



The Cochrane review of assistive technology for rheumatoid arthritis

H. TUNTLAND, I. KJEKEN, L. NORDHEIM, L. FALZON, G. JAMTVEDT, K. HAGEN

Aim. The aim of this systematic review is to summarise the available evidence on the effectiveness of assistive technology for adults with rheumatoid arthritis in terms of improving functional ability and reducing pain, and to assess potential adverse effects related to device use.

Methods. In this review, randomised controlled trials, clinical controlled trials, controlled before and after studies and interrupted time series available through systematic searches (electronic databases, grey literature, contact with authors, reference lists) up to October 2008 were included. Two reviewers independently selected trials for inclusion, assessed the validity of included trials, and extracted data. Investigators were contacted to obtain missing information.

Results. Out of 7 177 hits, 13 articles were reviewed in full text and only one trial was finally included (N.=29). The study was a randomised crossover trial, in which the use of an eye drop device was compared to a standard bottle in people with rheumatoid arthritis suffering from persistent dry eyes. The results show that the eye drop device improved application of eye drops and prevented adverse effects in terms of touching the eye with the bottle tip. The study was considered to have low quality of evidence.

Conclusion. Since only one trial met the inclusion criteria for this review, there is very limited evidence for the effect of assistive technology for adults with rheumatoid arthritis. There is an urgent need for high-quality research in this field, in order to reach sufficient evi-

dence on the effectiveness of this commonly used intervention.

KEY WORDS: Self-Help Devices - Arthritis, rheumatoid - Review, systematic.

Rheumatoid arthritis (RA) is the most common inflammatory rheumatic disease, affecting 0.5% to 1% of the population.¹ The average age of onset is mainly comprised between 45 and 65 years, it occurs twice as often in women as in men, and the etiology is still unknown. RA causes pain, stiffness, fatigue and impaired physical function, including limited ability to perform daily activities and to participate in society.²⁻⁵

Assistive technology includes a wide range of products, from low-tech devices to technologically complex equipment. Some of these devices are designed for the general population, while others are developed to meet the needs of people with functional limitations or disabilities. Different terms describing assistive technology are used interchangeably, such as aids, technical aids, assistive devices, self-help devices, adaptive devices, assistive technology and adaptive equipment.⁶ In this review, the authors chose to use the term assistive technology, *i.e.*, "any item, piece or equipment, or product system whether acquired

Received on March 30, 2010.

Accepted for publication on April 8, 2010.

Corresponding author: H. Tuntland, Department of Social Education and Social Work, Faculty of Health and Social Sciences, Bergen University College, Haugeveien 28, 0047-93054074, Bergen 5005, Norway.
E-mail. htu@hib.no

commercially off the shelf, modified or customised, that is used to increase, maintain, or improve functional capabilities of individuals with disabilities".⁷ However, in order to improve readability, the terms aid, device, and assistive device have been used as well.

People with RA often use assistive technology, and the intervention is one of the most frequent self-help strategies reported by this group of patients.^{8, 9} Devices are prescribed and used to reduce pain, and compensate for impairment and environmental demands. Although use of assistive technology is often combined with other self-management strategies, probably few other interventions can replace well-designed assistive devices.

The use of assistive technology is associated with a more severe disease, a longer disease duration, and loss of grip strength and functional ability.¹⁰⁻¹² In addition, differences in countries' health care systems are an important determinant of the possession of devices among persons with rheumatoid arthritis.¹³ Studies indicate that two thirds of all persons with arthritis use assistive devices on a daily basis.^{14, 15} In a study of people with early rheumatoid arthritis, men used an average of three devices, while women used an average of five, and eating and drinking were the most frequently reported activities where the use of devices has a beneficial effect.¹¹ In another study, people with severe rheumatoid arthritis used an average of 10 devices.¹⁶ Provision of assistive technology was the most frequent intervention in a Swedish study describing occupational therapy during the first 10 years of rheumatoid arthritis.¹⁷ However, the overall usage of assistive technology used on a regular basis in persons with arthritis varies considerably, from 41% of all devices still in use three months after hip replacements,¹⁸ to 91% of the provided devices still being used approximately one year after completing a joint protection education program.¹⁹ Reasons people give for abandoning assistive technology are that they have not been involved in the process of provision, that they have not been given sufficient instruction, that their functional ability changes, that the devices do not have the intended effect, and a lack of follow-up during and after provision.²⁰⁻²⁵

To date, two reviews concerning the use of assistive technology by patients with arthritis have been published. One is a literature review on the use of assistive technology for people with rheumatoid arthritis and osteoarthritis,¹⁵ the other is a systematic review of

occupational therapy for people with rheumatoid arthritis, in which assistive devices were one of six interventions evaluated.²⁶ However, assistive devices may be provided by a variety of health professionals and also purchased by individuals with rheumatoid arthritis themselves. Thus, they should be classified and studied as a specific intervention rather than a professional strategy.²⁷ Furthermore, a review including only people with rheumatoid arthritis would foster better understanding of the benefits and adverse effects of assistive technology in this population.

The aim of this paper was, therefore, to systematically review the benefits of assistive technology for adults with rheumatoid arthritis in terms of improving functional ability and reducing pain, and to assess potential adverse effects related to device use.

Materials and methods

Design of the study

Studies were included if they were: 1) randomised controlled trials (RCTs); 2) controlled clinical trials (CCTs) using inadequate generation of sequence allocation; 3) controlled before and after studies (CBA) and interrupted time series (ITS), and 4) comparative observational studies. The latter design was only included if adverse effects were assessed.

Subjects

Inclusion criteria were trials with participants aged 18 years or older diagnosed with rheumatoid arthritis by a rheumatologist. Studies combining participants with a variety of rheumatic diseases were also included if 50% or more of the participants had a diagnosis of rheumatoid arthritis, and if data could be extracted for the RA group separately.

Intervention

The intervention involved assistive technology provided by a health professional or obtained/purchased by the study participants. In accordance with "Assistive products for persons with disability - Classification and terminology",²⁸ the following classes of assistive devices were included in the review:

— aids for medical treatment (ISO class 04): aids for improving, controlling and maintaining a person's medical condition, for instance an anti-decubitus cushion;

- aids for training skills (ISO class 05): aids for improving a person's physical, mental or social skills, such as aids for communication training;
- aids for personal care and protection (ISO class 09), such as aids for dressing, aids for toileting, and aids for washing/bathing/showering;
- aids for personal mobility (ISO class 12), such as wheelchair, walking aids and bikes;
- aids for housekeeping (ISO class 15), such as aids for food preparation, aids for eating and drinking, and aids for house cleaning;
- furnishings and adaptations to homes and other premises (ISO class 18), such as special bed, chair/stool, aids for height adjustment of furniture, support aids, lift/ramp, and ergonomic equipment;
- aids for communication, information and signalling (ISO class 22), such as computers, telephones, and aids for writing and typing;
- aids for handling products and goods (ISO class 24), such as aids for opening containers, aids for grip function, reach extenders, carrying aids, and environmental control systems;
- aids for equipment for environmental improvement, tools and machines (ISO class 27). These are aids for improving personal environment, including manual and electrical tools;
- aids for recreation (ISO class 30), such as toys, games and sport aids.

We excluded studies regarding orthoses and prostheses (ISO class 06), because these devices have been addressed in another review.²⁹ Aids for seeing and hearing (from ISO class 22) were regarded as irrelevant and also excluded. Old studies with assistive devices that are no longer in use were also excluded if found.

The control intervention could be other interventions, such as patient education programs, other assistive devices, or no intervention.

Outcomes

The primary outcomes were functional ability in activities of daily living (ADL), pain, and adverse effects. Adverse effects could be psychological discomfort, personal injury, or material damage related to device use. The secondary outcomes were fatigue, self-efficacy, psychological well-being, health related quality of life (HRQoL), change in time spent in completing tasks, caregiver burden/stress, and device usability.

Literature search

Within the selected classes of assistive technology, the different types of devices are numerous. In addition, there are several synonyms for every type of device. A broad and detailed search strategy was therefore developed, using search terms relevant to each included class of assistive device. Furthermore, we chose search terms for different types of devices within each class of devices, based on identified studies where specific devices for rheumatoid arthritis were included and described. Selection of search terms was also based on the authors' clinical experience regarding what kind of devices persons with rheumatoid arthritis use. Finally, we added all the synonyms we could find for the term assistive technology to the search strategy. The complete search strategy is presented in the full review.³⁰

Relevant studies were identified by searching the Cochrane Library (CENTRAL, DARE, NHS EED), AMED, MEDLINE, Embase, CINAHL, OT seeker, PEDro, and ISI Web of Science (up to October 2008), with no language restrictions. We considered only full-length articles and full written reports for inclusion in the review. To identify unpublished and on-going trials, we corresponded with authors and field experts, and searched The International Standard Randomised Controlled Trial Number Register. Grey literature was sought by contacting experts and by searching the following databases: New York Academic of Medicine Grey Literature Collection, Open SIGLE, Google Scholar, British Library Catalogue, ISI Web of Knowledge Cited Reference Search, and Dissertation Abstracts. In addition, reference lists in relevant studies and reviews were examined.

Data collection and analysis

Two review authors (HT and IK) independently screened titles and abstracts against the inclusion criteria, extracted data by using a specially designed data collection form, and assessed study quality. Uncertainty or disagreement was resolved by discussion with a third review author (KBH). The following six criteria for judging risk of bias were used: adequate sequence generation; allocation concealment; blinding of participants, personnel, and outcome assessors; incomplete outcome data; selective outcome reporting; and other sources of bias. Each criterion was rated as: Yes, No, or Unclear. If data were missing or unclear, the first author of the paper was

TABLE I.—*Description and assessment of the included study (Averns, 1999).*³²

Methods	This is a randomised controlled study with a crossover design. There was only one crossover. Randomisation was performed by using numbers on a calculator. The intervention period was two weeks.
Participants	The study was a part of a larger study that took place in the United Kingdom, in which the participants were attending an outpatients' follow up. Of the 340 participants included in the large study, 85 participants had symptoms of Sjögren's syndrome and 30 of these were included in an eye drop delivery study. Among the 29 participants followed in the small sample, the gender distribution was 86% female and 14% male, all participants were above 18 years of age, and all participants were diagnosed with rheumatoid arthritis by a rheumatologist (personal communication with first author). Inclusion criteria were having Schirmer test <5 mm in 5 minutes and duration of persistent dry eyes or gritty eyes > 3 months. Exclusion criteria were other ocular conditions requiring treatment and taking medication known to cause symptoms of dry eyes.
Intervention	Intervention: use of an Opticare eye drop dispenser device. A standard bottle with artificial tears was put into the dispenser. Comparison: use of eye drops from a standard bottle without the dispenser device. The participants used the eye drops from the standard bottle in week 1 and the Opticare device in week 2, or vice versa.
Outcomes	The outcome measures after each intervention week were (for the small sample): <ul style="list-style-type: none"> • patient reported experience with the use of the standard bottle or Opticare device; • observer reported rating of the participant's ability to instil the artificial tears. The outcomes measured after each intervention week were ability to squeeze out drops, get drops into the eye, squeeze the bottle, control the number of drops, and aim the drops. In addition, device usability and adverse effects in form of touching the eye with the bottle tip were registered.
Methodological quality assessment	The concealment of allocation is considered unclear, as there was no information in the article regarding method of randomisation or concealment of allocation. When asked to clarify this, the first author described the method of randomisation as using random numbers on a calculator. This is considered to be an adequate method of sequence generation. No information was given about who assigned the participants to their groups and whether the allocation was concealed. Selection bias therefore cannot be excluded. The assessor was aware of the assigned treatment when collecting outcome measures. Neither the participants nor the personnel were blinded for the intervention. Possible interventions other than the intervention of interest are controlled for, as participants in both groups are the same and the study period was rather short. Thirty participants were recruited, however one participant failed to attend to the treatment. Among the 29 participants followed, there were four losses to follow up for some of the outcome assessments, which is less than 20% of the sample. We therefore consider the criterion of incomplete outcome data to be met. The study had selective outcome reporting as only statistically significant results were reported in tables. When it comes to 'other potential sources of bias', all participants were analysed in the group into which they were randomised. We therefore consider the study apparently free of other sources of bias.

contacted for clarification. As only one study met the inclusion criteria, a quantitative data synthesis was not relevant.

Evidence was graded using the GRADE approach as recommended for Cochrane reviews.³¹ This approach specifies four levels of quality of evidence: high, moderate, low, and very low.

Results

The literature searches identified 7 177 hits (6 913 retrieved articles from conventional databases and 264

hits from grey literature databases). After screening the titles and abstracts, and reading 13 of the articles in full text, only one study met the inclusion criteria.³²

The intervention in the included study was classified as medical treatment. The aim of the study was to assess the ability to use medication correctly and safely, in this case to instil artificial tears using an eye drop dispenser device (Opticare) compared to a standard bottle. The study included 29 participants with RA and persistent dry eyes due to Sjögren's syndrome, and had a randomised crossover design. The proportions with observed difficulties when using the device to squeeze out drops and getting the drops in

TABLE II.— *Characteristics of excluded studies.*

Galumbeck 2004 ³⁶	This is not a randomised controlled trial (RCT), clinical controlled trial (CCT), controlled before and after study (CBA), interrupted time series (ITS), or a comparative observational study. It is a single-subject design. Diagnoses of study participants were not described.
Hass 1997 ³⁷	This is a comparative observational study, but as no adverse effects are registered, the study is excluded.
Hoening 2007 ⁴²	This is an RCT. Due to mixed patient population (osteoarthritis and rheumatoid arthritis) without separate analysis for the RA-population, the trial is excluded.
Löfkvist 1988 ³⁵	This is not an RCT, CCT, CBA, ITS or a comparative observational study. It is an uncontrolled study with before and after comparison.
Munro 1998 ³⁸	This is not a RCT, CCT, CBA, ITS or a comparative observational study. It is a single-subject design.
Munro 2000 ³⁴	This is not a RCT, CCT, CBA, ITS or a comparative observational study. It is a single-subject design.
Nordenskiöld 1994 ¹⁹	This is not a RCT, CCT, CBA, ITS or a comparative observational study. When it comes to testing effects, the study is cross-sectional.
Nordenskiöld 1996 ³⁹	This is not a RCT, CCT, CBA, ITS or a comparative observational study. When it comes to testing effects, the study is cross-sectional.
Nordenskiöld 1998 ⁴⁰	This is not a RCT, CCT, CBA, ITS or a comparative observational study. It is a cross-sectional study.
Thyberg 2004 ¹¹	This is not a RCT, CCT, CBA, ITS or a comparative observational study. When it comes to testing effects, the study is cross-sectional.
Torrens 2000 ³³	This is not a RCT, CCT, CBA, ITS or a comparative observational study. It is a single-subject design.
Price 2003 ⁴¹	This is not an RCT, CCT, CBA, ITS or a comparative observational study. It is an uncontrolled study with before and after comparison.

the eyes were 10% and 14%, respectively, compared to 52% and 52% when using the standard bottle ($P=0.001$; $P=0.003$, respectively). The proportions of participants reporting difficulties with squeezing the bottle, controlling the number of drops, and aiming the drops when using the device were 40%, 44%, and 46% respectively, while the proportions with difficulties were 72%, 84%, and 76% when using the standard bottle ($P=0.001$; $P=0.003$; $P=0.031$, respectively). Median number of times the drops were used was four times a day. Regarding usability of the device, 17 out of the 29 participants found it very useful, and nine moderately useful.

The results of the study show that a dispenser device may improve application of eye drops and prevent adverse effects in terms of touching the eye with the bottle tip. However, the trial had moderate risk of bias due to unclear concealment of allocation and lack of blinded assessors, and consequently we graded the quality of evidence as low. This implies that new research will change our confidence in the estimates of effect. Table I outlines the description and methodological quality assessment of the study.

Of the 12 other studies reviewed, 11 studies were excluded due to study design,^{11, 19, 33-41} and one was excluded due to participant's characteristics.⁴² Further details are given in Table II.

TABLE III.— *Recommendations for future research on the effectiveness of assistive technology.*

- Future studies should concentrate on investigating devices with moderate or high costs where effects are uncertain or moderate.
- Effect of large and costly devices should be tested one at the time, while minor assistive devices can be tested as a group if they are homogenous regarding potential outcomes.
- The assistive technology selection and advisory process should be based on explicit theories or models and the use of valid and reliable instruments
- Patient populations should be homogeneous.
- If a randomised controlled trial is difficult to perform due to ethical or practical circumstances, the n-of-1 RCT can be a good alternative.
- Care should be taken to ensure a close correspondence between the purpose of using a device, and the outcome measure(s) used to test the effect of the device(s).
- One should use instruments where performance of activities is rated according to current performance, and where the use of any device is understood as an integrated part of the performance.
- A combination of performance tests, self-reported questionnaires and patient specific measures are optimal.

Discussion

Despite an unusual extensive literature search, only one study could be included in the review. The results of this study showed that an eye drop dispenser made it easier for persons with RA to administer eye drops

correctly and safely. However, the dispenser is not a commonly used device, and the study was considered to provide low quality of evidence due to unclear concealment of allocation and lack of blinded assessors. This review, therefore, demonstrates a critical lack of well controlled studies addressing the effectiveness of assistive technology in rheumatoid arthritis.

As in other reviews addressing effectiveness of assistive technology,^{26, 43} the most frequent reason for excluding relevant studies was the failure to meet the criteria for adequate study design, in this case defined as RCT, CCT, CBA, and ITS.^{26, 43} One reason is probably that such studies in some cases are regarded as unethical, as they presuppose giving a control group an inferior intervention, putting participants on a waiting list or giving no intervention at all.⁴³ Indeed, the doubt regarding the effectiveness of a particular intervention should be compelling for an RCT to be conducted.²⁶ For some devices, (such as the use of crutches following knee or hip replacement surgery), the effect is so obvious that biases can be ruled out without randomised trials.⁴⁴ Further, research may seem unnecessary on low cost and high usage devices, such as can openers and knives with ergonomic handles.⁴⁵ Rheumatoid arthritis is a chronic disease and the need of an assistive device is seldom acute. Except for the use of devices following surgery, most people will be able to manage without a device for a short period. The emphasis should therefore be on examining technologically complex and highly expensive devices, using high quality designs, including cost-benefit analyses. However, smaller assistive devices can be tested as a group if they are homogenous with regard to potential outcome.⁴⁵ In brief, if the costs of assistive devices are moderate or high and effects are uncertain or moderate, randomised controlled trials are worthwhile.

One design that may be particularly well suited for testing the effects of assistive technology in rheumatoid arthritis is the n-of-1 RCT-design, in which each participant is randomised to receive the intervention or comparison in different periods. Thus, the multiple crossovers will help the participant and provider to decide on which therapy is the best.⁴⁶ RA meets the design criteria of being a chronic and relatively stable condition, and assistive technology meets the criteria of being a long-term intervention with rapid onset and determination. Another advantage of this design is that the participants are their own control, and few-

er participants are needed to ensure satisfactory statistical power.

Another factor contributing to the lack of well controlled studies may be the complex nature of assistive technology, as the effectiveness of such technology is determined by the interaction between the person using the device(s), the assistive technology, and the context and environment in which the device is used.^{43, 47-48}

Further, there is a lack of models and standardised, reliable and valid instruments to guide the assistive technology selection process.⁴⁹ However, these challenges are common to most rehabilitation interventions, and may to a large degree be solved through methodological modifications.^{50, 51}

The large number and the diversity in design of assistive devices might also contribute to the impression that research in this area is complicated. However, pain and functioning are recognised as the most important study outcomes in rheumatoid arthritis studies.^{52, 53} Thus, the number of relevant outcomes is much smaller than the number of devices.⁵⁴ In addition, many of the measures used within rheumatology have been analyzed and linked to the International Classification of Functioning, Disability and Health (ICF).⁵⁵⁻⁵⁷ The ICF could therefore be used as a tool to ensure a close correspondence between the purpose of using a device and the outcome measure(s) used to test the effect of the device.⁵⁸

An important aspect to consider when choosing instruments for measuring outcomes is whether using a device has implications for the scoring. In the Evaluation of Daily Activities Questionnaire,⁴⁰ which was used in several of the excluded studies, the participants rate their performance of each activity twice, first according to how they perform 102 activities using assistive devices and/or altered working methods, and thereafter how they perform the same activities without using devices or altered methods. In some of the excluded studies, the effect was calculated as the difference between these two scores, which both were collected at the follow-up visit. This introduces some methodological problems, as the data were collected cross-sectionally, even if the studies had a longitudinal design. Further, the repeated scorings jeopardise the reliability of the assessment, as participants who have started to use devices on a routinely basis must rate performance of activities without using devices based on recalling performance in the past.

Another example is the Health Assessment Questionnaire,⁵⁹ in which the participants' reports regarding use of device when performing an activity have implications for the calculation of the sum score, since the use of a device will often result in a lower (or poorer) score. Thus, the use of assistive technology automatically devalues the performance of that activity, and consequently the final sum score. To avoid such problems one should use instruments in which participants rate performance of activities according to current performance, and in which using or not using a device is understood as an integrated part of the performance.

Until recently, the instruments used in studies on assistive devices have been performance tests or questionnaires. The strength of these measures is that they include standardised activities or items, and therefore allow for comparisons between individuals as well as groups of participants. A weakness is, however, that a person's ability to perform a specific activity may be more important than his/her ability to perform a standardised task item in a test situation or in a questionnaire.⁶⁰ To overcome these shortcomings, patient specific measures that capture the activities and issues that are important to individual participants have been developed.⁶¹ Consequently, patient specific instruments that have been tested for psychometric properties should be used in addition to other functional measures when studying the effect of assistive technology.

Conclusions

There is very limited evidence for the effect of assistive technology for adults with rheumatoid arthritis. Given the costs and dissemination of assistive devices, the research gap is surprising, and the need for high-quality studies addressing this issue is urgent. Points to consider when designing future studies are summarised in Table III.

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