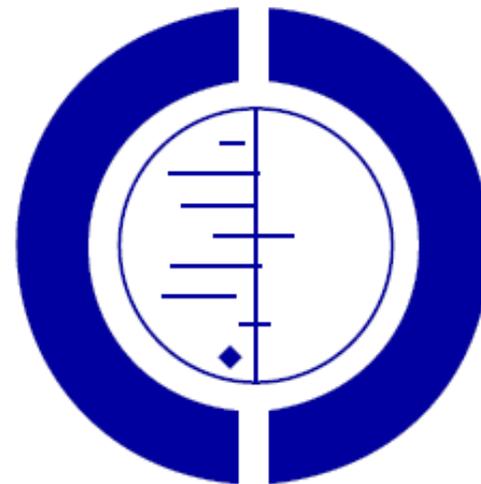
“This review has shown the positive effects of balneotherapy on important outcomes for patients with RA. The reviewers concluded that balneotherapy can be used as an adjunct therapy. However, these conclusions are undermined by the poor methodological quality of the trials available and the potential harmful side effects for arthritic patients with associated medical conditions.”

Balneotherapy for osteoarthritis (Review) 2007

Verhagen AP, Bierma-Zeinstra SMA, Boers M, Cardoso JR, Lambeck J, de Bie RA, de Vet HCW

Balneotherapy for rheumatoid arthritis (Review) 2004

Verhagen AP, Bierma-Zeinstra SMA, Cardoso JR, de Bie RA, Boers M, de Vet HCW



**THE COCHRANE
COLLABORATION®**

- One cannot ignore the positive findings reported in most studies, however, there is insufficient evidence to support the claims of positive findings in most studies.
- Because of methodological flaws (the absence of an adequate statistical analysis, and the absence of, for the patient, essential outcome measures (pain, quality of life))
- an answer about the effectiveness of balneotherapy cannot be provided on the basis of the included studies.

Balneotherapy for rheumatoid arthritis (Review)

Verhagen AP, Bierma-Zeinstra SMA, Cardoso JR, de Bie RA, Boers M, de Vet HCW



Balneotherapy for osteoarthritis (Review)

Verhagen AP, Bierma-Zeinstra SMA, Boers M, Cardoso JR, Lambeck J, de Bie RA, de Vet HCW

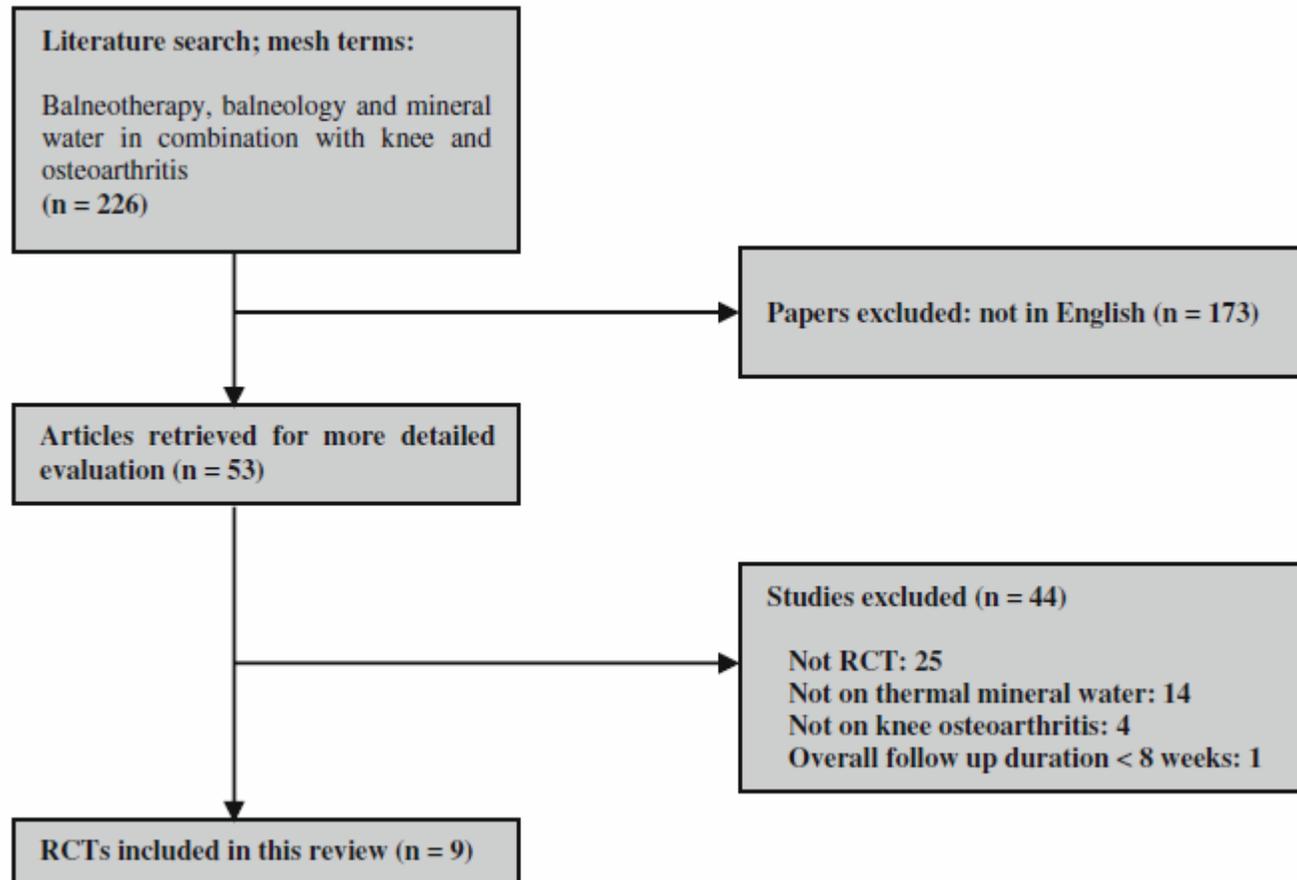


Our conclusion of this review is that

- there appeared to be silver level evidence in favour of balneotherapy when compared to no treatment
- a firm conclusion on the effectiveness of several forms of balneotherapy in patients with OA cannot be drawn.
- These results are comparable with the results of another Cochrane review on balneotherapy in patients with rheumatoid arthritis.

Short- and long-term therapeutic effects of thermal mineral waters in knee osteoarthritis: a systematic review of randomized controlled trials

Taoufik Harzy · Najoua Chani · Nourine Abachi ·
Wafaa Bono · Chakib



Short- and long-term therapeutic effects of thermal mineral waters in knee osteoarthritis: a systematic review of randomized controlled trials

Taufik Harzy · Najoua Ghani · Nessrine Akashi · Wafaa Bono · Chakib Nejari

Table 2 Main results of included studies

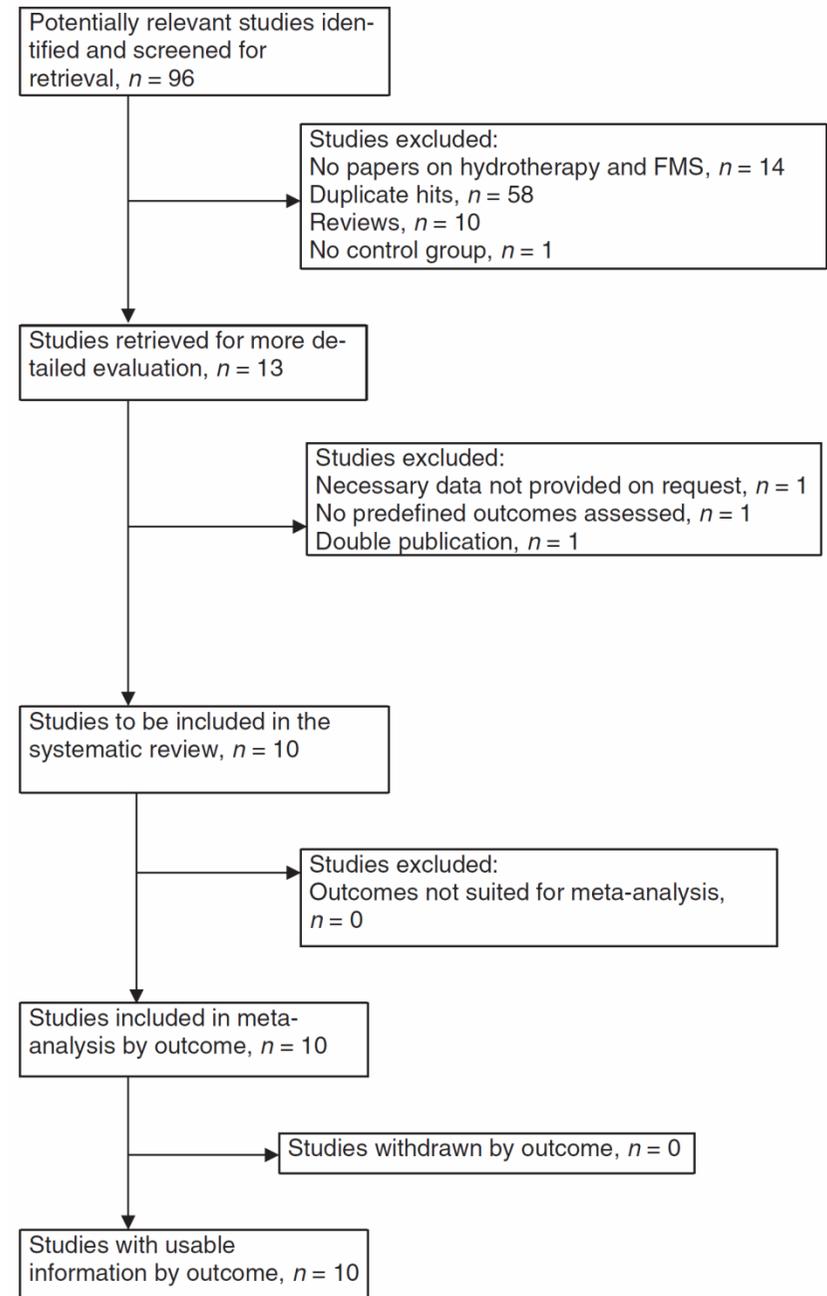
First author, year	Outcome extracted	Main results	Adverse events
Balint, 2007	Total WOMAC scores	Improvement of the activity, pain, and total WOMAC ($p < 0.05$) After 3 months, improvement was observed compared to the scores before the treatment or to TW treatment	Itching: 2 patients. Increased diuresis: 3 patients
Wigler, 1995	100 mm pain VAS, analgesic drug intake	VAS: Reduction in the three groups. However, it did not reach statistical significance A and C: Significant decrease in analgesic consumption B: No significant change	None
Karagülle, 2007	100 mm pain VAS, LAFI	LAFI—A: decrease during the whole follow-up period. B: no significant changes VAS—A: significantly lower. B: no significant change	Transient pain increase without causing any further problems: 2 patients
Yurtkuran, 2006	100 mm pain VAS, WOMAC index	VAS, WOMAC, improved in group A and group B. Comparison of the groups just after treatment showed that only VAS in favor of group A at the 2nd or 12th week	None
Kovacs, 2002	100 mm pain VAS	After the 15 days course: significant improvement of parameters 3 months later: this improvement persisted only in the actively treated group	NA
Cantarini, 2007	100 mm pain VAS, LAFI, NSAIDs and analgesic intake	A and B: Reduction in spontaneous pain (VAS) C: Worsening A and B: Decrease of LAFI, marked reduction of the use of symptomatic drugs	Side effects of light intensity without interruption of the therapy: 9 patients.
Nguyen, 1997	100 mm pain VAS, LAFI, NSAID and analgesic intake,	Significant improvement in VAS, LAFI and analgesic consumption NSAID consumption: not significant	NA
Tishler, 2004	100 mm pain VAS, WOMAC index, LAFI, NSAID and/or analgesic intake	A: Significant improvement of most outcome parameters (except WOMAC stiffness index) until the end of the study. B: No significant changes in any outcome parameters	None
Evcik, 2007	100 mm pain, VAS WOMAC index	Improvement in VAS and WOMAC pain scores in group A, group B and C. The WOMAC functional and global index also decreased in group A, group B and hot-pack group.	NA

Concise Report

Efficacy of hydrotherapy in fibromyalgia syndrome—a meta-analysis of randomized controlled clinical trials

Jost Langhorst¹, Frauke Musial¹, Petra Klose¹ and Winfried Häuser^{2,3}

- MEDLINE, PsychInfo, EMBASE, CAMBASE and CENTRAL (through December 2008)
- reference sections of original studies and systematic reviews
- Randomized controlled trials (RCTs) on the treatment of FMS with hydrotherapy (spa-, balneo- and thalassotherapy, hydrotherapy and packing and compresses)



Concise Report

Efficacy of hydrotherapy in fibromyalgia syndrome—a meta-analysis of randomized controlled clinical trials

Jost Langhorst¹, Frauke Musial¹, Petra Klose¹ and Winfried Häuser^{2,3}

Rheumatology key messages

- Spa therapy reduces pain and improves HRQOL in patients with fibromyalgia syndrome.
- High quality studies with larger sample sizes are necessary to confirm these results.
- Spa therapy is one first line non-pharmacological treatment option in FMS patients living near spa resorts.

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REVIEW

Authors	Sample size	Intervention	Outcome measures	Follow-up	Results
Yurtkuran ²²	A: 20 B: 20	A: Bal. (20 min × 5 days/week for 2 weeks at 37 °C) + relaxations exercises B: Exercises only	VAS, PAS	6 weeks	Significant changes on VAS and PAS for group A at the end of treatment and at 6 weeks
Buskila ²³	A: 24 B: 24	A: Bal. (20 min daily for 10 days at 37 °C) B: No treatment	VAS (Pain and other minor symptoms), FIQ, TPC, Dolorimeter, FDI	3 months	Significant between group improvement in pain and TPC in favour of A, still seen after 3 months
Neumann ²⁴	A: 24 B: 24	A: Bal. (20 min daily × 10 days at 37 °C) B: No treatment	SF36, AIMS, VAS (Pain and other minor symptoms)	3 months	Significant improvement in most subscales of the SF36 for both groups. The improvement in physical components of the QoL index lasted 3 months, whereas improvement in measures of psychological well-being was of shorter duration. Subjects in group A reported greater and longerlasting improvement than subjects in the group B
Evcik ²⁵	A: 22 B: 20	A: Bal. (20 min × 5 days/week for 3 weeks at 36 °C) B: No treatment	VAS, FIQ, TPC, BDI	6 months	The group A showed statistically significant improvement in TPC, VAS, FIQ and BDI at the end of the therapy and this improvement persisted at 6 months except for BDI
Dönmez ²⁶	A: 16 B: 14	A: Spa therapy (thermal pool baths 20 min × 6 days/week for 2 weeks at 36 ± 1 °C, pressurized shower at 37 °C or classical massage for 15 min each on alternate days) B: No treatment	VAS (Pain and other minor symptoms), FIQ, TPC, BDI	9 months	Significant improvement in pain, TPC and FIQ for group A. The pain and TPC results persisted for up to one month and the FIQ results for up to 6 months
Ardıç ²⁷	A: 12 B: 12	A: Bal. (20 min × 5 days/week for 3 weeks at 37 °C) B: No treatment	VAS, TPC, FIQ, BDI	3 weeks	Statistically significant improvement in VAS, BDI, TPC and FIQ was only found in group A at the end of the treatment cycle
Fioravanti ²⁸	A: 40 B: 40	A: Mud-packs (15 min daily for 2 weeks at 45 °C) and baths (10 min daily for 2 weeks at 37 °C–38 °C) B: No treatment	FIQ, TPC, VAS (Pain and other minor symptoms), AIMS, HAQ	16 weeks	In group A, a significant improvement in all parameters was recorded after mud-pack therapy and after 16 weeks
Özkurt ²⁹	A: 25 B: 25	A: Bal. (20 min twice/day for 2 weeks at 36 °C ± 1 °C) B: No treatment	VAS, FIQ, BDI, PGA, IGA, SF-36, TPC	3 months	Statistically significant improvement was recorded in group A for all outcome parameters at the end of the treatment cycle and after 3 months, except for BDI and IGA



Conclusions

In conclusion, spa therapy seems to be effective and useful in FS, reducing pain, improving function, and ameliorating QoL. The improvement reported in some clinical studies lasts over time. Nevertheless,

Clinical researches on the efficacy of spa therapy in fibromyalgia. A systematic review

Antonio Fraioli^(a), † Marcello Grassi^(a), Gioacchino Mennuni^(a), Andrea Geraci^(d), Luisa Petraccia^(a), Mario Fontana^(b), Stefano Conte^(a) and Angelo Serio^(c)

^(a) Dipartimento di Medicina Interna e Specialità Mediche, UOC Medicina Interna E, Terapia Medica e Medicina Termale, Sapienza Università di Roma, Rome, Italy

^(b) Dipartimento di Scienze Biochimiche, Sapienza Università di Roma, Rome, Italy

^(c) Università Campus Bio-Medico, Rome, Italy

^(d) Dipartimento del Farmaco, Istituto Superiore di Sanità, Rome, Italy

Studies on spa therapy for fibromyalgia syndrome (FMS) included in the review

Authors	Location of spa	Mineral water content
Fioravanti <i>et al.</i> [46]	Sardara (Italy) Rapolano (Italy) Montegrotto (Italy) Agnano (Italy)	Sulfate-bicarbonate Sulfate-bicarbonate Sodium bromide/sodium iodide Sodium bromide/sodium iodide
Ardıç <i>et al.</i> [47]	Denizli (Turkey)	Sulfate-bicarbonate-calcium-magnesium
Evcik <i>et al.</i> [48]	Afyon (Turkey)	Sodium bicarbonate
Dönmez <i>et al.</i> [49]	Balçova (Turkey)	Sodium chloride/sodium bicarbonate
Altan <i>et al.</i> [50]	Bursa (Turkey)	Sodium, sulfate
Özkurt <i>et al.</i> [51]	Tuzla (Turkey)	Sodium chloride, calcium
Cimbiz <i>et al.</i> [52]	Tutav (Turkey)	Sodium, sulfate, calcium, magnesium

Clinical researches on the efficacy of spa therapy in fibromyalgia. A systematic review

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^(a) *Dipartimento di Medicina Interna e Specialità Mediche, UOC Medicina Interna E, Terapia Medica e Medicina Termale, Sapienza Università di Roma, Rome, Italy*

^(b) *Dipartimento di Scienze Biochimiche, Sapienza Università di Roma, Rome, Italy*

^(c) *Università Campus Bio-Medico, Rome, Italy*

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Therefore, on the basis of our review, mineral-water balneotherapy appears to offer proven efficacy for the treatment of fibromyalgia. Naturally, these findings might receive additional confirmation in the future from more in-depth studies conducted in multiple spas. For patients with a disease like FMS, which has clear psychological components, spa therapy offer additional benefits that could be therapeutic, such as a pleasant climate, relaxing natural scenery, and clean air.

The therapeutic effect of balneotherapy: evaluation of the evidence from randomised controlled trials

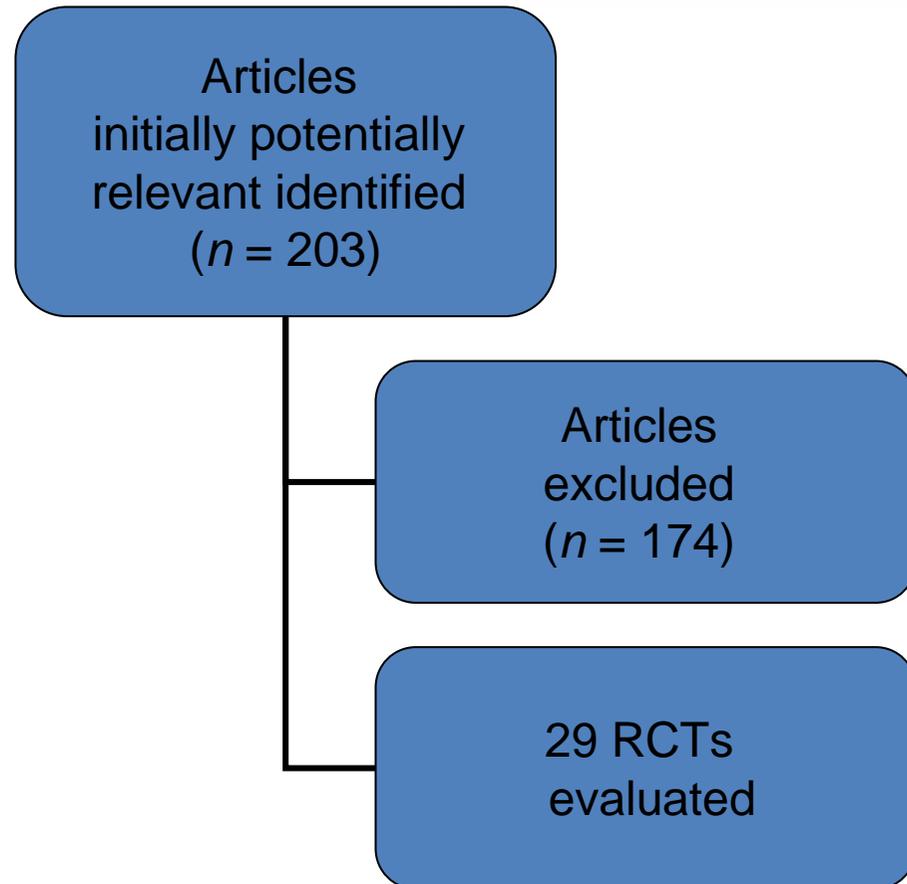
M. E. Falagas,^{1,2} E. Zarkadoulia,^{1†} P. I. Rafailidis¹

Int J Clin Pract, July 2009, 63, 7, 1068–1084

¹Alfa Institute of Biomedical Sciences (AIBS), Athens, Greece
²Department of Medicine, Tufts University School of Medicine, Boston, MA, USA

Review Criteria

- Search (1950–2006)
 - PubMed
 - Scopus
 - Cochrane library
- (RCTs), examining the clinical effect of balneotherapy (both as a solitary approach and in the context of spa) on various diseases.



META-ANALYSIS

 THE INTERNATIONAL JOURNAL OF
CLINICAL PRACTICE

The therapeutic effect of balneotherapy: evaluation of the evidence from randomised controlled trials

M. E. Falagas,^{1,2} E. Zarkadoulia,^{1†} P. I. Rafailidis¹

Int J Clin Pract, July 2009, **63**, 7, 1068–1084

¹Alfa Institute of Biomedical Sciences (AIBS), Athens, Greece
²Department of Medicine, Tufts University School of Medicine, Boston, MA, USA

Message for the Clinic

The available evidence suggests that balneotherapy may help patients with various rheumatological diseases;

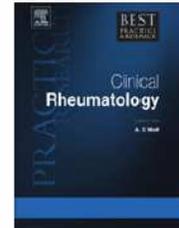
- Osteoarthritis
- Fibromyalgia
- Ankylosing Spondylitis
- Rheumatoid arthritis
- Chronic low back pain



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Best Practice & Research Clinical Rheumatology

journal homepage: www.elsevier.com/locate/berh



4

Aquatic exercise & balneotherapy in musculoskeletal conditions

Arianne P. Verhagen, PT, MSc, PhD^{a,*}, Jefferson R. Cardoso, PT, MSc, PhD^b,
Sita M.A. Bierma-Zeinstra, PT, MSc, PhD, Prof^{a,c}

^aDept General Practice, Erasmus Medical Centre University, Rotterdam, PO Box 2040, 3000 CA Rotterdam, The Netherlands

^bDept Physical Therapy, Laboratory of Biomechanics and Clinical Epidemiology, Universidade Estadual de Londrina, Londrina, Brazil

^cDept Orthopaedic Surgery, Erasmus Medical Centre University, Rotterdam, The Netherlands

Practice points

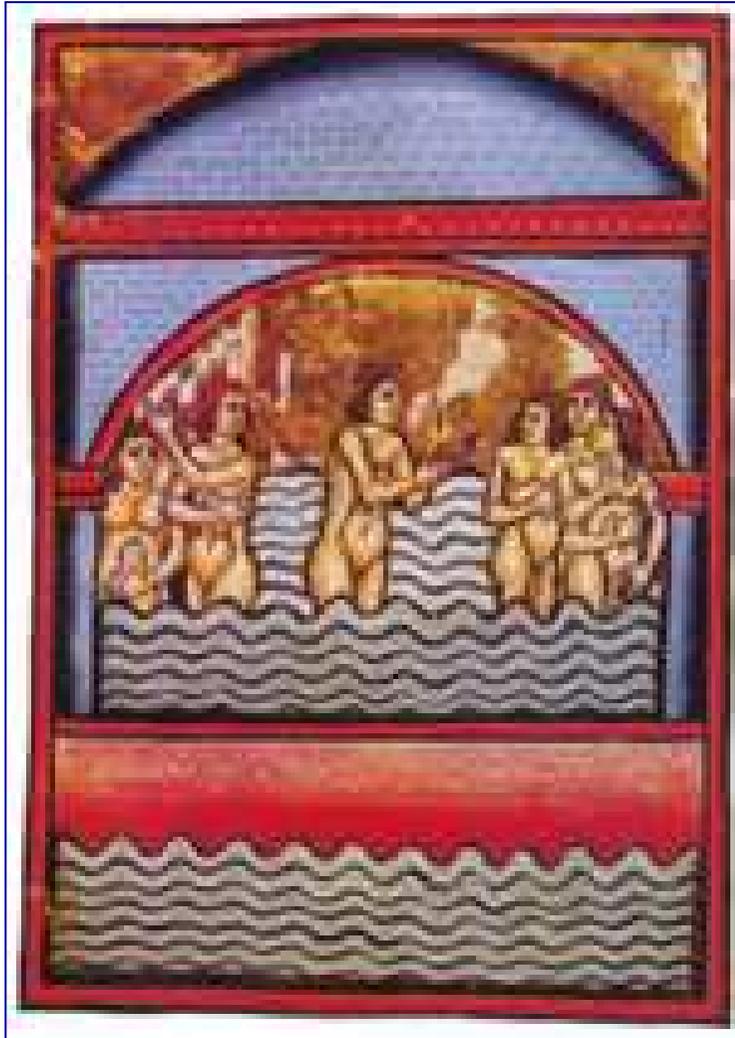
- Aquatic therapy is a popular treatment for many patients with musculoskeletal disorders, and seems a beneficial treatment in patients with osteoarthritis, chronic low back pain and fibromyalgia.
- It remains unclear whether balneotherapy is more or less effective than aquatic exercises. They seem equally effective and these treatments seem particularly useful when patients are unable to exercise on land.
- For patients with osteoarthritis aquatic exercise is not a costly intervention and it might be cost-effective, but further research on cost-effectiveness is warranted.

Question?



Is there any evidence for balneotherapy in the treatment of rheumatic disease ?

Conclusion!



**“Yes there is
some or weak
vs encouraging
or compelling
evidence !”**

TAMAS BENDER

Europe; Heart of Thermalism

**Intensive scientific
research has
been always taking place
predominantly
in Europe !**

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39th ISMH Congress 2014 in Japan

40th ISMH Congress 2015 in Brasil

41st ISMH Congress 2016 in Italy !?



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