A randomised controlled trial of combined hydrotherapy programmes compared with physiotherapy land techniques in children with juvenile idiopathic arthritis

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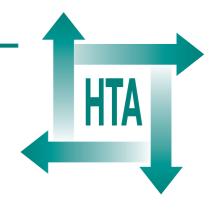
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# **Executive summary**

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# **Executive summary**

## **Objectives**

The objectives of this study were to compare the effects of combined hydrotherapy and land-based physiotherapy (**combined**) with land-based physiotherapy only (**land**) on cost, health-related quality of life (HRQoL) and outcome of disease in children with juvenile idiopathic arthritis (JIA). Also to determine the cost-effectiveness of combined hydrotherapy and **land**-based physiotherapy in JIA.

## **Design**

A multicentre randomised controlled, partially blinded trial was designed with 100 patients in a control arm receiving land-based physiotherapy only (land group) and 100 patients in an intervention arm receiving a combination of hydrotherapy and land-based physiotherapy (combined group).

## **Participants**

Patients aged 4–19 years diagnosed more than 3 months with idiopathic arthritides, onset before their 16th birthday, stable on medication with at least one active joint were recruited from three tertiary centres in the UK.

#### Intervention

Patients in the **combined** and **land** groups received 16 1-hour sessions of treatment at one of the three centres over 2 weeks followed by local physiotherapy attendances for 2 months.

### Main outcome measures

Disease improvement defined as a decrease of ≥30% in any three of six core set variables without there being a 30% increase in more than one of the remaining three variables was used as the primary outcome measure and assessed at 2 months following completion of intervention. Health services resource use (in- and outpatient

care, GP visits, drugs, interventions, and investigations) and productivity costs (parents' time away from paid work) were collected at 6 months follow-up. HRQoL was measured at baseline and 2 and 6 months following intervention using the EQ-5D, and quality-adjusted life-years (QALYS) were calculated. Secondary outcome measures at 2 and 6 months included cardiovascular fitness, pain, isometric muscle strength and patient satisfaction.

#### Results

Seventy-eight patients were recruited into the trial and received treatment. Two months after intervention 47% patients in the **combined** group and 61% patients in the **land** group had improved disease with 11 and 5% with worsened disease, respectively. The analysis showed no significant differences in mean costs and QALYs between the two groups. The **combined** group had slightly lower mean costs (–£6.91) and lower mean QALYs (–0.0478, 95% confidence interval –0.11294 to 0.0163 based on 1000 bootstrap replications). All secondary measures demonstrated a mean improvement in both groups, with the **combined** group showing greater improvements in physical aspects of HRQoL and cardiovascular fitness.

#### **Conclusions**

#### Implications for healthcare

JIA is a disease in which a cure is not available. This research demonstrates a beneficial effect from both **combined** hydrotherapy and land-based physiotherapy treatment and land-based physiotherapy treatment alone in JIA without any exacerbation of disease, indicating that treatments are safe.

The caveat to the results of the cost-effectiveness and clinical efficacy analysis is that the restricted sample size could have prevented a true difference being detected between the groups. Nevertheless, there appears to be no evidence to justify the costs of building pools or initiating new services specifically for use in this disease. However, this conclusion may not apply to patients with

unremitting active disease who could not be entered into the trial because of specified exclusion criteria. For this group, hydrotherapy or **combined** treatment may still be the only physiotherapy option.

#### **Recommendations for research**

- The following areas are suggested for further research: investigation and development of appropriate and sensitive outcome measures for use in future hydrotherapy and physiotherapy trials of IIA.
- Preliminary studies of methodologies in complex interventions such as physiotherapy and hydrotherapy to improve recruitment and ensure protocol is acceptable to patients and carers.
- Investigation of hydrotherapy in the most common paediatric user group, children with

- neurological dysfunction, ensuring appropriate outcome measures are available and methodologies previously tried.
- Comparison of patient satisfaction and compliance between land-based physiotherapy and hydrotherapy.
- European studies of hydrotherapy in rare disorders such as JIA.

#### **Publication**

Epps H, Ginnelly L, Utley M, Southwood T, Gallivan S, Sculpher M, et al. Is hydrotherapy cost-effective? A randomised controlled trial of combined hydrotherapy programmes compared with physiotherapy land techniques in children with juvenile idiopathic arthritis. *Health Technol Assess* 2005;**9**(39).

# **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.

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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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Reviews in *Health Technology Assessment* are termed 'systematic' when the account of the search, appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

The research reported in this monograph was commissioned by the HTA Programme as project number 96/32/08. The contractual start date was in September 1999. The draft report began editorial review in September 2002 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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