

Strengthening And stretching for Rheumatoid Arthritis of the Hand (SARAH). A randomised controlled trial and economic evaluation

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Scientific summary

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Scientific summary

Background

Rheumatoid arthritis (RA) is the most common inflammatory arthritis, affecting approximately 1% of the UK adult population. In the majority of people with this condition, hands and wrists are affected by pain, swelling, weakness and restricted mobility resulting in loss of function and social participation. Clinical guidelines recommend strengthening and stretching exercises for the hands and wrists to maximise strength, mobility and ultimately patient's function but there is a distinct lack of research evidence to support these treatments.

Objectives

1. To estimate the clinical effectiveness of adding an optimised exercise programme for hands and upper limbs in addition to usual care in the reduction of hand dysfunction and pain for patients with RA.
2. To estimate the cost-effectiveness of adding this programme to usual care.
3. To qualitatively describe the experience of participants in the trial with a particular emphasis on acceptability of the intervention, exercise behaviours and reasons for adherence/non-adherence.

Methods

Design

A pragmatic, multicentre randomised controlled trial (RCT). Participants were individually randomised to usual care or usual care plus an individualised exercise programme consisting of strengthening and stretching exercises for the hands and upper limbs. An economic evaluation and qualitative study were run in parallel with the trial.

Setting

Seventeen NHS trusts in England comprising 21 rheumatology/therapy departments.

Participants

All adult patients with RA who had pain and dysfunction of hands and/or wrists and had been stable on medication for at least 3 months were screened in rheumatology and hand therapy clinics. Patients who had upper limb surgery or fracture in the previous 6 months or were pregnant were excluded.

Interventions

The control intervention was best practice usual care with an occupational therapist or physiotherapist consisting of joint protection education, advice on simple mobility exercises for the whole body and, if appropriate, functional splinting.

The experimental intervention was usual care plus an optimised exercise programme with an occupational therapist or physiotherapist consisting of strengthening and stretching exercises for the hand, wrist and upper limb delivered over six sessions. These sessions were supported by a home exercise programme facilitated by strategies to maximise adherence.

Follow-up

We collected follow-up data at 4 and 12 months post randomisation. The primary method of data capture was face-to-face research clinic appointments. This was supplemented with postal and telephone data collection for individuals who were unable to attend appointments but who consented to provide information. We also conducted an extended follow-up by postal questionnaire at approximately 2 years post randomisation following completion of the main study.

Clinical outcomes and analysis

The primary outcome measure was the Michigan Hand Outcome Questionnaire (MHQ) overall hand function subscale score at 12 months. Secondary outcome measures included the full MHQ, pain (troublesomeness), impairment (grip strength, dexterity, hand and wrist range of motion and joint alignment), self-efficacy, disease activity, health-related quality of life (Short Form Questionnaire-12 items) and adverse events.

The planned sample size was 480 participants assuming 25% of participants would be lost to follow-up at 12 months. The difference between the intervention groups in mean MHQ overall hand function score from baseline to 4 and 12 months was analysed by a linear model, adjusted for baseline, with further analyses adjusting for covariates including current drug regime. The primary analysis used an intention-to-treat approach.

Economic analysis

The cost-utility of the treatments was evaluated from a UK NHS perspective, using a within-trial intention-to-treat analysis. Quality-adjusted life-years (QALYs) were estimated from European Quality of Life-5 Dimensions-3 Levels (EQ-5D-3L) data at baseline and 4 and 12 months. For comparison, we also estimated QALYs using the Short Form questionnaire-6 dimensions utility index. Costs were estimated for each participant over 12 months of follow-up, based on patient-reported use of a list of health services potentially influenced by hand function, RA status or side effects of treatment. Discounting was not applied.

Results

We recruited 490 patients between October 2009 and May 2011; 244 were randomised to usual care and 246 were randomised to the exercise programme arm. The percentage of female participants was 76%, median age was 63 years and on average participants had been diagnosed with RA for 10 years. The two groups of participants were well matched in terms of demographic data, primary outcome measure and clinical assessment findings. Outcome data were obtained for 89% (438) of participants at 12 months. At the extended follow-up time point (median 26 months) 326 (67%) participants provided data.

Clinical results

The exercise programme resulted in improvements in hand function in comparison with usual care at 4 and 12 months [difference in MHQ hand function 4.6, 95% confidence interval (CI) 2.2 to 7.0; and 4.4, 95% CI 1.6 to 7.1, respectively]. This statistically significant difference was mirrored for the full MHQ score. Between-group differences in secondary outcomes were consistent with the exercise programme providing improvement in physical function of the hand, physical roles including activities of daily living and work, and confidence in managing the condition. There was no significant difference in pain scores or adverse events between groups. At the extended follow-up time point participants in the exercise group had, on average, better hand function scores than the control group but the difference was no longer statistically significant. There were no longer any statistically significant differences between the groups for the secondary outcome measures.

Economic results

The estimated mean health-care costs with the exercise programme were approximately £100 higher than with usual care alone (mean difference £102.90, 95% CI –£622 to £828). The estimated difference in mean QALYs accrued over 12 months was 0.01 greater (95% CI –0.03 to 0.05) in the exercise programme group than in the usual care group. The best estimate of the incremental cost-effectiveness ratio (ICER) was £17,941 (EQ-5D-3L based, with multiple imputation for missing data). The estimated probability that the ICER lies below £30,000 per QALY was 59–78% (depending on the method of analysis).

Qualitative study

We explored trial participants' perspectives on the experiences of taking part in the Strengthening And stretching for Rheumatoid Arthritis of the Hand exercise programme, including their satisfaction and how they gauged its effectiveness. We also explored how acceptable the intervention was and, in particular, the use of the adherence strategies embedded within it. We purposively sampled participants randomised to the experimental intervention who reported benefiting and not benefiting from the treatments at their 4-month follow-up. Semistructured interviews were conducted with 14 participants (10 benefit reporters and four non-benefit reporters). Participants were interviewed following their 4- and 12-month follow-up appointments.

All interviewees said they were satisfied with the programme and would recommend it to others and they seemed confident in the delivery and use of the exercises. This study has highlighted the importance of the therapist in enabling patients to establish a routine and incorporate the exercises into their lives. Establishing a routine was easy for some interviewees, but others required support and encouragement. Interviewees found some elements of the programme challenging, for example the strengthening exercises, which needed the most adaptation to ensure they were completed.

Conclusions

Implications for health care

The results of this large, definitive RCT suggest that the addition of an optimised exercise programme for RA hands and wrists is clinically effective and cost-effective when compared with best-practice usual care alone over a 12-month period. The exercise programme is feasible and acceptable to patients with stable RA. Improvements in physical hand function, self-efficacy and impairment measures are maintained over 12 months. A post-hoc extended follow-up study shows that these improvements are reduced at approximately 2 years, which is probably associated with a reduction in performance of the specific exercises. From a NHS perspective, although the exercise programme is approximately £100 per patient more expensive than usual care, it is likely to be cost-effective at current levels of willingness to pay over a 1-year time horizon.

Recommendations for research

With the findings of the extended follow-up indicating participants found it hard to maintain the exercise programme beyond 1 year, it would be beneficial to explore the effects of different motivational techniques such as top-up contacts on adherence to the programme. Investigation of clinical effectiveness and cost-effectiveness of the programme in a population of people with earlier RA is also needed.

Trial registration

Current Controlled Trials ISRCTN 89936343.

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