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Joint Protection Programs for People with Hand Arthritis

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Abstract

The fact that Joint Protection Programs (JPP) can reduce pain and improve function is based on small, but definitive Randomized Controlled Trials (RCTs), conducted in the 1980s. However, changes over time in the nature of hand use, the rapid expansion of technology, and improvements in our understanding of health literacy mean that these programs are now outdated. Further, problems with adherence to JPP are well documented. The purpose of this thesis was 1) to conduct a scoping review to map all the available evidence around joint protection programs in published and unpublished studies 2) to evaluate the effectiveness of joint protection programs when compared to usual care/no joint protection/advice on pain reduction and improvement of hand function for individuals with hand arthritis 3) to conduct an overview of systematic reviews to establish the current state of evidence evaluating the effectiveness of joint protection for people with hand RA and OA 4) to investigate the barriers, facilitators, expectations and patient preferences regarding joint protection programs in people with hand arthritis 5) to evaluate the Content Validity Index (CVI) of Patient-Rated Wrist Evaluation (PRWE), Australian/Canadian Osteoarthritis hand Index (AUSCAN) and Thumb Disability Exam (TDX) in patients with hand arthritis and 6) to design a single center, investigator-blinded, randomized, 12-month, parallel-group, superiority study for the evaluation of the efficacy of a hand exercise and a joint protection program on pain Intensity levels in people with hand osteoarthritis. From the existing literature, we found evidence of very-low to low quality that the effects of joint protection programs compared to usual care/control on pain and hand function are too small to be clinically important at short-, intermediate- and long-term follow-ups for people with hand arthritis. We also found that awareness of the potential benefits of JP, and prior experience with JP program were very low. Common potentially modifiable patient-reported barriers to participate in future JP interventions, included: cost, work commitments distance from home to clinic and times that the JP intervention were provided. These barriers might be addressed with free and accessible forms of delivery of JP, which may lead to better uptake and participation in JP. Our findings also demonstrated very high content validity indices for the PRWHE, AUSCAN, and TDX; with strong consensus across reviewers. This augments prior statistical evidence supporting statistical measurement properties, to provide support for the content validity.

Keywords

Osteoarthritis, rheumatoid arthritis, hand osteoarthritis, joint protection, systematic review, meta-analysis, barriers, facilitators, content validity

Summary for Lay Audience

The most common location for osteoarthritis (OA) is the hand. Hand OA is responsible for pain and limitations in hand function that can limit peoples' ability to work or remain independent. As hand OA progresses, the joints become deformed. Joint Protection Programs (JPP) were developed in the 1980's to help people with hand OA do tasks in daily life, alleviate pain, and prevent joint deformity. JPP teach people how to change, or pace tasks, and how to use devices that reduce joint loading. Although studies have shown these programs can be effective, many people do not fully understand or use JPP. The JPP in use today have not been updated to reflect the life tasks and tools of the 21st century. Much has changed - like how we use our phones.

This thesis aimed to investigate the efficacy of JPP and to update the JPP to better address the important daily tasks that people do, by working with patients and engineers to find the best solutions. This study will lead to more useful, accessible and effective JPP that will help people with hand OA avoid pain and prevent joint deformity.

Co-Authorship Statement

The thesis question and the design of the studies were formulated by Pavlos Bobos and by her supervisor, Joy C MacDermid. Co-investigators were recruited when additional expertise was required. The specific roles of each of the authors are listed below:

Chapter 1: Introduction

Pavlos Bobos – sole author

Chapter 2: A scoping review of joint protection programs for people with hand arthritis

Pavlos Bobos – primary author, study design, data collection, data analysis and manuscript interpretation

Goris Nazari – co-author, was involved in literature search, and interpretation of data and drafting

Emily A Lalone – co-author, involved in the drafting and review of the manuscript

Louis Ferreira – co-author, involved in drafting and review of the manuscript

Ruby Grewal – co-author, manuscript reviewer

Joy C MacDermid – co-author, involved in the conception and design of the study, drafting, and revised the manuscript for important intellectual content

Chapter 3: The effectiveness of joint protection programs on pain, hand function and grip strength levels in patients with hand arthritis. A systematic review and meta-analysis

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Goris Nazari – co-author, second reviewer, critical appraisal

Mike Szekeres – co-author, second reviewer for quality assessment

Emily A. Lalone – co-author, manuscript reviewer

Louis Ferreira – co-author, manuscript reviewer

Joy C. MacDermid – co-author, study design, manuscript reviewer

Chapter 4: Joint protection programs for people with osteoarthritis and rheumatoid arthritis of the hand: An overview of systematic reviews

Pavlos Bobos – primary author, study design, data collection, critical appraisal, data analysis and data interpretation

Joy C. MacDermid – co-author, study design, manuscript reviewer

Goris Nazari – co-author, second reviewer, rater for critical appraisal

Emily A Lalone – co-author, manuscript reviewer

Louis Ferreira – co-author, manuscript reviewer

Ruby Grewal – co-author, involved in drafting and review of the manuscript

Chapter 5: Barriers, facilitators, preferences and expectations of joint protection programs for patients with hand arthritis

Pavlos Bobos – primary author, study design, data collection, data analysis and data interpretation

Joy C. MacDermid – co-author, study design, manuscript reviewer

Christina Ziebart – co-author, involved in data collection and review of the manuscript

Elena C Boutsikari – co-author, assist in data coding and involved in drafting the manuscript

Emily A Lalone – co-author, manuscript reviewer

Louis Ferreira – co-author, manuscript reviewer

Ruby Grewal – co-author, assist in recruitment, manuscript reviewer

Chapter 6: Evaluation of the content validity index of the Australian/Canadian osteoarthritis hand index, the Patient-Rated Wrist/Hand Evaluation and the Thumb Disability Exam in people with hand arthritis

Pavlos Bobos – primary author, study design, data collection, data analysis and data interpretation

Joy C. MacDermid – co-author, study design, assist in data interpretation

Elena C Boutsikari – co-author, assist in data coding and involved in drafting the manuscript

Emily A Lalone – co-author, manuscript reviewer

Louis Ferreira – co-author, manuscript reviewer

Ruby Grewal – co-author, assist in recruitment, manuscript reviewer

Chapter 7: The efficacy of a hand exercise and a joint protection program on pain intensity levels in people with hand osteoarthritis. A protocol design for a single center, investigator blinded, randomized 12-month, parallel-group, 2-arm, superiority study

Pavlos Bobos – primary author, study design, statistical analysis plan and trial methodology

Joy C. MacDermid – co-author, study design, consult in trial preparation

Christina Ziebart– co-author, assist in methods preparation and drafting the protocol

Emily A Lalone – co-author, review design and methods

Ruby Grewal – co-author, expert in hand pathology, protocol drafting

Chapter 8: General discussion and future direction

Pavlos Bobos – sole author

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Chapter 1

1 Introduction

1.1 Osteoarthritis

Osteoarthritis (OA) affects up to 18% of the population above 60.[1] Prevalence of OA is steadily increasing as the average age and risk factors such as obesity increases. This painful condition is the main cause of disability in older individuals, and is thus, unsurprisingly, associated with lower quality of life and a higher risk of depression and mortality. The condition is characterized by loss of articular cartilage in synovial joints, accompanied by subchondral bone changes, osteophyte formation at the joint margins, thickening of the joint capsule, and mild synovitis. Conventional radiographs show joint space narrowing as a reflection of cartilage loss, osteophyte formation and, in some cases, subchondral bone changes, but these signs are not consistently associated with symptoms.[2]

1.2 Rheumatoid arthritis

Rheumatoid arthritis (RA) is a systemic auto-immune disease.[3] RA prevalence and incidence rates are increasing globally and RA has become a major public health challenge.[4,5] Quality of life for people with RA has been reported to be lower than in patients suffering from the four main non-communicable diseases.[6] The primary clinical manifestation of RA is the symmetrical inflammatory polyarthritis that usually is starting in the small joints of the hands and the feet, and then expanding to the bigger joints.[3] The condition is resulting in tender swelling joints, pain, limited range of motion and stiffness.[7] RA is often characterized by irreversible tissue damage and destruction of bone and of the cartilage which leads to joint deformity and muscle atrophy.[7]

1.3 Etiology and pathogenesis of hand osteoarthritis

Joints have a layer of articular cartilage which helps to eliminate friction between the bones when movement is occurred.[8] As a person gets older, the tissues of bone and cartilage are starting to degenerate progressively resulting in a compromise of the functional integrity of the joint. Ligaments and tendons may play also a potential role to aid the erosion of the joint and in the development of Heberden's nodes.[9] Joints from everyday movement are subjected to mechanical loading however, the stress from the movements is not enough to cause a healthy joint to develop osteoarthritis.[8] On the other hand, injured or vulnerable joints such as misalignment have a higher risk of developing osteoarthritis because of joint thickening and joint space narrowing respectively.[8] OA has been reported as a form of non-inflammatory arthritis however, many studies have indicated the upregulation of several inflammatory pathways.[8] Onset to early OA has been linked with changes in the extracellular matrix of cartilage. A highly negative charged protein named aggrecan assist the cartilage to maintain its compressive stiffness with electrical repulsion which is enforced by collagen fibers.[10] Typically, OA is classified either as primary or as secondary type. Primary type is defined when the joint develops OA and has no history of injury or trauma.[11] Secondary type of OA is referred to the development of the disease after an injury or trauma in the joint that it is usually caused from physical injury, accident or any other condition or disorder.[12,13] Bony abnormalities in the presence of hand OA are the Heberden's and Bouchard's nodes that affect part of the fingers. Heberden's nodes are defined as bony abnormalities and are located in the distal interphalangeal joints while Bouchard's are located in the proximal interphalangeal joints.[11,14] The prevalence of these nodes has been extensively investigated and documented however, their etiology and pathogenesis have not been determined yet.[15] The most commonly affected joint in the hand is the distal interphalangeal joints which often progresses after 40 to 50 years of age. The second most commonly affected joint is the carpometacarpal joint of the thumb and progress around the age of 50 years.[16,17] The metacarpophalangeal joint of the thumb may be also affected from OA while other joints in the hand are more often affected from secondary type of OA.[16,17]

1.4 Osteoarthritis and risk factors

Several risk factors have been associated with the development of osteoarthritis such as age, obesity, sex, smoking, race and environment, diet, occupation and genetics.[18] Age has been linked with an increased risk after the age of 20, with most individuals at the age of 40 will appear to have some damage in their joints whereas 50% of people aged greater than 65 will present characteristics of OA.[19,20] The increased risk in hand OA, is during the average age of menopause for females approximately at 55 to 60 years whereas the risk is starting to decrease after that age period.[21] When compared hand OA and knee/hip OA the risk is increased at the age of 50 years old and then the risk is starting to decrease after that age of 75 years old.[21] Obesity has been reported as a risk factor however, studies in the literature have presented conflicting findings. Previous studies such as the Baltimore Longitudinal Study of Aging for men or the National Health Examination Survey for women found no relationship between OA and obesity respectively.[18,19,22] On the other hand, subsequent studies have indicated that obesity is a risk factor for developing hand OA. Carman et al. found that obese individuals had a higher incidence of developing hand OA when compared to average weight individuals.[23] A 10-years study that was conducted in 1675 subjects indicated a weak association of hand OA and obesity.[24] Reasons why obesity is a risk factor for OA is poorly understood however, it has been reported that the higher body weight may increase the mechanical loading in the joints, may affect the hormone composition, the metabolism of the cartilage as well as the muscles.[24] Hormone production from the adipose tissue regulates inflammatory activity which has been linked to OA. Systemic factors such as (leptin, adiponectin, resistin, visfatin and chemerin) are probably more associated to the higher prevalence of hand OA in obese people than the mechanical loading factors.[25-27] Sex has been reported as a risk factor for developing hand OA with women being at 2.6 times higher risk in comparison with men.[23] The higher prevalence of OA in women after the age of 55 indicates that hormones (i.e. estrogen) may play a role for the development of hand OA.[18,19] As with obesity, the literature around smoking as a risk factor of developing OA is very ambiguous. Several studies that conducted in the past were not able to establish a relationship between smoking and OA in the most affected areas (hip, knee, and hand).[28-30] A subsequent study that was conducted

back in 2005 indicated that smoking may have a beneficial effect in terms of lower the risk for developing hip or knee OA.[31] In contrast, Amin and colleagues showed that smoking was associated with greater cartilage loss and pain in the knee.[32] While the literature shows conflicting results for smoking as a risk factors it is important to note that this risk or benefitted relationship has not been thoroughly examined for people with hand OA. [33] Prevalence of OA is very different depending on ethnicity and culture. For instance, an epidemiological study in China found that females had lower rates of radiographically confirmed OA in the hip and hand when compared with Caucasian females.[34] This finding further supports the role of genetics in the risk of developing OA. The role of diet has not been clearly understood but studies have showed that there is a relationship between hand OA and vitamin K.[35] Several studies have investigated the relationship between an individual's occupation and hand OA. More specifically, people with high labor working occupations that required repetitive movements (i.e. clothing industry) had a higher risk of developing hand OA.[36] A subsequent study confirmed this finding and suggested that females with hand OA had jobs that required to push something with their joints.[37]

1.5 Available treatments for osteoarthritis

Osteoarthritis treatment is mainly symptomatic; there is no cure. Available treatments can be divided into subgroups for didactical reasons: advice and self-help, conservative treatments requiring supervision, and surgery.[2] Advice and self-help includes patient education about OA, paracetamol, topical agents, physical agents, and food supplements such as glucosamine and chondroitin. Conservative treatments requiring supervision includes non-steroidal anti-inflammatory drugs (NSAIDs), weight loss, acupuncture, manual therapy, physical exercise, physical aids and supports, growth factor injections and/or platelet rich plasma, intra-articular corticosteroids, and intra-articular hyaluronic acids. Surgical treatments include arthroscopic surgery and total joint replacement. Recent clinical practice guidelines have reached somewhat conflicting conclusions regarding the usefulness of conservative treatment in osteoarthritis.[38-41] Hand OA leads to reduction in grip strength, difficulties when performing activities of daily living, loss of productive

work time and a decreased ability to perform manual activities.[42,43] In the clinical setting, pain is a major symptom among patients with hand OA which also contributes to patient report of reduced joint function.[44,45] Aspirational goals of hand OA treatment are to maximize long-term health-related quality of life through control of symptoms such as pain, prevention of structural damage and normalization of function. Management recommendations advise applying non-pharmacological and pharmacological treatments.[46] Medications include non-steroidal anti-inflammatory drugs (NSAIDs) and analgesics to relieve musculoskeletal signs and symptoms during all phases of treatment; however in general disease modifying drugs have not been effective.[47-49] Tumor necrosis factor inhibitors such as adalimumab, etanercept, golimumab and infliximab have a positive role in inflammatory arthritis, and have been studied in OA.[50,51] Previous studies on psoriatic arthritis[50] and rheumatoid arthritis[52] have supported the benefits of using anti-TNF drugs with respect to pain, swelling, function, quality of life, fatigue and radiographic progression. Literature is scattered with hypotheses and hopes for a positive effect of anti-TNFs on hand OA. On the other hand, non-pharmacological treatments for hand OA may include joint protection, exercise therapy and muscle strengthening, paraffin bath therapy, electrotherapy or acupuncture mainly for the management of symptoms.[46,53]

1.6 Joint protection programs

Joint protection programs are a self-management strategy to help patients with hand arthritis reduce pain and improve hand function.[54] This self-management approach usually involves training in safe movement patterns, the use of assistive devices and behavior modifications such as activity to avoid or pacing in active daily living.[54,55] Joint protection programs were primarily developed for people with rheumatoid arthritis in the hand and later this approach was expanded for patients with hand OA.[54,56]

1.7 The gap in the knowledge

One of the few handbooks (Kleinert Kutz – Joint protection Handbook for Persons with

Arthritis) for joint protection programs was published back in 1988. The book has several examples of joint protection techniques however, it is evident that these programs are clearly outdated and have not considered recent adaptations in technology use or how daily tasks are performed. The American College of Rheumatology conditionally recommends joint protection techniques for the management of hand OA which indicates that there is lack of evidence to support their efficacy.[39] More recent systematic review that investigated the effectiveness of joint protection programs provided strong evidence for people with rheumatoid arthritis in the hand but no evidence was presented for hand OA.[57] This is an indication that more evidence is needed on updated joint protection programs for people with hand OA. Another potential problem is that the literature does not describe adequately what constitutes joint protection and how the different aspects of the programs are implemented. For example, description of joint protection is often mentioned as leaflet, educational sessions or written course material and no other details are presented.[57,58] Furthermore, intervention dosage parameters and what training tools are most effective are currently unknown. This makes it very difficult to transfer the best available evidence to clinical practice. Previous reports have indicated that adherence to joint protection has been suboptimal.[59,60] Reasons for poor adherence have not been well documented and it is unclear what barriers may contribute to poor compliance in joint protection programs. Previous conducted trials have found that people with rheumatoid arthritis in the hand used joint protection approaches only when experienced pain symptoms.[56] Patients may not fully understand that they need to practice joint protection techniques consistently in their daily life and develop new patterns of daily activity so the cumulative joint loading can be reduced.

1.8 Objectives of this dissertation

The fact that Joint Protection Programs (JPP) can reduce pain and improve function is based on small, but definitive Randomized Controlled Trials (RCTs), conducted in the 1980s. However, changes over time in the nature of hand use, the rapid expansion of technology, and improvements in our understanding of health literacy mean that these

programs are now outdated. Further, problems with adherence to JPP are well documented. JPP can be enhanced by incorporating recent biomechanical and clinical evidence, technology innovations, and insights gained in collaboration with people with hand OA. JPP can be more salient, useful and effectively implemented. Therefore, the purpose of this thesis is to provide evidence to better understand the efficacy of JPP in patients with hand OA. More specifically, a series of studies were conducted:

1. To conduct a scoping review to map all the available evidence around joint protection programs in published and unpublished studies
2. To evaluate the effectiveness of joint protection programs when compared to usual care/no joint protection/advice on pain reduction and improvement of hand function for individuals with hand arthritis
3. To conduct an overview of systematic reviews to establish the current state of evidence evaluating the effectiveness of joint protection for people with hand RA and OA
4. To investigate the barriers, facilitators, expectations and patient preferences regarding joint protection programs in people with hand arthritis.
5. To evaluate the Content Validity Index (CVI) of Patient-Rated Wrist Evaluation (PRWE), Australian/Canadian Osteoarthritis hand Index (AUSCAN) and Thumb Disability Exam (TDX) in patients with hand arthritis
6. To design a single center, investigator-blinded, randomized, 12-month, parallel-group, superiority study for the evaluation of the efficacy of a joint protection program on pain intensity levels in people with hand osteoarthritis

1.9 Overview of this dissertation

Chapter 2 is a scoping review which aims to map all the available evidence around joint protection programs. More specifically, the scoping review examined what are the sources of evidence around joint protection, what are the main outcomes that are being used in joint

protection studies, by whom the program is implemented, what are the current principles of joint protection and what is available in the "grey" literature for joint protection. Chapter 3 is an evidence synthesis that aimed to investigate the effectiveness of joint protection on pain intensity and on hand function outcomes in people with hand arthritis. A meta-analysis of all the eligible RCTs was performed to pool all the extracted outcomes on pain and hand function. Chapter 4 is an overview of systematic reviews that critically appraise all the available evidence synthesis reviews and aims to explain why the different reviews provide different results. Chapter 5 is a cross-sectional survey that aimed to understand the barriers, facilitators, preferences and expectations in people with hand arthritis. Patients were recruited from a tertiary clinic in London, Ontario as well as with the help from The Arthritis Society of Canada social network. Chapter 6 is a measurement study that quantified the content validity of three self-reported outcomes in terms of their relevancy and clarity in people with hand arthritis. Chapter 7 is a design of superiority trial that integrates all the previous information from the previous studies of this thesis and aims to assess the efficacy of the updated joint protection and hand exercises programs in people with hand OA. Chapter 8 is a discussion section and overview of this thesis. In Chapter 8 we discuss the strength, limitations and the future research and clinical implications.

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Chapter 2

2 A Scoping Review of Joint Protection Programs for People with Hand Arthritis

Abstract

Background: Joint protection (JP) can be enhanced by incorporating recent evidence and innovations in collaboration with people with hand arthritis to be salient, useful and effectively implemented.

Objective: The purpose of this study is to map the current research on JP principles and guide future research on JP programs for the management of hand arthritis.

Methods: A search was performed in 4 databases (PubMed, EMBASE, Google SCHOLAR, CINHAL) from January 1990 to February 2017. A Grey literature was also conducted through the Google web search engine. A combination of search terms was used such as hand osteoarthritis, rheumatoid arthritis, joint protection and/or self-management strategies.

Results: Our search found 8,788 citations which 231 articles were deemed relevant and after duplication 111 articles were retrieved for a full-text review. In total, 40 articles were eligible for data extraction. The majority of the articles were (19) randomized controlled trials (RCTs), (6) systematic reviews and (3) overviews of reviews that investigated joint protection for hand arthritis. Joint protection was tested mostly in rheumatoid arthritis (RA) population and to a lesser extent on hand osteoarthritis and was provided mainly by an occupational therapist.

Conclusion: This review synthesized and critically examined the scope of JP for the management of hand arthritis and found that RCTs, systematic reviews and overviews of reviews constituted two-thirds of the current body of literature. Furthermore, it identified a lack of clarity regarding the specific elements of joint protection programs used in clinical studies.

2.1 Introduction

Hand osteoarthritis (h-OA) is one the most common type of osteoarthritis (OA), and it is a leading cause of disability in the elderly population around the world.[1] Asymptomatic h-OA is characterized by nodes and deformities in the finger joints. Symptomatic h-OA is usually associated with pain, stiffness and limited functional ability.[2] Reports from "The Framingham study" in 2002 showed that the prevalence of symptoms in h-OA was higher than the symptoms in the knee.[1] Management of h-OA typically includes pharmacological (medications) and/or non-pharmacological interventions such as joint protection programs, assistive devices, and hand exercises. Currently, there is no cure for h-OA and individuals with symptomatic h-OA need strategies and approaches on how to maintain their active daily living and functioning.

Joint protection programs were primarily developed for people with Rheumatoid Arthritis (RA) and had been reported to be beneficial.[3] Joint protection includes self-management strategies to alleviate pain, reduce inflammation and reduce the risk of deformities.[4] Also, joint protection has been developed as an approach to improve the performance of daily tasks by enhancing the control perceptions and improve the psychological status of the patient.[5] Joint protection is considered a multimodal intervention that aims to alter working methods by using proper body mechanics and by using assistive devices. It is often integrated with stretching and hand exercises .[6] Individuals with RA can play an essential role in the management of their disease progression, but this requires their involvement. The American College of Rheumatology in 2012 guidelines[7] suggested the use of joint protection for the management of h-OA however, no definite recommendations have been made so far. The European League Against Rheumatism (EULAR) evidence-based recommendations[3] reported that the joint protection programs is a well-established

approach for the management of RA but whether this method can be generalized to h-OA remains unclear. A scoping review of joint protection programs will be a narrative synthesis that aims to map the basic principles of joint protection and identify the primary sources of the current scientific evidence.

2.1.1 Purpose of the Study

The purpose of this scoping review is to gather, synthesize and critically examine the scope of joint protection principles for the management of h-OA and guide future research on joint protection programs for the future management of h-OA. The following questions were generated:

1. What are the main sources of scientific evidence of the current joint protection programs?
2. What are the main outcome measures that are used for joint protection?
3. What are the current approaches of the joint protection programs?
4. What is available in "Grey Literature" for joint protection programs?

2.2 Methods

This study followed the steps of reporting guidelines by Arksey and O' Malley's.[8] The steps were the following: identifying the research question (1), identifying relevant studies (2), study selection (3), charting the data (4) and synthesizing, summarizing and reporting the results.[8]

2.2.1 Study identification

The first author *(PB)* performed the literature search in 4 databases (PubMed, EMBASE, Google SCHOLAR and CINHAL) from January 1990 to February 2017. A combination of search terms was used such as hand osteoarthritis or/and rheumatoid arthritis, joint

protection and/or hand exercises and/or self-management strategies. A Grey literature was also conducted through the Google web search engine. The grey literature was investigated through google manual searches in the first 10 pages of results. Also, relevant articles from the scientific databases and the grey literature were selected from the title and entered into a word database file.

2.2.2 Study Selection

The title and the abstract from all the articles and the grey literature were independently screened by 2 investigators *(PB) and (GN)* and discrepancies were resolved by discussion with a 3rd investigator *(JM).* We included all articles and handbooks (grey literature) that contained information about joint protection programs for people with hand osteoarthritis and/or rheumatoid arthritis. Studies, where the primary language was not in English, were excluded from the review process. Also, studies and grey literature that focused exclusively on assistive devices or orthotic devices or hand exercises were excluded from our review. Articles with the same data presentation were prioritized as the ones that have the most details, and the others were eliminated. A flow diagram of the search results and selection process is shown in **Figure 1**.

2.2.3 Data Charting

Data were extracted from the first author (PB) from the included studies. Data information included Author(s) name or source, year of publication, type of research, study population, age, outcome measures, joint protection approaches, and by whom it was provided, and if authors made any recommendations.

2.2.4 Analyzing, synthesizing and reporting the results

Description of the study design, the population that was examined and by whom the joint protection was delivered. The reported summarized findings were presented in a summary table (Table 1). To answer our research questions, we categorized each type of study by level of evidence. Current joint protection approaches/principles and outcome measures were listed and reported in separate tables (Table 2-3). Grey literature was reported in a different category (Table 4-6).

2.3 Results

Our search found 8,788 citations. After the duplication 231 articles were deemed relevant from the title and abstract. Review of abstracts identified 111 articles and were assessed for a full-text review. In total, 40 articles were eligible for inclusion in the scoping review (Figure 1). The most common reason that studies were excluded was that either they did not test joint protection on hand or they talked about patient education in general and not for joint protection. Approximately 72% of the included articles reported rheumatoid arthritis (RA) as a patient population and only 20% reported patients with hand osteoarthritis (h-OA). A small portion of studies (8%) included both populations for joint protection programs. The average age of the included population was ranging from 48.95 to 67.2 years old. In terms of sex, more than 75% of the included sample size were females across the studies.

2.3.1 Study Description

The majority of the articles which consisted of 70% of the included articles were: (19) randomized controlled trials [5,9,18–25,10–17], (6) systematic reviews [26–31] and (3) overviews of reviews [32–34]. The rest of the studies were critical review of the literature [35–37], cohort studies [38,39], surveys [4,40], mixed methods studies [41], pilot [42] and cross-sectional studies [43]. The characteristics of the included studies are summarized in Table 1.

2.3.2 Outcome Measures

The outcome measures that were used in the included studies are summarized in Table 2. Pain was the most evaluated outcome measure, and it was evaluated with Visual Analog Scale (VAS) or by pain subscale of Health Assessment Questionnaire (HAQ) or by Numeric Pain Rating Scale (NRS) and by Michigan Hand Questionnaire. Self-report measures for psychological domains were evaluated with the Arthritis Self-Efficacy Scale (ASES), Hospital Anxiety and Depression Scale (HADS), Arthritis Helplessness Index (AHI) and Sense of Coherence (SoC). Disease-specific activity outcome measures were evaluated with the Disease Activity Score 28 (DAS28), Rheumatoid Arthritis Disease Activity Index (RADAI), Arthritis Impact Measurement Scale (AIMS2). Quality of life was assessed with EUROHIS-QOL 8 and health status with SF-12 and EQ-5D-3L. Functional ability was evaluated with HAQ, Dreiser Functional Index (DFI), Australian Canadian Osteoarthritis Index (AUSCAN), and Functional Index for Hand Osteoarthritis (FIHOA). The adherence of joint protection programs was measured with the Joint Protection Behaviour Assessment (JPBA), and joint deformity was assessed with Hand Joint Alignment and Motion Scale. Efficacy was measured with general self-efficacy scale and with global change. Disability was assessed with HAQ and with Disabilities of the Arm, Shoulder, and Hand (DASH). Performance-based tests were performed to assess grip and pinch strength as well as hand dexterity. Clinician based outcomes included wrist range of motion and finger range of motion.

2.3.3 Joint Protection Approaches

In half of the studies, it was not clear who was primarily involved in delivering the joint protection program. Only two studies reported that the joint protection was provided by medical staff (nurse or physician) and by a research assistant. Joint protection and energy conservation were administered mostly with two methods such as an educational-behavioral approach or as an approach that was focused on personal goals and available resources. The average time of a standardized joint protection education lasted from 1.5 to 3.25 hours approximately over two sessions. The usual content of the joint protection

education was to educate the participants about the disease and how the joints are affected by h-OA or RA. The education sessions included information about the joint protection principles with short time demonstrations (15 to 30 minutes) of hand joint protection approaches usually for household activities. At the end of the joint protection education, there was a discussion about patients' needs and problems that were mostly supported by a leaflet. The joint protection tasks are summarized in detail in Table 3. Assistive devices were not reported in the vast majority of the studies.

2.3.4 Grey Literature

Our grey literature search identified several online sources that are: (1) non-profit organizations (e.g. National Agricultural Safety Database (NASD), East Sussex Healthcare NHS, OASIS-Vancouver Coastal Health. Hand Osteoarthritis) (68) (2) educational e-learning communities (e.g. Physiopedia) (69) that have available online material for joint protection for people with hand arthritis and (3) Thesis from post-graduate and doctoral studies. General joint protection principles for hand consideration included: avoid tight grasp, avoid pressure on back of knuckles, use both hands when possible, avoid repetitive hand activities, avoid stress to tip or pad of thumb, avoid to pressure against the radial side of each finger thumb side, avoid prolonged period of holding hands in the same position, use more prominent joints to complete a task, plan ahead, use orthotic devices to protect your joints and respect pain. , and further details are summarized in Table 4-6.

2.4 Discussion

This study aimed to summarize the extent of the evidence for joint protection principles for the management of RA / h-OA and identified randomized controlled trials, systematic reviews and overviews of reviews as the primary sources of scientific evidence for the current joint protection programs. Pain, function, psychological domains, adherence, quality of life and health-status were the main outcomes that were administered. More specifically, pain levels were mainly examined by Visual Analog Scale, Health Assessment Questionnaire, Numeric Rating Scale and self-reported psychological domains Arthritis

Self-Efficacy Scale, Health Anxiety and Depression Scale, Arthritis Helplessness Index and Self of Coherence. Function was mostly examined by Australian Canadian Osteoarthritis index (AUSCAN), Michigan Hand Questionnaire (MHQ) and Health Assessment Questionnaire (HAQ). While the occupational therapist was primarily responsible for the delivery of joint protection, in half of the included studies, it was unclear who was mainly involved in delivering the joint protection program. Also, the current joint protection programs primarily focused on tasks associated with home care and kitchen, and the review of the grey literature yielded principles such as avoiding tight grips, awareness of pain, limiting prolonged periods of holding and use of larger joints.

This scoping study did not evaluate the effectiveness of Joint protection programs but identified 18 RCTs that can be synthesized to investigate their effectiveness. The two most recent systematic reviews [26,27] provided recommendations from 8 RCTs in total leading to the exclusion of 10 additional trials. Therefore, an update of the most recent evidence is highly recommended.

Joint protection as a multimodal intervention includes the following components (1) altering working methods, (2) use of proper joint and body mechanics through applying ergonomic principles, (3) use of assistive devices, and (4) modifying functional performance and environments.[6] It is often integrated with fatigue management, working splints and flexibility and strengthening exercises.[6] We were unable to extract all the components mentioned above of joint protection because either there was a lack of reporting or either the joint protection intervention was not fully implemented. Joint protection programs may include specific principles and techniques such as avoiding tight grips or use of larger joints or utilize particular exercises or energy conservation methods. Therefore, it is crucial to ensure comprehensive reporting of all the components of such programs when used in clinical studies. In this review, we were unable to extract specific information on what exactly included in joint protection programs from most of the clinical studies because the information was not available.

Future research needs to focus on clear and concise reporting of different principles included in joint protection programs utilized in clinical studies and ensure adequate representation of men and women. It is crucial to assess the effectiveness of such joint

protection programs in large-scaled well-designed randomized controlled trials by incorporating all the components of joint protection and not only parts of joint protection. The strengths of this review are that we summarized all the reported joint protection principles in peer-reviewed and grey literature. We highlighted the main outcome measures that were used in most of the studies to help future clinical studies to select the most commonly used self-report outcome measures and performance-based tests. We identified a lack of clarity and lack of detailed description on the components of joint protection that were tested. Finally, we indicated that many RCTs (n=10) have been published that have not been considered in a recent evidence synthesis.

Despite the authors' efforts to follow rigorous guidelines from Arksey and O'Malley [8], this scoping study is subjected to several limitations. A thorough literature search was performed; however, we may have missed research articles that were under development during the study period. Also, a search of the grey literature was conducted through google search web engine, but we have decided to stop after the first ten pages of google web. Therefore, online material that addresses joint protection strategies may have been missed during the search process.

2.5 Conclusions

This review synthesized and critically examined the scope of joint protection programs for management of h-OA and found that RCTs, systematic reviews and overviews of reviews constituted two-thirds of the current body of literature. Furthermore, it identified a lack of clarity regarding the specific elements of joint protection programs used in studies.

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Table 2-1. Characteristics of the included studies

Author or Source	Year	Study	Population	Provider
1. Siegel[26]	2017	SR	RA	N/A
2. McGee[43]	2017	CS	OA	N/A
3. Carandang[27]	2016	SR	RA	N/A
4. Williams[44]	2015	RCT	RA	N/A
5. Hammond[45]	2015	Book	OA	OT/PT
6. Oppong[46]	2015	RCT	OA	N/A
7. Dziedzic[47]	2015	RCT	OA	N/A
8. Spaans[28]	2015	SR	OA	OT
9. Ekelman[32]	2014	Overview	RA	N/A
10. Dilek[12]	2013	RCT	OA	OT
11. Niedermann[13]	2012	RCT	RA	Researcher
12. Beasley[35]	2012	Review	Both	OT
13. Swann[36]	2011	Review	RA	N/A
14. Niedermann[14]	2011	RCT	RA	N/A
15. Niedermann[41]	2010	Mixed	RA	OT
16. Valdes[29]	2010	SR	OA	OT
17. Boustedt[48]	2010	Cohort	OA	N/A
18. Vlieland[33]	2009	Overview	RA	OT
19. Hammond[15]	2008	RCT	RA	OT)
20. Steultjens[30]	2008	SR	RA	OT
21. Masiero[16]	2007	RCT	RA	OT
22. Quintrec[24]	2007	RCT	RA	N/A
23. Christie[49]	2007	Overview	RA	PT/OT/MD
24. O'Brien[50]	2006	RCT	RA	N/A

25. Gossec[51]	2006	CPG	RA	N/A
26. Steultjens [31]	2005	SR	RA	N/A
27. Veitiene[40]	2005	Survey	Both	N/A
28. Hammond[37]	2004	Review	RA	N/A
29. Hammond[18]	2004	RCT	RA	N/A
30. Stamm[19]	2002	RCT	OA	N/A
31. Hammond[52]	2002	RCT	RA	OT
32. Hammond[20]	2001	RCT	RA	OT
33. Hammond[5]	1999	RCT	RA	OT
34. Hammond[39]	1999	Cohort	RA	N/A
35. Scholten[25]	1999	RCT	RA	N/A
36. Hammond[4]	1998	Survey	RA	N/A
37. Lindroth[21]	1997	RCT	RA	OT/PT/MD/Nurse
38. Lindroth[23]	1995	RCT	RA	N/A
39. Hammond[53]	1994	Pilot	RA	N/A
40. Neuberger[54]	1993	RCT	RA	OT

RCT, randomized controlled trial; SR, systematic review; CPG, clinical practice guidelines; CS, cross-sectional study; OA, osteoarthritis; RA, rheumatoid arthritis; OT, occupational therapist; PT, physical therapist; MD, medical doctor

Table 2-2. Outcome measures that were reported

Author(s)	Year	Outcome Measures
Siegel	2017	Joint protection behavior, function, pain, fatigue, self-efficacy, stiffness
McGee	2017	Grip Strength, Numeric Rating Scale (NRS), Arthritis Impact Measurement Scale 2 (AIMS2)
Carandang	2016	Joint protection behavior
Williams	2015	The Arthritis Self-Efficacy Scale (ASES), Grip Strength, Finger Range of Motion (ROM), Michigan Hand Questionnaire (MHQ), Hand Dexterity, European Quality of Life 5 (EQ-5D-3L), Wrist Range of Motion (ROM), Short-Form 12 (SF-12), Self-Efficacy, Global Change, Pain (MHQ), Adherence
Oppong	2015	European Quality of Life 5 (EQ-5D-3L), Osteoarthritis Research Society International (OARSI)
Dziedzic	2013	The Arthritis Self-Efficacy Scale (ASES), Grip Strength, Short- Form 12 (v2), AUSCAN, Numeric Rating Scale (NRS), Pinch Strength, Global Change, functional performance using the grip ability test (GAT)
Ekelman	2014	morning stiffness, pain, and functional capacity
Dilek	2013	Visual Analog Scale (VAS), Grip Strength, AUSCAN, Pinch Strength, Dreiser Functional Index, Wrist Range of Motion (ROM)
Niedermann	2012	The Arthritis Self-Efficacy Scale (ASES), Joint Protection behavior Assessment (JPBA), Health Anxiety and Depression Scale (HADS), Visual Analog Scale (VAS), Disease Activity Score (DAS 28), Grip Strength, EUROHIS-QUOL 8, JP-specific self-efficacy (JP-SES)
Niedermann	2011	The Arthritis Self-Efficacy Scale (ASES), Joint Protection behaviour Assessment (JPBA), Health Anxiety and Depression Scale (HADS), Visual Analog Scale (VAS), Disease Activity Score (DAS 28), Grip Strength, Hand Joint Alignment and Motion Scale (H-JAM), Health Assessment Questionnaire (HAQ), Sense of Coherence (SOC), EUROHIS-QUOL 8, Wrist Range of Motion (ROM), JP self-efficacy scale (J-SES),
Niedermann	2010	Disease Activity Score (DAS 28), Health Assessment Questionnaire (HAQ)
Boustedt	2010	Visual Analog Scale (VAS), Grip Strength, Pinch Strength, DASH
Quintric	2009	Health Assessment Questionnaire (HAQ)
Hammond	2008	The Arthritis Self-Efficacy Scale (ASES), the Visual Analog Scale (VAS), Health Assessment Questionnaire (HAQ), RA Self-efficacy (RASE) Scale, the Arthritis Stages of Change Questionnaire
Steultjens	2008	Pain, fatigue, functional abilities (including dexterity), physical independence, quality of life (including well-being and depression). knowledge about disease management, compliance, self-efficacy, range of motion, muscle strength
Masiero	2007	Visual Analog Scale (VAS), Health Assessment Questionnaire (HAQ), Arthritis Impact Measurement Scale 2 (AIMS2)
Christie	2007	Pain, function, and patient global assessment.
O'Brien	2006	Grip Strength, Hand Dexterity, Pinch Strength, Arthritis Impact Measurement Scale 2 (AIMS2), finger flexion ROM goniometry, Jebsen–Taylor hand function test
Hammond	2004	The Arthritis Self-Efficacy Scale (ASES), Joint Protection behavior Assessment (JPBA), Visual Analog Scale (VAS), Grip Strength, Rheumatoid Arthritis Disease Activity Index (RADAI), Wrist Range of Motion (ROM), Arthritis Impact Measurement Scale 2 (AIMS2), EULAR 28,
Stamm	2002	Visual Analog Scale (VAS), Grip Strength, Health Assessment Questionnaire (HAQ)

Hammond	2002	The Arthritis Self-Efficacy Scale (ASES), Joint Protection behavior Assessment (JPBA), Visual Analog Scale (VAS), Grip Strength, Health Assessment Questionnaire (HAQ), Self-Efficacy, Patient Knowledge Questionnaire, Rheumatology Attitudes Index (RAI)
Hammond	2001	Joint Protection behavior Assessment (JPBA), Visual Analog Scale (VAS), Grip Strength, Hand Joint Alignment and Motion Scale (H-JAM), Arthritis Impact Measurement Scale 2 (AIMS2), Self-Efficacy, EULAR 28 tender, Rheumatoid Attitudes Index (RAI)
Hammond	1999	The Arthritis Self-Efficacy Scale (ASES), Joint Protection behaviour Assessment (JPBA), Visual Analog Scale (VAS), Grip Strength, Hand Joint Alignment and Motion Scale (H-JAM), Health Assessment Questionnaire (HAQ), Arthritis Helplessness Index (AHI), Hand Joint Count, Joint Protection Knowledge Assessment (JPKA)
Hammond	1999	Joint Protection behavior Assessment (JPBA), Visual Analog Scale (VAS), Health Assessment Questionnaire (HAQ), Hand Joint Count, knowledge questionnaire
Scholten	1999	Stanford Health Assessment Questionnaire, German version of the Freiburg Questionnaire of Coping with Illness (FQCI), Beck Depression Inventory (BDI)
Hammond	1998	Health Assessment Questionnaire (HAQ)
Lindroth	1997	Visual Analog Scale (VAS), Arthritis Helplessness Index (AHI), Stanford Health Assessment Questionnaire
Lindroth	1995	Health Assessment Questionnaire (HAQ), Pain (VAS
Hammond	1994	Joint Protection behavior Assessment (JPBA)
Neuberger	1993	Visual Analog Scale (VAS), Center for Epidemiologic Studies Depression Scale (CES-D)

Table 2-3. Joint protection Principles/Approaches that were reported

Author(s)	Year	Joint Protection Principles
Siegel	2017	the session was ranging from 45 minutes to 120 minutes
McGee	2017	In a standing position, participants maintained standardized glenohumeral and elbow joint positions as well as hand placements to control for the distal kinetic variance that might result from non-standardized posturing.
Carandang	2016	Uses guidelines that include techniques such as balancing rest and activity and the use of large joints Stresses education about disease, symptoms, and prognosis (especially effects of synovitis); incorporates family and routine
Williams	2015	The Number of sessions dependent on clinical need up to a maximum of three sessions or 1.5 hours in total. Rheumatoid Arthritis, a booklet providing general information about the disease and its management; Looking After Your Joints When You Have Arthritis, describing various self-management techniques and JP advice; and Keep Moving – How a few Simple Exercises can Make You Feel Better About Yourself and Your Arthritis, a booklet providing general exercise information along with suggestions as to specific exercises that could be performed for all parts of the body
Hammond	2015	Joint protection: Respect pain; distribute the load over several joints; use the strongest, largest joint to perform an activity; avoid working in positions of potential deformity; reduce effort by using assistive devices and avoiding lifting and carrying and avoid prolonged periods of working in the same position. • Energy conservation: Pace by balancing rest and work and alternate heavy and light activities; use work simplification; use correct working positions and postures.
Dziedzic	2013	distributing the weight of what you lift over several joints (e.g., spread the load over two hands) ‣ avoiding putting strain on the thumb and repetitive thumb movements ‣ avoiding prolonged grips in one position ‣ using as large a grip as possible ‣ reducing the effort needed to do a task (e.g., use labor-saving gadgets; avoid lifting heavy objects, and reduce the weight of what you lift) ‣ energy conservation (activity pacing and planning)
Ekelman	2014	Training includes movement training to promote daily manual work by reducing pain and joint strain, preventing deformity, and maintaining functional capacity; self-exercise programs for hands; and provision of information on assistive devices, methods to adapt the environment, and the value, use, and handling of orthoses.
Niedermann	2012	Demonstrations and supervised practice of hand JP methods, mostly in kitchen activities, and demonstration of appropriate assistive devices. The interventions consisted of five 45-minute sessions, four over a three-week period and one booster session two months later
Beasley	2012	Respect pain, balance rest and activity, perform the exercise in a pain-free range, avoid positions of deformity, reduce the effort and force, use larger/stronger joints
Swann	2011	The main techniques for joint protection are to (Arthritis Research UK, 2010): Use larger, stronger joints, Spread the load over several joints, reduce effort by using labor-saving gadgets, Avoid gripping things tightly, Avoid positions that push joints towards
Boustedt	2010	Joint protection consists of information about hand anatomy, osteoarthritis, and theoretical and practical information about pain and how to cope with it [6]. To introduce alternate working methods to reduce difficulties of daily activities the women tried grip assistive devices and elastic thumb splints during the day both at the clinic and at home.
Hammond	2008	joint protection (including 45min demonstration and practice), managing fatigue, aims of splinting, managing stress and relaxation (45 min practice)
Masiero	2007	Principles of JP and energy conservation, including a demonstration of various hand-JP techniques, plus a homework task to identify problem activities and find solutions based on the imparted principles, work difficulties, etc.
O'Brien	2006	basic principles of joint protection, energy conservation, 'top tips' relating to personal and household activities,
Hammond	2004	Both education programs consisted of four 2-hour weekly meetings.
Stamm	2002	joint protection instruction: the need for balance between movement and resting a joint; dividing stress between as many joints as possible; using larger and stronger joints; using each joint in its most stable plane to reduce pressure on the joint; avoiding staying in one position, and avoiding vibrations for the finger joints.

Hammond	2001	principles of joint protection and energy conservation; demonstration of some hand-joint protection methods; and a homework task to identify problem activities and to find solutions using the principles taught.
Hammond	1999	Arthritis and Rheumatism council leaflets
Hammond	1998	Altering ways of moving hands during daily activities to reduce joint strain
Hammond	1994	Four JP principles were assessed: (1) distributing the load over several joints; (2) using each joint in its most stable position; (3) reducing effort by use of aids and avoiding lifting; and (4) avoiding positions of possible joint deformity
Neuberger	1993	Joint Protection Principles

Table 2-4. Joint protection principles from Physiopedia

1. AVOID TIGHT GRASP	• Use a relaxed grip. • Enlarge handles. • Place the palm on the jar lid, and using the weight of the body, turn arm at the shoulder to open the jar. A sponge or wet towel under the jar prevents sliding • Hold the knife or mixing spoon like a dagger, with the handle parallel to knuckles. Cutting is then changed from sawing to pulling • Don't carry heavy handbags, pails, and bags by the handle. • Hold everything no tighter than necessary. • Release tight grasp frequently if you must use it. • Use built-up handles on writing utensils, pot handles, tools, etc. • Use adaptive equipment such as jar openers
2. AVOID PRESSURE ON BACK OF KNUCKLES	• Avoid all pressures against the backs of fingers: this type of pressure contributes to dislocation of the large joints between the palm and the fingers (metacarpal-phalangeal joints). • This occurs while pushing up from a chair using a closed fist or resting chin on the backs of fingers. • Use palms while holding fingers straight.
3. USE BOTH HANDS WHEN POSSIBLE	• Not specified how
4. AVOID REPETITIVE HAND ACTIVITIES	• Take breaks • Change activity, i.e., using screwdriver, crocheting
5. AVOID PRESSURE TO TIP OR PAD OF THUMB	• The thumb is necessary for 40 percent of hand activities • Example: opening car doors, ringing doorbells • To protect thumb joints, open milk containers with heels of the hands rather than thumbs.
6. AVOID PRESSURE AGAINST THE RADIAL SIDE OF EACH FINGER THUMB SIDE	• Don't rest chin on the side of fingers. • Add levers to keys, handles, and knobs. • Hold handles straight across the palm.
7. AVOID PROLONGED PERIODS OF HOLDING HANDS IN THE SAME POSITION	• Sit if the task takes more than 10 minutes. • Stand up after sitting for 20-30 minutes. • Reposition yourself often.

Table 2-5. OASIS-Vancouver Coastal Health - Protecting Your Hands

1. Use your bigger joints to complete a task	• Carry your handbag with your shoulder or forearm. Carry only what you need. • Push or pull items rather than carry them, e.g., use a wheeled cart for groceries • Carry large or heavy items with two hands. Hug the object close to your body. • Close drawers/doors with your hip or choose automatic doors when possible • Push up from a chair using the palm of your hand, not your fingers. Choose higher chairs or use a firm cushion on your chair.	
2. Plan ahead	• Vary tasks and change your hand position often. Take breaks every 20-30 minutes. • Spread heavier tasks throughout the week • Rest your hands before they are tired or sore • Organize your workspace to ensure hands and wrists are in a neutral posture	
3. Use splints to protect your joints, either at rest or during activity	• Talk to your care team to determine if a hand or thumb splint would be helpful for you	
4. Change your grip and use adapted equipment to avoid tight gripping/squeezing and force through the thumb	Writing, gardening	Buy large-handled tools or make your handles larger with foam tubing
	Cooking	Adapted kitchen aids, e.g., finger vegetable peeler, ergonomic salad spinner
	Opening jars and cans	Jar seal-opener, non-slip grip, electric can opener
	Twisting tops, squeezing tubes	Products with pumps
	Wringing out clothes	Use the heel of your hand; sponge or washing brush
	Driving	Foam steering wheel cover
	Pumping gas	Use the lever on the handle to avoid squeezing for a long time
	Pinching a key	Keyholder
	Reading	Bookholder, books on tape, e-books
	Opening mail	Easy-to-squeeze scissors
	Dressing	Button hook, zipper pull
	Opening doors, turning taps	Lever taps and door handles
	Gripping slippery items, e.g., removing credit cards from a wallet	Use a piece of non-slip mat, e.g., Dycem; accordion-style wallet
	Self-care, e.g., cutting nails, washing hair, etc.	Adapted equipment from a pharmacy or medical supply store
5. Follow the exercises given to you by your health care team to keep your joints moving and your muscles strong	No further instructions were given	

Table 2-6. East Sussex Healthcare NHS

1. Use joints in a stable position	• Sit or stand as close as you can when working at a table or bench as this reduces stretching • and bending. • Use a grip that keeps the wrists straight and the fingers in line with the wrist as much as • possible.
2. Avoid activities that do not allow for a change of position	• Be mindful of how long you have been doing specific activities, joint and muscles do not like to be held in the same position. They become stiff and work less effectively which leads to pain, damage and further deformity. When writing, doing hand work, release your grip every 10 to 15 minutes. On long car trips, get out of the car, stretch and move around at least every one to two hours.
3. Respect pain	• If you have arthritis, you may always have some pain. If pain continues for hours after the activity has stopped, this indicates that the event was too much and should have been changed or stopped sooner.
4. Avoid tight grips or gripping for long periods	• Gripping tightly increases pain and can cause further joint damage. Gripping small objects require greater force
5. Avoid deforming positions	• When opening new or tight jars consider using a gripping aid and direct the force through the palm of your hand rather than just through the fingers. There are several types of jar opening devices. Ask others to undo the lids, while you close them. • Use a flat hand when possible for cleaning, wiping, dusting. • Try using cups with larger, straighter handles than cups with curved handles. • In general, finger motions should be in the direction of the thumb whenever possible.
6. Use one large joint or many joints	• Carry objects with your palm open to distribute weight equally over your forearms. • Slide objects along a counter or workbench rather than lifting and carrying them. • Carry light bags on your shoulders rather than with your hands. • When standing up from a chair or bed, rock forward and use your leg muscles rather than pushing up from your knuckles or wrists. • Use your hip or lower leg to close drawers.

claiming source Arthritis Research UK, www.arthritisresearchuk.org.

Table 2-7. Energy conservation and joint protection from NASD

1.	Respect **PAIN** as a signal to **STOP** the activity.
2.	Make a **SCHEDULE** of daily activities. Write down when **PAIN** and **FATIGUE** occur and schedule in **REST BREAKS** as needed.
3.	Avoid **POSITIONS OF DEFORMITY** and **FORCES** in their direction. Finger motions should be in the direction of the thumb whenever possible. When getting up from a chair or holding a magazine, use the palms of the hands rather than the knuckles.
4.	Use the **LARGEST** and **STRONGEST** joints available for a job. Save weaker joints for the specific tasks that only they can handle. For example, carry bags on the shoulder instead of at the elbow, wrist, or fingers.
5.	Avoid staying in **ONE POSITION** for a **LONG PERIOD OF TIME**. Don't give your joints the chance to become stiff. When writing or doing handwork, release your grip every 10 to 15 minutes. On long car trips, get out of the car, stretch and move around at least every hour. While watching television get up and walk around every 30 minutes.
6.	Use a **CART** to carry heavy items. If no cart is available, it is better to take several trips to get a job done than to overload and make one trip.
7.	**SLIDE** or **PUSH** items whenever possible.
8.	Avoid making a **TIGHT FIST** or **PINCHING** objects tightly. Instead, use a grasp that places your **KNUCKLES PARALLEL** to the handle of the tool or utensil being used.
9.	**DO NOT** start an activity that cannot be **STOPPED IMMEDIATELY** if pain or fatigue should occur.

NASD, National Agricultural Safety Database

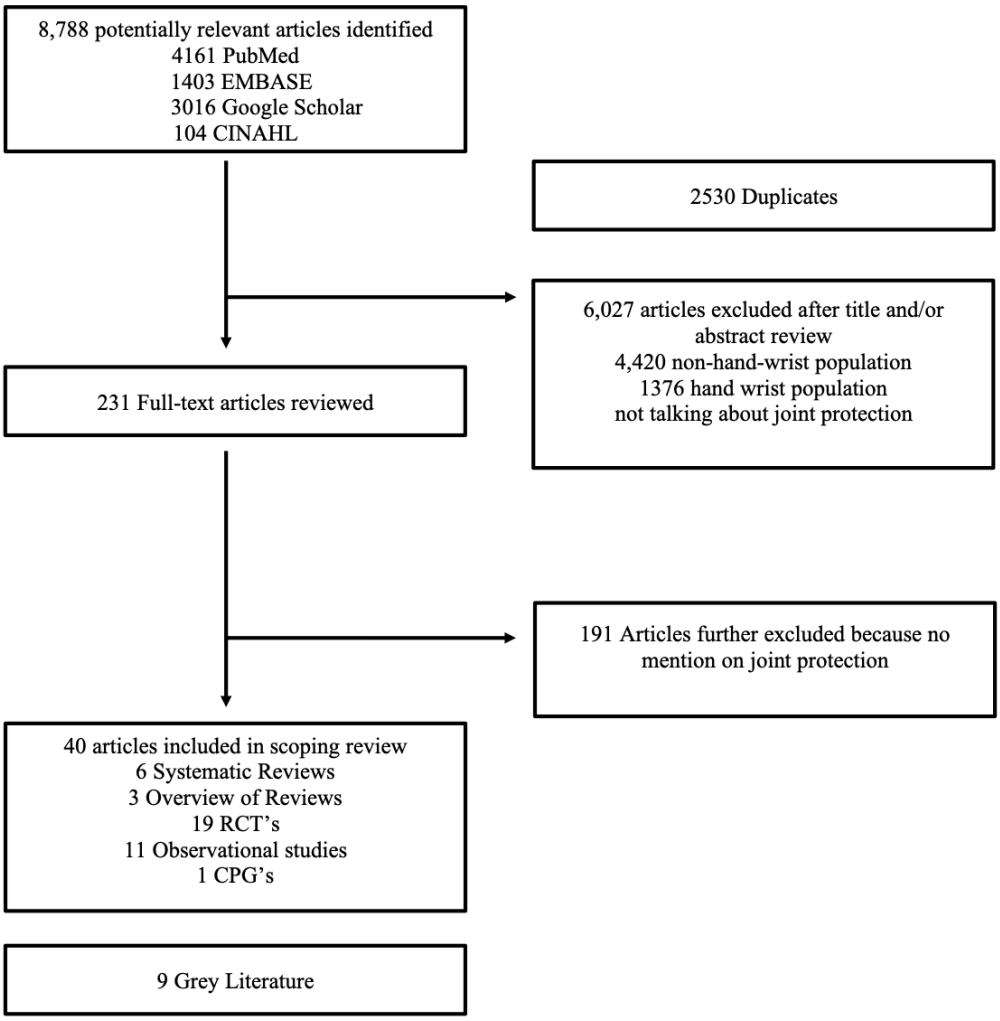

Figure 2-1. Selection of included articles

Chapter 3

3 The Effectiveness of Joint Protection Programs on Pain, Hand Function and Grip Strength Levels in Patients with Hand Arthritis. A Systematic Review and Meta-Analysis

Abstract

Study Design: Systematic review with meta-analysis

Introduction: Joint protection (JP) has been developed as a self-management intervention to assist people with hand arthritis to improve occupational performance and minimize joint deterioration over time.

Purpose of the Study: We examined the effectiveness between JP and usual care/control on pain, hand function and grip strength levels for people with hand osteoarthritis (OA) and rheumatoid arthritis (RA).

Methods: A search was performed in 5 databases from January 1990 to February 2017. Two independent assessors applied Cochrane's risk of bias tool, and a GRADE approach was adopted.

Results: For pain levels at short-term, we found similar effects between JP and control standardized mean difference (SMD) -0.00, 95% CI: -0.42 to 0.42, I^2=49%, at mid and long-term follow-up JP was favored over usual care SMD: -0.32, 95% CI: -0.53 to -0.11, I^2=0 and SMD -0.27, 95% CI: -0.41 to -0.12, I^2=9% respectively. For function levels at mid and long-term follow-up JP was favored over usual care SMD -0.49, 95% CI: -0.75 to -0.22, I^2=34% and SMD -0.31, 95% CI: -0.50 to -0.11, I^2=56% respectively. For grip strength levels, at long term JP was inferior over usual care Mean Difference (MD) 0.93, 95% CI: -0.74 to 2.61, I^2= 0%.

Conclusions: This systematic review provides the most updated evidence on the effectiveness of joint protection programs vs. usual care/control in patients with rheumatoid arthritis and hand osteoarthritis on clinical outcomes. Evidence of very-low to low quality indicates that the effects of joint protection programs compared to usual care/control on pain and hand function are too small to be clinically important at short-, intermediate- and long-term follow-ups for people with hand arthritis.

Keywords: joint protection, hand osteoarthritis, rheumatoid arthritis

Prospero registration number: CRD42018090698

3.1 Introduction

Osteoarthritis (OA) is a degenerative joint disease that affects approximately 27 million adults and is ranked in the top three causes of disability in the United States[1]. The economic burden for OA, rheumatoid arthritis (RA), and other rheumatoid conditions in the United States were estimated to be approximately 128 billion dollars which represent 1.2% of the 2003 U.S. gross domestic product [2]. Today, more than 272,000 people are living with RA, comprising 0.9% of the Canadian adult population, which will increase to 1.3% over the next 30 years[3]. In Canada between 2008 and 2009, the socioeconomic cost of arthritis was over 4.4 billion dollars. About 80% of these costs were attributed to the unemployment and underemployment [4]. Pain from OA has a significant impact on the quality of life, work productivity and in the usage of healthcare resources among workers [1]. Recent evidence from a systematic review suggests that the reduction in health care costs for services to manage arthritis is as necessary as the improvement of the quality of life of this patient population [5].

The most common site of OA is in hand, and the most commonly described symptoms are pain, joint deformity, loss of grip strength and loss of hand function [6]. RA can also affect small joints in the hands and may cause painful swelling, joint deformity, loss of joint function and increased disability [4]. Conservative management of hand arthritis includes both pharmacological (e.g., NSAIDs) and non-pharmacological interventions, such as joint protection programs, assistive devices, and exercises [7,8]. Currently, there is no cure for hand arthritis, but many rehabilitation interventions are targeting towards helping individuals to

maintain functional performance with activities of daily living (ADLs), mediate symptoms, and prevent deformities.

Joint protection programs were initially developed for people with RA and had been expanded to treat patients with hand OA [9]. Joint protection intervention includes education in altering working habits, use of proper joint and body mechanics by applying ergonomic principles, use of assistive devices and orthotics, and modifying functional performance and environments. It is often integrated with fatigue management and flexibility and strength hand exercises[10]. It has been suggested that joint protection for people with RA may reduce load and effort during daily activities of daily living. Therefore, it is theoretically resulting in strain reduction on joint structures which have been weakened by the disease, pain mediation, irritation prevention of the synovial membrane and reduction of local inflammation and fatigue. Also, it has been suggested that joint protection for people with hand OA is aiming to reduce loading on articular cartilage, strengthen muscle support, and improve shock-absorbing capabilities of joints[10,11].

Two recent systematic reviews (SRs) [7,12] examined the effectiveness of joint protection on people with RA. Each study examined joint protection and provided recommendations from 5 RCT's and 3 RCT's respectively[7,12]. Those 2 SRs reported strong evidence that joint protection may improve function [7] and pain [7,13]. For people with hand OA, a SR found that programs of joint protection, advice, and home exercises are effective at improving grip strength and hand function[14]. While those reviews provide valuable insights, they have important limitations. Both studies reported effects mostly as statistical differences and not as magnitude of the effects. Also, both reviews did not interpret and discussed the potential impact of risk of bias when they provide recommendations. Given the limited number of RCT's that were included for joint protection for people with hand OA and RA, an appraisal of the most recent evidence is needed. Therefore, the objective of this systematic review is to evaluate the effectiveness of joint protection programs when compared to usual care/no joint protection/advice on pain reduction and improvement of hand function for individuals with hand arthritis.

3.2 Methods

3.2.1 Search Strategy

An electronic search was performed to identify RCT's in PubMed, Google Scholar, CINAHL, PEDro and EMBASE from January 1990 to February 2017. Several different combinations of keywords were used such as: "rheumatoid arthritis" or "osteoarthritis" and/or "joint protection" or "hand osteoarthritis" or "self-management and osteoarthritis". The complete search strategy is summarized in Appendix 1. The references of systematic reviews and overviews found in the electronic search were then hand searched to retrieve further RCT's.

3.2.2 Inclusion/Exclusion Criteria

Only randomized controlled trials (RCT's) were eligible for inclusion by fulfilling the following criteria: (1) RCT's included people with RA or hand OA, (2) patients received joint protection[10,11] (3) outcome measures were adequately reported. Studies were excluded if: (1) were not written in English, (2) they only examined a specific component of joint protection such as an assistive device or orthosis or they did just hand exercises without joint protection advice.

3.2.3 Study Selection

Two independent reviewers (PB and MS) performed the electronic search to screen relevant articles based upon title and abstract. After duplications were removed, inclusion criteria were applied to retrieve the articles for a full-text review. Disagreements were resolved using a consensus method via a third reviewer (JM).

3.2.4 Data Extraction

Two independent researchers (BP and MS) extracted the data from the included RCT's. A third person checked the data extraction (JM). Data extraction included the following information: (1) author, (2) year, (3) study population, (4) sample size (5) intervention method, (6) primary outcome measures, (7) secondary outcome measures (8) results, and (9) recommendations made by authors (if any). We categorized the follow-up periods as short-term (3-4 months or less), mid-term (6-8 months) and long-term (12 months or more).

3.2.5 Missing data from Included Studies

When values (Mean and SD) were not available an attempt was made to contact the corresponding authors to request the data. Additionally, we searched other tables from previous SR's to identify Means, and SD's of the included RCTs to facilitate our data analysis.

3.2.6 Risk of Bias Assessment

Two reviewers (PB and MS) independently assessed the risk of bias of each RCT. If there was a disagreement, consensus came from a third reviewer (JM). Risk of bias assessment was performed with Cochrane Collaboration's tool [15] which contains seven domains (random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting and other bias) to score sources of bias. Each domain can be rated as "low risk of bias," "unclear risk of bias" or "high risk of bias." The interpretation of this tool is as follows: 1) low risk indicates that if bias is present, results will be unlikely to be altered, 2) unclear risk of bias induces some doubts surrounding the results of the study, and 3) high risk of

bias indicates that bias may change the results seriously [15]. Publication bias was planned to assess with funnel plots if more than ten studies were pooled [16].

3.2.7 Assessing the quality of individual RCTs

The GRADE guidelines for systematic reviews were used to evaluate the quality of individual RCTs related to five outcomes: hand function/functional ability, grip strength and pain/hand pain levels [17–22]. GRADE approach includes the rating of the quality of evidence such as study limitations, risk of bias, publication bias, imprecision and indirectness [17–21]. The rating of the quality of individual RCTs per outcome across trials was carried out to summarize the extent of our confidence that the estimates of the effect were correct. This GRADE approach resulted in an assessment of the quality of each RCT for each outcome across trials as high, moderate, low, or very low [17–21]. The domains of GRADE approach that may decrease the quality of evidence are: 1) imprecision, 2) indirectness, 3) limitations in study design, 4) inconsistency and 5) reporting bias. An optimal information size (OIS) was calculated to define the minimum amount of sample size needed for precision in the meta-analysis.

3.2.8 Summary Measures

To interpret our data a standard deviation of 0.5 points for pain and function was used to indicate clinical importance[23]. We analyzed outcomes at short-term (3 – 4 months), mid-term (6 – 8 months) and long-term (12 months) follow-ups.

3.2.9 Subgroup Analysis and Exploring Heterogeneity

In the presence of clinical or statistical heterogeneity (i.e., Chi^2 with $p<.05$ and $I^2>50\%$)[15], we planned to perform the following subgroup analyses (a priori): trials at low risk of bias (low risk of bias in allocation concealment and blinding of outcome assessor if objective outcomes were used) and type/duration joint protection program received.

3.2.10 Synthesis of Results

We performed six meta-analyses of trials comparing joint protection programs vs. usual care/control in patients with rheumatoid arthritis using the outcomes function, pain, and grip strength at short-, mid- and long-term follow-ups. When necessary, data direction was adjusted appropriately to reflect improvements in pain reduction and functional ability. We used the Review Manager 5.3 (RevMan 5.3) software to conduct our review and a random-effects model to pool outcomes. For outcomes of the same construct that were measured using a different metric, we used the standardized mean difference (SMD). If all eligible trials measured an outcome using the same metric, we used a weighted mean difference (WMD).

3.3 Results

3.3.1 Characteristics of Included studies

Initially, 8,837 articles were identified (Pubmed: 4,161 EMBASE: 1,403 Google Scholar: 3,016 CINAHL: 104 PEDro: 49). After removal of duplicates, 6,027 articles were then excluded (4,420 non-hand wrist population, 1,376 not talking about joint protection). Of the 29 studies were deemed relevant from the abstract, 17 met our inclusion criteria and were included in the analysis (Figure 1). Joint protection programs were examined in 3 RCT's for hand OA and in 14 RCT'S for patients with RA. The characteristics of the included RCT's are summarized in Table 1.

3.3.2 Excluded Studies

Of the 29 studies that were deemed relevant for a full-text review, 12 articles were excluded for the following reasons:

1. Ineligible study design – Non-randomized studies (n=1, Boustedt et al. 2009[24])

2. Used same data/participants with included RCT (n=1, Oppong et al. 2015[25])

3. Ineligible population – RCT (n=1, Maggs et al. 1996[26])

4. Ineligible intervention – RCT (n=7, Grønning et al. 2014[27], Grønning et al. 2012[28], Lorig et al. 2009[29], Barlow et al. 2008[30], Brus et al. 1998[31], Riemsma et al. 1997[32], Fries et al. 1997[33])

5. Both groups examined the same JP intervention with a different approach – RCT (n=2, Niedermann et al. 2012[34], Niedermann et al. 2011[35])

3.3.3 Risk of bias and Quality assessment

Overall, all the 17 studies were judged to be high risk of bias (Table 2); (Figure 2). Selection bias, performance bias, and reporting bias were the main contributors that influence our results (Figure 2). Funding sources were reported in the majority of the included RCTs. Quality assessment was ranging from very low to low, and most of the studies were downgraded for imprecision and high risk of bias. The summary of the findings is presented in Table 3.

3.3.4 Selection Bias

Randomization and allocation concealment were not reported appropriately in many of the studies and was the main reason that studies were rated as high risk. More specifically, randomization sequence generation and allocation concealment were rated as high risk in 8 studies while nine studies were rated low risk of bias (Table 2).

3.3.5 Performance Bias

Blinding of participants and personnel was rated as high risk in 12 studies because the blinding procedure was not performed adequately. Only five studies were rated as low risk, and they managed to blind the participants and providers effectively (Table 2).

3.3.6 Detection Bias

The majority of the studies (10 RCTs) were rated as low risk, and they managed to blind the outcome assessor effectively. Seven studies rated as high risk because the blinding of the outcome assessor could not be achieved (Table 2).

3.3.7 Attrition Bias

Sixteen studies were rated as low risk of bias for attrition bias, and only one was rated as high risk. The RCT that was rated at high risk did not report any dropouts and did not report if all the participants were analyzed after randomization (Table 2).

3.3.8 Reporting and Other Bias

Most of the studies (16 RCTs) reported the timing of outcome assessment. Description of co-interventions was unclear in 16 studies because of poor reporting and only 2 RCTs[36,37] performed trial registration and published their protocol. Seven studies[38–44] did not report their sources of funding and only 2 studies[37,45] report adverse effects (Table 2).

3.3.9 Publication Bias

We assessed publication bias for the meta-analysis of pain and function outcomes (Figure 3-4). The asymmetrical funnel plot (Figure 4) demonstrates that the smaller RCTs produced exaggerated treatment effects.

3.3.10 Participants

Data from a total of 1,847 participants with hand arthritis were included in this systematic review. The majority of them (n=1,504) have been clinically diagnosed with RA and only 343 participants with hand OA. The average age of the participants with hand OA was 61 years old, and 70% or more were females. The average age of the participants with RA was 62.8 years old, and more than 70% of the sample was females.

3.3.11 Interventions

Studies that included in this systematic review compared joint protection programs that had an exercise component, or the participants received instruction on exercise, joint protection education and either was administered individually or to a group and was mostly delivered by an occupational therapist. Comparisons consisted of no treatment, advice, usual care, patient education. Treatment dose and frequency were varied a lot across the studies but typically was on average 3-5 times per week from 45 minutes to 1.5 hours. A summary of the interventions and the comparators is presented in Table 1.

3.3.12 Outcomes

Outcomes of interest that were extracted from the included studies were: pain levels[36,42,54–56,46–53] and was examined with the following outcome measures: (1) Michigan Hand

Outcome Questionnaire pain subscale (MHQ) (0-100) with lower scores indicating better pain scores, (2) Numerical Rating Scale (0-10) higher score is worse and (3) Visual Analog Scale (VAS) (0-100mm) higher score is worse. Self-report hand function[42,43,54,56–58,44–48,50,52,53] was assessed with the following outcome measures: (1) Michigan Hand Questionnaire (MHQ) (0-100) higher scores indicating better performance, (2) Australian/Canadian (AUSCAN) Osteoarthritis Hand Index (0-36), (3) Health Assessment Questionnaire (HAQ) (range from 0-3) higher is worse and (4) Arthritis Impact Measurement Scales II (AIMS II; upper limb, and hand and finger function subscales) Subscales range score of 5–25 (25 indicating severe functional difficulties). Grip strength[45,46,49–53,56] levels were assessed with a Jamar hand-held dynamometer and with a Smith and Nephew Rolyan Digital Dynamometer.

3.3.13 Effects of interventions on RA

Short-term effects of interventions on pain levels

Three studies were pooled to examine the short-term effect of a joint protection program vs. usual care on pain levels. We found similar effects between joint protection programs and usual care/control (very low quality, 3 RCTs, 548 participants with RA, standardized mean difference (SMD) -0.00, 95% CI: -0.42 to 0.42, I^2=49%). The analysis is illustrated in Figure 5.

Mid-term effects of interventions on pain levels

Three studies were pooled to investigate the mid-term effects of a join protection programs vs. usual care/ control on pain levels. We determined that joint protection was favored over control (very low quality, 3 RCTs, 358 participants with RA, SMD: -0.32, 95% CI: -0.53 to -0.11, I^2=0). The analysis is summarized in Figure 5.

Long-term effects of interventions on pain levels

Four studies were pooled to examine the long-term effects of joint protection programs vs. usual care/control on pain levels. We determined that joint protection was superior when compared with control (low quality, 4 RCTs, 857 participants with RA, SMD -0.27, 95% CI: -0.41 to -0.12, I^2=9%. The analysis is presented in Figure 5.

Short-term effects of interventions on function levels

Only one study reported values of the function that we could calculate the SMD. We found that the JP intervention was superior when compared to usual care (very low quality, 1 RCT, 451 Participants with RA, SMD 0.18, 95% CI: -0.01 to 0.36).

Mid-term effects of interventions on function levels

Three studies were pooled to investigate the mid-term effects of joint protection vs. control on function levels. We determined that intervention groups were superior over control (very low quality, 3 RCTs, 358 participants with RA, SMD -0.49, 95% CI: -0.75 to -0.22, I^2=34%. The forest plot is illustrated in Figure 6.

Long-term effects of interventions on function levels

Six studies were pooled to investigate the long-term effects of joint protection vs. control on function levels. We determined that intervention groups were superior over control (very low quality, 6 RCTs, 1,077 participants with RA, SMD -0.34, 95% CI: -0.50 to -0.11, I^2=56%. The forest plot is illustrated in Figure 6.

Short-term effects of interventions on grip strength levels

One study reported the short-term effects of joint protection vs. control/usual care on grip strength levels. We determined that joint protection programs were inferior when compared to usual care/control (very low quality, 1 RCTs, 400 participants with RA, MD 1.38, 95% CI: -0.29 to 3.05). The analysis is presented in Figure 7.

Mid-term effects of interventions on grip strength levels

One study investigated the mid-term effects of joint protection programs vs. usual care/control on grip strength levels. We found that join protection programs were superior over usual care/control (very low quality, 1 RCTs, 121 participants with RA, MD -1.39, 95% CI: -5.02 to 2.24). Analysis and the strength of evidence are presented in Figure 7.

Long-term effects of interventions on grip strength levels

Two studies were pooled to examine the long-term effects of join protection programs vs. usual care/control on grip strength levels. We determined that joint protection programs were inferior when compared to control (very low quality, 2 RCTs, 478 participants with RA, MD 0.93, 95% CI: -0.74 to 2.61, I^2=0). Analysis and the strength of evidence are presented in Figure 8.

3.3.14 Effects of interventions on hand OA

From the three studies that included participants with hand OA only 1 RCT[46] reported clear means and SD. For short-term effects on pain levels, we found similar effects when joint protection compared to no joint protection (high risk of bias, relatively small sample size; 257 participants with hand OA, MD -0.10, 95% CI: -0.60 to 0.40) for function levels, we found that joint protection was no better than no joint protection (high risk of bias, relatively small sample size; MD -0.20, 95% CI: -1.59 to 1.99). For midterm effects on pain and function levels, we found similar effects when joint protection compared to no joint protection (high risk of bias, relatively small sample size; MD -0.30, 95% CI: -0.23 to 0.83), (high risk of bias, relatively small sample size; MD 0.50, 95% CI: -1.38 to 2.38) respectively. For midterm effects on grip strength levels, we determined that joint protection was superior when compared to no joint protection (high risk of bias, relatively small sample size; MD -2.20, 95% CI: -7.53 to 3.13). For long-term effects on pain and function levels, there was no difference between joint protection and no join protection

intervention (high risk of bias, relatively small sample size; MD 0.10, 95% CI: -0.45 to 0.65), (high risk of bias, relatively small sample size; MD 1.20, 95% CI: -0.68 to 3.08) respectively.

3.3.15 Unknown Treatment Effects on Extracted Outcomes

There were five studies for participants with RA and two studies for people with hand OA that were unable to calculate SMDs or effect sizes due to lack of reporting and are summarized below.

Hand RA

O'Brien et al. 2006[57] (n=67) investigated the effectiveness of 3 different joint protection groups on function and pain at 1, 3 and 6 months follow-up (high risk of bias, relatively small sample size; low quality). Hammond et al. 2004[49] (n=127) examined the effectiveness of educational-behavioral joint protection programme vs. a standard programme on pain, functional ability and grip strength at 24 months follow-up (high risk of bias, relatively small sample size; low quality). Hammond et al. 2002[50] (n=30) examined the effectiveness of joint protection first vs. joint protection second on pain functional ability and grip strength at 3 and 6 months follow-up (high risk of bias, relatively small sample size; very low quality). Helliwell et al. 1999[40] (n=77) examined the effectiveness of a joint protection programme vs. control on functional ability at 1 and 12 months follow-up (high risk of bias, relatively small sample size; very low quality). Lindroth et al. 1997[54] (n=100) examined the effectiveness of a joint protection programme vs. control at 3 and 12 months follow-up (high risk of bias, relatively small sample size; very low quality).

Hand OA

Dilek et al. 2013[56] (n=46) examined the effectiveness of paraffin bath therapy and joint protection vs. joint protection on pain, self-report function and grip strength levels in patients with hand OA at 3 weeks and 3 months follow-up (high risk of bias, relatively small sample size; very low quality). Stamm et al. 2002[59] (n=40) assessed the effectiveness of a joint protection program plus hand exercises vs. a control group (information only), on grip strength levels, pain and functional ability, in patient with osteoarthritis, at 3 months follow up (high risk of bias, relatively small sample size; very low quality) [60]. We were unable to calculate effect sizes or report between-group (mean/median difference) improvements for pain and functional levels due to lack of reporting in group means, standard deviations, standard errors of means, confidence intervals or p-values. Only grip strength values were reported, and we found similar effects between joint protection intervention and control with an MD -0.01, 95% CI: 0.12-0.10 (Units: bar) between the joint protection and control at 3 months follow-up.

3.4 Discussion

We aimed to summarise the current evidence of the effects of joint protection programs vs. usual care/control in patients with rheumatoid arthritis and hand osteoarthritis on clinical outcomes of pain, functional ability, and grip strength. Based on the results of this study, we found no clinically important differences in function, grip strength or pain levels at short-, mid- and long-term follow-ups. Our study provides more definitive estimates of joint protection treatment effects for people with rheumatoid arthritis based on our meta-analysis. Imprecision and high risk of bias were the main reasons that the quality of evidence was downgraded.

Nine different studies reported comparable outcomes and had multimodal JP interventions that enabled the statistical pooling. For pain levels at short-term, we found similar effects

between treatment groups and usual care/control. The wide confidence intervals that crossed the vertical line imply that the studies' results did not find a statistically significant between the tested groups and also, that the sample size was low. While JP as multimodal intervention reduced pain for people with RA at mid and long-term follow-up, the magnitude of the pooled estimates was smaller than the predefined clinically important difference (SMD>0.5). At long-term follow-up, the number of pooled participants (n=857) exceeded the estimated optimal information size (OIS) (n=685) which it indicates that we had adequate sample size to be precise in our pain level estimates. The effect sizes of the pooled estimates regarding function levels were improved from short-term to mid-term (SMD -0.49, 95% CI: -0.75 to -0.22) and at long-term follow-up slightly declined (SMD -0.34 95% CI: -0.50 to -0.11). While these estimates are lower than the predefined clinically important difference, it is evident that the hand function at mid-term was improved (SMD -0.49) very close to the clinically important margin. The upper bound of the 95% CI indicates an SMD of -0.70 however, due to imprecision issues (n=358<OIS) we cannot be confident for the treatment effect if it can be clinically worthwhile or not. Regarding grip strength, our short and long-term effect estimates indicated that joint protection programs were inferior to usual care/control. At mid-term JP programs were superior to usual care/control in terms of grip strength levels. However, the tested power was very low because of the wide confidence intervals and also, that the studies' results did not observe a statistically significant difference. Generally, the measurement of grip strength as a performance-based test provide very useful information in clinical practice because it's an indication of hand function. Previous studies have indicated a negative correlation between grip strength and disease activity for people with RA and showed that the grip strength becomes worse when the disease is more active[61,62]. While joint protection principles indicate to maintain your muscle strength and range of movement, it is unclear if the instructed exercises are optimal to improve hand grip strength. Given the disease activity and the lack of clarity of joint protection programs, the results of grip strength are even more ambiguous. For patients with hand OA, only one study reported means and SDs for pain, function and grip strength and compared a joint protection program vs. no joint

protection. However, this study was rated as high risk of bias with a relatively small sample, and therefore, we have very little confidence about the treatment effects.

Previous recent systematic reviews (SR) reported strong evidence that joint protection may improve function [7] and pain [7,13]. Our findings are not in concordance with those 2 SR, and this can be attributed to the following main reasons. First, we included more studies (14 RCT's and 3 RCT's) in our analysis for people with RA and hand OA respectively. We reported treatment effects of MD, SMD and 95% confidence intervals to indicate the magnitude of the effects. Second, we took a more conservative approach while synthesizing the evidence by using the Cochrane risk of bias tool and using GRADE approach to rate the quality of the evidence.

Publication bias was assessed with two different funnel plots (Figure 3-4). While an asymmetry was detected in both figures, we deem that they do not indicate publication bias. In our meta-analysis, we pooled less than ten studies to examine the effects of interventions. However, the tested power was low, and it was very difficult to distinguish from the real asymmetry[16]. A statistical heterogeneity was detected at long-term function levels ($p=0.05$, $I^2=56\%$). For that reason, we downgraded the quality of the evidence by 1 level for long-term function levels. A potential explanation for the causes of statistical heterogeneity it may be due to variations in the treatment effects of a particular study from the pooled studies. This study[43] favors control over the experimental group when examining the function levels at long-term follow-up which was not consistent with the other studies. The contributing percentage in the I^2 value when this trial added in the analysis was an additional 36% which it may be attributed to a false variation from the real treatment effect.

Strengths of this SR are that we used the most conservative approach to assess risk of bias with Cochrane risk of bias tool. We interpreted our results by summarizing the results by providing GRADE rating. We calculated effect sizes and we presented confidence intervals to indicate the magnitude of the effects and whether the effects were meaningful or not. We estimated the optimal information size (OIS) to demonstrate whether our results had precision or not.

3.4.1 Future Implications

While this is beyond the scope of this systematic review, the current state of the literature is not clear about the dosage, intensity, and frequency of joint protection programs and when other aspects are incorporated (e.g., assistive devices, orthotic devices, exercises) when this therapeutic approach is delivered to people with hand arthritis. We were unable to extract instructions on joint protection in a specific and measurable way because of lack of reporting. Future research should aim to be more specific for all the components of joint protection programs for better head to head comparisons.

3.4.2 Limitations

Our study has some limitations that need to be addressed. While a thorough literature review was conducted, trials that were under development may have been missed. Also, we were unable to calculate the effect sizes from some of the included studies, and therefore, we are uncertain of their effect. We extracted outcome measures for pain, hand function, grip/pinch strength and we did not analyze further outcomes for the effectiveness of joint protection.

3.5 Conclusions

This systematic review provides the most updated evidence on the effectiveness of joint protection programs vs. usual care/control in patients with rheumatoid arthritis and hand osteoarthritis on clinical outcomes. Evidence of very-low to low quality indicates that the effects of joint protection programs compared to usual care/control on pain and hand function are too small to be clinically important at short-, intermediate- and long-term follow-ups for people with hand arthritis.

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Table 3-1. Summary of the included studies

Study	Population	Groups	Outcomes	Follow ups	Experimental group	Comparison group
Williams 2015	n = 490 (374 females) Rheumatoid Arthritis Age (yr.) = exp. 61.3 (SD 12), con. 63.5 (SD 11)	Hand exercise plus usual care vs. usual care	-overall hand function subscale of the Michigan Hand Outcome Questionnaire (MHQ), (0 – 100) higher indicating better performance -Pain sub-scale of MHQ (0–100; high score is worse) -grip strength (Newton)	4 and 12 months	-assessment and advice session plus five 30- to 45-minute exercise sessions spread over 12 weeks l content of usual care arm treatment. -an exercise programme aiming to improve strength, mobility and dexterity (including four strength -exercises for the hand and seven mobility exercises of all the upper limb joints) -a home exercise plan with exercises performed daily -a standardised protocol for progression or regression -strategies to improve programme adherence including exercise diaries -no resting orthotic devices, no manual therapy or electrotherapy, assessment and treatment documented using a standardised log.	-individual appointment(s) with a therapist (number of sessions dependent on clinical need up to a maximum of three sessions or 1.5 hours in total) -JP advice -provision of Arthritis Research Campaign (ARC) booklets containing further advice and -exercise information -functional splinting as deemed necessary by the therapist -assistive devices as required -no resting orthotic devices provided, no explicit exercise prescription, no manual therapy (i.e. joint mobilisations) or electrotherapy assessment and treatment documented using a standardised log
Dziedzic 2013	n = 257 (female 66%) Hand Osteoarthritis Age (yr.) = leaflet & advice 67.2 (SD 9.5), Joint protection (JP) 65.5 (SD 8.6), Hand exercises (Hex) 64.5 (SD 9), JP and Hex 66 (SD 9.3)	(1) joint protection vs no joint protection (2) hand exercises vs joint protection and hand exercises combined;	-average pain severity over the past 3 days (0–10 numerical rating scale) -AUSCAN function (0-36) -Grip strength (kg)	3, 6 and 12 months	For the remaining 75% of participants, in addition to receiving the leaflet, they received one of three interventions: joint protection, hand exercises, or a combination of the two. The interventions were all delivered over four group sessions (held once a week) by nine occupational therapists (OTs) in two hospital centres. OTs were rotated every 3 months to minimise the potential for bias. The rotation order was determined by the OTs availability to deliver the specific intervention. Groups included up to six participants and lasted for a maximum of one hour (1.5 h for the combined intervention). Treatment session duration and participant attendances were recorded by the OTs on case report forms (CRFs). Attendance adherence was audited by the study coordinator (SH), and was defined (a priori) to be per protocol if participants attended: session 1, 2, 3 and 4; sessions 1, 2 and 4; sessions 1, 3 and 4; or sessions 1 and 4. Any participant unable to attend week 1 was booked on to the following course.	All participants were given standardised written information on self-management approaches for hand osteoarthritis (OA) including general information on looking after hand joints and using analgesia (reproduced with permission from the Arthritis Research UK leaflets 'Looking after your joints when you have arthritis' and 'Osteoarthritis', respectively (http://www.arthritisresearchuk.org/), and the National Institute of Health and Care Excellence (NICE) good practice guidelines. Participants were advised to continue with any self-management approaches they were currently using and were given advice to consult their general practitioner if symptoms continued to be troublesome. For 25% of participants this was the sole intervention.
Dilek 2013	N=46 (40 females) Hand Osteoarthritis Age (yr.) = exp. 58.87 (SD 9.47), con. 59.95 (SD 8.71)	Paraffin bath therapy plus Joint Protection vs Joint Protection	-Pain (visual analogue scale) (0–100; high score is worse) -AUSCAN function - Grip strength (Jamar) (kg)	3 weeks and 3 months	Experimental group treated with dip-wrap paraffin bath therapy and Joint protection. The temperature of the paraffin bath was 50C. Patients dipped both hands into the paraffin, removed them, and waited for the layer of paraffin to harden and become opaque. Then they redipped both hands. These steps were repeated 10 times. When the last layer hardened, their hands were wrapped within a plastic bag and covered with a towel. They then waited for 15 minutes until the paraffin cooled. A physiotherapist in the Department of Physical Medicine and Rehabilitation in the university hospital conducted these treatments 5 days per week for a period of 3 weeks.	Control group received joint protection techniques

Hammond 2008	n = 218 (108 females) Rheumatoid Arthritis Age (yr.) = exp. 55.56 (SD 13.10), con. 55.29 (SD 11.84)	Standard programme vs modular cognitive–behavioural approach programme (the LMAP)	-Pain (visual analogue scale) (0–100; high score is worse) -HAQ assessing functional ability (0–3 scale)	6 and 12 months	The LMAP included two modules, each with four 2.5h meetings, and one 2-h review meeting. To standardize programme delivery, a two-day training course for each module (led by A.H.) was completed by therapists. This explained: evidence for programme interventions; patient education and behavioural change methods; tips for good teaching practice (e.g. voice modulation, eye contact, open questions, reflecting back, positive feedback); programme structure; and role play of sessions emphasizing group processes, teaching techniques and skills teaching. A.H. delivered a programme observed by the therapists. The therapists were then observed delivering a programme and given feedback on performance. Module manuals enabled adherence to programme content. Participants could attend the two LMAP modules and review meeting over a 3- to 9-month period, as convenient to them. Six people could attend module 1 ('Looking After Your Joints'), 7–10 module 2 ('Keeping Mobile and Managing Pain and Mood') and up to 12 the review meeting. Each meeting included self-monitoring, skills training with individualized feedback and advice, goal-setting and action planning to follow individually determined home activity and exercise programmes working towards recommended frequency targets.	Standard programme consisted of five 2-h meetings including talks each week from a different member of the team and group discussion. Meeting 1 included: what is arthritis, how it affects joints and other parts of the body, drug treatments and tests, managing arthritis (rheumatology nurse and consultant rheumatologist); Meeting 2: exercise (including stretch programme with 30 min demonstration and practice), rest, posture and pain management [using heat and cold, transcutaneous electrical stimulation (TENS), massage] [physiotherapist (PT)]; Meetings 3 and 4: joint protection (including 45 min demonstration and practice), managing fatigue, aims of splinting, managing stress and relaxation (45min practice), foot care [occupational therapist (OT)]; Meeting 5: healthy diet, complementary therapies, Social Security benefits and open discussion (nurse, OT, PT, social worker). Usually the same OT attended each week to facilitate discussion and programme management. Relevant Arthritis Research Campaign and Arthritis Care booklets were provided. Eight to 12 people were invited to attend each programme.
Quintrec 2007	n = 208 (177 females) Rheumatoid Arthritis Age (yr.) = exp. 55.32 (SD 11.80), con. 54.31 (SD 14.37)	Educational intervention program vs. Usual care	Functional status, Health Assessment Questionnaire (HAQ) (0-3), 0 (no functional limitation) to 3 (serious functional limitation	12 months	An intensive education program was proposed to deliver a large quantity of information about the disease and the treatment, but also to point the possibilities to reduce pain and stress at home, to understand how to use nonchemical treatment (e.g., physical activities or sports, social and professional behaviors, nutritional advice). The interactive multidisciplinary education program consisted of passive information on the disease, on medical treatment, and on lifestyle advice concerning diet, but also included information on active coping strategies, joint protection, relaxation, and physical exercise, with the teaching of an exercise program to be followed at home. Sessions were conducted on Thursdays for 6 hours for 8 consecutive weeks.	Usual care
Masiero 2007	n = 85 (57 females) Rheumatoid Arthritis Age (yr.) = exp. 54.2 (SD 9.8), con. 52.2 (SD 11.9)	Drug treatment (with infliximab) with educational behavioral JP training vs Drug treatment (with infliximab) only	-Pain (visual analogue scale) (0–100; high score is worse) -Functional status was evaluated using the Health Assessment Questionnaire (HAQ), which is an ordinal score measure (range 0–3)	8 months	The Experimental Group continued with their usual drug treatment (with infliximab) in the follow-up months, but additional educational–behavioral JP training was provided. This training consisted of four meetings based on approximately 3-h sessions, every 3 weeks, for groups of 4–6 patients at a time, with one or more family member (the patients were encouraged to bring a partner). The education methods used were group discussion, problem solving, guided practice, and lectures designed to facilitate understanding of the program. At the beginning of each session, feedback was provided, and the results of and problems with home practice were discussed. At the end of each meeting, patients received an illustrated brochure on the program meeting with a home guide.	The Control Group patients received only anti-TNFα drugs (infliximab) and continued with their usual drug monitoring and medical management regimen in the follow-up months, but no physiotherapy, occupational therapy, or other additional treatments were performed or permitted
O'Brien 2006	n = 67 (46 females) Rheumatoid Arthritis Age (yr.) = group1 62.3 (SD 9.95), group 2 57.3 (SD	Joint protection leaflet with hand strengthening and	-Arthritis Impact Measurement Scales II (AIMS II; upper limb, and hand and finger function subscales) Subscales range	1, 3 and 6 months	Group 1 received JP and additional instruction on how to perform a total of eight simple strengthening and mobilizing (stretching) 'tendon gliding' exercises. These encouraged a maximum range of movement of all small joints of the fingers, thumb and wrist, as well as radial finger walking (fingers moving towards the	Joint protection leaflet which covered the basic principles of joint protection, energy conservation, 'top tips' relating to personal and household activities, postural advice, types of splinting and issues related to sexuality

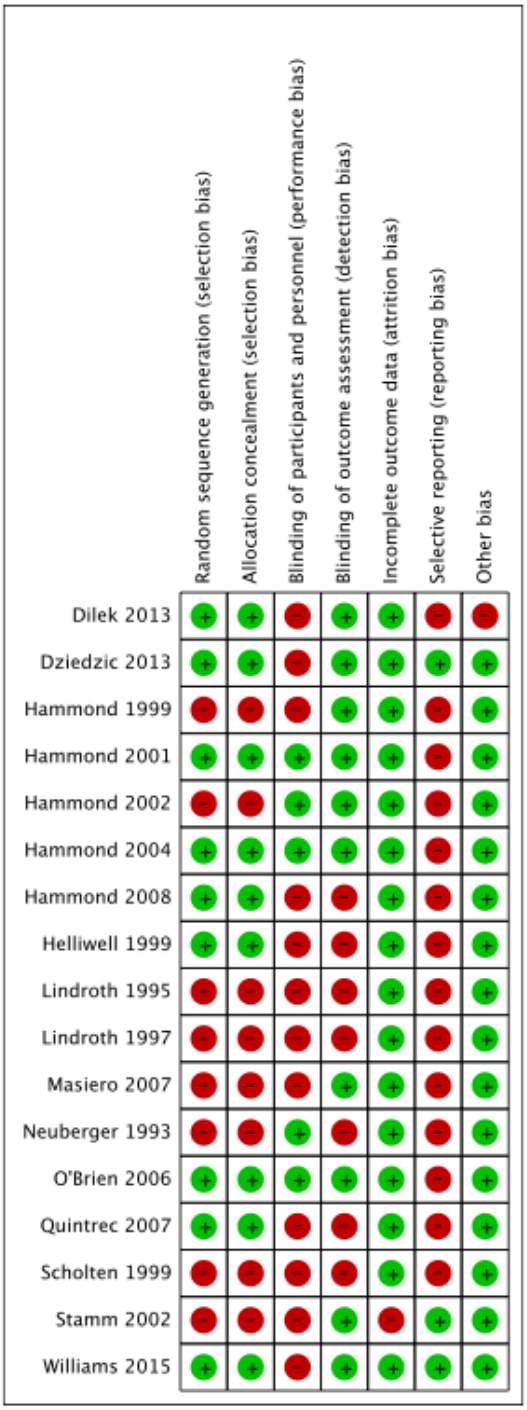
	8.24), group 3 59.5 (SD 12.92)	mobilizing exercises vs Joint protection leaflet with hand mobilizing exercises vs Joint protection leaflet	score of 5–25 (25 indicating severe functional difficulties). This score was then normalized so that the potential range of scores was 0–10 where higher scores indicate more problems -Grip Strength (Jamar) lbs		radius only thus avoiding exacerbating ulnar deviation), pinch grip exercises, strengthening the intrinsic, and thenar eminence muscles (using a towel) and wrist extensor muscle groups with a 'Theratubes' resistive band (Promedics, UK). Group 2 participants received the joint protection leaflet together with a set of eight stretching exercises, without any specific strengthening exercises. Exercises included wrist flexion, extension and circumduction, pronation and supination, radial deviation as well as global flexion and abduction of all finger joints, thumb opposition and interphalangeal flexion to the end of the possible range.	
Hammond 2004	n = 127 (46 females) Rheumatoid Arthritis Age (yr.) = exp. 51, con. 52	Standard programme vs Educational -behavioural joint protection programme	-Pain (visual analogue scale) (0–100; high score is worse) -TheAIMS2 (Arthritis Impact Measurement Scales2) was used to assess activities of daily living (ADL) (0-10, 0 indicates good function) -Grip Strength (kg)	24 months	The educational behavioural JP consisted of four 2-hour weekly meetings. The Educational-behavioural joint protection programme applied educational, behavioural, motor learning and self-efficacy enhancing strategies to increase adherence.	The education consisted of four 2-hour weekly meetings. The standard programme included talks from the rheumatology teams on: RA, drug treatments, diet, exercise, pain management, relaxation and joint protection.
Hammond 2002	n = 30 (27 females) Rheumatoid Arthritis Age (yr.) = 52.3 (SD 12.08	Group 1 – Education First vs Group 2 – Education Second	-Pain (visual analogue scale) (0–100; high score is worse) -Health Assessment Questionnaire (HAQ) (0-3), higher scores indicating poorer functional ability. -Grip Strength (Jamar)	3 and 6 months	The 'Looking After Your Joints' programme included: information about RA and disease management, joint protection and energy conservation education. About 5 hours of joint protection practice was included, using motor learning, mental rehearsal, problem-solving and behavioural methods, with the setting of weekly goals to practise joint protection methods at home. It also included self-efficacy and adherence-enhancing strategies. Structured teaching methods were used to enhance recall, such as explicit categorisation, repetition, checking understanding by asking regular questions and structured visual aids. An information pack and a workbook were provided, containing summaries of the four sessions and a home programme, as well as other information about the disease, its management (including drug therapy), exercise, rest, energy conservation and splinting; these were also briefly discussed in the programme.	Same as experimental

Stamm 2002	N=40 (40 females) Hand Osteoarthritis Age (yr.) = exp. 58.87 (SD 9.47), con. 59.95 (SD 8.71)	Joint protection and home hand exercises (JPE group) vs information session about hand OA	-Pain (visual analogue scale) (0–100; high score is worse) -Health Assessment Questionnaire (HAQ) -Grip Strength (Martin vigorimeter)	3 months	The JPE group received oral and written instruction for joint protection and a home hand exercise program, which was to be performed daily throughout a study period of 3 months. The following principles were explained during the joint protection instruction: the need for balance between movement and resting a joint; dividing stress between as many joints as possible; using larger and stronger joints; using each joint in its most stable plane to reduce pressure on the joint; avoiding staying in one position; and avoiding vibrations for the finger joints. In addition, patients were trained to protect their joints, using assistive devices if necessary to perform Activities of Daily Living (ADL). Patients were trained to do the following activities in a protective way: wringing a cloth; using enlarged grips for writing; opening jars, cans, or boxes with Dycem; using a book holder for reading; and using a rocker or angled knife for cutting food. Patients were encouraged to find exam- ples for application of these principles in their own daily activities, which were discussed. Oral and written information was provided. The joint protection instruction and ADL training took 30 minutes for each patient. The exercise program consisted of 7 exercises: making a fist, making a small fist (flexing the PIP and DIP joints only), flexing the MCP joints while keeping the PIP and DIP joints stretched, touching the tip of each finger with the tip of the thumb while keeping each finger flexed, spreading the fingers as far as possible with the hand lying flat on a table, pushing each finger in the direction of the thumb with the hand lying flat on a table, and touching the MCP V joint with the tip of the thumb.	The control group was given oral and written information about hand OA to ensure that these persons also received proper attention. The information about hand OA included information on joint anatomy and pathogenesis of OA. During this session, each control person also received a piece of Dycem (nonslip matting), which they were told to use for opening jars throughout the period of 3 months. Duration of this session was 20 minutes.
Hammond 2001	n = 127 (46 females) Rheumatoid Arthritis Age (yr.) = exp. 51.56 (SD 9.73), con. 49.49 (SD 11.49)	Standard programme vs Educational -behavioural joint protection programme	-Pain (visual analogue scale) (0–100; high score is worse) -Function The AIMS2 (Arthritis Impact Measurement Scales) 0 to 10, with 0 representing good function -Grip Strength (Jamar)	6 and 12 months	The joint protection programme was based on the health belief model and the theories of social learning and self-management and was conducted by an experienced rheumatology occupational therapist. Between three and six participants usually attended and, with partners included, numbers were between four and eight. Participants were provided with an information pack and workbook detailing the principles of joint protection, with photographs of a range of joint protection methods. The programme applied educational, behavioural, motor learning and self-efficacy enhancing strategies to increase adherence to the joint protection programme, as well as a range of educational methods to match different group members' learning styles. Two-thirds of the programme was spent practising hand-joint protection methods in small groups with feedback on performance from each other and the group leader. People were shown a range of options for task performance, so that they could select which methods worked best for them. Education programmes was of 8 h duration over four afternoon or evening sessions of 2 h each	The standard programme included short talks from nursing, medical, occupational therapy and physiotherapy staff on the following: RA; drug treatments; alternative therapies, diet; exercise, rest and positioning; energy conservation; joint protection; assistive devices; splinting; pain and relaxation; and other methods of controlling pain (e.g. heat and ice). Some demonstration and practise of exercise, joint protection and relaxation was included (15–45 min for each). Meetings allowed time for discussion and information leaflets were provided. Education programmes was of 8 h duration over four afternoon or evening sessions of 2 h each

Helliwell 1999	n = 77 (51 females) Rheumatoid Arthritis Age (yr.) = exp. 55, con. 56.5	Educational programme vs Control	-Health Assessment Questionnaire (HAQ) (0-3)	1 and 12 months	The education classes took place over 4 weeks in four afternoon sessions lasting 2 h. Subjects were encouraged to bring a partner, although this happened infrequently. For people who were still working or who preferred to come with a partner, evening sessions were arranged. The format of the sessions was a talk from a non- medical health professional using overhead projection, a discussion period and the distribution of supporting literature. The content of the sessions included the pathophysiology of rheumatoid arthritis, drug treatments, local treatments, mechanisms and control of pain, stress, exercise and rest, joint protection, task allocation, splinting and assistive equipment.	Not reported/No details
Scholten 1999	n = 68 (53 females) Rheumatoid Arthritis Age (yr.) = 48.3 (SD 5.6)	Arthritis Training program vs Control	Health Assessment Questionnaire (HAQ) (0-5), 0 represents good function	12 months	The following fields were covered: pathogenesis and mechanisms of RA, benefits and limitations of drug therapy, the impact of physiotherapy, practical exercise in remedial gymnastics aimed at relieving pain and muscle tension, use of joint protection devices, orthopedic perspectives including methods and indications of joint replacement, psychological counseling including coping strategies, Jacobson stress management and relaxation exercise, 20 dietetics, information about unproven cures, and social assistance to improve the patients' utilization of public social resources. Psychological counseling emphasized a general sense of control or efficacy, and skill in coping with variability of the disease and its sequelae. Training in the proper execution of remedial gymnastics was offered and advice on joint protection was included in the program. The aim of the exercise practice sessions was to keep the patients mobile by feasible therapeutic exercises preserving the axis of the joints destroyed by RA and by reinforcing the weakened muscles. Within a daily l0-minute training program nearly every joint had to be moved in the right position and direction. The patients were taught performance of everyday activities and how to use auxiliary devices like special scissors or knives. The importance of wearing orthotic devices at night or during manual activities was emphasized.	Control/No additional details
Hammond 1999	n = 35 (29 females) Rheumatoid Arthritis Age (yr.) = 55.17 (SD 9.39)		-Pain (visual analogue scale) (0–100; high score is worse) -Health Assessment Questionnaire (HAQ) (0-3) -Grip Strength (Smith and Nephew Rolyan Digital Dynamometer)	3 and 6 months	The JP group education programme consisted of four weekly 2-h sessions, plus an optional home visit within 2 weeks of the end of the programme. It was led by an experienced rheumatology occupational therapist. Partners or significant others were invited to attend. Between four and eight people attended each programme. A teaching manual was followed throughout to standardise the programme content and delivery. Patients were provided with a workbook 'Managing Your Arthritis: Joint Care Workbook', 'Coping with Rheumatoid Arthritis' and patient education leaflets produced by the Arthritis and Rheumatism Council (ARC) such as 'Rheumatoid Arthritis', 'Your Home and Your Rheumatism', 'Exercise and Arthritis', 'Drug Therapy', 'Gardening and Arthritis', and 'Diet and Arthritis'. The ARC videotape 'Help is at Hand— getting the better of your arthritis' is shown at the first meeting to promote discussion of members' own alternate methods and gadgets they found useful, as well as on the impact of living with arthritis.	Control/No further details

Lindroth 1997	n = 100 (84 females) Rheumatoid Arthritis Age (yr.) = 55.17 (SD 9.39)	Education programme vs Control	-Pain (visual analogue scale) (0–100; high score is worse)	3 and 12 months	A handbook for patients presented facts about each session. During 8 sessions, 2.5 hours once a week, group discussions were led by a team of health professionals. The group members were encouraged to understand the terms of the disease process such as inflammation, seropositive, erosion, and anemia. In the session on therapy a nurse led discussions about medication, surgery, and alter- native treatments. Diet, fasting, and basic nutrition were discussed with a dietitian. The session led by a physiotherapist concentrated on pain management by rest, exercise, and relaxation. Acupuncture and other forms of nonpharmaceutical pain relief procedures were discussed. Home exercise was explained by ad-dressing the topics of why, how, when, and how much. The occupational therapist discussed problems related to hand function, hand program, and technical aids used to alleviate hand problems.	Control/No further details
Lindroth 1995	n=92 (84 females) Rheumatoid Arthritis Age (yr.) = exp. 64.8 (SD 13.6), con. 63.5 (SD 14.5)	Education programme vs Control	-Pain (visual analogue scale) (0–100; high score is worse) -Health Assessment Questionnaire (HAQ) (0-12)	12 months and 5 years	Six sessions 2/h each focused on medical aspects, pain management, available treatments, stress management, self-awareness and communication skills, exercise, joint protection and work simplification practices	Control
Neuberger 1993	n = 53 (35 females) Rheumatoid Arthritis Age (yr.) = 52.56 (SD 14.32)	Group1(exp erimental) – LARA* (self-instructional program) Group 2 (experiment al)LARA and range of motion (ROM) exercises and joint protection practices (JPPs) Group 3 (experiment al) LARA, ROM exercises and JPP Group 4 (control)	-Pain analogue scale) (0–10; high score is worse)	4 months	The self-instructional program LARA was used in this study. Practice time consisted of 10-20 min time periods, in which a subject gave a return demonstration of ROM exercises to the Investigator. Another 10-20 min time period, on a different clinic visit, was provided for the subject to give (3 return demonstration of tasks using JPPs. The effectiveness of the unit on joint protection was further tested by asking subjects to perform four tasks: drinking from a coffee mug, carrying a handbag, moving a pot with a handle from one flat surface to another 2 feet away, and transferring a book from one flat surface to another 2 feet away. One point was assigned to each task performed satisfactorily, with a possible sum total of four points. These tasks were performed by the experimental group and after reading the third unit of the instructional program on rest, pacing, and joint protection.	Did not read the instructional program but received the same attention time from the investigators.

Table 3-2. Risk of bias summary: Review authors' judgements about each risk of bias item for each included study



Key + Low risk of bias, − High risk of bias

Table 3-3 Summary of Findings - Joint Protection Programs vs Usual care/control in Patients with Rheumatoid Arthritis (short-term)

Population: patients with rheumatoid arthritis
Settings: inpatient clinics.
Intervention: joint protection programs
Comparison: usual care/control
Follow up: short-term (3 – 4 months).

Outcomes	SMD / MD (95% C.I.)	No of participants (studies)	Quality of the evidence (GRADE)
Pain: - MHQ (0-100) Lower scores indicating better pain scores. - NRS (0-10) Higher score is worse -VAS (0-100) Higher score is worse.	SMD -0.00 (-0.42 to 0.42)	548 (3 studies)	⊕⊖⊖⊖ very low[1,2]
Function: - MHQ (0-100) Higher scores indicating better performance.	SMD 0.18 (-0.01 to 0.36)	451 (1 study)	⊕⊖⊖⊖ very low[1,2]
Grip strength: -HHD (kg) Higher values indicate better strength	MD 1.38 (-0.29 to 3.05)	400 (1 study)	⊕⊖⊖⊖ very low[1,2,3]

Abbreviations: VAS; visual analogue scale, NRS; Numerical Rating Scale, MHQ; Michigan Hand Outcome Questionnaire, HHD; hand held dynamometer, SMD; standardized mean difference, MD; mean difference, CI; confidence interval.

[1]We downgraded by two levels due to high risk of bias.
[2]We downgraded by one level due to a relatively small sample size.
[3]We downgraded by one level due to indirectness (surrogate outcomes).
[4]We downgraded by one level due to publication bias.
[5]We downgraded by one level due to inconsistency.

GRADE quality of evidence:
High quality: We are very confident that the true effect lies close to that of the estimate of the effect.
Moderate quality: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it's substantially different.
Low quality: our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.
Very low quality: we have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect.

Table 3-4. Summary of Findings - Joint Protection Programs vs Usual care/control in Patients with Rheumatoid Arthritis (mid-term)

Population: patients with rheumatoid arthritis
Settings: inpatient clinics.
Intervention: joint protection programs
Comparison: usual care/control
Follow up: mid-term (5 – 8 months).

Outcomes	SMD / MD (95% C.I.)	No of participants (studies)	Quality of the evidence (GRADE)
Pain: - MHQ (0-100) Lower scores indicating better pain scores. - NRS (0-10) Higher score is worse -VAS (0-100) Higher score is worse.	SMD -0.32 (-0.53 to -0.11)	358 (3 studies)	⊕⊖⊖⊖ very low[1,2]
Function: - HAQ (0-3) Higher is worse. -AIMS2 (0 to 10) Lower scores represent better function	SMD -0.49 (-0.75 to -0.22)	358 (3 studies)	⊕⊖⊖⊖ very low[1,2]
Grip strength: -HHD (kg) Higher values indicate better strength	MD -1.39 (-5.02 to 2.24)	121 (1 study)	⊕⊖⊖⊖ very low[1,2,3]

Abbreviations: VAS; visual analogue scale, NRS; Numerical Rating Scale, MHQ; Michigan Hand Outcome Questionnaire, HHD; hand held dynamometer, HAQ; Health Assessment Questionnaire, SMD; standardized mean difference, MD; mean difference, CI; confidence interval.

[1]We downgraded by two levels due to high risk of bias.
[2]We downgraded by one level due to a relatively small sample size.
[3]We downgraded by one level due to indirectness (surrogate outcomes).
[4]We downgraded by one level due to publication bias.
[5]We downgraded by one level due to inconsistency.

GRADE quality of evidence:
High quality: We are very confident that the true effect lies close to that of the estimate of the effect.
Moderate quality: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it's substantially different.
Low quality: our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.
Very low quality: we have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect.

Table 3-5. Summary of Findings - Joint Protection Programs vs Usual care/control in Patients with Rheumatoid Arthritis (long-term)

Population: patients with rheumatoid arthritis
Settings: inpatient clinics.
Intervention: joint protection programs
Comparison: usual care/control
Follow up: long-term (12 – months).

Outcomes	SMD / MD (95% C.I.)	No of participants (studies)	Quality of the evidence (GRADE)
Pain: - MHQ (0-100) Lower scores indicating better pain scores. - NRS (0-10) Higher score is worse -VAS (0-100) Higher score is worse.	SMD -0.27 (-0.41 to -0.12)	857 (4 studies)	⊕⊕⊖⊖ low[1]
Function: - MHQ (0-100) Higher scores indicating better performance. - HAQ (0-3) Higher is worse. -AIMS2 (0 to 10) Lower scores represent better function	SMD -0.34 (-0.48 to -0.20)	1,077 (6 studies)	⊕⊖⊖⊖ very low[1,5]
Grip strength: -HHD (kg) Higher values indicate better strength	MD 0.93 (-0.74 to 2.61)	478 (2 studies)	⊕⊖⊖⊖ very low[1,2,3,4]

Abbreviations: VAS; visual analogue scale, NRS; Numerical Rating Scale, MHQ; Michigan Hand Outcome Questionnaire, AIMS2; Arthritis Impact Measurement Scales, HHD; hand held dynamometer, HAQ; Health Assessment Questionnaire, SMD; standardized mean difference, MD; mean difference, CI; confidence interval.

[1]We downgraded by two levels due to high risk of bias.
[2]We downgraded by one level due to a relatively small sample size.
[3]We downgraded by one level due to indirectness (surrogate outcomes).
[4]We downgraded by one level due to publication bias.
[5]We downgraded by one level due to inconsistency.

GRADE quality of evidence:
High quality: We are very confident that the true effect lies close to that of the estimate of the effect.
Moderate quality: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it's substantially different.
Low quality: our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.
Very low quality: we have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect.

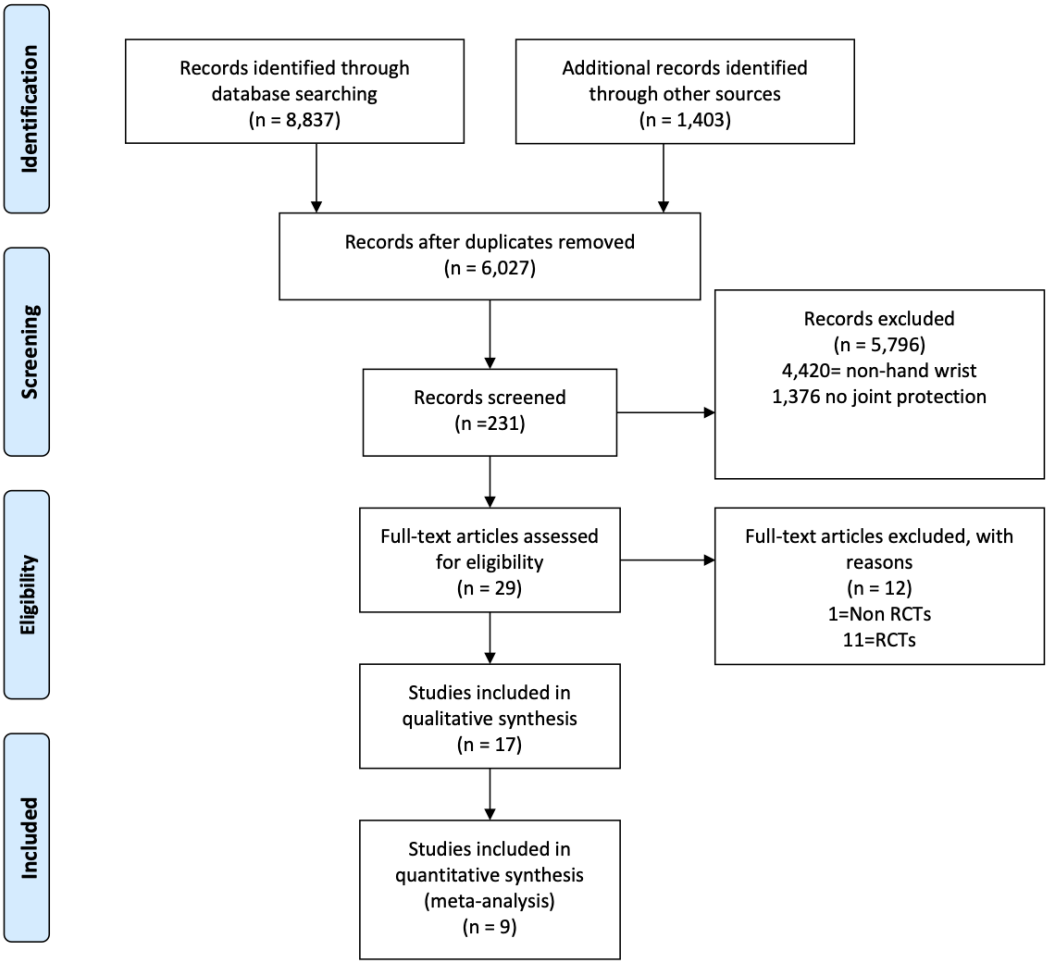


Figure 3-1. Flow diagram

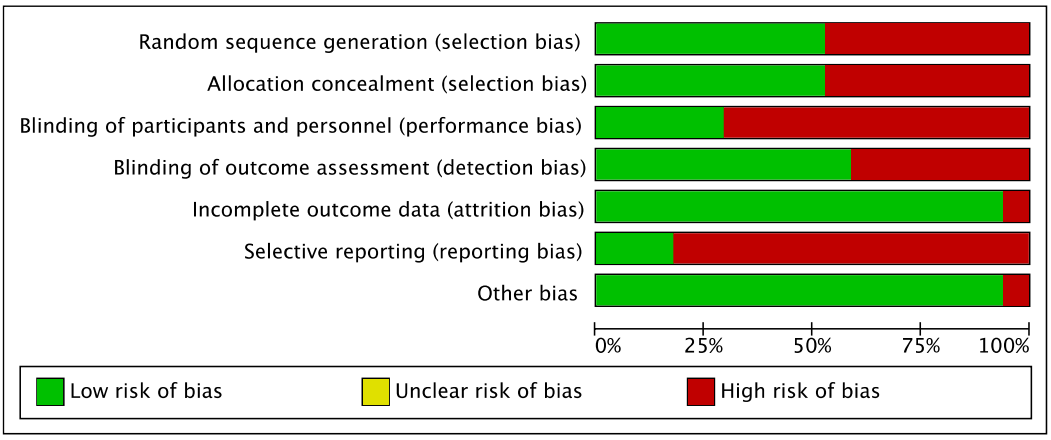


Figure 3-2. Risk of Bias Graph

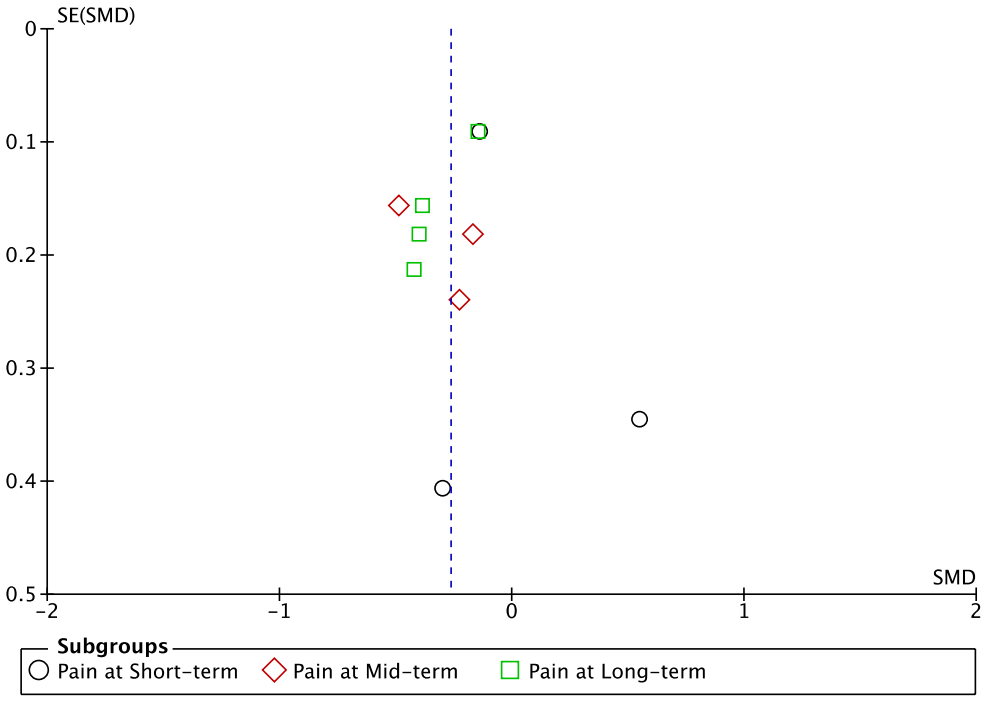


Figure 3-3. Funnel plot for pain levels

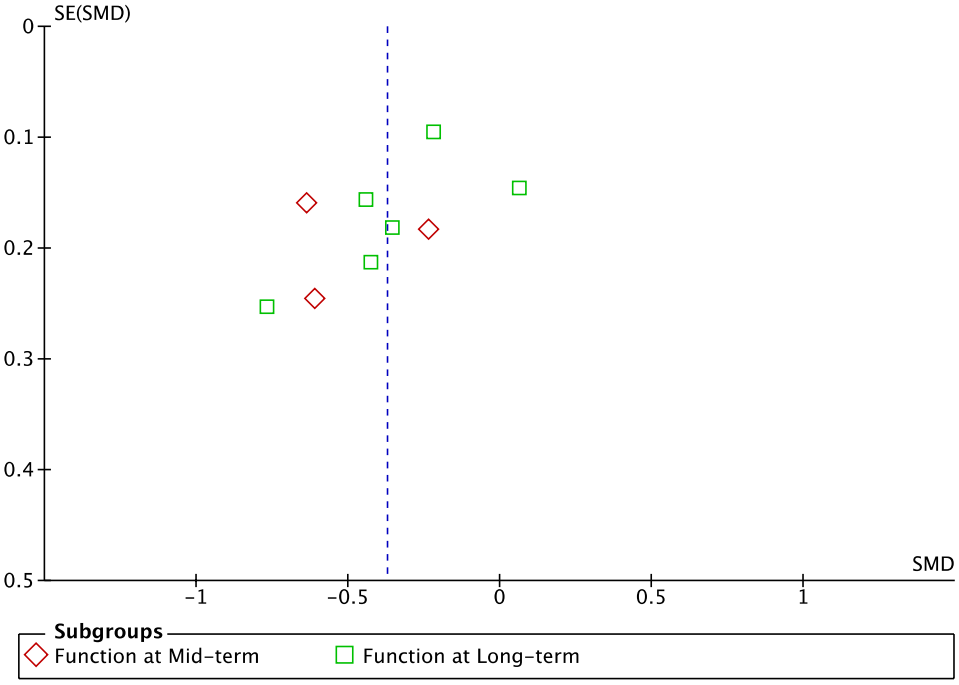


Figure 3-4. Funnel plot for function levels

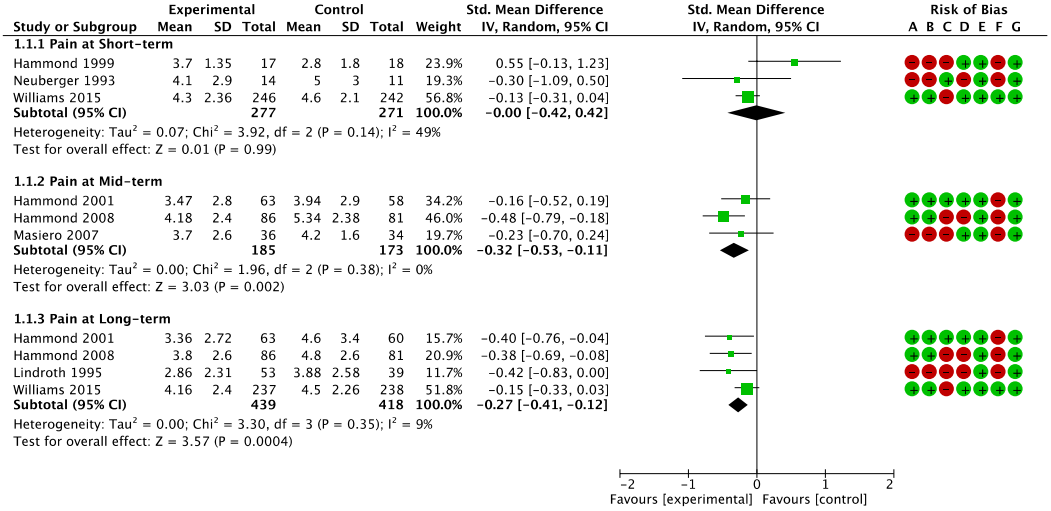


Figure 3-5. Short, mid and long-term effects of interventions on pain levels

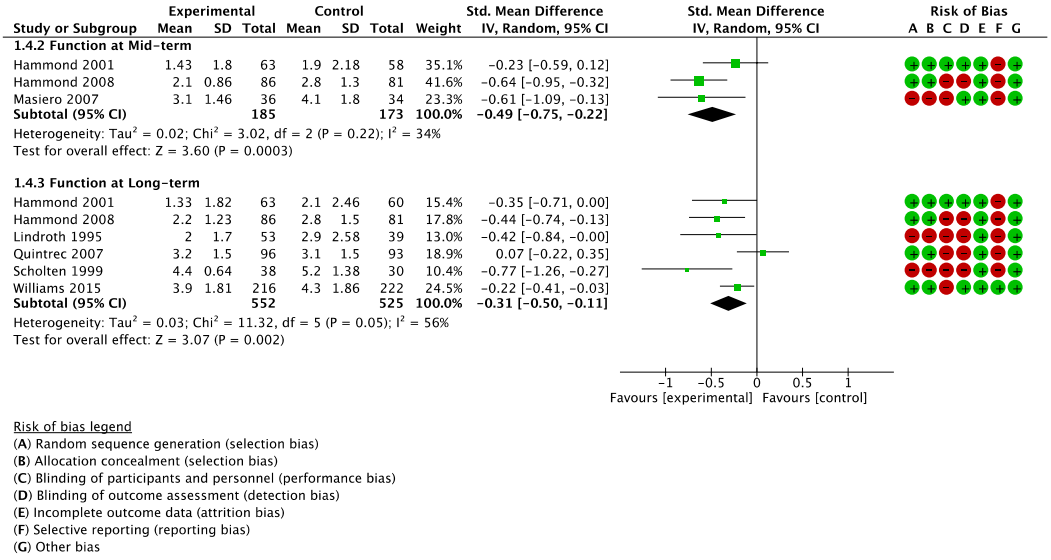


Figure 3-6. Mid and long-term effects of interventions on function levels

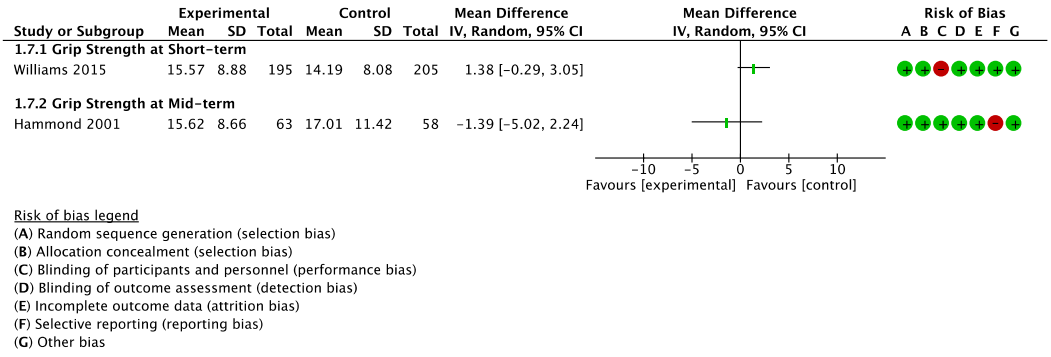


Figure 3-7. Short and mid-term effects of interventions on grip strength levels

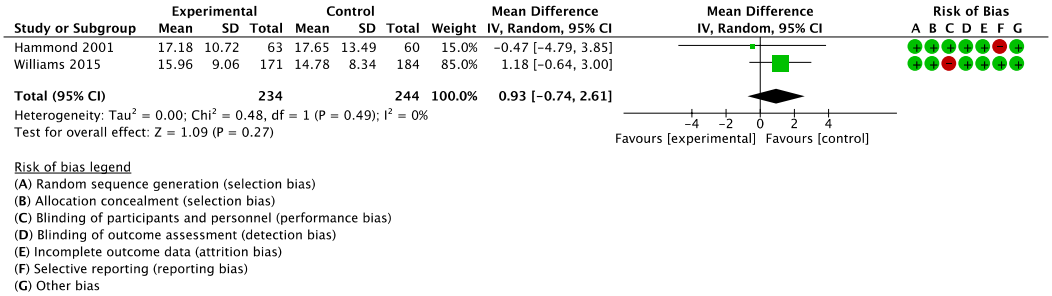


Figure 3-8. Long term effects of interventions on grip strength levels

Chapter 4

4 Joint Protection Programmes for People with Osteoarthritis and Rheumatoid Arthritis of the Hand: An Overview of Systematic Reviews

Abstract

Purpose: Joint protection has been introduced as a self-management strategy for people with rheumatoid arthritis (RA) and osteoarthritis (OA) of the hand. The purpose of this study was to conduct an overview of systematic reviews (SRs) and critically appraise the evidence to establish the current effectiveness of joint protection for people with hand RA and OA.

Method: A comprehensive search was conducted of six databases from January 2008 to May 2018. SRs that evaluated the effectiveness of joint protection for people with hand arthritis were eligible for inclusion. The A MeaSurement Tool to Assess systematic Reviews (AMSTAR) 2 checklist was used to assess the methodological quality of each SR.

Results: Nine SRs were included: two were rated as high quality, and seven were rated as low quality. Seven of the nine did not take into account risk of bias when interpreting or discussing their findings, six did not assess publication bias, and five did not register their protocol. The high-quality reviews found no clinically important benefit of joint protection for pain, hand function, and grip strength levels. The low-quality reviews reported improvements in function, pain, grip strength, fatigue, depression, self-efficacy, joint protection behaviours, and disease symptoms in people with RA.

Conclusions: High-quality evidence from high-quality reviews found a lack of any clinically important benefit of joint protection programmes for pain, hand function, and grip strength outcomes, whereas low-quality evidence from low-quality reviews found improvements in these outcomes.

4.1 Introduction

Clinical manifestations of rheumatoid arthritis (RA) can be unpredictable, but pain, disability, fatigue, joint deformities, and poor quality of life are common features.[1] Although medications such as biological agents and drugs are increasingly effective,[1,2] arthritis currently has no cure. Conservative management aims to prevent or control joint deformities, reduce pain and swelling, increase hand function, and improve quality of life.[3] Numerous studies investigating various hand pathologies have demonstrated that hand function is an important factor.[4–8] Joint protection was first introduced in the 1960s as a self-management strategy for people with RA, and the indications were later extended to other arthritic conditions, such as hand osteoarthritis (OA) and soft-tissue rheumatic disorders.[9] Joint protection consists of a wide range of strategies such as education for strengthening or stretching exercises, joint protection education for activity and pacing, use of proper body mechanics, and assistive devices to improve pain, reduce inflammation, lower additional risk of deformities, and enhance performance.[9,10]

Systematic reviews (SRs) are a recognized approach to synthesizing research evidence on the effectiveness of therapeutic interventions.[11] Because the number of SRs is rapidly increasing, there is a need to summarize the evidence and inform health care professionals about conflicting or inconsistent evidence. Although the aim of these SRs in facilitating evidence-based practice is commendable, poor-quality SRs may contain significant bias that can mislead readers. An overview of SRs can summarize a large body of evidence and identify conflicting or inconsistent results and the potential reasons for them. For example, a 2007 overview that examined non-pharmacological and non-surgical joint protection interventions for people with hand RA reported high-quality evidence for a positive effect on function and no difference in pain.[12] A subsequent overview in 2009 that examined non-pharmacological and non-surgical interventions for people with hand OA found insufficient high-quality evidence for these types of intervention.[13] Still another overview published in 2014 that examined the effectiveness of occupational therapy interventions for adults with RA found that the evidence to support the use of joint protection was sufficient.[14]

These overviews had some limitations that justify the need to conduct another overview of SRs. The first limitation is that those reviews are outdated because they are based on SRs that were published between 2000 to 2013. The second relates to how the SRs were evaluated. Ekelman and colleagues based their quality assessment on guidelines that had been described by Stern,[14,15] and they categorized the included SRs according to the levels of evidence for SRs established by the Oxford Centre for Evidence-Based Medicine in 2009.[16] Although SRs and randomized controlled trials (RCTs) are considered high-quality evidence in that categorization, this way of rating methodological quality is imprecise because it does not consider how an SR or RCT was conducted. Christie and colleagues assessed the quality of SRs using a nine-item checklist that had been developed from Oxman and Guyatt in 1991.[12,17] Moe and colleagues assessed the methodological quality of the first version of the A MeaSurement Tool to Assess systematic Reviews (AMSTAR) checklist.[13] Although these instruments do assess SR methods, they have been superseded by tools that more thoroughly consider risk of bias.[12,13] Therefore, we set out to conduct an overview of SRs to establish the current state of evidence evaluating the effectiveness of joint protection for people with hand RA and OA.

4.2 Methods

4.2.1 Study design

We followed a standard methodology for overviews.[18–21] This study was registered in the International Prospective Register of Systematic Reviews (PROSPERO) database (Registration No. CRD42018094725).

4.2.2 Eligibility criteria

We included SRs of RCTs in our overview if they met the following criteria:

- *Population:* patients with hand RA and hand OA

- *Interventions:* joint protection programme with other treatments or joint protection alone
- *Comparison:* other treatment or no treatment
- *Outcomes:* pain, function, and grip and pinch strength.

4.2.3 Search strategy

A search for SRs that had been published between January 2008 and May 2018 was conducted on May 15, 2018, in the following databases with no language restriction set: MEDLINE, Embase, CINAHL, Cochrane Library, Physiotherapy Evidence Database (PEDro), and Latin American and Caribbean Health Sciences Literature (LILACS). The search strategy was designed to locate SRs that addressed the effectiveness of joint protection programmes on pain, function, and grip and pinch strength in patients with hand RA and hand OA. In addition, the PROSPERO database was searched to identify ongoing studies of joint protection. Reference lists of included studies were searched to identify and retrieve other eligible SRs. Our search strategy, which includes words and Boolean operators, is summarized in the Appendix.

4.2.4 Study selection

Two independent reviewers (PB and GN) screened relevant titles and abstracts. Relevant studies (SRs) were then screened at full-text review and included if the following criteria were met: (1) SR of the effectiveness of joint protection programmes (defined by Hammond[9]) plus other treatments or joint protection programmes compared with other treatment or no treatment; (2) studied population included patients with hand RA or hand OA; and (3) SR of RCTs. Studies were excluded if they (1) were narrative, critical, or scoping reviews; (2) were not written in English; or (3) described joint protection not as a whole intervention but only in part (e.g., assistive devices only).

4.2.5 Quality assessment

Three reviewers (PB, GN, and EAL) independently applied the AMSTAR 2 risk-of-bias tool to assess the risk of bias of each SR.[22] Disagreements on the AMSTAR 2 rating were resolved by consensus with the help from a fourth reviewer (JCM) if needed. AMSTAR 2 is composed of 16 items and has adequate interrater reliability for measuring the risk of bias of SRs and for rating overall confidence in the results of an SR.[22] For each SR, we considered the 16 items included on the AMSTAR 2 checklist along with the checklist guidelines and scored the SR as "yes," "partial yes," "no," or, for some domains, "not applicable." The AMSTAR 2 rating is based not on an overall score but on identification of the following critical domains:

- Protocol registered before commencement of the review (Item 2)
- Adequacy of the literature search (Item 4)
- Justification for excluding individual studies (Item 7)
- Review includes risk of bias of individual studies (Item 9)
- Appropriateness of meta-analytical methods (Item 11)
- Consideration of risk of bias when interpreting the results of the review (Item 13)
- Assessment of presence and likely impact of publication bias (Item 15).

The overall AMSTAR 2 rating of confidence are as follow:[22]

- *High – no or one non-critical weakness:* the SR provides an accurate and comprehensive summary of the results of the available studies that addresses the question of interest.
- *Moderate – more than one non-critical weakness:* the SR has more than one weakness but no critical flaws. It may provide an accurate summary of the results of the available studies that were included in the SR.
- *Low – one critical flaw with or without non-critical weaknesses:* the SR has a critical flaw and may not provide an accurate and comprehensive summary of the available studies that address the question of interest.
- *Critically low – more than one critical flaw with or without non-critical weaknesses:* the SR has more than one critical flaw and should not be relied on to provide an accurate and comprehensive summary of the available studies.

4.2.6 Data extraction

Two review authors (PB and JCM) were trained and calibrated on the use of the data extraction form. Data extraction was performed by one author (PB) and checked by a second (JCM). The following descriptive characteristics were extracted from the eligible SRs: (1) author and year, (2) number of primary studies, (3) population, (4) risk-of-bias assessment, (5) quality-of-evidence assessment, (6) outcomes reported in the SR, and (7) conclusions drawn by the authors of the SR.

4.2.7 Data analysis and synthesis

A qualitative synthesis was conducted to summarize the findings across the multiple SRs. We synthesized the results on the basis of quality of evidence and on the populations studied. The risk of bias and the quality assessment of primary studies were extracted as reported in the included SRs. Rather than re-scoring the data from the primary studies included in each SR, we relied on the judgment and reporting of the SR authors.

4.3 Results

4.3.1 Selection process

Our literature search identified 14 SRs for a full-text review. Of these, 4 were excluded because they evaluated the effect of hand exercises,[23,24] splints,[25] or Web-based multi-modal interventions with no mention of joint protection.[26] One SR was excluded because it did not include any study that had evaluated joint protection as an intervention or control.[27] Overall, nine SRs met our inclusion criteria and were included in our analysis. A summary of the selection process is presented in Figure 1.

4.3.2 Characteristics of the included systematic reviews

Five reviews evaluated the effectiveness of joint protection for people with hand OA,[28–32] and three evaluated its effectiveness for people with hand RA;[33–35] one review (Bobos and colleagues[36]) included studies for both hand OA and RA. Risk of bias was evaluated in six reviews: five used the Cochrane risk-of-bias tool,[29,30,33,34,36] and one used a list recommended by VanTulder and colleagues.[35] Quality of evidence was assessed in six reviews: two using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) guidelines,[29,36] one using the Jadad scoring checklist,[28] one using the PEDro scale,[31] one using the Structured Effectiveness for Quality Evaluation Scale (SEQES) and levels of evidence,[32] and one using a list recommended by VanTulder and colleagues.[35] One review rated the evidence as strong, moderate, mixed, or limited on the basis of consistent or conflicting results from the RCTs,[33] and Carandang and colleagues rated the evidence as low, unknown, or high quality to reflect the language used in the quality assessment (i.e., high risk, unknown risk, and low risk of bias).[34] Six reviews assessed pain levels and function,[29,30,32,33,35,36] four reviews examined grip strength as an outcome of interest, [29,31,32,36,37] and two reviews assessed behavioural change.[33,34] The characteristics of the included reviews are summarized and presented in Table 1.

4.3.3 Description of joint protection programmes

Most joint protection programmes used guidelines that included an educational component that addressed disease and symptom severity (RA or OA) and techniques to influence behavioural change such as energy conservation, coping skills for pain management, assistive devices, and the use of large joints.[36] Interventions included on average three to four 2-hour, face-to-face interventions and home programmes.[33,36] In the majority of studies, an occupational or physical therapist was primarily responsible for delivering the programmes.[36]

4.3.4 Quality assessment

Two SRs[29,36] were rated as high quality, seven as low quality.[28,30–35] Regarding the critical domains of AMSTAR 2, five reviews did not perform a priori registration,[28,31–34] two did not perform a comprehensive search,[32,34] and three partially met this criterion.[28,30,33] Three reviews did not provide justification for excluding studies,[28,30,31] and four did not use a satisfactory technique to assess the risk of bias of the primary studies.[30–32,35] Seven reviews did not take into account the risk-of-bias assessment in their interpretation or discussion,[28,30–35] and six reviews[28,30-34] did not assess publication bias of the included studies. The summary of AMSTAR 2 ratings is presented in Table 2.

4.3.5 Findings from high-quality reviews for hand osteoarthritis and rheumatoid arthritis

Two high-quality SRs reported the effects of joint protection versus usual care or control and hand exercises versus joint protection for pain, hand function, and grip strength outcomes for patients with hand RA and OA.[29,36] The review by Bobos and colleagues reported results from 14 RCTs for people with hand RA and three RCTs for people with hand OA for pain, grip strength, and hand function.[36] This review found very-low- to low-quality evidence (according to GRADE guidelines) that, compared with usual care or control, the effects of joint protection programmes on pain and hand function for people with hand arthritis are too small to be clinically important at short-, intermediate- and long-term follow-up. Pain levels were quantified by pooling the results from five low-quality primary studies for the short, mid-, and long term for people with hand RA. Pooling the results indicated that joint protection is no better than usual care or control at short-term follow-up (3–4 mo). For the mid- (6 mo) and long term (12 mo), joint protection was favored over usual care or control but did not exceed the cutoff scores for minimal clinically important difference. For hand function, joint protection was favored over usual care or control with small effects at mid- and long-term follow-up. The Cochrane review by Østerås and colleagues[29] reported the effects of hand exercise versus no exercise (joint protection) for patients with hand OA from one study. The overall estimate effect was in

favor of hand exercises for the short, mid-, and long term for hand pain and function and for grip and pinch strength. No specific recommendation was made for joint protection, only for hand exercises.

4.3.6 Findings from low-quality systematic reviews for hand osteoarthritis

Four SRs summarized findings of reported outcomes for pain, hand function, and grip strength for people with hand OA.[28,30–32] Lue and colleagues reported the results from two high-quality RCTs (Jadad score > 3) for people with hand OA.[28] This review did not report the effect on outcomes specifically for joint protection studies but concluded that joint protection was conditionally recommended. Aebischer and colleagues reported findings from one RCT (risk of bias not reported) for pain and function and found that joint protection improved solely pain, not function.[30] Ye and colleagues reported findings from one high-quality RCT (PEDro scale > 6) and found that joint protection improved grip strength and hand function.[31] Valdes and Marik[32] reported findings from one high-quality RCT (SEQES scores for quality of research) and found that the evidence to support joint protection for increased hand function was moderate.

4.3.7 Findings from low-quality reviews for hand rheumatoid arthritis

Three SRs provided summarized findings on reported outcomes of function, pain, fatigue, depression, self-efficacy, behavioural change, and knowledge.[33–35] Siegel and colleagues reported the results from five high risk-of-bias RCTs and found strong evidence to support the use of psychoeducational interventions (joint protection) to improve function, pain, fatigue, depression, self-efficacy, and disease symptoms in people with RA.[33] Carandang and colleagues reported findings from three RCTs (one with low risk of bias, two with high risk of bias) and found that the evidence for joint protection and energy conservation interventions to improve joint protection behaviours was moderate. [34] Stueultjens and

colleagues reported findings from four RCTs and found strong evidence to support the efficacy of joint protection.[35]

4.4 Discussion

Our overview shows that the majority of the evidence supporting the effects of joint protection for patients with hand arthritis is of low quality. The summarized findings from the high-quality reviews indicate that, when compared with usual care or control, joint protection does not improve pain by a clinically important amount at 6- and 12-month follow-up. Joint protection was superior to usual care or control in improving hand function but did not exceed the predefined cut-off scores. The majority of the included SRs had very poor overall methodological quality in the critical domains of AMSTAR 2. Seven of the nine reviews did not take risk of bias into account in the interpretation and discussion of findings, six reviews did not assess publication bias, and five reviews did not register their protocol. Another important finding is that differences in the risk-of-bias and quality assessment tools seemed to affect the SRs' overall recommendations (Table 3).

Seven of the nine SRs were rated as low quality, and the majority of the included SRs did not follow the recommended Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.[38] Six of the nine SRs were published between 2015 and 2018, and only two followed the PRISMA guidelines. Not following these predefined guidelines may be diminish the usefulness of the results when they are interpreted by clinicians or policymakers. It is important to note that low-quality evidence implies not that joint protection has no effect but that the low-quality evidence is insufficient to draw definite conclusions.

Our included SRs used a variety of risk-of-bias and quality assessment tools. The authors of the included reviews seemed to lack an understanding of what constitutes risk-of-bias and quality assessment. Authors have at their disposal a wide variety of tools to critically appraise and synthesize evidence, and which one they use is a matter of personal preference. However, the methodological quality of the included reviews may have a very important effect on estimates of the results and may affect the validity of the authors'

conclusions.[39] For instance, a primary study (RCT) that had been rated with four separate approaches was reported as being high quality when using the PEDro scale, high quality when using SEQES, high risk when using only the Cochrane risk-of-bias tool, and very low quality when using the Cochrane risk-of-bias tool and the GRADE approach combined.

This overview had several limitations that need to be taken into account when interpreting our findings. First, the included SRs did not differ significantly in their eligibility criteria.[20] Second, they did not clearly report potential harms. Third, there was minor overlap among the primary studies, although this is common for reviews.[19,20,28] Next, we focused on SRs of RCTs and did not include SRs that included other study designs (i.e., prospective or retrospective observational designs), and it is possible that such inclusion criteria could lead to publication bias. However, our objective was to summarize the highest level of evidence available.

4.5 Conclusions

This overview provided high-quality evidence (AMSTAR 2) from two SRs that, compared with usual care or control, the effects of joint protection programmes on pain and hand function are too small to be clinically important at short-, intermediate- and long-term follow-up. It is important to note that the primary studies included in these SRs were graded as very-low-quality to low-quality evidence.

Key Messages

What is already known on this topic

Several systematic reviews (SRs) have been published on the effectiveness of joint protection programmes for patients with osteoarthritis or rheumatoid arthritis of the hand, but the quality of the evidence synthesized by these SRs varies.

What this study adds

Our review shows that the majority of the current evidence from systematic reviews that supports the effects of joint protection for patients with osteoarthritis or rheumatoid arthritis of the hand is of low quality. The summarized findings from the high-quality reviews indicate that, when compared with usual care or control, joint protection does not improve pain by a clinically important amount at 6- and 12-month follow-up.

4.6 Reference

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Table 4-1. Characteristics of the included systematic reviews

Author (Year)	Population	No. of studies of joint protection included	Risk-of-bias tool	Quality of evidence	Reported outcomes for joint protection
Bobos et al.[36]	OA and RA	14 for RA, 3 for OA	Cochrane	GRADE	Pain, function, grip strength
Siegel et al.[33]	RA	5	Cochrane	Evidence was considered strong, moderate, mixed, and limited on the basis of consistent or conflicting results from RCTs	Function, pain, fatigue, depression, self-efficacy, behaviour
Lue et al.[28]	OA	2	Not assessed	Jadad's scoring checklist (0–5)	Unclear
Østerås et al. (2017)[29]	OA	1	Cochrane	GRADE	Pain, hand function, grip and pinch strength
Carandang et al.[34]	RA	3	Cochrane	Low, unknown, and high quality; adapted to reflect the language used in the quality assessment (e.g., high risk, unknown risk, low risk of bias)	Behavioural change
Aebischer et al.[30]	OA	1	Cochrane	Unclear	Pain, function
Ye et al.[31]	OA	1	Not assessed	PEDro scale	Grip strength, hand function
Valdes & Marik[32]	OA	1	Not assessed	SEQES and LOE	HAQ; VAS for pain and hand function; grip strength
Steultjens et al.[35]	RA	4	List recommended by VanTulder and colleagues (1997)	Methodological quality of RCTs and CCTs rated using a list recommended by VanTulder et al. (1997)	Pain, functional ability, knowledge

OA = osteoarthritis; RA = rheumatoid arthritis; GRADE = Grading of Recommendations Assessment, Development and Evaluation; RCT = randomized controlled trial; PEDro = Physiotherapy Evidence Database scale; SEQES = Structured Effectiveness for Quality Evaluation of Study; LOE = levels of evidence; HAQ = health assessment questionnaire; VAS = visual analog scale; CCT = controlled clinical trials

Table 4-2. AMSTAR 2 Rating

Question	Bobos et al.[36]	Siegel et al.[33]	Lue et al.[28]	Østerås et al.[29]	Carandang et al.[34]	Aebischer et al.[30]	Ye et al.[31]	Valdes & Marik[32]	Steultjens et al.[35]
1. Research question and inclusion criteria aligned with PICO	+	? No outcomes, comparator	–	+	+	? No comparator	–	+	+
2. A priori protocol used*	+	–	–	+	–	+	–	–	+
3. Study design selection explained	+	+	+	+	+	+	+	+	+
4. Comprehensive search carried out*	? Did not justify language restriction	? Did not justify language restriction	? Did not justify language restriction	+	–	? Did not justify language restriction	+	–	+
5. Duplicate study selection used	+	+	+	+	+	+	+	–	+
6. Duplicate data extraction used	+	+	+	+	+	+	–	+	+
7. List of excluded studies included, with justification*	+	+	? No list of excluded studies	+	+	? No list of excluded studies	? No list of excluded studies	–	+
8. Included studies described in adequate detail	+	? No outcomes, comparator	+	+	+	+	+	+	+
9. Satisfactory technique used for assessing risk of bias*	+	–	? Lack of blinding	+	+	–	–	–	–
10. Sources of funding of included studies reported in review	+	–	–	+	–	–	–	–	+
11. If meta-analysis, combination of data justified	+	N/A	N/A	+	N/A	+	N/A	N/A	+
12. If meta-analysis, risk of bias of included studies taken into account	+	N/A	N/A	+	N/A	–	N/A	N/A	–

13. Risk of bias taken into account in interpretation and discussion*	+	–	–	+	–	–	–	–	–
14. Satisfactory explanation given for any heterogeneity	+	N/A	N/A	+	N/A	+	N/A	N/A	–
15. Publication bias in included studies assessed*	+	–	–	+	–	–	–	–	+
16. Review authors reported on any of their own conflicts of interest	+	–	+	+	–	+	+	+	+
Overall quality	High	Low	Low	High	Low	Low	Low	Low	Low

***** Indicates a critical domain.

AMSTAR 2 = A MeaSurement Tool to Assess systematic Reviews; – = no; + = yes; ? = partial yes;

N/A = not applicable; PICO = Patient Intervention Comparator Outcome.

Table 4-3. Summary of Recommendations Made for Joint Protection

Author (Year)	Quality of evidence	Recommendations
Bobos et al.[36]	High	Very-low- to low-quality evidence that the effects of joint protection programmes compared with usual care or control on pain and hand function are too small to be clinically important at short-, intermediate- and long-term follow-ups for people with hand arthritis
Siegel et al.[33]	Low	Strong evidence to support the use of physical activity and psychoeducational interventions (joint protection) to improve function, pain, fatigue, depression, self-efficacy, and disease symptoms in people with RA
Lue et al.[28]	Low	Joint protection conditionally recommended
Østerås et al.[29] (2017)	High	No specific recommendation made for joint protection, only for hand exercises
Carandang et al.[34]	Low	Moderate evidence for joint protection and energy conservation interventions improving joint protection behaviours
Aebischer et al.[30]	Low	*Main finding:* moderate to high evidence that multimodal physiotherapy and occupational therapy–related interventions have beneficial effects on pain; no statistical evidence for improvement of function, only narrative; joint protection improved pain but not function
Ye et al.[31]	Low	Evidence suggests that programmes of joint protection, advice, and home exercises are effective at improving grip strength and hand function
Valdes & Marik[32]	Low	Moderate evidence to support joint protection education and providing adaptive equipment to increase hand function and reduce pain
Steultjens et al.[35]	Low	Results of best-evidence synthesis show that there is strong evidence for the efficacy of instruction on joint protection (an absolute benefit of 17.5 to 22.5, relative benefit of 100%)

RA = rheumatoid arthritis.

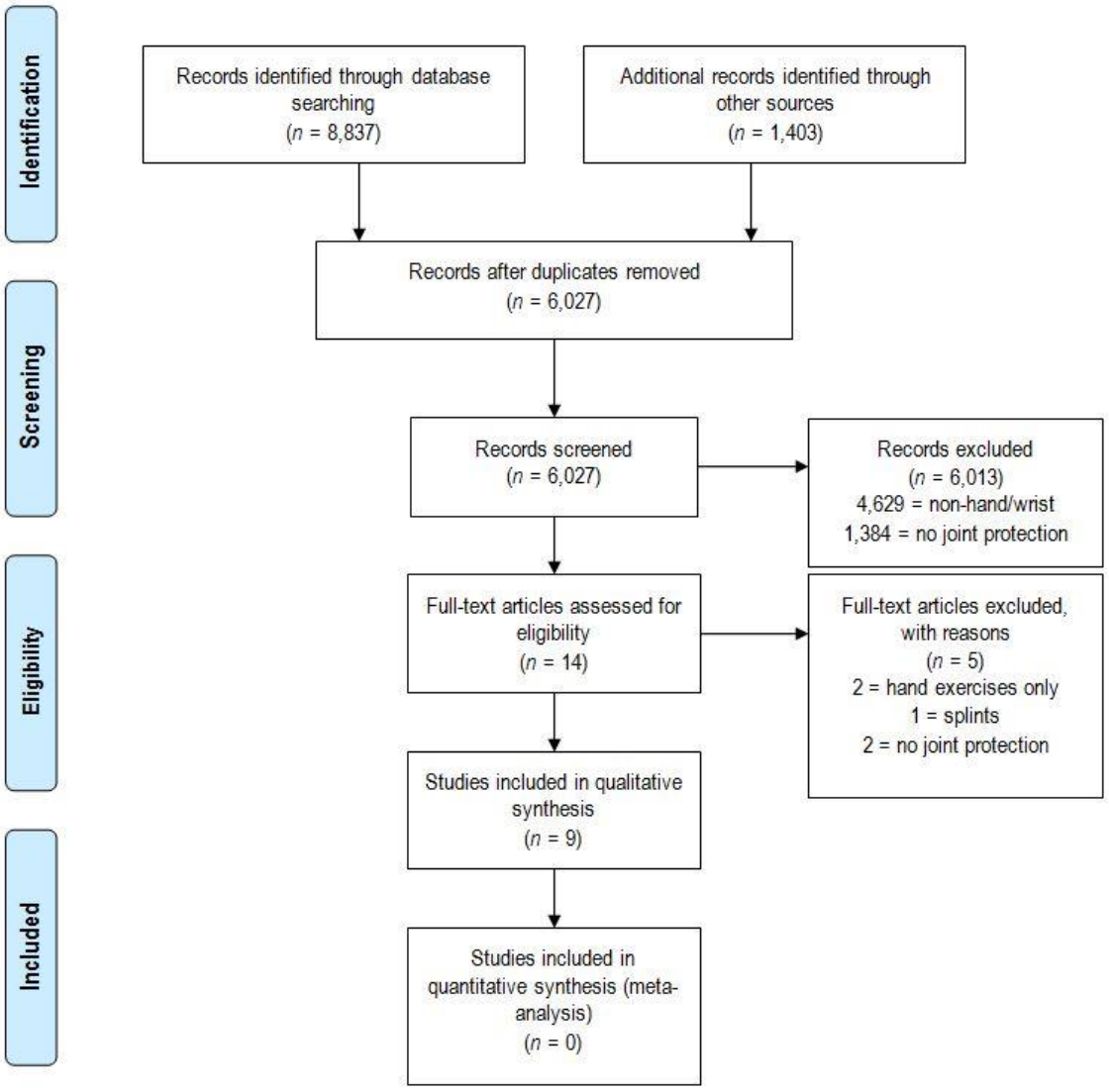

Figure 4-1 Flow diagram showing the selection process.

Chapter 5

5 Barriers, Facilitators, Preferences and Expectations of Joint Protection Programs for Patients with Hand Arthritis. A Cross-sectional Survey

Abstract

Objectives: The objective of this survey is to investigate the barriers, facilitators, expectations and patient preferences regarding joint protection (JP) programs in people with hand arthritis.

Design: Cross-sectional survey

Setting: Tertiary clinic

Participants: Patients with hand arthritis: osteoarthritis (OA), rheumatoid arthritis (RA), psoriatic arthritis (PsA) and other forms of arthritis.

Primary and secondary outcome measures: This study utilized a survey among people with hand arthritis. Descriptive statistics and percentages were reported for all the data about the barriers, facilitators and preferences around JP.

Results: A total of 192 patients consented to participate**.** Most of the patients (82%) were unaware of JP. Factors that may act as barriers to participation and were regarded as "a very big concern" were: cost of the program (44%), time of offering the program (39%), work commitments (36%) and having a centre/clinic close to the house (28%). Factors that may act as facilitators and rated as "extremely helpful" were: research that shows that JP works (26%) and having the centre/clinic close to the house (25%). An online format for JP was the most preferred option (54%). Half (46 %) preferred a timeframe of 1 hour, 3 times per week and 44 % preferred a 2-hour program, for 3 times per week.

Conclusions: Awareness of the potential benefits of JP, and prior experience with JP program were very low. Common potentially modifiable patient-reported barriers to participate in future JP interventions, included: cost, work commitments, distance from home to clinic and times that the intervention were provided. These barriers might be addressed with free and accessible forms of delivery of JP, which may lead to better uptake and participation in JP programs.

Strengths and limitations of this study

- The survey was adapted to people with hand arthritis from a validated questionnaire developed to assess the barriers, facilitators and preferences to exercise used in other clinical populations.
- A small sample of people with experience of JP prevented us from adequately exploring the perceptions of patients who had completed the program.
- The survey was designed for English speakers with hand arthritis therefore, people speaking other languages were not represented.

5.1 Introduction

Osteoarthritis (OA) is characterized as a degenerative joint disease that affects approximately 27 million adults in the USA and is one of the leading causes of disability. [1] Osteoarthritis affects 60-70% of the population above the age of 65 years, and is likely to increase further in the future, due to the aging population. [2,3] The most common site of OA is the hand and it typically involves the interphalangeal (proximal and distal) and first carpometacarpal joints. [4] In a clinical setting, pain is a major symptom among patients with hand OA as it contributes to a reduction in joint function.[1,4] Currently there is no cure for hand OA, but goals of treatment include maximizing long-term health-related quality of life, by controlling symptoms such as pain, prevention of structural damage and normalization of function.[5]

Joint protection (JP) is a self-management strategy for patients living with arthritis to help preserve joint function and reduce pain.[6] JP involve training on "safer movement patterns, the use of adaptive devices (e.g. built up handles, hands free technologies) and behavior modifications (e.g. activities to avoid, pacing)during physical activity.[6] However, JP can

be implemented in many different ways, and patient preferences are rarely reported as being considered in program design. There are many unknown barriers that may reduce participation in JP programs, and these may be related to personal beliefs, preferences or circumstances. For example, patients may believe that JP will not slow joint damage, may not like engaging in groups or may have life/location issues that make it difficult to attend clinics. Identifying these barriers at group and individual levels may be a strategy to design and customize future JP to increase participation in JP programs.

Considering preferences and customizing JP may be critical to improving adherence. Prior reports suggest that adherence is a major concern. Previous systematic review and meta-analysis indicated that only 6 out of the 17 trials used strategies to maximize adherence for JP.[7] Although the evaluation of adherence from these trials was ranging from low to moderate adherence has not been properly studied in the published literature yet. The purpose of this cross-sectional survey is to investigate the barriers, facilitators, expectations and patient preferences regarding joint protection programs in people with hand arthritis.

5.2 Methods

5.2.1 Patient and Public Involvement

Patients or the public were not involved in the design, or conduct, or reporting, or dissemination plans of our research.

5.2.2 Study Design

This study utilized a cross-sectional survey among people with hand arthritis that was open for response from March 2019 to February 2020. Ethical approval was granted by Hamilton Research Ethics Board (HiREB) at McMaster University, Hamilton, Canada (Project Number: 3727). Patients were asked to provide consent to proceed and complete the survey questions.

5.2.3 Inclusion criteria and exclusion criteria

Participants were eligible to complete the anonymized survey if they were able and willing to provide informed consent, were between 18 to 85 years old, they have been diagnosed with hand arthritis and they could read and write English. Participants which have not been diagnosed with hand arthritis or they could not answer the survey questions, or they did not understand English were excluded from the study.

5.2.4 Setting and recruitment

Participants were recruited through advertisements in the main website of The Arthritis Society of Canada and from the Roth McFarlane Hand and Upper Limb Centre (HULC) at St. Joseph's Health Care Hospital in London, Ontario. Research assistants and research coordinators from HULC contacted people with hand arthritis who had previously expressed interest in participating in research. Also, an informative poster was setup at HULC patient waiting area providing details about the study. Two separate approaches were used for data collection. An online form to complete the survey and a paper-based version of the survey form at HULC clinical research lab.

5.2.5 Data protection

No participant identifying information was collected in this anonymized survey. Data were kept at the HULC clinical research laboratory where only authorized personnel have access, and all paper-based files were stored in a locked cabinet. Electronic files were stored in encrypted file and apart from the study investigators no other person had access to the electronic records.

5.2.6 Survey

The survey was adapted to people with hand arthritis based on previous experience of the study investigator (JCM) with JP, from a validated questionnaire initially developed to assess the barriers, facilitators and preferences to exercise for people with osteoporosis and for shoulder arthritis.[8,9] The survey consisted of 31 questions with sections related to barriers, facilitators, expectations and patient preferences for joint protection programs in people with hand arthritis. The survey questions are presented in the Web Appendix.

5.3 Data analysis

5.3.1 Quantitative

Descriptive statistics and percentages were reported for all the data about the barriers, facilitators and preferences around JP programs. In 2014 (Statistics, Canada), 16.5% of Canadians (around 4.8 million people) reported that they had been diagnosed with any form of arthritis by a health professional. The Ontario province represents the 18.5% of 4.8 million which is 888,000 individuals with arthritis approximately. Sample size calculation was based on a population size of 888,000 individuals, a confidence level of 95% and with 7% margin of error and it was determined that 196 individuals were needed to complete the survey.[10] Data analyses were completed using STATA 16.0 version.

5.3.2 Qualitative

Some of the survey questions (Questions 7, 8, 10, 11, 12, 13) were written responses. For these questions qualitative data analyses techniques were used. Data were analyzed by response line to identify emerging codes. Relationships and similarities among codes were discussed leading to the formation of themes. Themes were particularly identified to provide new information to the quantitative responses, in an effort to better understand the barriers and facilitators to use of JP programs. [11–13]

5.4 Results

A total of 192 patients consented to participate and completed our survey. They provided information about JP barriers and facilitators regarding their possible prospective participation in a JP program, the impact of JP programs on domains of their everyday life and their preferred frequency of use of JP. Out of the 192 survey respondents, 92 (50%) were diagnosed with Rheumatoid Arthritis (RA) in the hand, 38 (21%) with hand OA, 29 (16%) with Psoriatic Arthritis (PsA), 13 (7%) had a diagnosis other than hand arthritis, and 10 (5%) reported none from the options provided. The majority of participants were aged between 34 to 54 years old representing the 53% of the sample of this survey. Thirteen (n=13) people disqualified from the survey, because three of them were under 18 years old and ten of them had arthritis in lower extremities and therefore, they were deemed ineligible to participate. The demographic description of the included sample is presented on Table 1.

5.4.1 Awareness of joint protection programs

Regarding patients' awareness of JP programs, from the 164 patients in total who had hand arthritis, most (82%) had never heard about JP programs before, 11% had heard about JP but had never taken part in such a program. A small percentage of respondents (5%) had previously taken part in a JP and only 4% were currently participating in a JP program. Amongst the 13 participants who took part in JP, 5 people participated in a program in an outpatient hospital department, 3 at a family's physician office, 2 in an inpatient unit, 2 in a rehabilitation center and 1 home. The JP program was provided most commonly by an occupational therapist (46%), a family physician or specialist (38%), and to a lesser extent by a physiotherapist (15 %) (Table 1).

5.4.2 Use, frequency and perceived impact of joint protection programs on outcomes

Out of 13 patients who participated in a JP program, five of them continued using the principles of the program at least once a week, four of them kept using them always, one participant applied them less than once a week while 3 of them while 3 of them did not use them at all. In Table 2, four patients that participated in the joint protection provided examples what joint protection principles they used. Within this small subsample of ten patients' experiences (Figure 1), eight patients reported "no change" to "very much better" in terms of impact on stiffness, pain, grip strength, hand function and swelling. Two patients reported feeling slighting worse to much worse in stiffness, pain, grips strength, hand function and swelling (Figure 1).

5.4.3 Information and awareness of the existence of joint protection programs

The majority of the respondents have never heard about joint protection programs until they undertook this survey, according to their comments in an open-ended question within the survey. None were informed about the existence of the joint protection programs by a family physician or a local community center. A small percentage of 14% were informed by a specialist about the existence of the JP programs, 10% of them heard it from television, 5% by their therapist and 3% from family or friends.

5.4.4 Factors affecting prospective participation in joint protection

Factors reported by 87 participants that were reported as important barriers to participation in a future JP are described in Figure 2. Factors that may act as barriers to participation and were regarded as "a very big concern" included: cost of the program (44%), time of offering the program (39%), work commitments (36%) and having a centre/clinic close to the house (28%). Factors that may act as facilitators to participation and rated as "extremely helpful" were: research that shows that joint protection works (26%) and having the centre/clinic

close to the house (25%). All the barriers and facilitators that may affect participation are presented in Figure 2.

5.4.5 Qualitative Data

A total of 73 participants provided additional information in open-ended responses to describe their barriers and facilitators to engaging in a joint protection program. Three major themes emerged: personal factors; environmental factors; and health factors. For the personal factors, common barriers were energy, other personal or work commitments, and fear of further injury. Environmental factors included having a centre close to the house, transportation, cost of the program, building accessibilities and social support from family or friends to participate with. Health condition factors included comorbidities associated with the disease, complications related to the disease, flare ups, and depression. For example, one participant noted that arthritis-related health issues limited participation: RA said "[permanent] RA voice loss, [permanent] RA lung damage", and another patient mentioned "flare ups".

Facilitators mentioned in open-ended responses included: having the centre/ clinic close to my house, transportation to the centre where program is provided, cost of the program, time when the program was offered, my work commitments, my personal commitments, support from family/ friends, having a friend to participate with, research that shows joint protect works and another patient finding joint protection helpful. A number of the barriers mentioned in open-ended responses related to health factors not specifically identified on the survey: flare ups, fear of further injury, and comorbid conditions were not listed as potential barriers in the survey.

5.4.6 Preference on method of delivery of Joint protection

An online format for JP was the most preferred option representing slightly over half of the respondents (54%). Amongst the remaining respondents there were preferences for at

home (20%), clinic (17%), videos (6%) and printed material (2%). Patient were open to a variety of health providers for JP programs, and stated preference for occupational therapists (22%), physiotherapists (20%), family physician or specialists such as rheumatologists(19%), hand therapists (17%), other patients with arthritis (13%), and kinesiologists with the other choices comprising 2%.

5.4.7 Preference of frequency of joint protection

Participants reported their top preference in terms of frequency and their possible prospective participation in a JP. Half of them (46 %) preferred a timeframe of 1 hour, 3 times per week for 10 weeks and 44 % preferred a 2 hour, 3 times a week for 5 weeks program.

5.4.8 Usefulness of joint protection components

Patient preferences for content in JP suggest that information about joint loading, reduction of joint stress, feedback on correctness and carefulness in tasks, information about pacing activities, advice from health professionals or other patients and demonstration of how to do things in ways that minimize effort and maximize efficiency, a JPP were considered as moderately to extremely useful (Figure 3). Respondents indicated that the following information would be moderately or extremely useful: activity pacing and how joint positions affect joint loading, ways to reduce joint loading and feedback on task performance. They indicated preference as “moderately” or “extremely useful” the following approaches: advice from health professionals, demonstrations/feedback on task performance, and advice from other patients (Figure 3).

5.4.9 Perceived importance of joint protection programs

Patients rated the following potential outcomes of JP as “extremely important”: pain reduction (92%), joint deformity prevention (83%), hand function (82%) and grip strength

(75%). On average 84 out of 192 of patients reported how often they use one or more of the following rehabilitation modalities such as heat, cold, exercise, joint protection, splints and modified equipment (Figure 4). Modalities such as heat, exercise and splints were reported that were used "very frequently" by 15% of the respondents. Heat (32%), exercise (25%) and cold modalities (19%) were used as "frequently" by the participants. On the other hand, modalities such TENS/electrical devices (68%), splints (46%), joint protection (48%) and modified equipment (43%) were never used by the respondents (Figure 4).

5.5 Discussion

This study found that very few patients with arthritis were aware of or had participated in a JP program, yet slightly more than half favored a JP program which could be offered 3 times per week at 1-2 hours of engagement in an online format. This suggests a profound need for better accessibility to JP programs for people with arthritis as a component of their overall self-management strategy.

It is also clear one single method of delivery is unlikely to meet all needs since variation in preferences was clear. An online format for JP was the most preferred option representing slightly over half of the respondents (54%). Other preferred options were JP programs that could be completed at home (21%) or at a clinic (16%). Our findings need to be tempered by two considerations. Firstly, some of the other preferred options overlap, for example preferences like "at home" or "videos" could include virtual components. Secondly, since the majority of the respondents (82%) were unaware of JP and were rarely using it, their preferences were based on a priori assumptions not on experience with such programs. However, preferences prior to participation are important since this is the time when patients make decisions about participation.

It was remarkable that so few respondents had participated in JPP, given that there is systematic review evidence demonstrating the effectiveness of these programs both for patients with RA and OA.[14] The included trials in this meta-analysis were of low methodological quality however, the effects of JP on function outcomes for people with rheumatoid arthritis in the hand were beneficial. In the few people who have used JP in our

survey the experiences were mostly positive in terms of perceived benefit in symptom control and very limited perceived harm. Lack of awareness of JPP was greater than anticipated and may reflect a lack of access to programs, a lack of awareness in clinicians who should be recommending JPP or a lack of interest in participating. Self-management strategies are important for patients with arthritis since is it a chronic disease. In fact, many of the patients in this survey were participating in some aspect of self-management. JP effectiveness has been supported by systematic reviews.[6,7,14] Therefore, our finding that only 10 had participated in suggests that there is a substantial gap in awareness, delivery and accessibility of these programs.

Respondents identified several challenges to participate in JP programs. This suggests that flexibility in how/when programs are offered is a critical factor in program planning. Patients placed high importance on participation in JP if research findings show that this program actually works. Pain reduction outcomes, joint deformity prevention, hand function and grip strength outcomes were all judged as being "extremely important" by the patients. Since all of these outcomes are important to patients it may be that adherence could to JP could be improved by clear explanations of how JP can benefit each of these outcomes both a conceptual level and with the current research evidence that suggests benefits to these outcomes.

The level of participation preferred by potential participants in JP in this study equates to 3-6 hours/week, and is similar to that performed in clinical trials of JP in patients with osteoarthritis and rheumatoid arthritis in the hand.[15–17] Half of the respondents ranked the online format as the first choice over all the other methods of delivery of JP with home program being the second most preferred choice. This finding is consistent with a recent study where patients with RA reported that a home version of a hand exercise program, which was held online was very useful and authors suggested that this might contribute to better adherence in long term.[18] Data from an RCT of behavioral and hand exercises interventions in women with arthritis also suggested home programs may increase participation.[19] The recent pandemic has forced many countries to re-evaluate how care is delivered to maintain social distancing or self-isolation.[20] The pandemic has heighted the lack of access to care for people with arthritis as this care is considered non-essential. At

the same time, it has opened up the pathway for innovation and acceptance of alternative delivery models that provide remote accessibility. Since our data was collected pre-pandemic, we can only assume that preference for online programs would have increased. While the efficacy of JP interventions with hand exercises has been evaluated it is difficult for patients with hand arthritis to have confidence that an online or remote intervention is equally effective method to control their symptoms without being tested in future trials.[7] This underlines the importance of trials and post-trial implementation studies to provide more definitive evidence on the impact of virtual JP programs.

The third most preferred choice of JP delivery was at the clinic. Our previous studies of information access preferences in patients with fibromyalgia[21,22] indicated that face-to face interaction with health care providers was the most preferred way of getting information and it likely that this is the positive aspect for attending a clinical site. Previous review has indicated that patient-centered interaction styles related to the provision of emotional support and allowing patient involvement in the consultation process may enhance the therapeutic alliance between clinician and patient.[23] Effective communication between the clinician and the patient is relied on verbal but also on non-verbal factors, and this can usually be achieved in an in-person encounter.[24] The value of face-to-face interaction may mean that online interventions although theoretically more accessible, may not instigate the same level of engagement or adherence.

Another key finding of this study is that the cost of the JP program, working commitments, the time that JP is offered as well as the distance from home to clinic were regarded as the main barriers and could substantially decrease participation in JP. Financial burden, time has been previously described for patients with rheumatoid arthritis as a perceived barrier.[25,26] From the qualitative analysis barriers associated with health factors were novel, and not well captured in the survey.

Respondents identified a variety of perceived important outcomes with pain reduction, joint deformity prevention and hand function being the main predominant ones. This is consistent with the core set outcome measures that has been proposed from OMERACT-Osteoarthritis Research Society International (OMERACT-OARSI) set of responder criteria.[27] Clinical outcomes for hand OA such as aesthetic damage in the joints and

measured performance and function have been recommended by patients.[28,29] Based on patients' perceived benefit, JP programs appeared to have neutral to positive impact on stiffness, pain, grip strength, hand function and swelling. While this is consistent with a recent meta-analysis[7,14] there was a very low number of respondents that used JP in our sample.

Our study has several limitations that need to be taken into account when interpreting our study findings. Since the survey was designed for English speakers with hand arthritis, people speaking other languages were not represented. Potentially cultural, language and health system issues could affect preferences. The survey responses were recorded online, and patients did not have access to electronic devices could not participate in the survey. However, we offered a paper version survey for individuals as an alternative. Finally, the small sample of people with experience of JP prevented us from adequately exploring the perceptions of patients who had completed the training.

5.6 Future research and clinical implications

While this survey is a first step to understand what factors affect participation rates in people who are candidates for JP, studies that collect patient perceptions of draft programs in a co-design process are needed to create a patient-preference based JP program. It is possible that preferences will change or become more specific through a co-design process. A future trial to compare alternative delivery models is highly needed. Our survey identified principles of JP that the patients perceived as extremely important and it is unclear if these components were present in the published efficacy trials, since these studies have inadequate reporting.[7] Adherence to guidelines such as Template for Intervention Description and Replication (TiDIER) and presentation of theoretical assumptions for the content of programs would improve fidelity across studies and in converting current JP programs to online formats.[30] One of the most important findings of our work is the lack of awareness about, and participation in JP in a sample of people for who current best evidence suggest this would be effective. Education of health care professionals about this option and improved accessibility to programs is indicated to improve clinical outcomes.

5.7 Conclusions

Awareness of the potential benefits of JP, and prior experience with JP program were very low. Common potentially modifiable patient-reported barriers to participate in future JP interventions, included: cost, work commitments distance from home to clinic and times that the JP intervention were provided. These barriers might be addressed with free and accessible forms of delivery of JP, which may lead to better uptake and participation in JP.

5.8 Author contributions

PB contributed significantly to conception and design of the study, data extraction, interpretation of data and drafting of the manuscript. PB and ECB contributed to data management. CZ and ECB were involved in interpretation of data and drafting. EL, LF and RG were involved in acquiring operating funds, project supervision, data interpretation and drafting. JM was also involved in the conception and design of the study, drafting, and revised the manuscript for important intellectual content. All authors have given their final approval on the manuscript to be published

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5.10 Declarations

5.10.1 Ethics approval and consent to participate

Ethical approval was granted by Hamilton Research Ethics Board (HiREB) at McMaster University, Hamilton, Canada. Patients were asked to provide consent to proceed and complete the survey questions

5.10.2 Consent for publication

Not applicable

5.10.3 Availability of data and material

No data are available. Data sharing is not allowed from our Institutional Research Ethics Board.

5.10.4 Funding Statement

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5.10.5 Competing Interest Statement

None to report

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Table 6-1. Sample characteristics

Variable	%	n
Age (years)		
18 – 24	3%	5
25 – 34	11%	19
35 – 44	26%	45
45 – 54	26%	45
55 – 64	23%	39
65 – 74	7%	12
75 – 84	1%	2
Diagnosis (hand)		182
Osteoarthritis	22%	38
Rheumatoid arthritis	51%	92
Psoriatic arthritis	16%	29
Other form of arthritis	7%	13
None of the above	5%	10
Joint Protection		
I am currently taking part in a joint protection program	4%	6
I have previously taken part in a joint protection program	5%	7
I have heard about joint protection but have not taken part in a program	10%	17
I have not heard about any joint protection programs	82%	134
Setting		
Inpatient- rehabilitation unit	8%	1
Inpatient- hospital	8%	1
Outpatient- hospital	38%	5
Home care	8%	1
A rehabilitation centre/ clinic	15%	2
Family Physician	23%	3
Joint protection provider		
Family physician or specialist	38%	5
Occupational therapist	46%	6
Physiotherapist	15%	2

Table 6-2. Examples provided of joint protection from patients that used them

Example 1	*"Learned how to do things safer for my hands, re-enforced pacing"*
Example 2	*"Wearing thumb caps for working in the garden, wrist guards while using my hands. Splints for hands and feet"*
Example 3	*"I choose to use larger muscles and joints to aid me in completing day to day tasks, and I use splinting to reduce pain, weakness, and fatigue"*
Example 4	*"I wore resting splints for 30 years. I have a key turner and a right-angled knife. I try to always use the largest joints. My taps and light switches are modified. I changed my cupboard handles. I use lightweight plates and an electric toothbrush"*

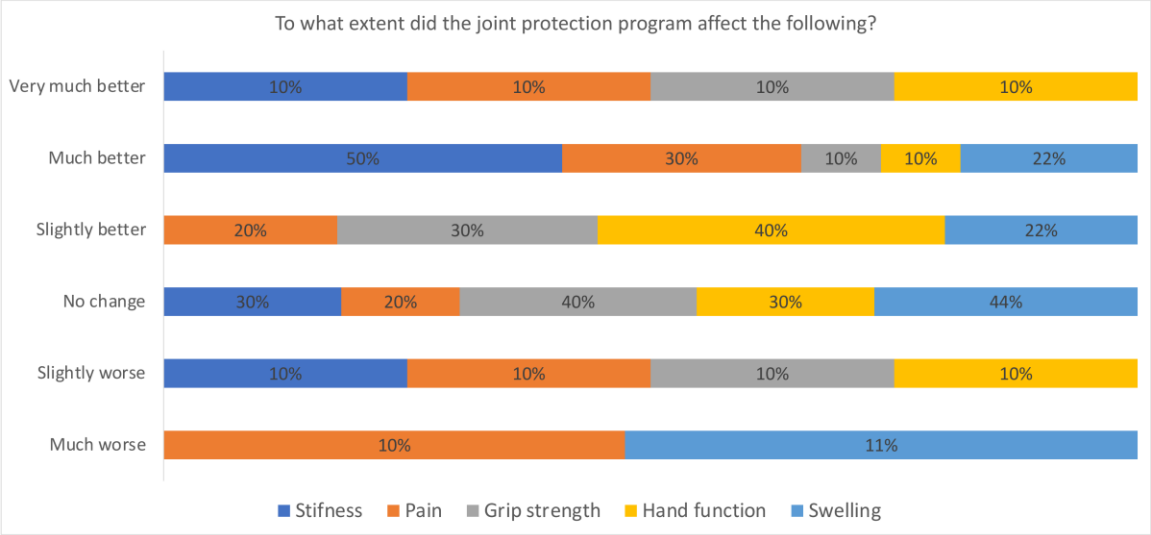

Figure 6-1. Individuals who took part into joint protection (n=10) where to asked to what extent did the joint protection (JP) affect stiffness, pain, grip strength, hand function and swelling. Only 2 out of 10 individuals that participated in JP experienced slightly worse to much worse outcomes

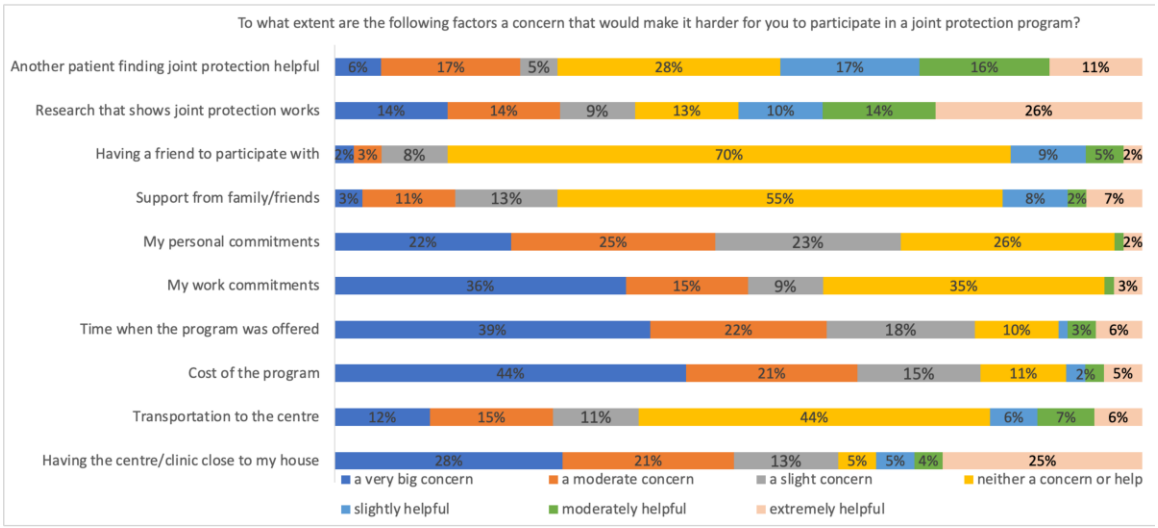

Figure 6-2. Factors perceived either as facilitators or barriers that may affect participation in a joint protection program.

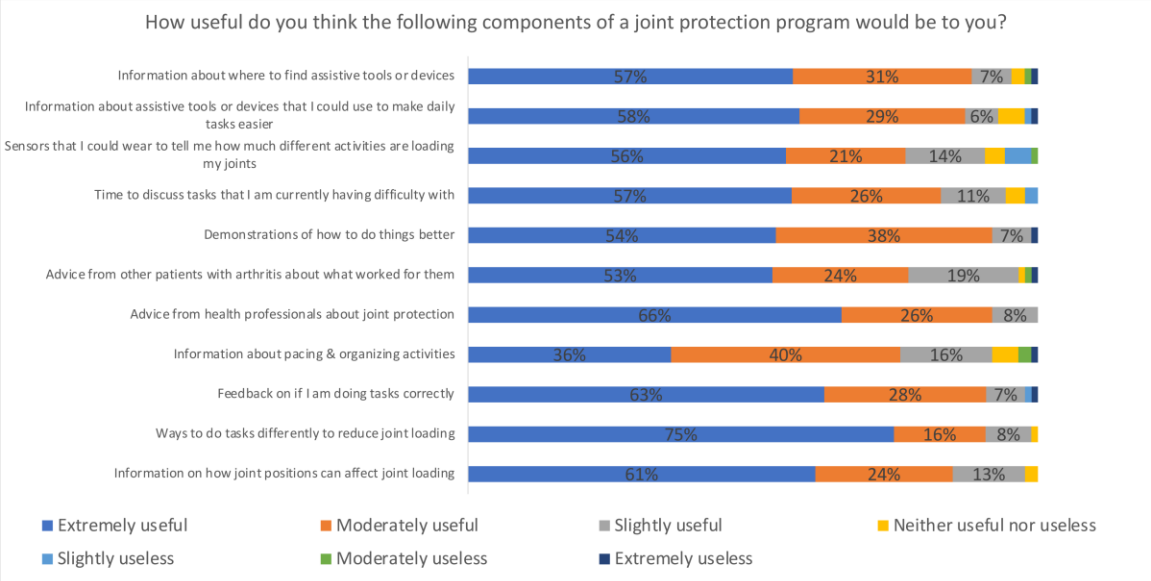

Figure 6-3. Participants were asked to rate the following components of joint protection from "extremely useful" to "extremely useless

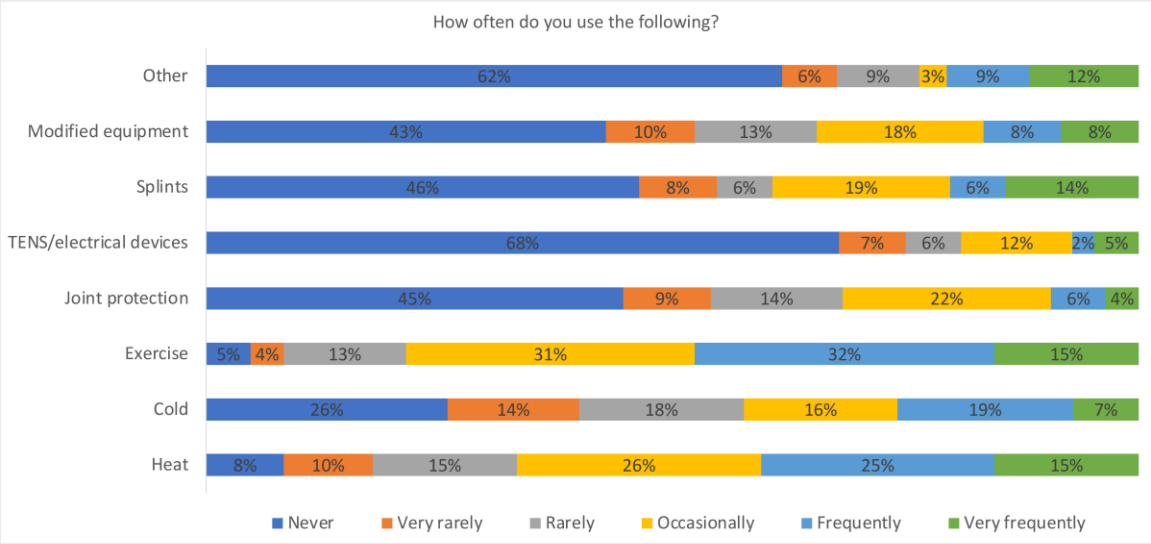

Figure 6-4. Individuals were asked how often they used the following modalities to manage their symptoms

Chapter 6

7 Evaluation of the Content Validity Index of the Australian/Canadian Osteoarthritis hand Index, the Patient-Rated Wrist/Hand Evaluation and the Thumb Disability Exam in people with hand arthritis

Abstract

Background

The Australian/Canadian Osteoarthritis Hand Index (AUSCAN), the Patient-Rated Wrist/Hand Evaluation (PRWHE) and the Thumb Disability Exam (TDX) are patient-reported outcome measures (PROM) designed to assess pain and hand function in patients with hand arthritis, hand pain and disability, or thumb pathology respectively. This study evaluated the content validity of AUSCAN, PRWHE and TDX in people with hand arthritis.

Methods

This study enrolled participants with hand arthritis to rate the items of all 3 PROM in terms of relevance and clarity. The Content Validity Index (CVI) was computed for each item in each scale (I-CVI) as well as for the overall scale (S-CVI). Kappa was used to determine the inter-rater agreement among the raters.

Results

Overall, 64 individuals with hand arthritis (27% with OA, 67% with rheumatoid arthritis and 6% with psoriatic arthritis) participated in the study. The I-CVI for all items and all scales were very high (I-CVI > 0.76) and the modified Kappa agreement among the raters demonstrated excellent agreement (k>0.76).The S-CVI for all PROMs was very high for relevance (AUSCAN = 0.92, 95% CI 0.90 to 0.94; PRWHE = 0.85, 95% CI 0.82 to 0.88 and TDX = 0.87, 95% CI 0.85 to 0.89) and for clarity (AUSCAN = 0.99, 95% CI 0.98 to 1.00; PRWHE = 0.95, 95% CI 0.93 to 0.97 and TDX = 0.91, 95% CI 0.89 to 0.94), respectively.

Conclusions

This study demonstrated very high content validity indices for the AUSCAN, PRWHE and TDX; with strong consensus across raters. This augments prior studies demonstrating appropriate statistical measurement properties, to provide confidence that all three measures assess important patient concepts of pain and disability.
Keywords: osteoarthritis, rheumatoid arthritis, psoriatic arthritis, content validity, hand arthritis

7.1 Introduction

Hand osteoarthritis (OA) is one of the most common musculoskeletal diseases and a leading cause of disability with an increasing prevalence mainly attributed to increased life expectancy.[1,2] Clinical characteristics of hand OA typically involve pain, reduced hand function, decreased hand grip strength, poor quality of life[3,4] joint degeneration, bony enlargements and joint swelling.[5]Rheumatoid arthritis, although leading to bone tissue abnormalities, loss of joint function and impact on quality of life similarly to OA, is a distinct pathology that mainly targets synovial and soft tissue structures.[6]

Patient-reported outcome measures (PROMs) are often administered to assess any health-related changes that may have occurred as a consequence of health-management interventions.[7,8] Many properties are important[9–13] during an instrument development such as reliability and validity but a key property is considered to be content validity.[14] Content validity can be defined as the degree of which the instrument or the questionnaire is an

adequate reflection of the construct being measured.[15] Based on the Consensus-based Standards of the selection of health Measurement Instruments (COSMIN) initiative content validity is considered as one of the most important measurement properties.[14] While reliability, responsiveness and other types of validity can be pivotal for an outcome assessment they may be insufficient to establish the validity of a PROM.[16] When PROMs include irrelevant items and lack of clarity they are inefficient, and may have weaker measurement properties.[14] Most importantly, if key aspects are missing or the questions are not relevant responses, they may not reflect patient status or concerns, and may be biased because patients may get frustrated.[17]

The Australian/Canadian Osteoarthritis Hand Index (AUSCAN) [18], the Patient-Rated Wrist/Hand Evaluation (PRWHE)[18]and the Thumb Disability Exam (TDX)[19] are clinical tools designed to assess pain and hand function in hand arthritis. [18–21] Both AUSCAN and PRWHE have demonstrated construct validity with verbal rating scale, had high internal consistency, and correlated with each other at baseline and follow-up time points in patients with early thumb carpometacarpal OA.[18] However, previous studies have reported inconsistent results about construct validity of AUSCAN.[22–24] Haugen et al showed that AUSCAN total index lacks construct validity with items contributing to separate scales of pain, stiffness, and physical functioning.[24] Also, a recent update of PRWHE was performed to improve the clarity and applicability of items, but this version has not been compared to the AUSCAN and it is important to assess the content validity of the revised scale. The TDX is a more recently developed scale that has not been compared to either the PRWHE or AUSCAN. Although, previous studies have demonstrated appropriate statistical measurement properties, content validity evaluations are needed to ensure that the

constructs being evaluated are those intended, and that items are interpreted probably by potential respondents. Limited investigation of content validity has been reported for any of these three questionnaires. Therefore, we aimed to investigate the quantification of content validity index by asking patients with hand arthritis to rate each of the instruments items in terms of relevance and clarity.

7.2 Primary Objective

To evaluate the Content Validity Index (CVI) of the Australian/Canadian Osteoarthritis Hand Index (AUSCAN), the Patient-Rated Wrist/Hand Evaluation (PRWHE), and the Thumb Disability Exam (TDX) in patients with hand arthritis.

7.3 *Methods*

7.3.1 Study Design

This study was a cross-sectional design that investigated the content validity of patient-reported outcomes (AUSCAN, PRWHE and TDX) for hand arthritis. Ethical approval was granted from the Hamilton Integrated Research Ethics Board (HiREB).

7.3.2 Inclusion criteria:

1. The participant was able and willing to provide informed consent

2. Participants were between 18 - 85 years old

4. The participant had hand arthritis.

5. The participant can read and write English.

7.3.3 Exclusion criteria

1. Hand pathologies or conditions other than arthritis

2. Inability to answer the survey questions in English.

7.3.4 Setting and Recruitment

Participants were recruited through poster advertisements at The Roth McFarlane Hand and Upper Limb Centre (HULC) at St. Joseph's Health Care Hospital in London, Ontario and through The Arthritis Society main website. The patients that expressed interest to participate in the study received a letter of information about the survey. Both electronic and paper versions of the survey were available for participants. An email with the link of the online survey was sent out to the participants that were interested to complete the electronic version. The electronic version was hosted on Qualtrics from May 2019 till February 2020 which is a secure data collection platform.[25] Participants were asked to provide consent to proceed into the survey questions. Allthe items were rated for relevance and clarity in an order (AUSCAN, PRWHE, TDX). Participants were asked to rate the relevance and clarity of each item of AUSCAN, PRWHE and TDX.

7.3.5 Patient-reported Outcome Measures

The Australian/Canadian Osteoarthritis Hand Index (AUSCAN) is a 15-item self-reported disease specific questionnaire measuring pain (5-items), function (9-items) and stiffness (1-item) in the hand on a scale from 0 – none to 4 – extreme for all items.[18,20] The Patient-Rated Wrist/Hand Evaluation (PRWHE)is a self-administered questionnaire which has 2 subscales of pain (5-items) and function (10-items). The PRWHE was originally developed and tested for people with distal radius fracture (DRF)[21,26,27] and later validated as applicable to the wrist/hand for multiple conditions including arthritis as the PRWHE. [18,28] Each item is scored from 0 to 10 scale which 10 indicates the worst possible pain or disability. The Thumb Disability Exam (TDX) is composed of 20 questions divided into 3 sections: hand function (11-items), pain (5-items) and satisfaction (4-items). Each item for hand function is scored from 1 – not difficult to 5 – unable, for level of pain 1 – never to 5 – always and for satisfaction from 1 – very satisfied to 5 – very dissatisfied. [19]

7.3.6 Data Analysis

Descriptive statistics were used to capture the demographics characteristics (age, diagnosis, medications and whether they had surgery or not) of the included sample. A Content Validity Index (CVI) value was computed for each item on the AUSCAN, PRWHE and TDX (I-CVI) as well as for the overall scale (S-CVI). To calculate an item-level CVI (I-CVI), patients with hand arthritis were asked to rate the relevance of each item, on a 4-point scale. Four ordinal points were used foreach scale which was 1=not relevant, 2=somewhat relevant, 3=quite relevant, 4=highly relevant. Then, for each item, the I-CVI

was computed as the number of patients giving a rating of either 3 or 4, divided by the number of raters—that is, the proportion in agreement about relevance and clarity which is between 0 and 1. The S-CVI was calculated by averaging across the I-CVIs of each PROM. To calculate the modified kappa statistic, the probability of chance agreement (Pc) was first calculated for each item by the following formula: $Pc= [N! /A! (N -A)!] *0.5^N$ with N being the number of raters (patients with arthritis) and A is the number of patients that agree that the item was clear or relevant.[29] Then Kappa was calculated of entering the probability of chance agreement (Pc) and content validity index of each item (I-CVI) in the following formula: K= (I-CVI - PC) / (1- PC).[29] Kappa values of 0.74 and above were considered as excellent, 0.60 to 0.74 as good and 0.54 to 0.59 as fair.[30] We performed a Shapiro-Wilk as the omnibus test for assessing univariate normality of each S-CVI distribution, in both relevance and clarity subscales of PROMs. Then, the S-CVI scores were compared with a paired student's t-Test if normality assumption was met or with Wilcoxon paired signed-ranks test, if assumptions of normality were violated. [31] We conducted all the analyses with STATA (StataCorp. 2019. Stata Statistical Software: Release 16. College Station, TX: StataCorp LLC)

7.4 Results

Overall, 64 individuals with hand arthritis (27% with hand OA, 67% with rheumatoid arthritis in the hand and 6% with psoriatic arthritis) participated in the study. Four individuals were excluded from the analysis because their arthritis was not affecting their

hand. The majority of the participants (66%) were taking pain medication on a daily basis (Table 1). All individuals completed the electronic version of the survey.

7.4.1 Content Validity Index and Modified Kappa agreement of the AUSCAN

The I-CVI and the S-CVI supported the content validity of the hand pain, stiffness and function items and subscales of the AUSCANs (Table 2). Five items of pain subscale were rated for relevancy and clarity with I-CVI scores ranging from 0.86 to 0.96 and from 0.92 to 1.00 respectively. For 1-item in stiffness subscale the I-CVI was found 0.93 for relevancy and 1.00 for clarity. For function subscale, 9-items were rated for relevancy and clarity with an I-CVI ranging from 0.88 to 0.97 and from 0.98 to 1.00 respectively. The S-CVI for AUSCAN was found 0.92,95% CI: 0.90 to 0.94 for relevance and 0.99, 95% CI: 0.98 to 1.00 for clarity. The modified Kappa agreement for every item of the AUSCAN demonstrated excellent agreement (K ranging from 0.86 to 1.00)

7.4.2 Content Validity Index and Modified Kappa agreement of the PRWHE

The I-CVI and the S-CVI of the PRWHE for pain subscale and function subscales all supported the content validity of the PRWHE (Table 3). Five items of pain subscale were rated for relevancy and clarity with I-CVI values ranging from 0.79 to 0.89 and from 0.87 to 0.94, respectively. For function subscales, 10 items were rated for relevancy and clarity with I-CVI values ranging from 0.79 to 0.95 and from 0.92 to 1.00 respectively. The S-

CVI for PRWHE was 0.85, 95% confidence intervals (CI): 0.82 to 0.88 for relevance and 0.95,95%CI: 0.93 to 0.97 for clarity. The modified Kappa agreement for every item of PRWHE demonstrated excellent agreement (K ranging from 0.79 to 1.00).

7.4.3 Content Validity Index and Modified Kappa agreement of the TDX

The I-CVI and the S-CVI supported the content validity of the TDX for hand function, pain and satisfaction subscales (Table 4). Eleven items of hand function were rated as relevant and clear with I-CVI values ranging from 0.82 to 0.93 and from 0.94 to 0.98 respectively. For pain subscale, five items were rated as relevant and clarity with I-CVI scores ranging from 0.78 to 0.85 and from 0.77 to 0.86 respectively. For the satisfaction subscale, four items were rated as relevant and clear based on I-CVI demonstrating scores from 0.83 to 0.95 and from 0.88 to 0.91. The S-CVI of TDX was rated as relevant and clear based on scores of 0.87,95% CI: 0.85 to 0.89 for relevancy and 0.91, 95% CI: 0.89 to 0.94 for clarity. The modified Kappa agreement demonstrated excellent inter-rater agreement on item ratings (K ranging from 0.77 to 0.98).

7.5 Discussion

This study established a high level of content validity for AUSCAN, PRWHE and TDX for patients with hand arthritis. The content validity index was very high for all the individual items for each questionnaire (I-CVI> 0.77) and for the overall score (S-CVI > 0.85) in terms of relevancy and clarity, exceeding the recommended benchmarks of 0.78

respectively.[29] The Kappa inter-rater agreement of >0.75 was excellent across all the individual items for all PROMs (AUSCAN, PRWHE and TDX) among the raters.[29] Together these data provide confidence in our assessment since multiple raters agreed on the high content validity scores obtained.

For the AUSCAN the content validity was established during development using a formal clinimetric process where patients in a tertiary care centre rated items by importance and frequency to establish relevance.[20] This study provides additional support for the content validity in a community sample of people living with hand arthritis, and by adding new data on the clarity of the items.

Content validity of PRHE was established during the development of the PRWHE by using semi-structured interviews in patients with distal radius fracture and expert opinion. [32] Later the extension to the PRWHE compared relevance to DASH, based on a comparative trial in a mixed clinical population with hand problems. However, neither were quantified, described specific findings in-depth or focused on patients with arthritis. Thus, this study provides novel information on the content validity of the items of the PRWHE, with specific reference to those with hand arthritis. All items of PRWHE were found with very high content validity index in terms of relevance (I-CVI > 0.79) and clarity (I-CVI > 0.87).

It might have been expected that the AUSCAN would have more relevance to our sample, than the PRWHE since it a disease-specific PROM. Both point estimate and CI comparisons indicate that AUSCAN had slightly higher overall scores in terms of relevancy (S-CVI = 0.92, 95% CI: 0.90 to 0.94) and clarity (S-CVI = 0.99, 95% CI: 0.98 to 1.00) than the PRWHE (S-CVI=0.85, 95% CI :0.82 to 0.88 for relevancy and S-

CVI=0.95, 95% CI: 0.93 to 0.97 for clarity). Although the CIs of the respective S-CVIs indicate that there was a small statistically significant difference (Table 5) between compared S-CVI values (AUSCAN vs TDX and AUSCAN vs PRWHE), all PROMs met standards of very high content validity. Further, since 6 to 8 additional raters assessed the PRWHE that did not assess the AUSCAN, the small differences may reflect differences in rater pools rather than an actual difference in perceptions.

The TDX is relatively new developed PROM (Noback et al. 2017)[19] that was tested in patients with basal joint arthritis. The TDX demonstrated very high content validity index when assessed in terms of relevancy (S-CVI = 0.87, 95% CI: 0.85 to 0.89) and clarity (S-CVI = 0.91, 95% CI: 0.89 to 0.94). All the individual items of the TDX had a very high content validity index (I-CVI >0.77). No previous studies have reported the content validity index of TDX. The item generation of TDX included the review of items from relevant scales (Michigan Hand Questionnaire (MHQ)[33], Disabilities of the Arm, Shoulder, and Hand (DASH)[34], AUSCAN[20], PRWHE[27] and McGill Pain questionnaire[35]). Then, the development process included item reduction and pilot testing and then final item reduction.[19] Thus the items may have benefited from content validity efforts made in developing the scales. Since the thumb is so important for overall hand function, it is not surprising that this thumb questionnaire was found to have validity for patients with hand arthritis.

Our kappa statistics indicated excellent agreement between patient raters after correcting for chance agreement. (K> 0.77). The assessment from a large pool of patients (n> 60) generated similar scores between the I-CVI and K scores. This has been previously

described in the literature when the number of raters increasing and the probability of chance (Pc) decreases the K agreement and I-CVI values tend to converge.[29]

This study provided novel data on the content validity index in 3 different PROMs in patients with hand arthritis. Since few studies address content validity, this is important to support the conceptual foundations of these measures and support their use in clinical practice. While the computation of CVI is relatively easy, its major weakness is the failure to adjust for chance agreement. However, the authors tried to mitigate this problem by calculating a modified kappa agreement.[29,36] A potential limitation is that the items of the PROMs were not randomized but the items were rated for relevance and clarity in an order (PRWHE, AUSCAN, TDX). Since all three scales were brief, we would think it is unlikely that there was an order effect, especially since the highest scores were found in the questionnaire administered in the middle. CVI is one method of assessing content validity and as a quantitative process are ideally suited to rating existing items, not to identification of potential gaps in important constructs. Ideally CVI should be augmented by qualitative techniques like cognitive interviewing or understanding the dimensions of the underlying construct to be measured. Also, all three questionnaires demonstrated high content validity, and existing evidence confirms that all three provide strong psychometric properties then practical considerations might be the predominant difference that would guide selection. For example, the AUSCAN requires that a licensee fee be paid to the developer, whereas the other questionnaires are copyrighted but freely available for all users.

7.6 Conclusions

This study demonstrated evidence of very high content validity index for all the individual items and for the overall scale of AUSCAN, PRWHE and TDX for patients with hand arthritis, with high agreement across raters. This augments prior statistical evidence supporting statistical measurement properties, to provide support for the content validity.

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Table 7-1 Demographics of study participants

Variable	n	Percentage %
Age, years		
18-24	1	12%
25-34	8	13%
35-44	13	20%
45-54	17	27%
55-64	19	27%
65-74	5	78%
75-84	1	2%
Diagnosis		
Osteoarthritis	17	27%
Rheumatoid arthritis	43	67%
Psoriatic arthritis	4	6%
Frequency of Medication		
Daily	42	66%
Upon pain	10	16%
Other	12	19%
Surgery		
No	49	77%
Yes	15	23%

Table 7-2. Content Validity Index of item relevancy and clarity, and Modified Kappa agreement of the Australian and Canadian Osteoarthritis Index (AUSCAN)

Item	Relevance				Clarity				Interpretation
	Agreement	I-CVI*	Pc**	K***	Agreement	I-CVI*	Pc**	K***	
Rate your pain									
At rest	49/57	0.86	$< 10^{-5}$	0.86	49/50	0.98	$< 10^{-5}$	0.98	Excellent
Gripping	55/57	0.96	$< 10^{-5}$	0.96	49/49	1.00	$< 10^{-5}$	1.00	Excellent
Lifting	55/57	0.96	$< 10^{-5}$	0.96	49/50	0.98	$< 10^{-5}$	0.98	Excellent
Turning	54/57	0.95	$< 10^{-5}$	0.95	46/50	0.92	$< 10^{-5}$	0.92	Excellent
Squeezing	55/57	0.96	$< 10^{-5}$	0.96	50/50	1.00	$< 10^{-5}$	1.00	Excellent
Rate your stiffness									
After first wakening in the morning	52/56	0.93	$< 10^{-5}$	0.93	48/48	1.00	$< 10^{-5}$	1.00	Excellent
Rate your difficulty when									
Turning taps/faucets on	51/58	0.88	$< 10^{-5}$	0.88	51/51	1.00	$< 10^{-5}$	1.00	Excellent
Turning a round doorknob or handle	54/59	0.92	$< 10^{-5}$	0.92	53/53	1.00	$< 10^{-5}$	1.00	Excellent
Doing up buttons	52/59	0.88	$< 10^{-5}$	0.88	52/52	1.00	$< 10^{-5}$	1.00	Excellent
Fastening jewellery	52/59	0.88	$< 10^{-5}$	0.88	53/53	1.00	$< 10^{-5}$	1.00	Excellent
Opening a new jar	57/59	0.97	$< 10^{-5}$	0.97	53/53	1.00	$< 10^{-5}$	1.00	Excellent
Carrying a full pot with one hand	56/59	0.95	$< 10^{-5}$	0.95	52/53	0.98	$< 10^{-5}$	0.98	Excellent
Peeling vegetables/fruits	56/59	0.95	$< 10^{-5}$	0.95	53/53	1.00	$< 10^{-5}$	1.00	Excellent
Picking up large heavy objects	55/59	0.93	$< 10^{-5}$	0.93	51/51	1.00	$< 10^{-5}$	1.00	Excellent
Wringing out wash cloths	52/59	0.88	$< 10^{-5}$	0.88	50/51	0.98	$< 10^{-5}$	0.98	Excellent
S - CVI	**0.92** (95% CI: 0.90 to 0.94)				**0.99** (95% CI: 0.98 to 1.00)				

NOTE: *I-CVI: item-level content validity index, **pc (probability of a chance occurrence) was computed using the formula: pc= [N! /A! (N -A)!] *$.5^{N}$ where N= number of experts and A= number of experts who agree that the item is relevant or clear, ***K(Modified Kappa) was computed using the formula: K= (I-CVI- PC)/(1- PC). Interpretation criteria for Kappa, using guidelines described in Cicchetti and Sparrow (1981): Fair=K of 0.40 to 0.59; Good=K of 0.60 to 0.74; and Excellent=K>0.74. I-CVI, item-level content validity index; scale-level content validity index, average (S-CVI/Ave).

Table 7-3. Content Validity Index of item relevancy and clarity and Modified Kappa agreement of Patient Rated Wrist/Hand Evaluation (PRWHE)

Item	Relevance				Clarity				Interpretation
1. Pain subscale	Agreement	I-CVI*	Pc**	K***	Agreement	I-CVI*	Pc**	K***	
Rate your pain: At rest	51/64	0.80	$< 10^{-5}$	0.80	50/53	0.94	$< 10^{-5}$	0.94	Excellent
Rate your pain: When doing a task with a repeated wrist movement	54/64	0.83	$< 10^{-5}$	0.83	49/53	0.92	$< 10^{-5}$	0.92	Excellent
Rate your pain: When lifting a heavy object	54/64	0.83	$< 10^{-5}$	0.83	50/53	0.94	$< 10^{-5}$	0.94	Excellent
Rate your pain: When it is at its worst	57/64	0.89	$< 10^{-5}$	0.89	49/53	0.92	$< 10^{-5}$	0.92	Excellent
How often do you have pain?	50/63	0.79	$< 10^{-5}$	0.79	47/54	0.87	$< 10^{-5}$	0.87	Excellent
2. Function									
A. Specific Activities									
Turn a doorknob using my affected hand	53/63	0.84	$< 10^{-5}$	0.84	52/52	1.00	$< 10^{-5}$	1.00	Excellent
Cut meat using a knife in my affected hand	54/63	0.86	$< 10^{-5}$	0.86	53/53	1.00	$< 10^{-5}$	1.00	Excellent
Fasten buttons on my shirt	51/63	0.81	$< 10^{-5}$	0.81	53/53	1.00	$< 10^{-5}$	1.00	Excellent
Use my affected hand to push up from a chair	50/63	0.79	$< 10^{-5}$	0.79	51/52	0.98	$< 10^{-5}$	0.98	Excellent
Carry a 10lb object in my affected hand	58/63	0.92	$< 10^{-5}$	0.92	52/53	0.98	$< 10^{-5}$	0.98	Excellent
Use bathroom tissue with my affected hand	50/63	0.79	$< 10^{-5}$	0.79	51/52	0.98	$< 10^{-5}$	0.98	Excellent
B. Usual activities									
Personal care activities (dressing, washing)	53/61	0.87	$< 10^{-5}$	0.87	50/53	0.94	$< 10^{-5}$	0.94	Excellent
Household work (cleaning, maintenance)	57/60	0.95	$< 10^{-5}$	0.95	49/53	0.92	$< 10^{-5}$	0.92	Excellent
Work (your job or usual everyday work)	52/60	0.87	$< 10^{-5}$	0.87	49/53	0.92	$< 10^{-5}$	0.92	Excellent
Recreational activities	54/60	0.90	$< 10^{-5}$	0.90	51/53	0.96	$< 10^{-5}$	0.96	Excellent
S – CVI/Ave	**0.85** (95% CI: 0.82 to 0.88)				**0.95** (95% CI: 0.93 to 0.97)				

NOTE: *I-CVI: item-level content validity index, **pc (probability of a chance occurrence) was computed using the formula: pc= [N! /A! (N -A)!] $*.5^{N}$ where N= number of experts and A= number of experts who agree that the item is relevant or clear, ***K(Modified Kappa) was computed using the formula: K= (I-CVI- PC)/(1- PC). Interpretation criteria for Kappa, using guidelines described in Cicchetti and Sparrow (1981): Fair=K of 0.40 to 0.59; Good=K of 0.60 to 0.74; and Excellent=K>0.74. I-CVI, item-level content validity index; scale-level content validity index, average (S-CVI/Ave).

Table 7-4. Content Validity Index of item relevancy and clarity, and Modified Kappa agreement of the Thumb Disability Exam (TDX)

Item	Relevance				Clarity				Interpretation
A. Please indicate your ability to perform these activities with the affected hand	Agreement	I-CVI*	Pc**	K***	Agreement	I-CVI*	Pc**	K***	
Turn a Key	54/61	0.89	$< 10^{-5}$	0.89	51/53	0.96	$< 10^{-5}$	0.96	Excellent
Pick up a coin	52/61	0.85	$< 10^{-5}$	0.85	49/51	0.96	$< 10^{-5}$	0.96	Excellent
Write	56/61	0.92	$< 10^{-5}$	0.92	51/54	0.94	$< 10^{-5}$	0.94	Excellent
Squeeze Toothpaste	52/60	0.87	$< 10^{-5}$	0.87	51/53	0.96	$< 10^{-5}$	0.96	Excellent
Hold a glass of water	50/61	0.82	$< 10^{-5}$	0.82	51/54	0.94	$< 10^{-5}$	0.94	Excellent
Turn a doorknob	52/61	0.85	$< 10^{-5}$	0.85	51/53	0.96	$< 10^{-5}$	0.96	
Use a knife to cut food	54/61	0.89	$< 10^{-5}$	0.89	51/53	0.96	$< 10^{-5}$	0.96	Excellent
B. Please indicate your ability to perform the following task while using both your hands									
Open a jar	57/61	0.93	$< 10^{-5}$	0.93	50/51	0.98	$< 10^{-5}$	0.98	Excellent
Button a shirt/blouse	53/61	0.87	$< 10^{-5}$	0.87	49/50	0.98	$< 10^{-5}$	0.98	Excellent
Tie your shoes	55/61	0.90	$< 10^{-5}$	0.90	50/51	0.98	$< 10^{-5}$	0.98	Excellent
Wring a dishcloth/washcloth	53/61	0.87	$< 10^{-5}$	0.87	49/51	0.96	$< 10^{-5}$	0.96	Excellent
II. The following questions refer to the level of pain in your thumb									
How often did you have pain in your thumb at rest?	50/61	0.82	$< 10^{-5}$	0.82	40/52	0.77	$< 10^{-5}$	0.77	Excellent
How often did the pain in your thumb interfere with your daily activities?	49/60	0.82	$< 10^{-5}$	0.82	44/51	0.86	$< 10^{-5}$	0.86	Excellent
How often did the pain in your hand interfere with recreational activities?	51/60	0.85	$< 10^{-5}$	0.85	44/52	0.85	$< 10^{-5}$	0.85	Excellent
How often did the pain in your thumb interfere with your sleep?	47/60	0.78	$< 10^{-5}$	0.78	44/52	0.85	$< 10^{-5}$	0.85	Excellent
How often did the pain in your thumb worsen your mood?	51/60	0.85	$< 10^{-5}$	0.85	42/52	0.81	$< 10^{-5}$	0.81	Excellent
III. The following questions ask about your satisfaction with the indicated hand or thumb over the past week.									
Motion in your affected thumb	48/58	0.83	$< 10^{-5}$	0.83	47/53	0.89	$< 10^{-5}$	0.89	Excellent
Strength of your affected hand	54/57	0.95	$< 10^{-5}$	0.95	48/53	0.91	$< 10^{-5}$	0.91	Excellent
Pain level of your affected hand	52/58	0.90	$< 10^{-5}$	0.90	48/53	0.91	$< 10^{-5}$	0.91	Excellent
Overall function of your hand	53/58	0.91	$< 10^{-5}$	0.91	46/52	0.88	$< 10^{-5}$	0.88	Excellent
S-CVI	**0.87** (95% CI: 0.85to 0.89)				**0.91** (95% CI: 0.89to 0.94)				

NOTE: *I-CVI: item-level content validity index, **pc (probability of a chance occurrence) was computed using the formula: pc= [N! /A! (N -A)!] *.5^{N} where N= number of experts and A= number of experts who agree that the item is relevant or clear, ***K(Modified Kappa) was computed using the formula: K= (I-CVI- PC)/(1- PC). Interpretation criteria for Kappa, using guidelines described in Cicchetti and Sparrow (1981): Fair=K of 0.40 to 0.59; Good=K of 0.60 to 0.74; and Excellent=K>0.74. I-CVI, item-level content validity index; scale-level content validity index, average (S-CVI/Ave).

Table 7-5. Comparison of content validity index (S-CVI) of Relevance and Clarity

	Relevance				Clarity			
	PRWHE	TDX	AUSCAN		PRWHE	TDX	AUSCAN
PRWE	0.85 (95% CI: 0.82-0.88)	*Paired t-Test*	*Paired t-Test*	PRWE	0.95 (95% CI: 0.93-0.97)	*Wilcoxon Signed ranks*	*Wilcoxon Signed ranks*
TDX	p=0.523	0.87 (95% CI: 0.85-0.89)	*Paired t-Test*	TDX	p = 0.153	0.91 (95% CI: 0.89-0.94)	*Wilcoxon Signed ranks*
AUSCAN	p <0.001	p = 0.001	0.92 (95% CI: 0.90-0.94)	AUSCAN	p = 0.001	p = 0.002	0.99 (95% CI: 0.98-1.00)

Paired t-Test: Student's t-Test for Matched Pairs; Wilcoxon Signed Ranks: Wilcoxon Matched-Pairs Signed-Ranks; Australian and Canadian Osteoarthritis Index (AUSCAN); Thumb Disability Exam (TDX); Patient Rated Wrist/Hand Evaluation (PRWHE)

Chapter 7

8 The Efficacy of a Joint Protection Program on Pain Intensity and Hand Function levels in People with Hand Osteoarthritis. A Protocol for a randomized controlled trial

Trial Summary

What is the principal research question? In patients with hand osteoarthritis does a joint protection program decrease pain intensity at 3 months compared to hand exercises.

PICOT Format

Population: Adult patients with primary type of hand osteoarthritis

Intervention: Joint protection program

Comparator: Hand exercises and joint protection

Outcome: Pain Intensity levels

Timeline: 1-year follow-up

Outcome: Primary outcome: Pain intensity levels at 3-months will be our primary outcome (dependent variable) and will be investigated by the Visual Analog Scale (VAS). It consists of a unidirectional 10 cm responsiveness scale with two anchors at either end of the scale; 0 - "no pain" and 10 - "worst possible pain". Patients will be instructed to draw a vertical mark on the scale indicating their pain level. Secondary outcomes: Secondary outcomes that will be collected consist of the Global Rating of Change, quality of life with EQ-5D, the Australian/Canadian Osteoarthritis Hand Index (AUSCAN), the Patient-Rated Wrist/Hand Evaluation and hand grip strength that will be assessed with a handheld dynamometer

Timeline: The maximum follow-up will be 1 year. The target of this trial is to demonstrate superiority of joint protection versus the exercise and joint protection on pain reduction at 3 months follow-up.

Study Design: This study will be a single center, investigator-blinded, randomized, 12-month, parallel-group, superiority study

Trial registration: ClinicalTrials.gov (intended)

8.1 Introduction

8.1.1 Impact of Osteoarthritis

Osteoarthritis (OA) is characterized as a degenerative joint disease that affects approximately 27 million adults in the USA and is one of the leading causes of disability.[1] Osteoarthritis affects 60-70% of the population above the age of 65 years, and is likely to increase further in the future.[2,3] The most common site of OA is the hand and it typically involves the interphalangeal (proximal and distal) and first carpometacarpal joints.[4] In a clinical setting, pain is a major symptom among patients with hand OA as it contributes to a reduction in joint function.[1,4] Currently there is no cure for hand OA, but goals of treatment include maximizing long-term health-related quality of life, by controlling symptoms such as pain, prevention of structural damage and normalization of function.

8.1.2 Age, Sex and Disease Progression in hand OA

Approximately 60–70% of the population above the age of 65 seek medical attention for OA, and the majority of these are women.[5–7] Hand OA has a strong genetic influence, indicating that if their mother had severe hand OA, they are likely to experience a similar disability.[5,6] The biological mechanisms by which increases hand OA disability for females, is poorly elucidated. However, it may be a result of the smaller size of hand joints, hormonally regulated soft tissue laxity, pregnancy-induced laxity and sex-differences in pain.[5–7] Gender may affect hand OA given the higher repetitive loading in paid and unpaid work tasks performed more often by women. However, men tend to be under-represented in studies of hand OA, so we may know less about how it manifests in men. Age has a pivotal effect to diseases as OA and at pain outcomes because of the degeneration nature of articular cartilage as we age.[5–7] Additionally, pain intensity levels for people with hand OA may vary depending on the disease progression and the structural modification.[7] This suggests that age, sex and disease progression must be considered in the design stage as potential confounding factors.

8.1.3 Why Joint Protection and hand exercises are important?

Joint protection programs (JPP) are a self- management strategy for patients living with arthritis to help preserve joint function and reduce pain.[8] JPP involve training on "safer movement patterns, the use of adaptive devices (e.g. built up handles, hands free technologies) and behavior modifications (e.g. activities to avoid, pacing). Originally shown to be effective for rheumatoid arthritis, the concept has been expanded to treat patients with OA.[9–11] Osteoarthritis causes excessive fluid to surround the joint, which when occurs for an extended period of time, causes the ligaments surrounding the joint to become elongated and no longer adequately stabilize the joint.[12,13] Overtime, the cartilage weight bearing surfaces become eroded and patients experience pain especially with joint loading. Unlike the lower extremity where joint loading takes place through weight bearing, joint loading in the upper limb is determined by the tasks performed. The lack of soft tissue support makes joints in the hand susceptible to deformity during tasks of daily life.[14] Muscle imbalance can further exacerbate deformity, and thus the kinematics of how tasks are performed are critical to cumulative loading.

8.1.4 The need for a trial in hand OA

Magni et al. has indicated clinically unimportant pain-relieving effects of hand exercises for people with hand OA.[15] A subsequent study reported that it is unclear if a combination of hand exercises and joint protection program can provide better pain outcomes for people with hand OA.[16] Both reviews[15,16] highlighted the low-quality certainty that was associated for pain outcomes. The majority of the included studies were rated as high risk of bias mostly for: selection, performance and detection bias domains.[17–19] Furthermore, problems with adherence to JPP and hand exercises were not documented. Hand dysfunction because of pain is a very common problem in hand OA. Hand exercises and joint protection are currently recommended in clinical practice but for people with rheumatoid arthritis only.[20–23] Also, these recommendations are not supported by high-quality evidence as recommended by Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) group.[24] To address this, we will design a long-term evaluation of a

joint protection program in large group of people living with hand OA. As part of this evaluation, it is important to integrate strategies to maximize program adherence. The null hypothesis of the study is that there will be no difference in pain outcomes between the two arms at 3-months follow-up. It is unclear if a combination of hand exercises and joint protection program can provide better pain outcomes for people with hand OA.

8.2 Objectives of the Study

8.2.1 Primary Objective

The first objective of this study is to assess if a JPP when compared to hand exercises and joint protection, can reduce pain intensity levels in people with hand osteoarthritis, at 3-months follow up

8.2.2 Secondary Objectives

1. To assess if JPP when compared to hand exercises and joint protection, can improve hand function in people with hand osteoarthritis, at 6-months follow up

2. To assess if JPP when compared to hand exercises and joint protection, can improve quality of life in people with hand osteoarthritis, at 12-months follow up

8.3 Methods

8.3.1 Study design

This study will be a single center, investigator-blinded, randomized, 12-month, parallel-group, superiority study. The study flow is presented in Figure 2.

8.3.2 Setting

This study will be conducted in a single center specialized tertiary hand clinic (Hand and Upper Limb Centre – HULC) in London Ontario Canada. Advertisements will be placed at regular intervals in local and regional newspapers and on social media platforms. This will be accompanied by regular posting of advertisements on hospitals, community noticeboards and in The Arthritis Society main webpage. Local health practitioners will be made aware of the study through information and advertising packages. Participants with hand OA will be contacted to schedule an initial visit at HULC. All participants who meet the eligibility criteria and provide an informed written signed consent, will be offered an opportunity to enroll in the study. Participants with hand OA will then complete a demographic data such as age, gender/sex, email address, height, weight, years of service, rank, educational level, use of NSAIDs and a set of outcome measures.

8.3.3 Eligibility Criteria

Our sample will include:

1. Participants (males and females) between 18 and 85 years old
2. Participants with primary type of hand osteoarthritis (non-traumatic)
3. Radiographic findings of OA
4. Meeting the ACR Classification criteria
5. Individuals able to speak and write in English
6. Have access to electronic devices (e.g. computer) and internet.

Participants will be excluded if they have:

1. Neurological disorders
2. Rheumatoid arthritis or any other type of arthritis than hand osteoarthritis
3. Dementia or any other cognitive condition that could interfere with the trial procedures
4. Age less than 18 years
5. Upper limb joint surgery, or fracture, in the previous 6 months
6. Being on a waiting list for upper limb orthopedic surgery

7. Pregnancy

8.3.4 Interventions

Exercises and Joint Protection (Ex+JP)

Participants that will be randomized to the Exercises and Joint protection (Ex+JP) arm will have a specific exercise program plus a joint protection that described above. The exercise program will include seven mobility exercises and four strength exercises against resistance. More specifically, they will perform: MCP flexion, tendon gliding, radial walking, eccentric wrist extension, gross grip, finger abduction and adduction, wrist circumduction and finger pinch. This intervention will involve a total of six sessions (1 hour per session). Individuals will be provided with an exercise booklet containing pictures and instructions describing the program, as well as the resistance materials required. They will be asked to perform the program daily at home between clinic sessions, for a period of approximately 12 weeks. The dosage consists of 1 set and 10 repetitions for each exercise. Adherence to the exercise program is pivotal in ensuring that the dosage will be carried out. Patients adherence in home exercise programs is usually poor, but it will be enhanced through the use of exercise diaries.

8.3.5 Joint Protection (JP)

Joint protection will include patient education, problem-solving to promote behavior modification; energy conservation; and selective use of splints and adaptive devices and provision of The Arthritis Society booklets containing further advice. The following principles will be explained during the joint protection instruction: the need for balance between movement and resting a joint; dividing stress between as many joints as possible; using larger and stronger joints; using each joint in its most stable plane to reduce pressure on the joint; avoiding staying in one position; and avoiding vibrations for the finger joints. In addition, patients were trained to protect their joints, using assistive devices if necessary, to perform Activities of Daily Living (ADL). Patients were trained to do the following activities in a protective way: wringing a cloth; using enlarged grips for writing; opening

jars, cans, or boxes with Dycem; using a book holder for reading; and using a rocker or angled knife for cutting food. Patients will be encouraged to find examples for application of these principles in their own daily activities, which were discussed. Oral and written information will be provided. Participants that will be randomized to the JP arm will have individual appointments with a therapist (number of sessions dependent on clinical need up to a maximum of three sessions or 1.5 hours in total). They will be no resting splints provided, no explicit exercise prescription, no manual therapy (i.e. joint mobilizations) or electrotherapy, with assessment and treatment to be documented using a standardized log.

8.3.6 Outcomes

Pain intensity levels at 3-months will be our primary outcome (dependent variable) and will be investigated by the Visual Analog Scale (VAS).[25] It consists of a bidirectional 10 cm responsiveness scale with two anchors at either end of the scale; 0 - "no pain" and 10 - "worst possible pain". Patients will be instructed to draw a vertical mark on the scale indicating their pain level.[25] Secondary outcomes that will be collected consist of the Global Rating of Change[26], quality of life with EQ-5D[27], the Australian/Canadian Osteoarthritis Hand Index (AUSCAN)[28], the PRWHE and grip strength.[29] While several domains can be assessed in OA trials, the Outcome Measures in Arthritis Clinical Trials (OMERACT) expert group[30] has identified 3 core variables (pain, function and global assessment) that require inclusions in OA studies.[30]

8.3.7 Participant Timeline

Outcome measures will be collected through Patient Reported Outcomes; at baseline (14-30 days after randomization for all participants), at 3-months, 6-months and 12-months.

8.3.8 Sample Size Estimation

Response to treatment will be based on OMERACT-OARSI criteria.[30,31] According to these criteria, a response has occurred if the patients experience a reduction of ≥50% from baseline and an absolute reduction of ≥20% in OA pain intensity (10 cm VAS). If we

consider a 20% as a clinical important margin on VAS pain scale, 80% power at 5% significance level and assuming a scenario of 25% loss of follow-up a total sample size of 347 patients will be needed (Figure 1)

8.3.9 Recruitment

Participants will be recruited through the email list of The Arthritis Society and from the Hand and Upper Limb Centre (HULC) at St. Joseph's Health Care Hospital in London, Ontario. This will be conducted by contacting people who have previously expressed interest in participating in research initiatives through the organization. The Arthritis Society is a non-profit organization a with a well-established network and facilitates at the Federal and Provincial level to raise awareness and community engagement for people with arthritis in more than 40 communities across Canada. The HULC Centre is a respected, world renowned center of excellence in education, research, and treatment of patients with complex conditions affecting hands, wrists, elbows and shoulders requiring specialized care. Patients that are covered under OHIP have accessibility to the HULC clinic. One of the most common conditions that is treated at HULC is patients with arthritis.

8.3.10 Allocation

We will use block randomization with blocks of randomly selected sizes through a central web- based randomization system in a 1:1 ratio for the two arms. Central randomization will be conducted using a central randomization web-based program. The randomization process will be initiated by the trial coordinator who will access the web-based system and enter the patient's information and confirmation of eligibility criteria. In order to secure the allocation concealment only once the participant will be registered in the trial then the random allocation will be generated by central randomization. Therefore, we will control for any confounding factors during randomization, but also to eliminate "selection bias".[19,32]

8.3.11 Blinding

To avoid performance bias, participants will be aware that two procedures (active treatments) are being compared. However, they will be unaware that one treatment is a control, as neither the consent forms nor the verbal explanations referred to the attention control intervention as a control treatment. Thus, participants could reasonably expect an improvement regardless of treatment received. All interventions will be delivered by physiotherapists who work at HULC which they are certified hand therapists. They will be independent of the recruitment and randomization procedures, and they will attend a training session delivered by the trial team. Participants will receive ongoing support and guidance regarding the intervention. Therapists will be trained to deliver both the experimental and control interventions without knowing which one it is. Contamination will be minimized through monitoring the treatment logs completed at each session. To protect against detection bias[18], the outcome assessor will be blind to group allocation and independent of the treatment delivery. Participants will be requested not to disclose group allocation to the outcome assessor. If an outcome assessor will be unblinded, this will be recorded

8.4 Data Collection

8.4.1 Primary outcome

Hand pain will be the primary outcome measure at 3 months, and it will be measured using a 100mmVAS by asking "on this line, where would you rate your pain, using the last 7 days as a timeframe. It consists of a bidirectional 100 mm responsiveness scale with two anchors at either end of the scale; 0 - "no pain" and 10 - "worst possible pain". Patients will be instructed to draw a vertical mark on the scale indicating their pain level.[25] The VAS scale is valid and retest reliable in an outpatient clinical practice setting.[33]

8.4.2 Secondary Outcomes

The Patient-Rated Wrist/Hand Evaluation (PRWE)is a self-administered questionnaire which has 2 subscales of pain (5-items) and function (10-items). The PRWE was originally developed and tested for people with distal radius fracture (DRF) and later validated as applicable to the wrist/hand for multiple conditions including arthritis as the PRWHE.[45] Each item is scored from 0 to 10 scale which 10 indicates the worst possible pain or disability.

The Australian and Canadian Osteoarthritis Index (AUSCAN) is a 15-item self-reported disease specific questionnaire measuring pain (5-items), function (9-items) and stiffness (1-item) in the hand on a scale from 0 – none to 4 – extreme for all items.[28]

Global rating of change (GROC) is patient-reported outcome that will be evaluated at 3-, 6- and 12-months follow-up. Participants will be asked to rate their overall change in hand pain on a six- point Likert scale (completely recovered, much improved, improved, no change, worse, much worse). GROC has been used to evaluate outcomes in clinical trials of OA pain.[26,35,36]

Hand grip strength will be evaluated at baseline, at 3-, 6- and 12-months follow-up with a Jamar hand-held dynamometer.[29] The testing procedure for evaluating hand grip strength will use a standardized positioning with Jamar grip dynamometers that will be calibrated. Participants will be requested to complete three trials of hand grip strength bilaterally with a 15 s time break across the three measurements. The mean of the three trials will be calculated. For each trial, participants were seated comfortably in a chair, had their elbow flexed with the forearm and wrist in a neutral position. They will be asked to hold the grip for 2 to 3 s to ensure that the maximum hand grip strength had been achieved. Hand grip strength assessment has been found a valid and reliable procedure. Pooled results from a recent meta-analysis have indicated an ICC 0.95, 95% CI: -0.93 to 0.97 for upper extremity conditions.[37] Regarding the minimum clinically important difference (MCID) of hand grip strength that was based on a distribution-based method indicated that MCID estimates are of 0.84 kg (affected side) and 1.12 kg (unaffected side) in the carpometacarpal osteoarthritis.[37]

The standard format of the EQ-5D-5L descriptive classification system developed by the EuroQoL Group consists of five dimensions of health, each with three levels of problems. It is a brief self- reported generic measure of current health that consists of five dimensions (Mobility, Self-Care, Usual Activities, Pain/Discomfort, and Anxiety/Depression), each with three levels of functioning (no problems, some problems, and unable to/extreme problems). The EQ-5D-5L appears to be a valid extension of the 3-level system which improves upon the measurement properties, reducing the ceiling while improving discriminatory power and establishing convergent and known-groups validity.[38]

8.5 Data Management

Data will single entered into the database by the study personnel. We will have 2 full-time clinical research coordinators and 2 research assistants with research-related duties that will include to prepare all study forms and materials, complete and maintain ethics approvals, maintain study databases, assist with data collection, database setup and management. The trial coordinator will be primarily responsible for subject recruitment and maintaining consent documentation, production of intervention tools (handbooks), maintaining and updating the trial policies and procedures manual, monitoring staff compliance with hospital research policies and certifications manual, updating participants in study processes and outcomes and support to the team conduct of the research.

8.6 Statistical Methods

8.6.1 Statistical Analysis

Participants will be analyzed according to the treatment group to which they will be randomized (intention-to-treat analysis). Descriptive statistics will be used to summarize for the baseline characteristics. For the primary outcome, Generalized Linear Modeling (GLM) will test the between group differences over time, with age and gender as covariates. The magnitude of the treatments will be reported as effect sizes for the whole group and by gender. Clinically important differences along with 95% confidence intervals

will also be calculated/reported for between- and within-group differences. The secondary outcomes will be analyzed in a similar manner to the primary outcome measure. In case of missing data, Multiple Imputation (MI) will be performed to resolve any missing data issues.

8.7 Data Monitoring

The data monitoring ethics committee (DMEC) will be independent of the trial and it will be tasked with monitoring ethical, safety and data integrity. The DMEC will be assembled by 1 rheumatologist, 1 physical therapist and 1 senior statistician. All adverse events occurring after entry into the study and until hospital discharge will be recorded.

8.8 Auditing

All sites will be visited to ensure smooth implementation of the interventions within the trial. This quality control process involved the same clinical research fellow auditing treatment logs and notes and observing experimental arm intervention sessions.

8.9 Ethics and Dissemination

8.9.1 Research Ethics Approval

The protocol will be reviewed and approved by the institutional research ethical board (REB) with respect to scientific content and compliance with applicable research and human subjects' regulations

8.9.2 Informed Consent Process

All patients will provide written informed consent to participate in the study. If patients are not capable of providing consent the informed consent will be requested from the substitute decision maker.

8.9.3 Confidentiality

Data collection will adhere to Health Insurance Portability and Accountability Act (HIPAA) guidelines.

8.9.4 Declaration of Interests

The authors declare no conflict of interest

8.9.5 Access to Data

Data will be stored at HULC lab which is very secure place and only authorized personnel have access to that area. Data can be available upon request to St. Joseph's Hospital Health Care London.

8.9.6 Ancillary and Post-trial Care

No specific post-trial care will be required

8.9.7 Dissemination and Policy

The study results will be presented in the Osteoarthritis Research Society international conferences. Data obtained from this trial will be published in open access peer review journal.

8.10 Feasibility

Successful enrolment of the patients is always a potential pitfall of clinical research. At HULC we have enrolled in the past more than 2000 patients in our clinical studies and have (Canada Foundation for Innovation) CFI-funded patient testing infrastructure to complete this work. HULC is situated as one of the biggest upper extremity unit in Canada. Over 14,000 patients visited annually this facility for therapy providing direct access to cohort of patients required for this work. Based on these experiences, we will develop an ambitious and impactful timeline that is reasonable given our expertise and resources. The cost will involve no special equipment, but only the payments of research and clinical personnel. The patient parking and commuting will be covered from our lab during the follow-up days.

8.11 Significance

While medications such as non-steroidal anti-inflammatory drugs and analgesics relieve musculoskeletal signs and symptoms; disease modifying drugs have shown to not be effective.[3,39,40] Tumor necrosis factor inhibitors have a positive role in inflammatory arthritis[41,42], but did not show any effect in reducing pain for hand OA. [43,44] Considering the lack of efficacy and the view of high costs of TNF inhibitors,[45] self-management is fundamental to "living well while creating a future without arthritis". Thus, it is important that research define strategies that are best to lessen pain and improve function and preserve joints. Our research will accomplish that aim in several ways. Most importantly, the exercise and the joint protection programs will be provided in an online version for open access use that will be free of charge.

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Outcome: *Pain levels (0 – 10) Visual Analogue Scale.*

Alpha α error = 0.05;

Beta β error = 0.2;

N=size per group;

z_x= the z-score/standard normal deviate for a two-sided x;

δ = a clinically acceptable margin;

S^2= Pooled standard deviation of both comparison groups;

$$N = 2 \times \left(\frac{z_{1-\frac{\alpha}{2}} + Z_{1-\beta}}{\delta} \right)^2 \times s^2$$

Figure 8-1. Sample Size calculation

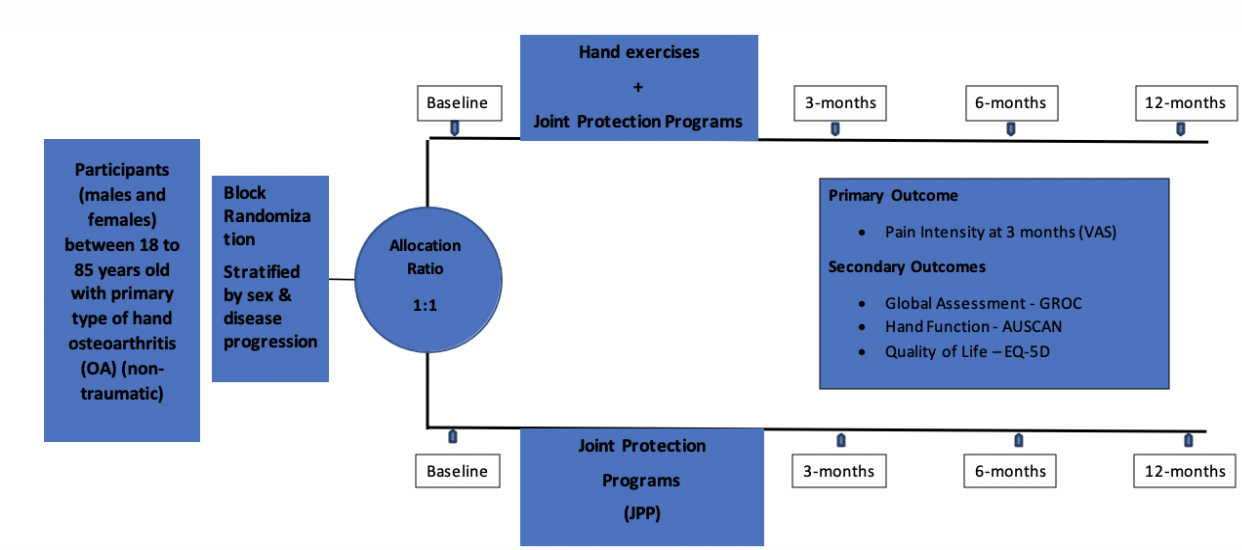

Figure 8-2. Flow diagram

Chapter 8

9 General discussion and future directions

9.1 Overview of this dissertation

The purpose of this thesis was to provide evidence to better understand joint protection interventions for people with hand arthritis. Arthritis is mainly symptomatic and treatment strategies like joint protection may help to preserve joint function and mediate pain. There are several factors that may affect the efficacy of joint protection intervention and how these techniques are implemented into practice. To better understand these factors, we conducted a thorough literature to investigate existing gaps on joint protection programs to identify existing gaps in knowledge. We conducted 5 studies and we design a protocol for a superiority trial to test the efficacy of standardized updated joint protection techniques with hand exercises.

The first study that we conducted was a scoping review to map all the available evidence in published and unpublished material around joint protection. This was an important step because we found many trials that were never synthesized and analyzed together. We also found that the most commonly reported responsible person for joint protection delivery was an Occupational Therapist. We mapped all the available joint protection principles from the grey literature, and we found that were many joint protection techniques that were never mentioned or it was unclear if were ever tested.

The literature search from the first study enabled an evidence synthesis of all the available RCTs for people with rheumatoid arthritis and osteoarthritis in the hand. We assessed the efficacy of joint protection in three main outcomes (pain, function and grip strength) and we found that there was low quality certainty of small effects on pain outcomes that did not reach the clinically important margin for people with rheumatoid arthritis in the hand. For people with hand OA, we found that the effects of joint protection were unknown because there was lack of reporting and we were unable to calculate the effects.

The third study was an overview of systematic reviews that was focused to gather the evidence from systematic reviews and to understand why nine different systematic reviews

had findings in different directions. We assessed all included reviews and only 2 reviews were of high quality. The majority of the reviews were mainly repeating the results from the primary studies without re-analyzing and calculating the effects, but their recommendations were based mainly on statistical significance. Our overview identified that reviews used different critical appraisal tools and rarely these tools were taken into account when results were interpreted from the authors.

The fourth study was a survey that aimed to understand individuals' barriers, facilitators, expectations and preferences. An important finding was that the majority of the people that participated in the study never heard of joint protection. This a very important finding because it highlights that there is a major gap in implementation of JPP between research and clinical practice. Several barriers were identified such as cost of the program, time when the program was offered and work commitments. Also, participants expressed their preferences about the joint protection components that they think are useful to them. More than 70% of respondents reported as extremely useful to find new ways to do tasks differently to reduce joint loading.

The fifth study was a measurement study that tried to quantify the content validity of three self-reported outcomes that are commonly used for people with hand arthritis. In this study we used statistical methods to calculate the content validity index for each of item of the scale, for the overall scale and kappa agreement among the raters. We found very high content validity index for the three self-reported outcomes in terms of their relevancy and their clarity for people hand arthritis. This finding will further support the use of these three self-reported outcomes in clinical studies to measure the construct that the scales represent.

The sixth study was a protocol design for a superiority trial. In this design, we considered all the previous findings that were identified in the systematic review, the survey and the measurement study of the three patient-reported outcomes. Our evidence synthesis found that no high-quality trials exist to test the efficacy of JP interventions in people with hand OA. Another important step was that we factored in the design of the trials the information that we gathered from our survey so the JPP can meet the patients' expectations and preferences. We performed sample size calculation and we found that approximately 347

patients are needed to demonstrate superiority of the experimental arm. The trial protocol adhered to the SPIRIT checklist guidelines.[1]

9.2 Clinical and research implications

In our systematic review we found low quality certainty evidence that joint protection did not improve pain and function scores by a clinically important amount. However, at mid- and long- term follow-up the effects of JP interventions were very close to be clinically meaningful for people with rheumatoid arthritis. The fact that the effects of JPP were unknown for people with hand OA further justifies the rationale of conducting a future trial with adequate power to detect if a real difference exists. In our systematic review, we were unable to extract specific information about JP therefore, we were uncertain what was actually implemented as joint protection programs.

In our survey we identified that very few patients with arthritis were aware of or had participated in a joint protection program, given that there is systematic review evidence demonstrating the effectiveness of these programs both for patients with rheumatoid arthritis and osteoarthritis in the hand. Lack of awareness of JPP was greater than anticipated and potentially reflects lack of access to programs, lack or interest in participating and lack of awareness from clinicians who should be recommending JPP. Trends for patients with arthritis to engage in a broad array of conservative approaches, and their responses to this survey suggest patients would engage in JP if accessible programs were offered. Given the evidence supporting JPP as an important component of self-management of arthritis, this appears to be a substantial gap between research and clinical practice. Therefore, education of health care professionals about this option will potentially improve accessibility to programs and potentially improve clinical outcomes.

In our measurement study we provided new information to support the conceptual foundations of the three selected patient reported outcome measures. The high content validity index of these self-reported questionnaires indicates that these measures can be used with confidence in future clinical studies and in clinical practice. Their evaluation of

relevance and clarity of all the individual items from each outcome measure by including patient input as experts is considered very important and was never quantified before.

Our trial protocol design takes into account all the gathered information from survey, but most importantly results from our meta-analysis indicate that there is a need for a trial for people with hand OA. In this trial, we will implement standardized JP interventions and hand exercises in a specific and measurable way, and we will use strategies to maximize adherence. This trial can provide more useful and effective JPP for people living with hand arthritis and it will contribute to longer-term multi-site studies that combine JPP with wearable sensors.[2]

9.3 Limitations

In this dissertation we conducted 5 studies and we designed a protocol for a superiority trial to provide more useful and effective patient centered JPP. Although, we have some interesting findings our work has several limitations that need to be taken into account when interpreting our findings.

First, the underlying methodology that was used to critically appraise the included RCTs as well as the half standard deviation units that was used as a cut-off score for clinically important benefit was a very conservative approach. We deem that even with a lower threshold the findings would have been inconclusive since the confidence intervals did not exclude even lower thresholds.

Second, in our survey we did not collect further descriptive data such socioeconomic status, education, sex and gender and therefore, this limited our ability to explore potential associations between other factors and participation rates in joint protection programs.

9.4 References

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10 Appendices

Appendix 1. Ethical Approval from Hamilton Research Ethics Board

HiREB
Hamilton Integrated Research Ethics Board

Feb-21-2019

Project Number:3727

Project Title: Barriers, Facilitators, Expectations and Preferences of Joint Protection Programs for Patients with Hand Arthritis.

Student Principal Investigator:

Local Principal Investigator: [redacted]

We have completed our review of your study and are please to issue our final approval. You may now begin your study.

The following documents have been approved on both ethical and scientific grounds:

Document Name	Document Date	Document Version
Consent Clean version	Feb-18-2019	2
[redacted] Questionnaire Version 2	Feb-18-2019	2
McMaster_poster_Clean version	Feb-18-2019	1
Personalized Exercise Questionnaire	Mar-20-2018	1
Protocol Version 2 Clean Version	Feb-18-2019	2

The following documents have been acknowledged:

Document Name	Document Date	Document Version
Cover letter revisions	Feb-18-2019	2
[redacted] Training 2017	May-15-2017	1

Any changes to this study must be submitted with an Amendment Request Form before they can be implemented.

This approval is effective for 12 months from the date of this letter. Upon completion of your study please submit a **Study Completion Form**.

If you require more time to complete your study, you must request an extension in writing before this approval expires. Please submit an **Annual Review Form** with your request.

PLEASE QUOTE THE ABOVE REFERENCED PROJECT NUMBER ON ALL FUTURE CORRESPONDENCE

Good luck with your research,

[redacted]
Chair, HiREB Student Research Committee
McMaster University

10.1 Appendix 2. Letter of Information/ Consent

A Study of joint protection for hand arthritis exercise preferences in Osteoarthritis

Principal Investigator: Dr. Joy Christine MacDermid

[redacted]

Co-Investigator: Pavlos Bobos

School of Rehabilitation Sciences

McMaster University

Hamilton, Ontario, Canada

- **Purpose of the Study:**

You are invited to take part in this study about expectations from joint protection and preferences for exercise. We want to identify the key expectations and preferences for joint protection and the critical barriers and facilitator for exercise in people with arthritis. We are hoping to learn how to design better joint protection programs and exercise programs.

- **Procedures involved in the Research:**

You will find two questionnaires attached with this consent form. You will be asked to complete both questionnaires. The questions will include queries about your preferences for exercise and about your thoughts about joint protection. You will also be asked questions about your diagnosis and management of arthritis. You will also be asked for some demographic/background information like your age and area code.

- **Potential Harms, Risks or Discomforts:**

There are no foreseeable risks involved in participating in this study. You may feel worried about your responses. There are no right and wrong answers and your responses will be kept confidential, so you do not need to worry about this. You do not need to answer questions that you do not want to answer or that make you feel uncomfortable.

- **Potential Benefits**

We cannot promise any personal benefits to you for your participation in this study. The results from this study may benefit society and the scientific community by providing health care providers with a better understanding of barriers and facilitators for exercise and preferences for joint protection in people with arthritis.

- **Confidentiality**

Your data will not be shared with anyone except with your consent or as required by law. All personal information such as your name and e-mail address will be removed from the data and will be replaced with a number. A list linking the number with your name will be kept in a secure place separate from your file. The data, with identifying information removed will be securely stored in a locked office in the research laboratory.

For the purposes of ensuring the proper monitoring of the research study, it is possible that a member of the Hamilton Integrated Research Ethics Board may consult your research data. However, no records which identify you by name or initials will be allowed to leave the hospital. By signing this consent form, you or your legally acceptable representative authorizes such access. If the results of the study are published, your name will not be used and no information that discloses your identity will be released or published without your specific consent to the disclosure.

- **Participation and Withdrawal:**

If you volunteer to be in this study, you may withdraw at any time. You have the option of removing your data from the study. You may also refuse to answer any questions you don't want to answer and still remain in the study. The investigator may withdraw you from this research if circumstances arise which warrant doing so.

- **Information about the Study Results:**

If you would like to receive a summary of this study's results, there is a provision for you to indicate so at the end of the consent form.

Questions about the Study: If you have questions or need more information about the study itself, please contact me at: [redacted]

This study has been reviewed by the Hamilton Integrated Research Ethics Board (HIREB). The HIREB is responsible for ensuring that participants are informed of the risks associated with the research, and that participants are free to decide if participation is right for them. If you have any questions about your rights as a research participant, please call the Office of the Chair, Hamilton Integrated Research Ethics Board at [redacted]

- **CONSENT**

□□I have read the information presented in the information letter about this study.

□□I have had the opportunity to ask questions about my involvement in this study and to receive additional details I requested.

□□I understand that if I agree to participate in this study, I may withdraw from the study at any time or up until ***September 1, 2019.***

□□I have been given a copy of this form.

□□I agree to participate in the study.

Signature: _____ Date: _____

Name of Participant (Printed) _____

1. I agree to have my responses from this project used in future related projects.

[ ] yes

[ ] no

2. [ ] Yes, I would like to receive a summary of the study's results.

Please send them to me at this email address

_____

_____

[ ] No, I do not want to receive a summary of the study's results.

3. I agree to be contacted about a follow-up interview, and understand that I can always decline

the request.

[ ] Yes, please contact me at:

____

[ ] No

10.2 Appendix 3. Survey Questionnaire

Patient opinions on joint protection programs

Start of Block: "Information about this survey"

Q50 **Patient opinions on joint protection programs**

This survey was developed to gain a better understanding of your priorities and goals, specific to joint protection. Your answers to these questions will help us to create more effective joint protection programs for patients living with arthritis in the future.

○ **End of Block: "Information about this survey"**

Start of Block: Block 1

Q1 Please select one of the following options

- ○ I have been diagnosed with hand osteoarthritis (1)
- ○ I have been diagnosed with hand rheumatoid arthritis (2)
- ○ I have been diagnosed with psoriatic arthritis (3)
- ○ I have been diagnosed with some form of arthritis other than hand (4)
- ○ None of the above (5)

Skip To: End of Survey If Please select one of the following options = None of the above

Q2 Please indicate your age below

▼ Under 18 (1) ... 85 or older (9)

Skip To: End of Survey If Please indicate your age below = Under 18

Skip To: End of Survey If Please indicate your age below = 85 or older

Q3 Please select one of the four following options

- ○ I am currently taking part in a joint protection program (1)
- ○ I have previously taken part in a joint protection program (2)
- ○ I have heard about joint protection but have not taken part in a program (3)
- ○ I have not heard about any joint protection programs (4)

Skip To: End of Block If Please select one of the four following options = I have not heard about any joint protection programs

Skip To: End of Block If Please select one of the four following options = I have heard about joint protection but have not taken part in a program

Q4 Where did you attend the joint protection program? Check all that apply.

- ☐ Inpatient- rehabilitation unit (1)
- ☐ Inpatient- hospital (2)
- ☐ Outpatient- hospital (3)
- ☐ Community recreation center (4)
- ☐ Home care (5)
- ☐ A rehabilitation centre/ clinic (6)
- ☐ Family physician's office (7)

Q5 Who provided the joint protection program? Check all that apply.

- ☐ Family physician or specialist (1)
- ☐ Occupational therapist (2)
- ☐ Physiotherapist (3)
- ☐ Hand therapist (4)
- ☐ Kinesiologist (5)
- ☐ Patients (6)

Q6 To what extent did the joint protection program affect the following?

	Very much worse (1)	Much worse (2)	Slightly worse (3)	No change (4)	Slightly better (5)	Much better (6)	Very much better (7)
Stifness (1)	○	○	○	○	○	○	○
Pain (2)	○	○	○	○	○	○	○
Grip strength (3)	○	○	○	○	○	○	○
Hand function (4)	○	○	○	○	○	○	○
Swelling (5)	○	○	○	○	○	○	○

Q7 What other benefits, if any, did joint protection principles cause in your well-being? Please specify.

_____

_____

_____

_____

_____

Q8 What other harms, if any, did joint protection principles cause in your well-being? Please provide examples.

_____

_____

_____

_____

_____

Q9 How often did you use joint protection principles after learning them?

- ○ Not at all (1)
- ○ Occasionally (once a week or less) (2)
- ○ Quite often (once a week at least) (3)
- ○ Always (4)

Q10 Give some examples for how joint protection principles affected you

_____

_____

_____

_____

_____

End of Block: Block 1

Start of Block: Block 1

Q12 Where did you hear about joint protection program? Check all that apply.

- ☐ From my family physician (1)
- ☐ From my therapist (2)
- ☐ From my specialist (e.g. rheumatologist, surgeon) (3)
- ☐ From my family or friends (4)
- ☐ From newspapers/ television/ internet/ radio (5)
- ☐ From my local community center (6)
- ☐ Other (7) _____

Q11 Everyone has barriers and facilitators that affect their ability to participate in health programs. Please list up to three barriers that might make it **difficult** for you to participate in a future joint protection program.

_____

_____

_____

_____

_____

Q13 Please list up to three factors that might make it **easier** for you to participate in a future joint protection program.

_____

_____

_____

_____

_____

Q14 To what extent are the following factors a concern that would make it harder for you to participate in a joint protection program?

	a very big concern (1)	a moderate concern (2)	a slight concnern (3)	neither a concern or help (4)	slightly helpful (5)	moderately helpful (6)	extremely helpful (7)
Having the centre/clinic close to my house (1)	○	○	○	○	○	○	○
Transportation to the centre where program is provided (2)	○	○	○	○	○	○	○
Cost of the program (4)	○	○	○	○	○	○	○
Time when the program was offered (5)	○	○	○	○	○	○	○
My work commitments (6)	○	○	○	○	○	○	○
My personal commitments (7)	○	○	○	○	○	○	○
Support from family/friends (8)	○	○	○	○	○	○	○

Having a friend to participate with (9)	○	○	○	○	○	○	○
Research that shows joint protection works (10)	○	○	○	○	○	○	○
Another patient finding joint protection helpful (11)	○	○	○	○	○	○	○

Q15 Most joint protection programs have pieces that cover:1. Things that affect the loading of your joints2. Products that can be used to make tasks easier3. Pacing4. How to organize tasks to make it easier for your joints5. Ways to manage symptoms 6. How to get or use helpCovering all this information requires about 30 hours of teaching and demonstration. What schedule would you prefer for this type of program? Check one.

- ○ 3 hours, 5 times per week, for 2 weeks (1)
- ○ 2 hours, 3 times per week, for 5 weeks (2)
- ○ 1 hour, 3 times per week, for 10 weeks (3)

Q16 How likely would you be to participate in a program if it is delivered in the following formats? Please rank the options below in order of preference (most preferred option at the top). Your can slide or place the option in it's order.

_____ Online (internet) (1)
_____ Videos (television, DVDs, YouTube etc) (2)
_____ Printed material mailed upon request (pamphlet, guidebook etc) (3)
_____ In clinic (4)
_____ At home (5)

Q17 Who would you like to teach you about joint protection? Check all that apply

- ☐ Family physician or specialist such as rheumatologist (1)
- ☐ Occupational therapist (2)
- ☐ Physiotherapist (3)
- ☐ Hand therapist (4)
- ☐ Kinesiologist (5)
- ☐ Patients living with arthritis (6)
- ☐ Other, please specify (7) _____

Q18 How useful do you think the following components of a joint protection program would be to you?

	Extremely useful (1)	Moderately useful (2)	Slightly useful (3)	Neither useful nor useless (4)	Slightly useless (5)	Moderately useless (6)	Extremely useless (7)
Information on how joint positions can affect joint loading (1)	○	○	○	○	○	○	○
Ways to do tasks differently to reduce joint loading (2)	○	○	○	○	○	○	○
Feedback on if I am doing tasks correctly (3)	○	○	○	○	○	○	○
Information about pacing & organizing activities (4)	○	○	○	○	○	○	○
Advice from health professionals about joint protection (5)	○	○	○	○	○	○	○

Advice from other patients with arthritis about what worked for them (6)	○	○	○	○	○	○	○
Demonstrations of how to do things better (7)	○	○	○	○	○	○	○
Time to discuss tasks that I am currently having difficulty with (8)	○	○	○	○	○	○	○
Sensors that I could wear to tell me how much different activities are loading my joints (9)	○	○	○	○	○	○	○
Information about assistive tools or devices that I could use to make daily tasks easier (10)	○	○	○	○	○	○	○

Information about where to find assistive tools or devices (11)	○	○	○	○	○	○	○

Q19 How important would the following outcomes be to you?

	Extremely important (1)	Very important (2)	Moderately important (3)	Slightly important (4)	Not at all important (5)
Preventing joint deformity (1)	○	○	○	○	○
Reducing pain (2)	○	○	○	○	○
Improving hand function/ activity (3)	○	○	○	○	○
Maintaining grip strength (4)	○	○	○	○	○

Q20 Would you like someone to contact you to see how you are doing after the joint protection program?

- ○ Yes (1)
- ○ No (2)

Skip To: End of Block If Would you like someone to contact you to see how you are doing after the joint protection program? = No

Q21 If you were to do it as a web-based program, how would you like to be contacted for follow-up? Rank these options from 1 to 3, with 1 being your most preferred option. Your can slide or place the option in it's order.

_____ Twice per week (1)
_____ Once a week (2)
_____ Once every two weeks (3)
_____ Once early and once at 6 month (4)
_____ Other, please specify (5)

Q22 After a web-based or in-person program, would you like someone to contact you to discuss your progress?

- ○ Yes (1)
- ○ No (2)

Skip To: End of Block If After a web-based or in-person program, would you like someone to contact you to discuss your pro... = No

Q23 When would you like to be contacted after the completion of the program?

- ○ After a week (1)
- ○ After two weeks (2)
- ○ After a month (3)
- ○ After two months (4)
- ○ Every 6 months (5)
- ○ Every year (6)

Q24 How would you like to be contacted for follow-up? Rank these options from 1 to 3, with 1 being your most preferred option. Your can slide or place the option in it's order.

_____ By telelphone (1)
_____ By email (2)
_____ By mail (3)

Q25 Whom would you prefer to speak with at your follow-up meeting? Rank these options from 1 to 4, with 1 being your most preferred option. Your can slide or place the option in it's order.

_____ The person who provided the joint protection program (1)
_____ Another participant from the joint protection program who I had met (2)
_____ Any person living with arthritis who knows about joint protection (3)
_____ Any knowledgeable health professional (4)

○ **End of Block: Block 1**

Start of Block: Block 4

Q26 Would you participate in web-based forums about joint protection (like a posting board, Facebook group or email list)?

○ Yes (1)

○ No (2)

Q27 How often do you use the following?

	Never (1)	Very rarely (2)	Rarely (3)	Occasionally (4)	Frequently (5)	Very frequently (6)
Heat (1)	)	)	)	)	)	)
Cold (2)	)	)	)	)	)	)
Exercise (3)	)	)	)	)	)	)
Joint protection (4)	)	)	)	)	)	)
TENS machine or other electrical devices (5)	)	)	)	)	)	)
Splints (6)	)	)	)	)	)	)
Modified equipment (7)	)	)	)	)	)	)
Other (8)	)	)	)	)	)	)

Q28 Have you had surgery because of your arthritis?

- ○ Yes, please specify (1) _____
- ○ No (2)

Skip To: End of Block If Have you had surgery because of your arthritis? = No

○ **End of Block: Block 4**

Start of Block: Block 4

Q29 How often do you use your medication?

- ○ Daily (1)
- ○ When you feel pain (2)
- ○ Other, please specify (3) _____

Q30 Is there anything you would like us to know as we work on developing a new joint protection program for people with hand arthritis?

_____

_____

_____

_____

_____

Q31 We are planning to develop a new joint protection program that would be updated and based on patient input. Would you be interested in participating in the following? Check all that apply

- ☐ Helping develop a new joint protection program (1)
- ☐ Participating in a study of a new joint protection program (2)
- ☐ Being a learner after the joint protection program has been tested (3)

Q32 If you would like to be contacted about the above, how would you prefer to be contacted?

- ○ By telephone (1) _____
- ○ By post mail (2) _____
- ○ By email (3) _____

Q33 Would you like to receive a summary of the results this survey

- ○ if yes, please provide your email (1) _____
- ○ No (2)

Q34 Would you be willing to answer a few more questions that would help us understand what outcomes we should be measuring in our research about hand arthritis? This will take another 5 minutes.

- ○ Yes (1)
- ○ No (2)

Skip To: End of Survey If Would you be willing to answer a few more questions that would help us understand what outcomes w... = No

○ **End of Block: Block 4**

Start of Block: Block 4

Q35 "**Instructions**" and **Items** that could be listed on a patient questionnaire are listed below. In each section there is an instruction 1st and then the items. For each item we would like you to tell us: (1) how relevant that item would be to you and other people living with arthritis, and (2) how clear that item is

	Do you think the instruction or the item is?				Do you think the instruction or the item is?			
	not relevant (1)	somewhat relevant (2)	quite relevant (3)	highly relevant (4)	not clear at all (1)	needs major revision (2)	needs minor revision (3)	very clear (4)
Rate the amount of pain in your wrist - At rest (1)	○	○	○	○	○	○	○	○
Rate the amount of pain in your wrist - When doing a task with a repeated wrist/hand movement (2)	○	○	○	○	○	○	○	○
Rate the amount of pain in your wrist - When lifting a heavy object (3)	○	○	○	○	○	○	○	○

Rate the amount of pain in your wrist - When it is at its worst (4)	○	○	○	○	○	○	○	○
How often do you have pain? (0 = never, 10 = always) (5)	○	○	○	○	○	○	○	○

Q41 "**Instructions**" and **Items** that could be listed on a patient questionnaire are listed below. In each section there is an instruction 1st and then the items. For each item we would like you to tell us: (1) how relevant that item would be to you and other people living with arthritis, and (2) how clear that item is

	Do you think the instruction or the item is?				Do you think the instruction or the item is?			
	not relevant (1)	somewhat relevant (2)	quite relevant (3)	highly relevant (4)	not clear at all (1)	needs major revision (2)	needs minor revision (3)	very clear (4)
Rate how difficult it was doing the things listed below, this week - Fasten buttons on your shirt? (1)	○	○	○	○	○	○	○	○
"Rate how difficult it was doing the things listed below, this week - Cut meat (or vegetables) using a knife? (2)	○	○	○	○	○	○	○	○
"Rate how difficult it was	○	○	○	○	○	○	○	○

doing the things listed below, this week - Turn a door knob with your affected hand (3)								
"Rate how difficult it was doing the things listed below, this week - Use your affected hand to push up from a chair? (4)	○	○	○	○	○	○	○	○
"Rate how difficult it was doing the things listed below, this week - Carry a heavy object in your affected hand? (5)	○	○	○	○	○	○	○	○
"Rate how difficult it was	○	○	○	○	○	○	○	○

doing the things listed below, this week - Use bathroom tissue with your affected hand? (6)								

Q42 "**Instructions**" and **Items** that could be listed on a patient questionnaire are listed below. In each section there is an instruction 1st and then the items. For each item we would like you to tell us: (1) how relevant that item would be to you and other people living with arthritis, and (2) how clear that item is

	Do you think the instruction or the item is?				Do you think the instruction or the item is?			
	not relevant (1)	somewhat relevant (2)	quite relevant (3)	highly relevant (4)	not clear at all (1)	item needs major revision (2)	item needs minor revision (3)	very clear (4)
"Rate how difficult it was doing your usual activities, this week. By usual activities, we mean what you did before you started having a problem with your wrist/hand." - Personal care activities (like dressing/washing) (1)								
"Rate how difficult it was doing your usual activities, this week. By usual activities, we mean what you did before you started having a problem with your wrist/hand." - Household work (like								

cleaning or maintenance) (2)								
"Rate how difficult it was doing your usual activities, this week. By usual activities, we mean what you did before you started having a problem with your wrist/hand." - Work (your job or other work) (3)								
"Rate how difficult it was doing your usual activities, this week. By usual activities, we mean what you did before you started having a problem with your wrist/hand." - Recreational activities (4)								

Q44 "**Instructions**" and **Items** that could be listed on a patient questionnaire are listed below. In each section there is an instruction 1st and then the items. For each item we would like you to tell us: (1) how relevant that item would be to you and other people living with arthritis, and (2) how clear that item is

	Do you think the instruction or the item is?				Do you think the instruction or the item is?			
	not relevant (1)	somewhat relevant (2)	quite relevant (3)	highly relevant (4)	not clear at all (1)	item needs major revision (2)	item needs minor revision (3)	very clear (4)
"Please indicate your ability to perform these activities with the affected hand."- Turn a Key (1)								
"Please indicate your ability to perform these activities with the affected hand."- Pick up a coin (2)								
"Please indicate your ability to perform these activities with the affected hand."- Write (3)								

"Please indicate your ability to perform these activities with the affected hand."- Squeeze Toothpaste (4)								
"Please indicate your ability to perform these activities with the affected hand."- Hold a glass of water (5)								
"Please indicate your ability to perform these activities with the affected hand."- Turn a Doorknob (6)								
"Please indicate your ability to perform these activities with the affected hand."- Use a Knife to Cut Food (7)								

Q45 "**Instructions**" and **Items** that could be listed on a patient questionnaire are listed below. In each section there is an instruction 1st and then the items. For each item we would like you to tell us: (1) how relevant that item would be to you and other people living with arthritis, and (2) how clear that item is

	Do you think the instruction or the item is?				Do you think the instruction or the item is?			
	not relevant (1)	somewhat relevant (2)	quite relevant (3)	highly relevant (4)	not clear at all (1)	item needs major revision (2)	item needs minor revision (3)	very clear (4)
"Please indicate your ability to perform the following task while using both your hands?" - Open a Jar (1)	)	)	)	)	)	)	)	)
"Please indicate your ability to perform the following task while using both your hands?" - Button a shirt/blouse (2)	)	)	)	)	)	)	)	)
"Please indicate your ability to perform the following task while using both your hands?" - Tie your shoes (3)	)	)	)	)	)	)	)	)
"Please indicate your ability to perform the following task while using both your hands?" - Wring a dishcloth/washcloth (4)	)	)	)	)	)	)	)	)

"Please indicate your ability to perform the following task while using both your hands?" - How often did you have pain in your thumb at rest? (5)	)	)	)	)	)	)	)	)
"Please indicate your ability to perform the following task while using both your hands?" - How often did the pain in your thumb interfere with your daily activities? (6)	)	)	)	)	)	)	)	)
"Please indicate your ability to perform the following task while using both your hands?" - How often did the pain in your hand interfere with recreational activities? (7)	)	)	)	)	)	)	)	)
"Please indicate your ability to perform the following task while using both your hands?" - How often did the pain in your thumb interfere with your sleep? (8)	)	)	)	)	)	)	)	)

"Please indicate your ability to perform the following task while using both your hands?" - How often did the pain in your thumb worsen your mood? (9)								

Q46 "**Instructions**" and **Items** that could be listed on a patient questionnaire are listed below. In each section there is an instruction 1st and then the items. For each item we would like you to tell us: (1) how relevant that item would be to you and other people living with arthritis, and (2) how clear that item is

	Do you think the instruction or the item is?				Do you think the instruction or the item is?			
	not relevant (1)	somewhat relevant (2)	quite relevant (3)	highly relevant (4)	not clear at all (1)	item needs major revision (2)	item needs minor revision (3)	very clear (4)
"The following questions ask about your satisfaction with the indicated hand or thumb over the past week." - Motion in your affected thumb (1)	○	○	○	○	○	○	○	○
"The following questions ask about your satisfaction with the indicated hand or thumb over the past week." - Strength of your affected hand (2)	○	○	○	○	○	○	○	○
"The following questions ask about your satisfaction with the indicated hand or thumb over the past week." - Pain level of your affected thumb (3)	○	○	○	○	○	○	○	○

"The following questions ask about your satisfaction with the indicated hand or thumb over the past week."- Overall function of your hand (4)	○	○	○	○	○	○	○	○

Q47 "**Instructions**" and **Items** that could be listed on a patient questionnaire are listed below. In each section there is an instruction 1st and then the items. For each item we would like you to tell us: (1) how relevant that item would be to you and other people living with arthritis, and (2) how clear that item is

	Do you think the instruction or the item is?				Do you think the instruction or the item is?			
	not relevant (1)	somewhat relevant (2)	quite relevant (3)	highly relevant (4)	not clear (1)	item need some revision (2)	clear but need minor revision (3)	very clear (4)
"Rate your pain" - At rest (1)	○	○	○	○	○	○	○	○
"Rate your pain" - Gripping (2)	○	○	○	○	○	○	○	○
"Rate your pain" - Lifting (3)	○	○	○	○	○	○	○	○
"Rate your pain" - Turning (4)	○	○	○	○	○	○	○	○
"Rate your pain" - Squeezing (5)	○	○	○	○	○	○	○	○
"Rate your stiffness" - After first wakening in the morning (6)	○	○	○	○	○	○	○	○

Q49 "**Instructions**" and **Items** that could be listed on a patient questionnaire are listed below. In each section there is an instruction 1st and then the items. For each item we would like you to tell us: (1) how relevant that item would be to you and other people living with arthritis, and (2) how clear that item is

	Do you think the instruction or the item is?				Do you think the instruction or the item is?			
	not relevant (1)	somewhat relevant (2)	quite relevant (3)	highly relevant (4)	not clear at all (1)	item needs major revision (2)	item needs minor revision (3)	very clear (4)
"Rate your difficulty when" - Turning taps/faucets on (1)	○	○	○	○	○	○	○	○
"Rate your difficulty when" - Turning a round doorknob or handle (2)	○	○	○	○	○	○	○	○
"Rate your difficulty when" - Doing up buttons (3)	○	○	○	○	○	○	○	○
"Rate your difficulty when" - Fastening jewellery (4)	○	○	○	○	○	○	○	○
"Rate your difficulty when" - Opening a new jar (5)	○	○	○	○	○	○	○	○
"Rate your difficulty when"- Carrying a full pot with one hand (6)	○	○	○	○	○	○	○	○
"Rate your difficulty when" - Peeling vegetables/fruits (7)	○	○	○	○	○	○	○	○
"Rate your difficulty when"- Picking up large heavy objects (8)	○	○	○	○	○	○	○	○

"Rate your difficulty when"- Wringing out wash cloths (9)	○	○	○	○	○	○	○	○

Curriculum Vitae

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Honours and Awards:	Ontario Graduate Scholarship (OGS) 2017-2018, 2018-2019 Canadian Institutes of Health Research Doctoral Award - Frederick Banting and Charles Best Canada Graduate Scholarships (CGS-D) 2018-2021
Related Work Experience	Research Coordinator Lawson Health Research Institute 2017-2019

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