CO33-003-e

Spa therapy in the treatment of knee osteoarthritis: A large randomized trial
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Objective – To determine whether spa therapy, plus home exercises and usual medical treatment provides any benefit over exercises and usual treatment, in the management of knee osteoarthritis.

Methods – Large multicentre randomised prospective clinical trial of patients with knee osteoarthritis according to the American College of Rheumatology criteria, attending French spa resorts as outpatients between June 2006 and April 2007. Zelen randomisation was used so patients were ignorant of the other group and spa personnel were not told which patients were participating. The main endpoint criteria were patient self-assessed. All patients continued usual treatments and performed daily standardised home exercises. The spa therapy group also received 18 days of spa therapy (massages, showers, mud and pool sessions).

Main Endpoint The number of patients achieving minimal clinically important improvement (MCII) at 6 months, defined as ≥ 19.9 mm on the visual analogue pain scale and/or ≥ 9.1 points in a normalised Western Ontario and McMaster Universities osteoarthritis index function score and no knee surgery.

Results – The intention to treat analysis included 187 controls and 195 spa therapy patients. At 6 months, 99/195 (50.8%) spa group patients had MCII and 68/187 (36.4%) controls (χ² = 8.05; df = 1; P = 0.005). However, no improvement in quality of life (Short Form 36) or patient acceptable symptom state was observed at 6 months.

Conclusion – For patients with knee osteoarthritis, a 3-week course of spa therapy together with home exercises and usual pharmacological treatments offers benefit after 6 months compared with exercises and usual treatment alone, and is well tolerated.

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Spa therapy in the treatment of chronic shoulder pain due to rotator cuff tendinopathy: Rotatherm, a large randomised multicentre trial
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Keywords: Balneotherapy; RCT; Shoulder; QOL; SF 36; DASH score

Objective – To determine whether spa therapy provides any benefit on pain and disability in the management of shoulder pain due to chronic rotator cuff lesions.

Methods – Multicentre randomized prospective clinical trial included patients with shoulder pain due to chronic degenerative rotator cuff tendinopathy, attending French spa resorts as outpatients between March 2009 and April 2010. Patients were randomized in two groups: immediate (18 days of standardized spa treatment) or 6-months-delayed Spa therapy (control group). All patients continued usual treatments during the 6-month follow-up period. Main endpoint was the mean change of the DASH score at 6 months. Effect size of spa therapy was calculated and proportion of patients reaching minimal clinical important improvement (MCII) was compared between groups. Secondary endpoints were the mean change on SF-36 components, treatments use and tolerance.

Results – One hundred and eighty-six patients were included in the study (94 in control group and 92 in spa therapy group) and analyzed in intention to treat. At 6 months, mean change in DASH score was statistically more important in Spa therapy patients compared to controls (∼32.6% and ∼8.15%, respectively (P < 0.001)) with an effect size for spa therapy calculated at 1.32. A statistically higher proportion of patients reached MCII at 6 months in the spa therapy group (59.3%) compared to controls (17.9%). Spa therapy was well tolerated, with a significant impact on SF-36 components but not on drugs consumption except for topics.

Conclusion – Spa therapy provides a highly statistical benefit on pain and function in patients with chronic shoulder pain after 6 months compared with usual treatment alone.

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Assessment of short intensive balneotherapy for patients with lower back pain: Protocol of a randomised controlled trial
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Objective – Evaluate the efficacy of a short standardised balneotherapy intervention on the return-to-work rate at one year among patients on sick leave for lower back pain for more than four weeks and less than 12 weeks.

Methods – Multicenter, comparative, randomised, pragmatic trial using the modified Zelen method. Seven hundred patients with lower back pain on sick leave for more than 4 weeks and less than 12 weeks received an information booklet on back pain and routine care (n = 350) or a standardised balneotherapy intervention for 5 days with balneotherapy (2 hr), exercises (30 min) and educational therapy (45 min) on three themes: physical activity, occupational activity, pain management. The main outcome was the return-to-work rate at one year. Secondary outcomes were the number of sick leave days during the period 6–12 months after inclusion, area under the pain curve during the last 48 h evaluated every week using a numerical scale from 0 to 100 at one year, evaluation of function at one year (Quebec scale), evaluation of quality of life (MOS SF-12) at one year, TWIST-pain at one year. Data will be analysed on an intention-to-treat basis. The return-to-work rate will be compared with the Mann-Whitney test. Other secondary outcomes will be compared with a linear model for mixed effects.

Conclusion – This is the first trial evaluating a standardised short balneotherapy intervention including a standardised therapeutic education session and using social efficacy as the outcome.

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A framework for an economic evaluation of spa treatment: Principles, case studies and modelisation
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