

Aquatic therapy exercise for treating rheumatoid arthritis [protocol]

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Background

The idea that aquatic therapy includes, but is not limited to, the rehabilitation, prevention and overall wellness of a wide patient population is readily accepted. Aquatic therapy, multifaceted in nature, is a way to describe a cluster of interventions (therapeutic exercise or specific methods already described in the literature such as: Halliwick Method, Bad Ragaz Ring Method, Watsu and so on) performed in the water, with supervision of a licensed physical therapist or other health allied professional (SALZMAN, 1999). It is also considered as a direct procedure that typically requires patient's participation and is developed in heated indoor pools with adaptation (lift, ramp, steps) or not.

Treatment with water has its roots in antiquity even before the spas and baths of Roman Empire. However, Western medicine only began recognize the value of this form of treatment in the third decade of this century. Greater understanding of the physiological and physical benefits of exercise in warm water led to increase in the number of purpose-built pools in Europe and the United States in the 1950 and 1960s (IRION, 1997). Nowadays around the world, the concepts of aquatic therapy were incorporated in facilities, communities, hospitals as well as university academic program through clinical training.

The understanding of physical principles and the thermodynamics can help to build a rationale for using aquatic therapy. Buoyancy allows the patient walk with diminished joint loading by reducing the effect of gravity and by consequence improving range of motion as well. Hydrostatic pressure exerts a positive effect during immersion (through the pressure in all directions as well as increasing with depth) the blood in the extremity of venous system can be displaced approximately 700 ml to the thorax, contributing in the decreasing of oedema (BECKER, 1997). Thermodynamics also must be into consideration and it is related to the capacity of the submerged body exchanged energy (heat) from the water through convection and conduction. Thus, it has a positive effect in the soft

tissue that can be easily mobilized, improving range of motion and decreasing joint pain.

Patients with rheumatoid arthritis, which involving inflammation of synovial joints (ARNETT, 1988) may be benefited not only due the physical and physiological potential of immersion but also due the exercise itself. Few studies have addressed the effectiveness of aquatic therapy exercise on range of motion, pain, strengthening, balance, activity daily living as well as psychological variables (well-being, mood, depression, quality of life).

Objectives

To examine the effectiveness of aquatic therapy interventions for treating rheumatoid arthritis when compared to "land" interventions (therapeutic exercises, home orientation) or no intervention.

Criteria for considering studies for this review

Types of Studies

Studies will be eligible if they are randomised controlled trials or quasi-randomised clinical trials.

Types of Participants

Patients with rheumatoid arthritis defined by the American Rheumatology Association (ARA) criteria, by Steinbrocker functional class or any other described criteria. Studies including rheumatoid arthritis in conjunction with osteoarthritis will be analysed separately.

Types of Intervention

Studies will include one treatment group in which aquatic therapy is applied. All types of exercises developed in the therapeutic / heated indoor pool (ROM, dynamics, and aerobics) will be permitted.

Types of Outcome Measures

The primary endpoints for measurement of effectiveness will be the outcome Measures recommended by the Conference on Outcome Measures for Rheumatoid Arthritis Clinical Trials 1993 (OMERACT, 1993). These measures include:

- a) Number of tender joints
- b) Number of swollen joints
- c) Pain
- d) Physician global assessment
- e) Patient global assessment
- f) Functional status (for example, measured by the Activities of Daily Living Scale)
- g) Acute phase reactants
- h) Radiological damage

In addition to these outcomes, a theoretical framework of important physical therapy outcomes, developed by (BROSSEAU, 1996) will be created to use for treatment of RA and will be assessed as secondary endpoints and include: 1) Articular mobility, 2) Muscular testing and, 3) Balance/Postural Sway.

Search strategy for identification of studies

See: Collaborative Review Group search strategy

1) Electronic database: EMBASE (1980 - 2001), LILACS (1982 - 2001), MEDLINE (1966 -2001), the Cochrane Controlled Trials Register, PEDro, Healthstar and CINAHL. There will not be restrictions in regard to language or date of publication.

The "optimal" sensitive search strategies designed to identify clinical trials will be used as described by Dickersin et al (1994) and Castro et al (1999). In addition, the following phrases will be added in order to identify studies relevant to the review:

#1 aquatic therapy
#2 aquatic physical therapy
#3 aquatic exercise
#4 water exercise
#5 water gymnastic
#6 water training
#7 pool therapy
#8 pool exercise
#9 aerobic aquatics
#10 aqua aerobics
#11 hydrotherapy
#12 rheumatoid arthritis
#13 rheumatic diseases
#14 arthritis
(#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11) AND (#12 OR #13 OR #14)

2) The database from Cochrane Field Rehabilitation and Related Therapies up to the end of December 2001, which contains studies published in journals not covered by MEDLINE.

3) Reference checking. The reference lists of all papers selected will be inspected for further relevant studies.

4) Full abstracts published in special issues of specialized journals (Journal of Aquatic Physical Therapy, Aqualines - Hydrotherapy Association of Chartered Society of Physiotherapy) or in Conference Proceedings (Annual Conference & Exposition of the American Physical Therapy Association (APTA), APTA Combined Sections Meeting). Institutions and subjects known to have expertise in aquatic therapy will be contacted for further information. All references in the identified trials will be checked and authors contacted to identify any additional published or unpublished data.

Methods of the review

Selection of Trials

Two reviewers (APGC) and (MRG) will screen the abstracts of all publications obtained by the search strategy. For articles that could be eligible RCTs, the full article will be obtained and assessed based on

inclusion and exclusion criteria. Trials excluded will be identified with reasons for exclusion.

Inclusion criteria application

An assessment of the quality of the included studies will be performed independently by two independent reviewers (ELL) and (SMRC). The reviewers will be not blinded to author, institution and journal of publication of results. The two assessors then will be reviewed each study together. The following dimensions and criteria will be used in a standard way adopted from the Cochrane Collaboration Handbook (CLARK, 2000) and Schulz et al (1995).

A. Adequate measures taken to conceal allocations such as central randomisation; serially numbered, opaque, sealed envelopes; or other description that contains convincing elements of adequate concealment.

B. Uncertain concealed trials, in which the authors either did not report the allocation concealment, or they reported an approach that did not fall into one of the categories in C.

C. Inadequately concealed trials, in which the method of allocation was not concealed, such as alternation methods or use of case record numbers (quasi-randomisation).

Studies will be eligible if classified in categories 'A' or 'B'. Studies that fell into category 'C' will be excluded.

Quality of Assessment of Included Studies:

In order to ensure that variation was not caused by systematic errors in the design of study, two independent reviewers (ELL) and (SMRC) will assess the methodological quality of the selected trials. Methodological quality of the included trials will be rated by using the Jadad Scale (1996) and the Delphi List (VERHAGEN, 1998).

The Jadad Scale consists of the following questions: 1) Was the trial described as randomised (this includes the use of words such as random, randomly and randomisation)? (one point). 2) Is the method of randomisation appropriate? One point is added if the method to generate the sequence of randomisation is described and it is appropriate (e.g., table of random numbers, computer generated). Zero points if the method of randomisation is not described. 3) Was the study described as double blind?

One point if yes. Zero points if no. 4) Is the method of blinding used appropriate? One point is added if the method of masking is described and appropriate (e.g., identical placebo). One point is deducted if the method of masking is inappropriate (e.g., comparison of tablet versus injection with no double dummy). Zero points if the method of masking is not described. 5) Is there a description of withdrawals and drop-outs? One point is given if the numbers and reasons for withdrawal in each group are stated. If there are no withdrawals, the report must say so. If there is no statement on withdrawals, this item is given no points. The Scale gives one to five points to a RCT. RCTs with one and two points are considered low quality and RCTs with three to five points are considered high quality (MOHER, 1998). When a discrepancy occurred, a third reviewer will be asked for opinion in order to reach consensus.

The Delphi list consists of 10 methodological criteria, adjusted and combined with criteria considered by the reviewers as relevant for the purpose of the review. The items are: 1) adequate allocation concealment; 2) groups similar at baseline; 3) specification of eligibility criteria; 4) sufficient description of intervention; 5) blinding of outcome assessor; 6) comparable co-interventions per group; 7) description of rate and reasons for dropping out; 8) description of rate of compliance; 9) presentation of point estimates and measures of variability; and 10) intention-to-treat-analysis. All selected methodological criteria will be scored as yes, no or unclear. Equal weight will be applied on all items resulting in a range from 0 to 10. RCTs of lower quality score (less than four points) will be excluded.

Analyses and presentation

The studies will be stratified in sub-categories according to:

- Length of follow-up (at the end of treatment and three, six and twelve months after treatment).
- Type of intervention (ROM exercise, aerobic exercise, group exercise, individual exercise)

Comparisons:

Comparisons will be made separately according to type of control group (no treatment, other treatment). Pooling of trials will only be attempted if at least two trials of comparable aquatic therapy protocols with

the same conditions and comparable outcome measurements are available. Statistical analysis will be performed using RevMan 4.1 software.

Continuous Outcomes

Weighted mean difference and 95% confidence interval using a fixed effects model will be used. In the event of significant heterogeneity a random effects model will be used.

Dichotomous Outcomes

Relative risk and 95% confidence intervals using a fixed effects model will be used for interpretation of the dichotomous outcome measures in this review. A random effects model will be selected if there is a large amount of heterogeneity among the primary trials. In the event of significant heterogeneity, trial results will not be pooled.

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