

# Randomised controlled trial of the cost-effectiveness of water-based therapy for lower limb osteoarthritis

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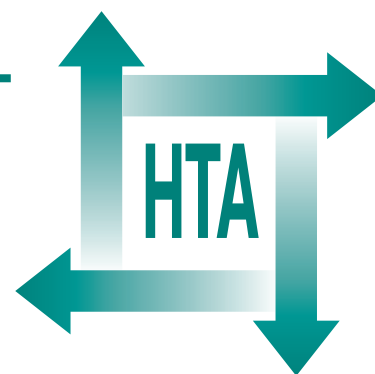
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## *Executive summary*

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## Executive summary

### Objectives

The objectives of the present study were:

- to determine the efficacy of community water-based therapy for the management of lower limb osteoarthritis (OA) in older patients: does the treatment work if taken by the recipients?
- to assess the cost-effectiveness of such an approach: is the treatment effective and is it cost-effective in practice?
- to establish the implications of delivering and sustaining a community-based water exercise programme for older patients with lower limb OA.

### Methods

#### Design

A pre-experimental matched-control study was used to estimate efficacy (over 12 weeks only) of water-based exercise treatment, to check design assumptions and delivery processes. This was followed by the main study, a randomised controlled trial (under pragmatic conditions pertaining to general practice and community settings in North Staffordshire, UK) of the effectiveness of water-based exercise (treatment) compared with usual care (control) in older patients with hip and/or knee OA. The latter was accompanied by an economic evaluation comparing societal costs and consequences of the two treatments.

#### Setting

Water exercise was delivered in public swimming pools. Five different venues were used, one in the preliminary and four in the main study. Patients were prescribed group sessions twice weekly from a total choice of three (preliminary study) or ten (main study). Physical function assessments were carried out in established laboratory settings.

#### Participants

One-hundred and six patients (93 women, 13 men) over the age of 60 years with confirmed hip and/or knee OA took part in the preliminary study. A similar, but larger, group of 312 patients

(196 women, 116 men) took part in the main study, randomised into control (159) and water exercise (153) groups. Participants in the main study were recruited from a combination of general practice registers (246) and advertisement in the local press (66).

#### Interventions

Randomisation was performed according to a computer-generated random number sequence by a member of the research team who was blinded to any patient details other than their name. Control group patients received usual care with quarterly semi-structured telephone interview follow-up only. The intervention in the main study lasted for 1 year, with a further follow-up period of 6 months. Each water exercise session lasted for approximately 1 hour and included: warm-up, strengthening, range of motion, stretch, cardiovascular conditioning, balance and coordination exercises and/or swimming.

#### Main outcome measures

Pain score on the Western Ontario and McMaster Universities OA index (WOMAC) was the main outcome measure to judge efficacy and effectiveness. Additional outcome measures were included to evaluate effects on quality of life (the Short Form 36), general health status (EuroQol Visual Analogue Scale and 5 Dimension) and activities of daily living (hamstrings and quadriceps strength, 8-foot walk, stair climb and descent). Healthcare resource use for the economic evaluation was obtained from a combination of patient questionnaire and interview at 1 year and review of patients' notes. Hospital episodes were obtained from locally maintained patient databases. Cost-effectiveness was evaluated from the incremental cost-effectiveness ratios (difference in mean cost divided by difference in mean effect in the two groups), derived from 1000 random samples from the set of individual cost and effect estimates from the study participants (non-parametric bootstrap sampling). Cost-effectiveness acceptability curves were constructed to provide ceiling valuations for comparison with other healthcare resource use options. Primary analysis was performed on an intention-to-treat basis, with last available measurement carried forward. ▶

Patients were not blinded to treatment allocation, but all assessors and data entry were blinded to group allocation using the following process. All questionnaires were marked only with a patient code and were processed by a research administrator without knowledge of group allocation. Physical function measurements were performed by the same independent researchers in the Sports Performance Centre, Staffordshire University, who had no knowledge of group allocation. Coding was only revealed after all data had been entered, checked and validated and before interim (for monitoring and reporting purposes) and final analysis.

## Results

Short-term efficacy of water exercise in the management of lower limb OA was confirmed, with effect sizes ranging from 0.44 [95% confidence interval (CI) 0.03 to 0.85] on WOMAC pain to 0.76 (95% CI 0.33 to 1.17) on WOMAC physical function.

Of 312 (153 treatment, 159 control) patients randomised in the main trial, 231 (74%) [111 (72.5%) treatment, 120 (75.5%) control] provided follow-up assessment data at the 1-year assessment point and 213 (68%) [100 (65%) treatment, 113 (71%) control] provided follow-up assessment data at the 18-month assessment point. Of 153 patients randomised to treatment, 82 (53.5%) were estimated to have complied satisfactorily with their treatment at the 1-year point. This had declined to 28 (18%) by the end of the 6-month follow-up period, during which support for the intervention had been removed and those wishing to continue exercise had to pay their own costs for maintaining their exercise treatment.

High levels of co-morbidity were recorded in both groups. Nearly two thirds of all patients had a significant other illness in addition to their OA. Fifty-four control and 53 exercise patients had hospital inpatient episodes during the study period.

Water exercise remained effective in the main study but overall effect size was small, [mean group difference = 0.89, effect size = 0.25 (95% CI 0.02 to 0.47),  $p = 0.031$ ] on WOMAC pain at 1 year, a reduction of about 10% in group mean pain score. This had declined, and was non-significant, at 18 months.

Ancillary analysis yielded a complier average causal effect estimate for those who complied with

their treatment of 1.65 (95% CI 0.13 to 3.17) WOMAC pain units, which was similar to that found in the 12-week pilot study

Mean cost difference estimates showed a saving in the water exercise group of £123–175 per patient per annum and incremental cost-effectiveness ratios ranged from £3838 to £5951 per quality-adjusted life-year (QALY), although it was not possible to determine a ceiling valuation (with 95% confidence) for comparison with competing approaches.

Net reduction in pain was achieved at a net saving of £135–175 per patient per annum, even after allowing for marginal costs of providing the exercise programme, and the ceiling valuation of £580–740 per unit of WOMAC pain reduction was favourably low.

## Conclusions

Group-based exercise in water over 1 year can produce significant reduction in pain and improvement in physical function in older adults with lower limb OA, and may be a useful adjunct in the management of hip and/or knee OA. Wide variation in both the individual costs and the utility measures, combined with small effect sizes, limited the power of the project to detect a difference between the groups on QALY-based analyses, but the water-exercise programme produced a favourable cost-benefit outcome, using reduction in WOMAC pain as the measure of benefit.

## Implications for healthcare

- Water exercise is an efficacious form of treatment for lower limb OA.
- Similar treatment effects were found in this longer term exercise study as have been reported for pharmacological interventions.
- There was no evidence either in favour of or against exercise in water compared with other forms of physical activity or strengthening programme for lower limb OA.
- Effect sizes were small but, since the intervention can be delivered, at least potentially, on a population basis, the benefit to the health service could be valuable.
- Exercise needs to be sustained to maintain the benefit.
- Current levels of support for water exercise programmes for older patients are inadequate to sustain adherence in this conservative method of management. Thus, advocacy or exercise advice alone is unlikely to lead to uptake in this patient group. ►

## Recommendations for research

The following recommendations for further research are suggested:

- More pragmatic research into public health interventions of the nature of that undertaken in this project is justified. To ease the additional research burden on any one community, to facilitate recruitment and to enhance the generalisability of the findings, it would be better if this could be multicentre and across multiple regions. The commissioning process could facilitate such collaboration by adopting a two-stage process: first, to assemble the expert group and potential collaborating centres and then to design and deliver the trial.
- Better and more cost-effective mechanisms need to be developed to obtain representative samples for public health interventions. Based on the experience encountered on this project, one research question (and, presumably, resource issue) that needs to be addressed is how best can general practice be supported to facilitate access to participants for research trials in healthcare?
- Infrastructure and workforce capacities for physical activity delivery and the potential extent to which healthcare may be supported in this way need to be determined.

- More detailed research is required to develop a better understanding of the types of exercise that will work for the different biomechanical subtypes of knee and hip OA. The stage of the disease process might also need to be taken into account since it is feasible that mechanical loading may work in the early and intermediate stages of the disease but may not do so in the later stages, when the structural integrity of the cartilage–bone interface has been lost.
- More research is needed on access and environmental issues for physical activity programmes for older people, from both a provider and a participant perspective.
- If evidence is to drive decisions on the appropriate mix of treatment options then more longitudinal data are needed on the societal costs of the different approaches to the management of OA and longer term trends in outcome measures (costs and effects). The body of evidence relating to conservative or public health interventions such as that evaluated here is particularly sparse.

## Publication

Cochrane T, Davey RC, Matthes Edwards SM. Randomised controlled trial of the cost-effectiveness of water-based therapy for lower limb osteoarthritis. *Health Technol Assess* 2005;**9**(31).

# NHS R&D HTA Programme

The research findings from the NHS R&D Health Technology Assessment (HTA) Programme directly influence key decision-making bodies such as the National Institute for Health and Clinical Excellence (NICE) and the National Screening Committee (NSC) who rely on HTA outputs to help raise standards of care. HTA findings also help to improve the quality of the service in the NHS indirectly in that they form a key component of the 'National Knowledge Service' that is being developed to improve the evidence of clinical practice throughout the NHS.

The HTA Programme was set up in 1993. Its role is to ensure that high-quality research information on the costs, effectiveness and broader impact of health technologies is produced in the most efficient way for those who use, manage and provide care in the NHS. 'Health technologies' are broadly defined to include all interventions used to promote health, prevent and treat disease, and improve rehabilitation and long-term care, rather than settings of care.

The HTA Programme commissions research only on topics where it has identified key gaps in the evidence needed by the NHS. Suggestions for topics are actively sought from people working in the NHS, the public, service-users groups and professional bodies such as Royal Colleges and NHS Trusts. Research suggestions are carefully considered by panels of independent experts (including service users) whose advice results in a ranked list of recommended research priorities. The HTA Programme then commissions the research team best suited to undertake the work, in the manner most appropriate to find the relevant answers. Some projects may take only months, others need several years to answer the research questions adequately. They may involve synthesising existing evidence or conducting a trial to produce new evidence where none currently exists.

Additionally, through its Technology Assessment Report (TAR) call-off contract, the HTA Programme is able to commission bespoke reports, principally for NICE, but also for other policy customers, such as a National Clinical Director. TARs bring together evidence on key aspects of the use of specific technologies and usually have to be completed within a short time period.

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The research reported in this monograph was commissioned by the HTA Programme as project number 96/32/99. The contractual start date was in April 2000. The draft report began editorial review in May 2004 and was accepted for publication in March 2005. As the funder, by devising a commissioning brief, the HTA Programme specified the research question and study design. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the referees for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

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