

**Task-oriented training with computer gaming in people with rheumatoid arthritis or  
hand osteoarthritis: A quasi-mixed methods pilot study**

by

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A thesis submitted to the Faculty of Graduate Studies of  
The University of Manitoba  
in partial fulfillment of the requirements of the degree of

Doctor of Philosophy

Applied Health Sciences PhD Program  
Faculty of Graduate Studies  
University of Manitoba  
Winnipeg

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## **Abstract**

### **Background**

A computer game based Telerehabilitation platform has been developed to provide a seamless system for hand exercise and assessment in home settings for people with arthritis. The exercise program involves task-oriented training of real life object manipulation tasks performed with computer gaming. The platform will also be integrated with a telemonitoring, computer game based hand function assessment application.

### **Objectives**

1) To determine test-retest reliability and convergent validity of the assessment application protocol in people with rheumatoid arthritis or hand osteoarthritis, 2) To conduct a pilot randomized controlled trial for assessing the feasibility, and therapeutic effects of the task-oriented training compared to conventional hand exercises, and 3) To qualitatively evaluate participants' experiences on their respective exercise programs.

### **Methods**

Performance during three different object manipulation tasks was evaluated by the assessment application protocol on 40 people with arthritis. The performance measures were correlated with other common hand function measures. A six-week pilot randomized trial was conducted on 16 individuals with arthritis. The Arthritis Hand Function Test (AHFT), the Disabilities of Arm, Shoulder and Hand (DASH) questionnaire, exercise compliance and task performance during three object manipulation tasks were the clinical outcomes. Focus group interviews were conducted on seven participants who had before received their home exercise programs.

## **Results**

The protocol demonstrated moderate to high test-retest reliability (ICCs between 0.5-0.84) of performance measures. Spearman correlation coefficients ( $\rho$ ) between task performance measures and other measures of hand function were low to moderate ( $0.4 < \rho < 0.5$  to  $0.7$ ). The pilot trial was not successful in terms of participant recruitment but demonstrated feasibility of study procedures, resources, and management. Except for two dexterity sub-scales of the AHFT, there were no significant differences in other clinical measures. Exercise compliance was  $>85\%$  in both groups. The qualitative study provided initial evidence on the appropriateness, acceptance, perceived benefits, and a few practical difficulties in performing each exercise program.

## **Conclusions**

The hand function assessment application warrants validation in a variety of object manipulation tasks and in different patient populations. In order to proceed to a full-fledged trial, additional recruitment strategies, and revisions in the inclusion criteria must be considered.

## **Acknowledgements**

I am forever grateful to my advisors Dr. Tony Szturm and Dr. Barbara Shay for the constant guidance, support and encouragement that they provided during my graduate program.

I would like to extend special gratitude to my advisory committee members, Dr. Elizabeth Ready and Dr. David B Robinson for their encouragement and advice during the course of my study. I also take this opportunity to thank Dr. Joy C MacDermid, for agreeing to be the external examiner, and for the feedback and questions.

This work would not have been possible without the commitment and active participation of the study participants. I thank each of them. Special thanks to Corrie Billedeau, Emeritus Member of Consumer Advisory Council, Canadian Arthritis Network for her valuable inputs and suggestions and assistance in the recruitment process.

I am also grateful to the study staff for their contributions towards this work and my other graduate student colleagues for all the good times in the lab. Special thanks to my husband Srikesavan Sabapathy for his constant encouragement throughout the program.

I thankfully acknowledge the Canadian Arthritis Network (CAN) operating grant that supported me with a graduate student funding to complete my graduate studies. I would also like to acknowledge the Graduate Student Travel Award, Faculty of Graduate Studies, and the Applied Health Sciences Graduate Student Travel Award, University of Manitoba which enabled me to present a few sections of this work at the Second

Singapore Rehabilitation Conference, Singapore in 2013 and at the American Physical Therapy Association-Combined Sections Meeting, Chicago in 2012.

Lastly, I am ever grateful to my undergraduate Physiotherapy teachers Miss. Mary Chidambaram and Mr. Srinivasan Ramanathan in India who will continue to be inspirations throughout my academic life.

### **Dedication**

This thesis work is dedicated to my son Andrew Samuel Srikesavan

Cynthia Swarnalatha Srikesavan

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## **Introduction**

### **Clinical features of rheumatoid arthritis and osteoarthritis**

Rheumatoid arthritis is a chronic, systemic inflammatory disease affecting the synovium and adjacent tissues of a joint. The condition presents itself as an acute symmetric polyarthritis developing over a few months or years, especially in the small joints of the hand, wrists or feet and in other major joints such as the hip and knee, leading to reduced function. In most people affected, the clinical course is progressive and unpredictable [1, 2] with remissions and exacerbations of joint inflammation leading to irreversible structural damage in joints and functional loss. The aetiology of rheumatoid arthritis is unclear, although some genetic and environmental factors are known to play a role. Thirty percent of concordance has been noted in monozygotic twins, while infections, vaccination, smoking, periodontal disease, and emotional trauma are some of the environmental factors. The presence of HLA-DR4 is a genetic risk factor identified in rheumatoid arthritis.

In rheumatoid arthritis, inflammation of the synovium and surrounding peri-articular structures contribute to ligament laxity, weakening of muscles, teno-synovitis, joint stiffness and reduced joint range of motion. Other common systemic manifestations of rheumatoid arthritis include rheumatoid nodules found in pressure areas around joints, ocular conditions such as scleritis and Kerato-conjunctivitis sicca, lung conditions such as interstitial disease and nodular lung disease and cardiac diseases such as pericarditis. In 80-90% of people affected with rheumatoid arthritis, the metacarpo-phalangeal and

proximal inter-phalangeal joints of the hands and wrist joints are involved [3, 4].

Inflammation and proliferation of synovial tissues eventually lead to weakening of adjacent joint structures, cartilage destruction and bone erosion resulting in muscle and tendon rupture, tendon imbalance, ligament laxity, joint instability and joint subluxation or dislocations in later stages. Progressing with time, these structural impairments tend to reinforce each other, transforming into severe joint deformities leading to reduced hand function [3].

Osteoarthritis is the most prevalent joint disease [5] primarily caused by ‘wear and tear’ of articular cartilage or secondarily due to injury. The Osteoarthritis Research Society International (OARSI) defines osteoarthritis as, “A progressive disease of synovial joints that represents failed repair of joint damage resulting from stresses that may be initiated by an abnormality in any of the joint tissues (articular cartilage, subchondral bone, ligaments, menisci, periarticular muscles, peripheral nerves and synovium) leading to breakdown of cartilage and bone leading to symptoms of pain, stiffness and functional disability” [6]. Osteoarthritis frequently involves the joints of knees, hips and hands. Osteoarthritis affecting the hands is characterized by progressive cartilage loss and associated damage to joint margins and periarticular structures in the basal thumb, proximal and distal inter-phalangeal finger joints [7]. The condition is highly reported in middle aged and elderly women with greater risk in menopausal stages [8]. With clinical features of joint pain, reduced grip strength and joint deformities such as inter phalangeal Heberden’s nodes, finger flexion deformity and subluxation and adduction of thumb, hand function is compromised by limitations of activities leading to functional dependence.

## **Prevalence of rheumatoid arthritis and hand osteoarthritis**

Worldwide, rheumatoid arthritis has an estimated prevalence of 1 to 2% of the total population. It is seen more in women with a ratio of 2.13:1 compared to men. Currently, more than 233,000 Canadian adults are living with moderate to severe disability from rheumatoid arthritis. Nearly 50,000 Canadians of this population have significant disability in self-care activities. By 2040, the number of new rheumatoid arthritis cases is expected to increase to 23,732 from 17,916 cases reported in 2010. 2.3% of the Canadian population over sixty years of age is living with rheumatoid arthritis and this is expected to increase by 40% in the next thirty years. There is over \$2 billion in direct health care costs for rheumatoid arthritis, which may increase to over \$95 billion in the next thirty years [9, 10].

Osteoarthritis is the leading musculoskeletal disease that causes disability. The Arthritis Alliance of Canada in its 2011 report titled [9], “The Impact of arthritis in Canada: Today and over the Next 30 Years” presents the facts and figures of the prevalence of arthritis in Canada. One out of 100 Canadian adults over the age of twenty years have experienced moderate to severe osteoarthritis pain resulting in limitations in their daily activities. Nearly 4.4 million Canadians were affected with osteoarthritis in 2010 and this is expected to exceed 10.4 million people by 2040. Osteoarthritis is seen more often in women than men by a ratio of 1.46: 1. Osteoarthritis is also expected to increase in numbers in people over the age of 70 years in the near future. Over 49% of people over 70 years of age reported with osteoarthritis in 2010 may increase to 71% by 2040. Approximately 373,428 new cases were observed in 2010, with 48% identified among Canadians over the age of 60 years. This figure is further expected to rise by

53%,reaching around 469,467 new osteoarthritis cases by the year 2040. It has also been assumed that in the next thirty years, for each second, there will be a diagnosis of osteoarthritis made. Approximately ten billion dollars of direct health costs was estimated in 2010, which may reach 550 billion dollars in thirty years.

Prevalence of radiographic hand osteoarthritis (HOA) is very frequent compared to the symptomatic HOA. The radiographic HOA is prevalent from the range of 29-76%, depending on the genetic backgrounds and environmental exposures [11, 12].

Radiographic HOA is seen in 81% of elderly population, while Heberden's nodes are seen in 58% and Bouchard's nodes in 30% of general population of America [13, 14].

The Canadian Community Health Survey 2000-01 [15] reported diagnosis of self reported HOA in 10% Canadians. In a Florida based longitudinal study that included 3327 individuals, 41% had HOA with the second distal phalangeal joint (DIP) demonstrating 35% prevalence , the third joint with 18% and the first carpometacarpal joint with 21% [16]. Prevalence of 13.2% and 26.2% in men and women aged above 70 years; 3.8% and 9.2% symptomatic HOA in men and women > 26 years was reported in a Framingham cohort study [11]. A study from the Netherlands reported 75% of women between 60-70 years of age with HOA in DIP joints, 10-20% aged below 40 years with OA in hands or feet [11]. In a rural sample from former Soviet Republic of Turkmenia, all males above 65 years of age had at least one hand joint with OA [17]. Lowest prevalence in Chinese individuals was reported from data that included 29,621 adults, irrespective of age or sex [18].

## **Statement of the research problem**

Significant restriction in the ability to participate in home, work, family and community life results from progressive impairments, including joint damage, pain and stiffness, reduced finger range of motion and grip strength, and finger deformities in people with rheumatoid arthritis or hand osteoarthritis. In order to improve functional outcomes in both populations, there is a definite need to include the client as an active partner with the health care team and develop cost-effective, supportive exercise platforms and assessment applications. It is also important to minimize pain and loss of manual dexterity and maximize functional independence. There is moderate evidence on the therapeutic effectiveness of exercise programs which often involve range of motion and grip strengthening exercises for people affected with rheumatoid arthritis or hand osteoarthritis. Other components of hand function, such as fine and gross motor skills, and in general, object manipulations, are often not part of the rehabilitation program. Home based programs and client support, which includes regular monitoring of hand function over time is also lacking in arthritis hand rehabilitation.

Therefore, a Tele-rehabilitation platform (TRP) has been designed consisting of a task-oriented hand exercise program coupled with interactive computer gaming. The TRP employs a task-oriented functional approach (i.e. transfer to real life activities). The design allows a broad range of common objects to be seamlessly transformed into ‘therapeutic’ input devices by instrumenting them with a motion-sense mouse. Objects are selected on the basis of physical and material properties, function and task goals to facilitate graded therapeutic exercises, in particular, two, three and four finger use or the whole hand, precision level, repetition and endurance, and resistance and strength. These

object manipulations are used to control and play any computer game, making practice a challenging and engaging experience. Maximizing motivation and engagement is a key consideration, especially for chronic conditions such as arthritis. The platform will also be integrated with a computer game based hand function assessment application that evaluates performance during functional object manipulation tasks. These objective outcomes can then be used to track change as a function of intensity, volume of practice, and tolerance.

### **Purposes of the thesis work**

This thesis work includes two studies that have been conducted on people with rheumatoid arthritis or hand osteoarthritis. The first (Part I) is a measurement focused study that evaluated test re-test reliability and convergent validity of the computer game based hand function assessment application protocol. The second study (Part II) is a quasi-mixed methods pilot study that describes the feasibility of conducting a randomized controlled trial and evaluating the therapeutic effects of the home based task-oriented hand exercise program compared to conventional hand exercises. An embedded phenomenological qualitative study explored the subjective experiences of the study participants' on performing their respective hand exercise programs.

This thesis document is organized into four major sections: 1) Part I, 2) Part II , 3) overall discussion and 4) conclusions.

Part I of the thesis is presented in six chapters. Chapter 1 presents a brief introduction on the scientific background for conducting the study. Chapter 2 presents a brief literature review on the International Classification of Functioning, Disability and Health (ICF) and common hand function measures used in clinical studies involving



people with rheumatoid arthritis or hand osteoarthritis. Chapter 3 presents the methodology describing the study objectives, study design, participants, recruitment, study setting, ethics approval, and study protocol and data analysis procedures. Chapter 4 presents the study findings, with illustrations and tables. Chapter 5 presents a discussion on the study findings and Chapter 6 includes a list of article and book references cited in the study.

Part II of the thesis is also presented in six chapters. Chapter 1 presents a brief overview of the study purpose and rationale for conducting it. Chapter 2 provides a review of published literature on, the effects of conventional hand exercises on people with rheumatoid arthritis or hand osteoarthritis, current recommendations in exercise therapies for people with arthritis of the hands, motivation with exercise programs, exercise compliance, hand function outcome measures, task-oriented training program for people with arthritis of the hands, interactive computer games in rehabilitation, and brief overview on topics such as mixed methods research, pilot clinical trials, phenomenological strategy of qualitative inquiry, and focus group interviews. Chapter 3 presents the study design, and methodology of the pilot randomized controlled trial and the qualitative study. Chapter 4 presents the results of the pilot trial and the qualitative study, with illustrations and tables. An overarching summary from both research methods is then followed. Chapter 5 includes discussion on the findings and the study limitations. Chapter 6 includes a list of article and book references cited in the study.

The overall discussion and conclusion sections include the general implications of the findings from Part I and Part II of the thesis.

**Part I: Test-retest reliability and convergent validity of the  
computer game based hand function assessment protocol**

## **Abstract**

### **Objectives**

A computer game based hand function assessment application has been developed to provide a standardized method in quantifying task performance during manipulations of common objects or tools or utensils with diverse physical properties and grip and grasp requirements for handling. The study objectives were to determine test-retest reliability and convergent validity of a custom tracking protocol of the assessment application in people with arthritis.

### **Methods**

Three different object manipulation tasks were evaluated twice on forty people with rheumatoid arthritis or hand osteoarthritis in a research facility. Each object was instrumented with a motion sensor and moved in concert with a computer generated visual target. Self-reported joint pain and stiffness levels were recorded before and after each task. Task performance was determined by comparing the object movement with the computer target motion. This was correlated with grip strength, nine hole peg test, Disabilities of Arm, Shoulder and Hand (DASH) questionnaire, and the health assessment questionnaire (HAQ) scores.

### **Results**

The tracking protocol indicated moderate to high test-retest reliability of performance measures for three manipulation tasks, Intra-class correlation coefficients (ICCs) ranging between 0.5 to 0.84,  $p < 0.05$ . Strength of association between task

performance measures with DASH and HAQ composite scores was low to moderate (Spearman rho <0.7). Low correlations (Spearman rho < 0.4) were observed between task performance measures and grip strength, and between all three object performance measures. Significant reduction in pain and joint stiffness ( $p<0.05$ ) was observed after performing each task.

## **Conclusions**

Future prospective studies should be planned for testing the custom tracking protocol in a wide range of object manipulation tasks and in different patient populations.

## **Chapter 1: Introduction**

This chapter provides a brief introduction to the background of the computer game based hand function assessment application.

Difficulties in many gross and fine dexterous activities such as opening jar lids, turning door knobs or keys, gripping small objects between finger tips, and holding heavy objects are well documented in people with rheumatoid arthritis [3, 4] and hand osteoarthritis [19, 20]. A number of performance based tests and self-report measures of hand function are available, however no measures are available to assess performance during object manipulation tasks and associated levels of joint pain and stiffness during those tasks. A computer game based hand function assessment application has been developed as a part of a computer game based Tele-rehabilitation platform (TRP) [21] which also includes a novel task-oriented hand exercise program designed for people with rheumatoid arthritis or hand osteoarthritis. The assessment application is paddle game based and has two custom modes: predictable tracking and an episodic or random game mode. Evaluation of test- retest reliability and convergent validity of the custom predictable tracking protocol in people with rheumatoid arthritis or hand osteoarthritis is discussed in this part of the thesis.

## **Chapter 2: Review of literature**

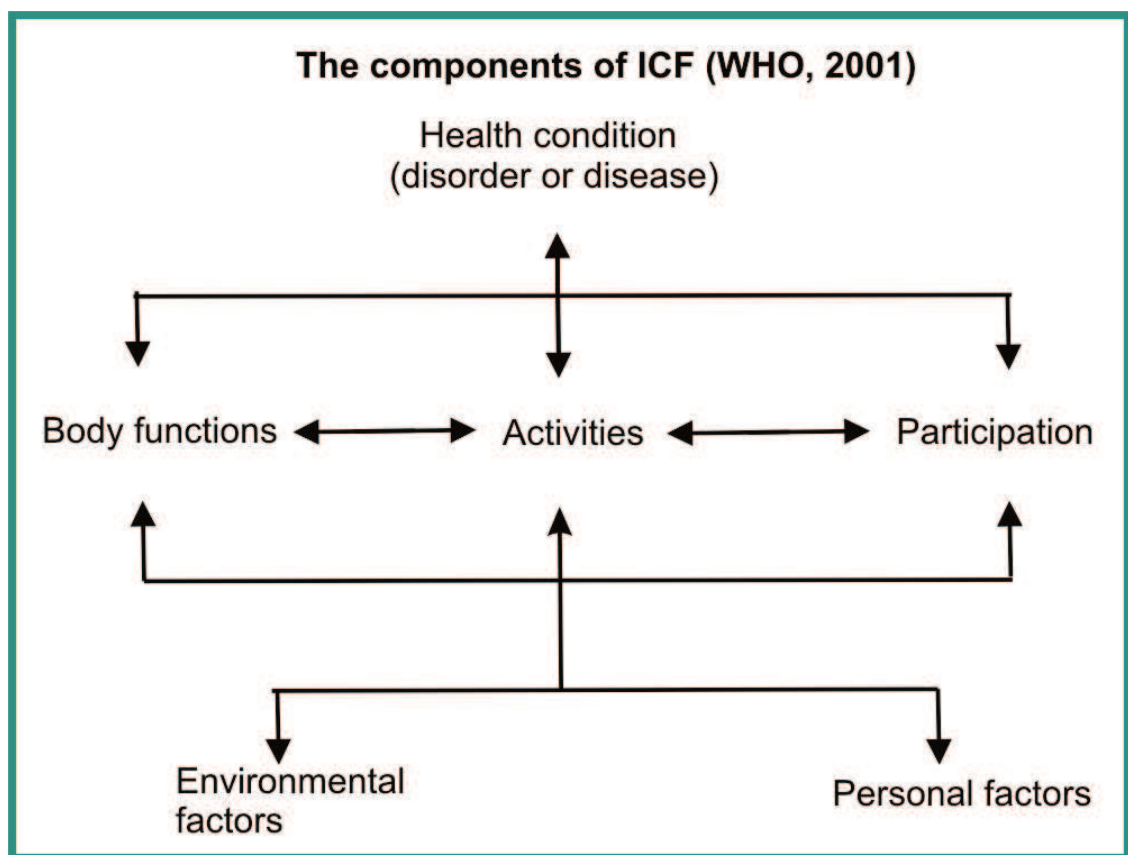
### **2.1. Introduction**

This chapter includes a brief overview on the components of the International Classification of Functioning, Disability and Health (ICF) model and the hand function outcome measures used in clinical research.

### **2. 2. International Classification of Functioning, Disability and Health (ICF)**

The International Classification of Functioning, Disability and Health (ICF) is a framework or classification system developed by the World Health Organization in 2001 to provide a universal language of health, functioning and disability between different users of the health care system. The framework provides a clinical basis of describing health and health related states, outcomes, determinants and changes in health status and functioning [22]. According to the ICF model, functioning and disability in the context of health, relates to the following components: body structures, body functions, activities, participation and personal and environmental factors. An individual's level of functioning involves a dynamic interaction between his or her health conditions, and environmental and personal factors. Impairments, activity limitations and participation restrictions are named for the problems related with deficits in body structures, functions and activities participation. Figure 1 shows the multidimensional and interactive ICF model developed by the WHO.

Figure 1: The components of model



The operating definitions [22] of the ICF components are as follows:

Body structures: Anatomical parts of the body such as organs, limbs and their components

Body functions: The physiological functions of body systems, including psychological functions

Activity: The execution of a task or action by an individual

Participation: Involvement in a life situation

Impairments: Problems in body structure and function, such as significant deviation or loss

Activity limitations: Difficulties an individual may have in executing activities

Participation restrictions: Problems an individual may experience in involvement in life situations

Environmental factors: The physical, social and attitudinal environment in which people live and conduct their lives. These are either barriers to, or facilitators of, the person's functioning.

Functioning: An umbrella term for body structures, functions, activities and participation. It denotes the positive aspects of the interaction between a person's health condition(s) and that individual's contextual factors (environmental and personal factors)



Disability: An umbrella term for impairments, activity limitations and participation restrictions. It denotes the negative aspects of the interaction between a person's health condition(s) and that individual's contextual factors (environmental and personal factors).

An example [22] for applying the components in describing a few of the disabilities associated with rheumatoid arthritis condition is presented in Table 1.

**Table 1 : Application of the ICF components**

Dimensions of disability	Examples
Impairments	Problems of joint structure and muscle power functions
Activity limitations	Difficulty with buttoning, climbing stairs
Participation restrictions	Restricted participation in sports activities
Environmental factors	Building design- Barriers
Personal factors	50 years, Employed

The components are classified as categories coded with an alphabet and a number. The letters b, s, d and e refer to the body functions (b), body structures (s), activities and participation (d) and environmental factors (e). The personal factors are not classified yet. The categories are further coded with numbers that denote the hierarchical levels of precision. The ICF chapters are the first levels of precision and the second, third and fourth levels are more precise. For example, s7 denotes structures related to movement (first ICF level), s730 denotes structure of upper extremity (second ICF level), s7302 denotes structure of hand (third ICF level) and s73021 denotes joints of hands and fingers (fourth ICF level). [17]. The ICF classification has more than 1400 categories and hence has limited use in daily clinical practice. For more practical ways of implementation, ICF core sets which would contain a limited number of the most important ICF categories specific for a health condition are being developed to describe an individual's level of functioning.

A first version of the ICF core set for hand conditions was developed in 2009 [23] through evidence based expert consensus and formal decisions made between 23 health care professionals who treat hand conditions. By considering the important aspects of functioning from the entire list of ICF categories, the ICF core set for hand conditions would provide a universal standard of measurement and reporting of function and disability related to hand conditions. Two types of core sets were developed: comprehensive and brief. Around 117 ICF categories (body structures, body functions, and activities and participation, environmental factors) were included in the comprehensive core set and 23 in the brief core set. The comprehensive ICF core set included 10 components of body structures, 27 of body functions, 38 of activities and participation, and 42 of the environmental factors. The brief core set included 3

components of body structures, 9 of body functions, 8 of activities and participation, and 3 of the environmental factors. All health professionals agreed 100% on including categories of fine hand use, hand and arm use and lifting and carrying objects. A few of the categories included in the brief ICF core set are presented in Table 2.

**Table 2: A few categories in the brief ICF core set for hand conditions**

ICF categories	Title
Body structures s730	Structure of upper extremity
Body functions b280 b710	Sensation of pain Mobility of joint functions
Activities and participation d440 d445 d430	Fine hand use Hand and arm use Lifting and carrying objects
Environmental factors e1	Products and technology

By following similar agreement processes among different health professionals, comprehensive and brief ICF core sets for rheumatoid arthritis and osteoarthritis have also been developed. In 2004, 17 experts from 12 different countries agreed to include 96 categories of the comprehensive ICF core set for rheumatoid arthritis with 18 components of body structures, 25 of body functions, 32 of activities and participation, and 21 of the environmental factors [24]. The brief core set included 25 categories with 7 components of body structures, 8 of body functions, 14 of activities and participation, and 10 of the environmental factors. The ICF categories of fine hand use, hand and arm use and lifting and carrying objects were included in both core sets. This further addresses their importance in relation to activities and participation aspects of functioning in people with rheumatoid arthritis.

In 2004, 17 experts from seven different countries agreed to include 55 categories of the comprehensive ICF core set for osteoarthritis with six components of body structures, 13 of body functions, 19 of activities and participation, and 17 of the environmental factors [25]. The brief core set included 13 categories with three components of body structures, three of body functions, three of activities and participation, and four of the environmental factors. The ICF categories of fine hand use, hand and arm use and lifting and carrying objects were included in the comprehensive core set, while hand and arm use was included in the brief core set.

It is obvious that strong emphasis has been placed on including the ICF activities and participation categories with approximately 32.5% (38/117) in the core set for hand conditions, 33% (32/96) in rheumatoid arthritis and 34.5% (19/55) in osteoarthritis. These support the fact that hand function assessments and intervention programs should strongly consider activities and participation related problems.

### **2.3. An overview of hand function outcome measures used in arthritis clinical studies**

The traditional hand function outcome measures are focused on measures of body structure and functions such as joint range of motion, anatomic deformity, strength, pain and stiffness. In recent years, the focus has shifted to measurement of activities and participation domains of the ICF to have a broader picture of functioning and disability. Two studies provide detailed descriptions on common outcome measurement tools of hand function [26, 27]. Some of the performance based applications are the Jebsen hand function test (JHFT), Sequential Occupational Dexterity Assessment (SODA), Purdue peg board test, Keitel hand functional index, Grip ability test (GAT) and Arthritis Hand Function Test (AHFT). The JHFT involves a standardized assessment of hand function with seven tasks: 1) writing a short sentence, 2) turning over cards, 3) picking up small objects and placing them in a container, 4) simulated feeding, (5) moving large empty cans, 6) moving large weighted can and 7) picking up checkers. SODA is used to assess the ability to complete twelve ADL-related tasks (clinician rated), pain (patient rated) and function (patient rated). The Purdue peg board test evaluates the ability of the individual to place prefabricated pins in holes of a peg board and assemble pins, washers and collars in each hole. The Keitel hand functional index uses 24 movement tests to measure upper extremity function. The GAT measures applied strength during three tasks such as 1) putting a flexi grip stocking over the non-dominant hand, 2) putting a paper clip on an envelope and 3) pouring water from a jug. The AHFT is an 11-item performance based test measuring domains such as grip strength, pinch strength, peg board dexterity, applied dexterity and applied strength. All of these performance based tests measure hand function by the time taken to complete a task. This approach has limited value [28]

because, 1) time does not directly relate to performance [29], 2) it is unclear how speed translates into hand use in daily life [30] and 3) speed should not be prioritized over quality [31].

Self-report measures on function and disability, such as the Health Assessment Questionnaire (HAQ), Arthritis Impact Measurement Scale-2 (AIMS-2), Michigan Hand Questionnaire (MHQ), Cochin hand disability scale, Australian Canadian osteoarthritis hand index (AUSCAN), Patient Rated Wrist Hand Evaluation (PRWHE) and the Disabilities of Arm, Hand and Shoulder (DASH) are being used in studies to measure outcomes on arthritis affecting the hands. The HAQ [32] measures global functioning and health status in people with arthritis, along the following domains: 1) disability 2) discomfort and pain 3) drug side effects (toxicity) and 4) dollar costs. This disability index is the most commonly used self-report measure and consists of 20 items measuring eight sub-scales: eating, walking, rising, hygiene, activities, grip, dressing and reaching. The AIMS-2 [26, 27] has 45 items that measure arthritis-specific health status along nine domains including mobility, physical activity, dexterity, household activities, ADLs, anxiety, depression, social activity and pain. The AUSCAN has 15 items rated on 0-4 scale in terms of arthritis pain, function and stiffness. The MHQ has 37 items designed to measure hand performance along 6 domains: function, activities of daily living, pain, work performance, aesthetics and satisfaction. The Cochin hand disability scale has 18 items aimed at assessing ability to complete ADLs, including the following five categories: 1) kitchen 2) dressing 3) hygiene 4) office and 5) others. The DASH [33-35] has 30 items to measure the functional ability in upper limb musculoskeletal disorders with questions pertaining to disability/ symptoms. The PRWHE is a self-report questionnaire [36-39]) with a total of 15 items, five items related to pain and ten items on

difficulty in performing usual (personal care, household, work and recreational) and specific activities (turning a door knob, fastening buttons, cutting meat with a knife etc.) in a variety of wrist or hand conditions. Each pain item is scored from 0-10, 0 indicating 'None', and 10 as 'Worst'. Each function item is scored from 0-10, 0 indicating 'No difficulty', and 10 as 'Unable to do'. The total score ranges from 0-100 with higher scores indicating more disability. Appearance of the affected hand is an additional item, which is scored separately. The scale was validated in 122 patients [36] who had undergone arthroplasty for OA of the carpo-metacarpal joint. The scores of PRWHE was correlated with impairment measures such as grip strength, tripod pinch strength, key pinch, wrist flexion and extension, dexterity, ulnar and radial deviations and thumb range of motions ranged from 0.02 to 0.47. Correlations between subscales of AUSCAN and PRWHE, and DASH disability score ranged from 0.49 to 0.96. The scale was also able to discriminate people with HOA from those with involvement of other joints. The scale also demonstrated larger responsiveness with standardized response mean of 1.51 in 60 people with hand or wrist problems [38], who had undergone three months of hand therapy. The scale was not tested for reliability or validity in RA populations.

More recently, computer-based hand function assessment applications are being developed which quantify fine and gross motor manipulation skills. For example, Culmera et al. [40] developed a standardized hand tracing task that measures both movement duration and spatial-temporal accuracy of fine and gross manipulation skills. However, it is limited to a narrow range of objects and tasks, for example: pegs, coins, a pen, or kitchen utensils.

A computer game based hand function application has been designed to, 1) provide a standardized method to objectively quantify task performance (movement quality) during manipulation of a broad range of common objects independent of physical properties, anatomical requirements and task goal and contexts, and 2) evaluate pain and joint stiffness related with each object manipulation task. Reliability and validity of the application has been demonstrated in asymptomatic individuals [29].

#### **2.4. Summary**

This chapter has briefly discussed on the components of the International Classification of Functioning, Disability and Health (ICF) model and the hand function outcome measures used in clinical research.



## **Chapter 3: Methodology**

### **3.1. Introduction**

This chapter includes the study objectives, participants, sample size justification, study protocol, measurement instruments and data analyses procedures.

### **3.2. Objectives and hypotheses**

The objectives were to determine test-retest reliability and convergent validity of a custom tracking protocol of the computer game based hand function application in people with arthritis. Task performance during three different object manipulation tasks were evaluated twice using the custom tracking protocol of the application. It was hypothesized that the performance measures of object manipulation tasks would exhibit high test retest reliability (ICCs  $>0.75$ ), and also demonstrate moderate correlations (Spearman rho between 0.4 and 0.7) with grip strength, NHPT, DASH and the HAQ. The secondary objectives were to evaluate joint pain and stiffness outcomes with three different object manipulation tasks.

### **3.3. Study protocol**

#### **3.3.1 Ethics approval**

The study was approved by the University of Manitoba Health Research Ethics Board (H2008: 216). Before evaluation, written informed consent was obtained from each study participant.

#### **3.3.2. Study participants**

Men and women between 30 and 65 years of age and diagnosed with rheumatoid arthritis or hand osteoarthritis were included. People with fixed finger joint deformities and recent upper limb surgeries or trauma (< 6 months) were excluded.

#### **3.3.3. Recruitment**

Forty eligible volunteer participants were recruited through advertisements in local newspapers and Rheumatology clinics in Winnipeg.

#### **3.3.4. Sample size justification**

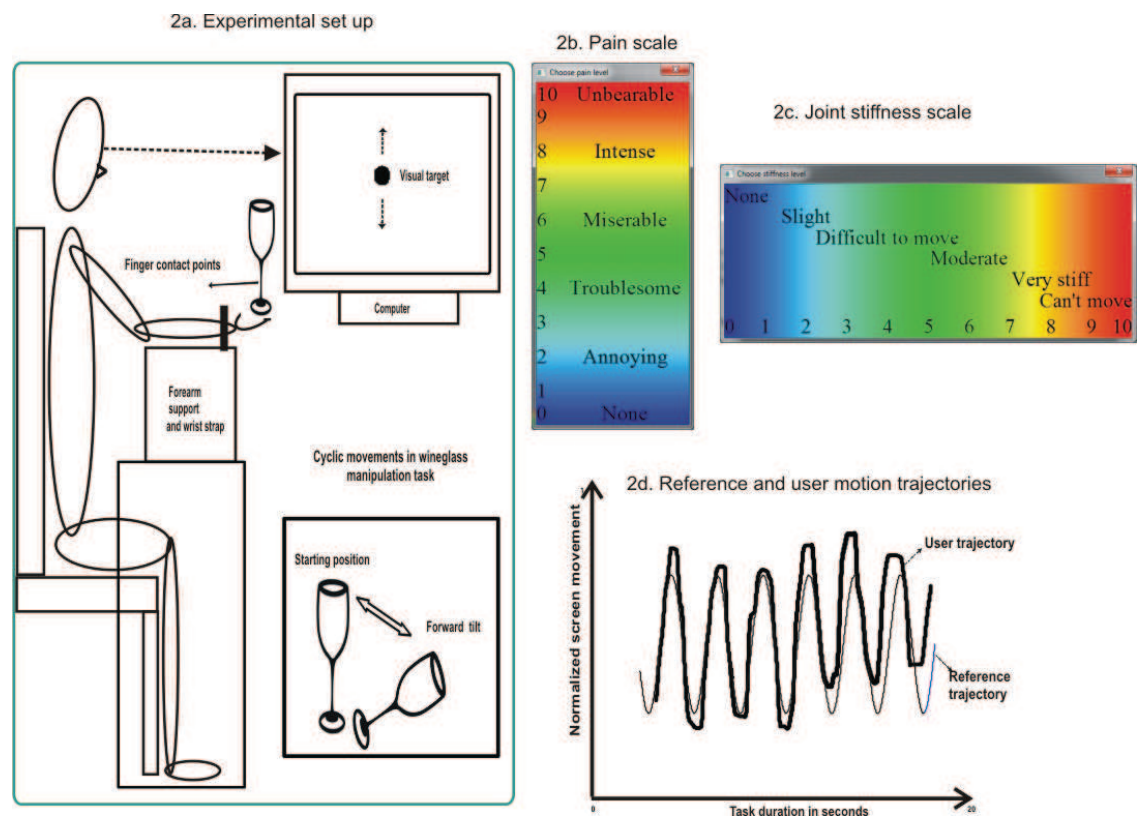
Assuming no drop-outs, a total of 39 participants was proposed for ICCs >0.6 with a power of 0.80 and a significance level of 0.05 [41]. A minimum of 30 participants is considered enough for estimates of reliability and validity, though larger numbers are often preferred [42].

### **3.3.5. Custom tracking protocol**

The custom tracking was designed with a visual target (a bright colored circular cursor) moving sinusoidally in the x or y axis and with configurable amplitude and frequency to serve as a standardized input in guiding a manipulation task. Figure 2a illustrates the experimental setup of the tracking protocol. The physical components of the application include a miniature motion sensor (5mm x10mm Minibird model 800, Ascension Technology, Burlington VT, USA) and a hardware interface. The sensor records the linear and angular position coordinates in the x, y, and z-axes at a sampling rate of 100Hz. The interface allows seamless translation of motion signals from any instrumented object and makes it behave as a standard mouse. The object motions are then used to perform the custom tracking (for example: a wineglass tilted up down as shown in Figure 2a insert). The moving visual target is set at a frequency of 0.5 Hz and onscreen amplitude of 15 cm representing optimal motion parameters experienced in daily activities. The position coordinates of the on-screen target cursor and the motion sensor (user motion) were synchronously logged and saved to a file. The application was also embedded with two separate 0-10 numerical verbal scales for self-reporting pain and stiffness (Figure 2b and 2c). Blue, green, yellow and red colors depict increasing intensities of pain and stiffness. These scales appeared in sequence on the computer screen and participants were asked to rate their pain and stiffness before and after the tracking task. The study staff recorded the scores which were automatically saved along with the user motion data. Figure 2d shows the reference and user motion trajectory for an object manipulation task. The bold lined waveform represents the user trajectory and the

light shaded waveform is the reference trajectory of performance. The Y-axis is the relative amplitude excursion on screen and the X-axis is time in seconds.

**Figure 2: Experimental set up**



### **3.3.6. First test session**

The first test session included administration of grip strength test; NHPT and DASH before evaluating the three object tasks. Grip strength of the dominant hand was tested using an isometric hand dynamometer (G100, Biometrics Ltd., UK) in the testing position recommended by American Society of Hand Therapists [43, 44]. Participants gripped the dynamometer as hard as possible once without any jerking. The best score out of three consecutive trials was used for analyses. Sufficient time was allowed for the participants to recover from any fatigue related to grip testing. Fine finger dexterity was then assessed by the time taken for placement and removal of nine pegs in the peg board using the NHPT [45]. Participants also completed the DASH questionnaire [33-35] which contains 30 items on disability and symptoms related to upper limb activities. The level of difficulty in performing each item is rated on a 1-5 point scale (1- no difficulty and 5- unable to do). Scores range between 0-100 with higher scores indicating greater disability.

For evaluation of object manipulation tasks, the participant was comfortably seated in front of a computer monitor positioned at eye level to perform the manipulation tasks. The arm was positioned with the shoulder flexed at 60 degrees and internally rotated, elbow flexed and forearm supported on a 15-inch Styrofoam block. A strap around the wrist stabilized the wrist, while allowing free hand movements in the air.

The objects included a long stem plastic wineglass, salad tongs and a jug half filled with water. These objects represent a wide range of physical properties requiring different modes of manipulation such as tripod grip, thumb opposition and whole hand grasp respectively. In both test sessions, the motion sensor was secured on a same point

marked on the mid portion of the wineglass bowl; the top arm of the salad tongs and on the mid portion of the jug's front surface (opposite to the handle).

Manipulation of the wineglass required a tripod grip involving the thumb, index and middle fingers. The wineglass held at the stem was tilted forward down (away from the body) and straight up to vertical (towards the body), bottom insert of Figure 2a. The task involved thumb opposition and interphalangeal (IP) flexion, index finger abduction, metacarpo-phalangeal (MCP) flexion, rotation and IP flexion or extension of index and middle fingers, and ulnar and radial deviations. The other two fingers could flex or extend. Manipulation of the salad tongs involved full opening and closing of the two arms together with the vertical movements of the visual target. They were held with the thumb placed on the top arm, while the index and middle fingers held the lower arm. The task involved thumb extension, adduction /abduction MCP and IP flexion, extension at the 2nd and 3rd digits. The jug was held with a power grasp and tilted left and right along the horizontally moving target. With the forearm in the mid prone position, the task included supination and pronation, and flexion at the MCP, IP joints of all fingers and the thumb in extension. The motion was restricted to the wrist and forearm, while the fingers provided a stable grip. Two to four minutes of rest was allowed in between the evaluations of the tasks. All of the participants were provided with a demonstration before testing. After one practice trial, each task was evaluated for 20 seconds, which produced 12 movement cycles.

### **3.3.7. Second test session**

A week later, the HAQ [32] which measures difficulties in daily activities using a 0-3 point scale (0-without difficulty, 3-unable to do) was completed. The three tasks were then evaluated in the same order by the same assessor.

### **3.4. Data analyses**

The user motion data from each task was processed using custom analysis routines written in Matlab (The Math Works, Natick, MA) and then exported for offline analysis. A non-linear least squares algorithm was used to obtain a sine-wave function of the target cursor waveform. Based on the known reference trajectory and the participant's actual motion, the co-efficient of determination (CoD) was calculated to represent task performance, i.e. how well each participant followed the cyclic cursor motion. CoDs range between 0 and 1 with values nearer to 1 representing more closeness. Based on the CoD values, task performance could be arbitrarily classified as good (CoD>0.8), fair (CoD between 0.5-0.8), and poor (CoD<0.5). Figure 2d shows the reference and user motion trajectories for one of the tasks.

### **3.5. Statistical analyses**

Relative test-retest reliability of the protocol was evaluated using Intra-class correlation co-efficient [ICC (2, 1)]. ICC values were interpreted [46] as very high (ICC>0.9), high (ICC > 0.75), moderate (ICC between 0.5- 0.75) and low (ICC < 0.5).

2) Absolute reliability was evaluated with the standard error of measurement (SEM), using the formula  $SEM = SD \times \sqrt{1 - ICC}$ , where SD is the average standard deviation of the two session scores [47].

3) Paired student 't' test was used to evaluate mean differences between the two session scores.

4) Convergent validity was analyzed using the Spearman rank correlation coefficient (rho) to determine the strength of the relationship between task performance measures and grip strength, NHPT, DASH and HAQ scores. The strength of correlation was interpreted as high ( $\rho > 0.7$ ), moderate (0.4 to 0.7) and low ( $< 0.4$ ) [48].

5) The Wilcoxon signed rank test was used to compare the levels of joint pain and stiffness before and after each manipulation task.

Data was analyzed with IBM SPSS Statistics for Windows, Version 19.0. Armonk, NY: IBM Corp. Statistical significance was set at  $p < 0.05$  (Two tailed).

### **3.6. Summary**

This chapter described the study objectives, participants, sample size justification, study protocol, measurement instruments and data analyses procedures. The next chapter will present the study findings, in the form of graphs and tables.



## Chapter 4: Results

### 4.1. Introduction

This chapter describes the study findings, illustrated with graphs and tables.

### 4.2. Study findings

#### 4.2.1. Demographics and clinical scores

Demographic characteristics and the Mean  $\pm$  SD scores of grip strength, NHPT, DASH and HAQ of the study participants are presented in Table 3.

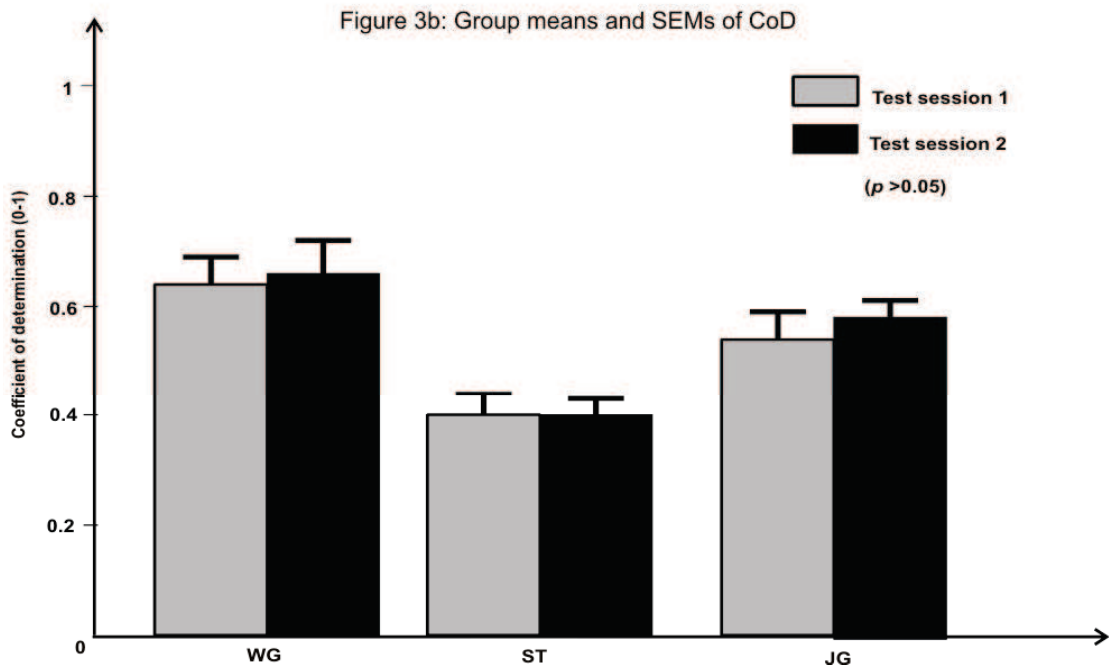
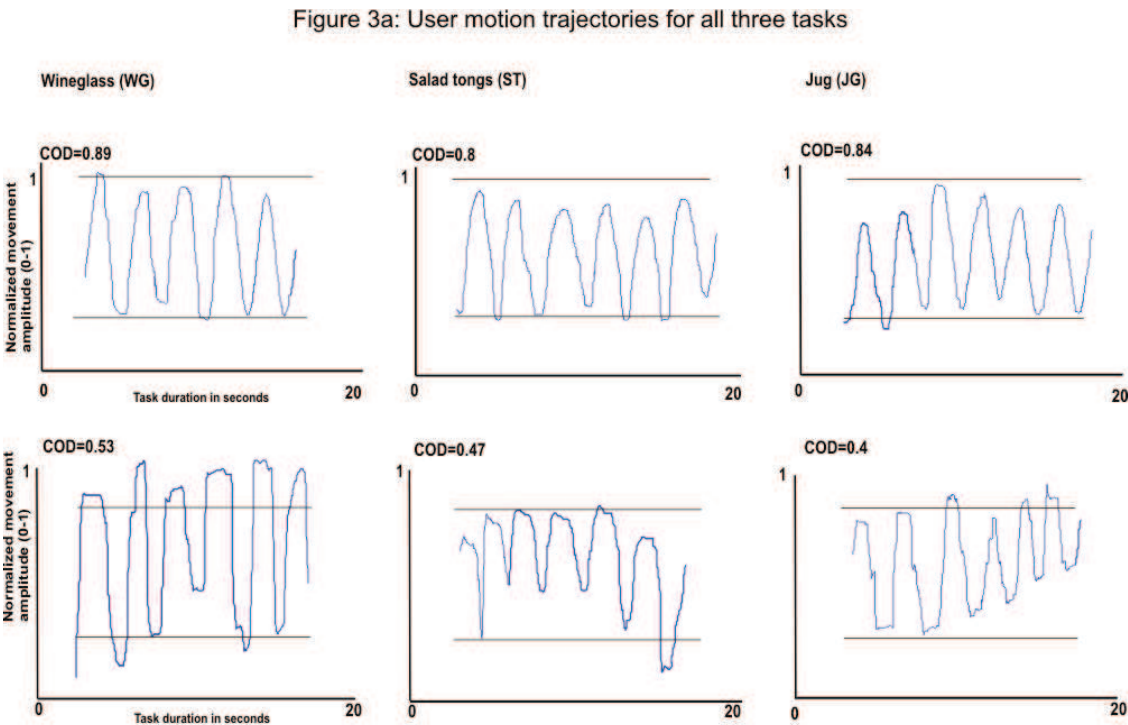
**Table 3: Demographic characteristics of the study participants**

Demographics	
Total participants	40
Rheumatoid arthritis	14
Hand osteoarthritis	26
Men / Women	6/34
Age range (years)	34-63
Age (Mean $\pm$ SD)	54 $\pm$ 6.7
NHPT (seconds)	28.2 $\pm$ 7.8
DASH (/100)	36.3 $\pm$ 16.1
HAQ-DI (/3)	1.1 $\pm$ 0.8

#### **4.2.2. Performance measures of the object manipulation tasks**

Figure 3a presents representative examples (and respective CoDs) of the user motion trajectories with the three tasks. The top panels of plots are examples of good performance (CoDs  $> 0.80$ ) and the bottom panels, of poor performance (CoDs  $< 0.50$ ). The maximum and minimum boundaries of reference waveform are highlighted by horizontal lines above and below each user trajectory. Figure 3b presents histograms of group means and standard error of means for CoD of wineglass (WG), salad tongs (ST) and jug (JG) tasks in test sessions 1 (grey bars) and 2 (black bars). CoD measured from 0-1, is represented on the y-axis.

Figure 3: CoDs of the user motion trajectories with the three tasks



#### 4.2.3. Test retest reliability

Table 4 presents the group means (SD) for CoD, ICCs and SEMs. Test re-test reliability of the task performance was high (ICC >0.75) for wineglass task and moderate (ICC between 0.5 and 0.75) for the jug and salad tongs tasks. Paired student's *t* tests showed no significant differences in mean performance measures for each task between the sessions ( $p>0.05$ ).

**Table 4: Test-retest CoD scores, ICC (95% CI) and SEM for each manipulation task**

Object	CoD scores		ICC (95% CI)	SEM
	Test 1	Retest		
Wineglass	0.64 ± 0.2	0.66 ± 0.2	0.84*(0.67-0.93)	0.08
Salad tongs	0.4 ± 0.24	0.4 ± 0.3	0.5*(0.07-0.77)	0.19
Jug	0.54 ± 0.23	0.6 ± 0.2	0.53* (0.1-0.83)	0.15

#### 4.2.4. Convergent validity

Table 5 presents the ‘rho’ values reported between 1) task performance measures of wineglass, salad tongs and jug manipulations with grip strength, NHPT, DASH and HAQ, 2) task performance measures of wineglass, salad tongs and jug manipulations, and 3) grip strength, NHPT, DASH and HAQ. The HAQ moderately correlated with the task performance measures of wineglass and jug tasks, but had low correlations with salad tongs task. Low correlations were observed between all task performance measures and grip strength, NHPT and the DASH, and between the task performance measures of three objects themselves. Moderate correlations were seen between the DASH and HAQ; and between grip strength and DASH and HAQ respectively.

**Table 5: Spearman correlation co-efficient ‘rho’ between task performances of object manipulations with other hand function measures**

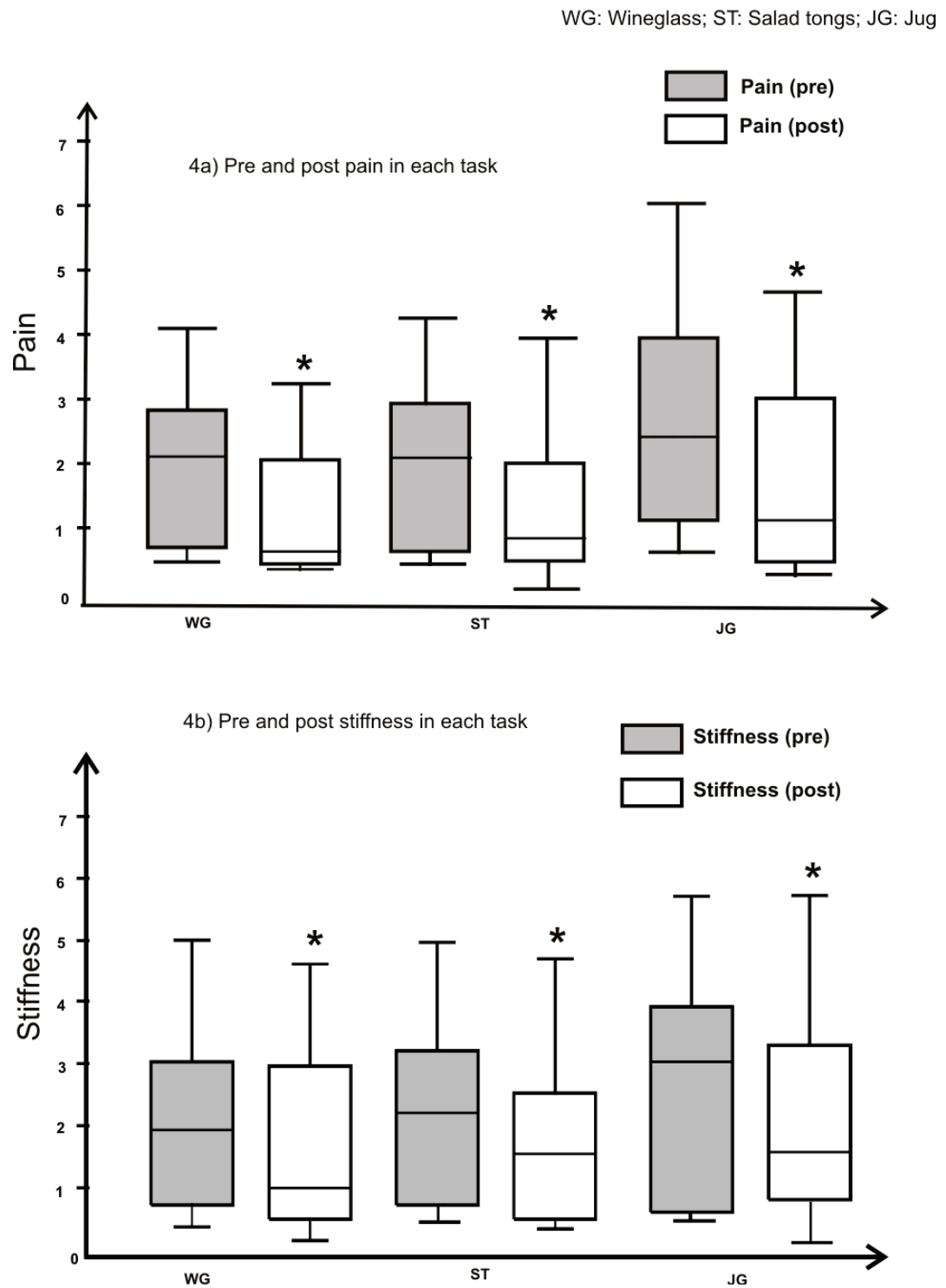
Variables	WG-CoD	ST-CoD	JG-CoD	Grip	NHPT	DASH	HAQ
WG-CoD	-	0.17	0.33*	-0.22	-0.15	-0.3*	-0.5*
ST-CoD	-	-	0.3	-0.1	-0.14	-0.23	-0.12
JG-CoD	-	-	-	-0.1	-0.2	-0.2	-0.4
Grip	-	-	-	-	-0.3*	-0.41*	0.5*
NHPT	-	-	-	-	-	-0.3*	-0.25
DASH	-	-	-	-	-	-	0.61*

WG-COD-Wineglass COD; ST-COD-Salad tongs COD; JG –COD-Jug COD; NHPT- Nine hole peg test; DASH-Disabilities of Shoulder Arm Hand; HAQ-Health Assessment Questionnaire; \*-Statistical significance,  $p < 0.05$ .

#### **4.2.5. Pain and stiffness outcomes**

Figures 4a and 4b present the box and whisker plots for group median and Inter-quartile range (IQR) for pain and stiffness scores reported before and after each task. The y axis represents the pain and stiffness scores on separate (0-10) scales. The top and bottom of the boxes represent the upper and lower quartiles, while the median is presented as the middle line. The top and bottom whiskers represent the maximum and minimum values. There was a significant reduction (shown with \*) in pain and stiffness levels after each task in both test sessions ( $p<0.001$ ).

**Figure 4: Pain and stiffness before and after each manipulation task**



### **4.3. Summary**

This chapter presented the study findings on test retest reliability and convergent validity of the hand function assessment application. The next chapter includes a discussion based on these findings.



## **Chapter 5: Discussion**

### **5.1. Introduction**

The purpose was to determine test retest reliability and convergent validity of a custom tracking protocol of a computer game based hand function assessment application on people with arthritis. Test-retest reliability of performance measures during manipulation of three common objects (wineglass, salad tongs and jug) ranged from high to moderate. In general, low correlations were observed between the task performance measures and grip strength, NHPT, DASH and HAQ. Exceptions were moderate correlations between the wineglass and jug task performance measures with the HAQ. In addition, performance measures between the objects demonstrated low correlations with each other. Interestingly, there was a significant reduction in joint pain and stiffness after performing each task.

### **5.2. Test retest reliability**

The protocol indicated moderate to high test-retest reliability of performance measures for three manipulation tasks using objects with a broad range of properties and functional requirements. These findings are comparable to other hand function measures such as the Arthritis Hand Function Test (ICCs range 0.53-0.96) [49]. It was interesting to note that the task with the best performance (wine glass) also had the highest ICC; the task with the poorest performance (salad tongs) had the lowest ICC. There is evidence that difficult tasks demonstrate low test-retest reliability, likely due to poor reproduction of task performance [50, 51]. For example, in people with hand disabilities, [50] the

simulated feeding subtest of the Jebsen hand function test was found to be less reproducible (Pearson  $r=0.60$ ) than the other subtests, such as picking up small objects and card turning ( $r > 0.80$ ). Similarly, the peg board dexterity of AHFT demonstrated an ICC of 0.53 compared to the other test items (ICC between 0.69 - 0.95) [49]. In the present study, the narrow range of variability in task performance measures would infer that the study sample was homogenous, thus influencing the magnitude of ICCs. The SEMs were 12%, 47.5% and 26% for the task performance measures of the wineglass, salad tongs and jug tasks respectively. Disease factors such as structural joint deformities, muscle weakness, daily variations in pain and stiffness and/or timing of pain medications [52] are some of the additional factors that can be considered for measurement variations.

### **5.3. Convergent validity**

The low correlations between grip strength and the task performance measures were not surprising. Isometric grip strength is an objective measure of maximal voluntary effort of wrist and hand muscles which is required for handling and moving heavy items. Manipulation of the salad tongs and the wineglass involved only the thumb, index and middle fingers where grip force is not important; similarly the jug task also required precise and cyclic tilting movements, in addition to a modest magnitude of grasp.

Low correlations were also observed between the NHPT and the task performance measures. The NHPT uses very small pegs requiring fine control of the thumb and index finger and minimal joint motions. Performance is graded by time in seconds. Neither movement quality nor efficiency is quantified, whereas CoD measures quality of

movement during different tasks irrespective of object used. This likely explains the low correlations between the NHPT and task performance measures. Similarly, low correlations between the task performance measures themselves may be explained as these three objects are completely different from each other in terms of physical properties, grip/grasp and functional requirements for handling.

In the present study, the DASH and HAQ showed low correlations with the task performance measures and the NHPT. The DASH and HAQ are questionnaires covering an individual's health and functioning, predominantly in terms of activity and participation. The DASH contains 21 items related to daily activities, social participation (four items), and body functions (five items). Only six items pertain to finger and hand use, while the other items require either whole upper limb or bilateral upper limb action. Similarly, out of the 20 HAQ items, only seven are specifically related to finger and hand use, while the other items require either whole body or lower extremity mobility for execution, e.g. walking. Both questionnaires have a limited proportion of items focused on finger and hand tasks, 25% in the DASH and 35% in the HAQ. The HAQ also has items of high content density ratio [53] which are difficult to answer, examples: 'are you able to dress yourself, including tying shoelaces and doing buttons' and 'are you able to do chores such as vacuuming or yard work'. In addition, factors such as compensatory movements and different adaptive strategies that are often learned to accomplish a task [53] may influence perceived level of difficulty. Taken together, these would explain why performance based CoD measures had low correlations with self-reported composite scores of activity and participation.

Consistent with previous studies [54-56], the present study showed modest correlations between grip strength and the DASH and HAQ. Both questionnaires measure the level of difficulty experienced during activities and also share similar items such as personal hygiene, opening jars, household work, and transportation activities. Since the majority of daily tasks are dexterity-based and less than 14% requires maximal grip strength [57] for execution, this is not surprising.

#### **5.4. Pain and stiffness outcomes**

One may have thought that repeated cyclic manipulation tasks would have aggravated pain and stiffness. Unexpectedly, pain and stiffness decreased after performing the cyclic tasks for all three objects during both test sessions. These findings are consistent with current practice in the use of mobility exercises for the management of pain and stiffness affecting larger joints, such as hip, knee and shoulder [58-60] in individuals with rheumatoid arthritis or hand osteoarthritis.

#### **5.5. Strengths and limitations**

The custom tracking protocol provides a standardized method to collect and analyze movement from a diverse range of objects, utensils or applications used in daily activities. A functional framework to select assessment objects relevant for individual clients has been developed and the present protocol allows quantification of the ability to manipulate a broad range of objects.

The disease severity and magnitude of finger joint deformities were not determined in the present study. Also, each of the tasks was tested only once in each session. These factors might have influenced the performance outcomes. Although the

custom tracking is easy and simple to follow, it does require some cognitive abilities, which was not specifically addressed before application. The immediate reduction of pain and joint stiffness after each task may possibly be an overestimation of beneficial effects and conclusions are uncertain. Neither analgesic use nor other hand therapy sessions attended by the clients were monitored in this study.

## **5.6. Summary**

This chapter included a discussion on the test retest reliability, convergent validity properties of the computer game based hand function assessment application during three different object manipulation tasks. Pre to post task changes in joint pain and stiffness during each object manipulation, and study limitations were also described. A pilot randomized trial has been conducted [61] using the assessment application as an exploratory outcome measure.

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## **Part II: A task-oriented training program for people with rheumatoid arthritis or hand osteoarthritis**

## **Abstract**

### **Background**

Rheumatoid arthritis and osteoarthritis are two common arthritis conditions frequently affecting the joints of the hands and wrists. Both conditions present with features such as joint pain, joint stiffness, reduced joint mobility and hand muscle strength and finger joint deformities which lead to limitations in many common tasks of daily living and restricted participation in activities. Conventional exercises for finger mobility and grip strength are usually prescribed as a part of non-pharmacological management in people affected with both these conditions. However, other components such as dexterity skills training are not included in hand exercise rehabilitation programs. There are also no exercise support strategies for motivation in people with arthritis of the hands. Taking account of these gaps in practice, a novel home based task-oriented training program incorporating real life object manipulations has been developed. To support this purpose, an innovative computer gaming platform that allows a broad range of common objects used for therapy to be transformed seamlessly into a common input device (i.e. equivalent to a plug and play computer mouse) has also been developed. Objects are selected and personalized to target specific training goals such as graded finger mobility, strength, endurance or fine and gross dexterity. The movements and object manipulation tasks that replicate common situations in everyday living will then be used to control and play any computer game, making practice challenging and engaging. A combination of quantitative and qualitative research methods was used for a comprehensive evaluation of this novel training program.

## **Objectives**

A pilot randomized controlled trial was designed to describe the feasibility of study procedures, resources used, management and home exercise programs for conducting a definitive trial, and to obtain preliminary data on the effects of the task-oriented training program in 20 people with rheumatoid arthritis or hand osteoarthritis. A qualitative study was embedded within the trial to explore participants' experiences with their respective home exercise program.

## **Methods**

The control group performed conventional hand exercises and the experimental group participated in the task-oriented training program for 6 weeks at home. Feasibility assessment of the study procedures, resources used, management and home exercise programs were described qualitatively. The Arthritis Hand Function Test (AHFT), Disabilities of Arm, Shoulder and Hand (DASH) questionnaire, exercise compliance and performance during three different object manipulation tasks were the clinical outcomes. The AHFT consists of 11 items categorized in four sub-scales: grip and pinch strength, pegboard dexterity, applied dexterity, and strength. The DASH measure is a self-report questionnaire to measure upper limb function during tasks of daily living. Performance during object manipulation tasks was evaluated by using the game based hand function assessment application as an exploratory measure. A mixed model repeated measures analysis of variance (ANOVA) was conducted to determine the between and within subjects, and interaction effects of the exercise programs on clinical outcomes. Exercise



compliance was reported in percentages by dividing the number of completed home exercise sessions with the recommended number of home exercise sessions in six weeks.

## **Results**

The proposed sample size of 20 participants was not reached in the specified time period. The pilot trial demonstrated feasibility of study procedures, resources and data management, and home exercise programs. No significant effects were noted in any of the clinical outcomes except for the peg board and applied dexterity of the AHFT. Exercise compliance rates were above 85% in both groups. The overall findings from both research methods provided initial evidence on feasibility, acceptability, appropriateness, safety and perceived benefits of the task-oriented training program.

## **Conclusions**

Implementation of additional recruitment strategies and flexible inclusion criteria must be considered before planning a future trial with a large sample size.

## **Chapter 1: Introduction**

Rheumatoid arthritis and osteoarthritis are two common arthritis conditions which affect the small joints of the hands and wrists. Both conditions present with structural and functional impairments such as joint damage, finger deformities, pain and stiffness, fatigue and reduced joint mobility and hand muscle strength which lead to limitations in activities of daily living and participation restrictions. Rehabilitation of people with rheumatoid arthritis or hand osteoarthritis includes a combination of pharmacological, non-pharmacological and or surgical approaches. In non-pharmacological approach, the use of assistive devices, splints, joint protection, exercises, therapeutic modalities and disease coping techniques are often recommended for pain reduction and maintenance of joint integrity and function. Exercise programs prescribed for people with rheumatoid arthritis or hand osteoarthritis includes finger joint mobility and hand muscle strengthening exercises. Dexterity skills and function based training for efficient transfer of skills into activities of daily life are not usually included in these exercise programs. Thus there is a need to develop exercise programs incorporating these features, along with strategies to maximize client participation and motivation in exercising.

A novel home based task-oriented training program has therefore been developed for training functionally relevant tasks that are reported difficult for people with arthritis. The training was performed through a computer gaming platform designed for keeping up the motivation and engagement during exercising.

The present study is focused on describing the feasibility of conducting a definitive trial involving the novel training program and conventional hand exercise program and to understand study completers' experiences on their home programs. To

address these purposes, a mixed methods study was planned, which included a combination of a pilot randomized controlled trial and an embedded qualitative study.

## **Chapter 2: Review of Literature**

### **2.1. Introduction**

This chapter provides a review of published literature on the effects of conventional hand exercises on people with rheumatoid arthritis, effects of conventional hand exercises on people with hand osteoarthritis, current recommendations in exercise therapies for people with arthritis of the hands, motivation with exercise programs, exercise compliance, hand function outcome measures, task-oriented training program for people with arthritis of the hands, interactive computer games in rehabilitation, and brief overview on topics such as mixed methods research, pilot clinical trials, phenomenological strategy of qualitative inquiry, and focus group interviews.

### **2.2. Effects of conventional hand exercises on people with rheumatoid arthritis**

The role of hand exercises in improving hand function on people with rheumatoid arthritis has not been commonly studied and presented. Early researchers supported a pragmatic approach with simple range of motion exercises of fingers and thumb that included finger flexion, extension, ulnar and radial deviations of fingers, wrist flexion /extension, opposition and thumb abduction [1] for people with rheumatoid arthritis. Active assisted exercises for stiff hands [2] and use of early and short gentle hand exercises as soon as the inflammation subsides were then proposed [3]. However, the operational definitions of these terms, number of repetitions or exercise sessions were not clearly explained. Later, ‘Tendon gliding exercises’ that allowed maximum excursion of finger flexion and extension tendons were prescribed [4]. Wehbe maintained that these exercises reduce the risk of adhesion formation or break those that are already formed due

to rheumatoid arthritis related synovitis. The maximum range of finger joint excursions was also believed to improve cartilage nutrition and range of joint motion. Another study [5] proposed that dynamic isotonic exercises were more beneficial than isometric exercises. However, there are no studies that strongly demonstrate the effectiveness of these exercises on people with rheumatoid arthritis. In spite of many different combinations of hand exercises as reviewed above, clear conclusions could not be reached on their benefits for people with rheumatoid arthritis.

A 2004 systematic review [6] of studies published between 1980 and 2003 synthesized the effectiveness of hand exercises in people with rheumatoid arthritis. Studies that evaluated any form of hand exercises prescribed either alone or in combination with therapeutic modalities were included. Nine studies that met the quality criteria were included in the review. Joint mobility or strengthening exercises combined with therapeutic modalities were included in most of the included studies. Major dependent variables considered in the review were pain, stiffness, range of motion, grip and pinch strength, dexterity and function. Out of four studies [7-10] that had non-exercising control groups, one reported significant changes in strength but non-significant changes in range of motion [8]. Another study [7] with range of motion and resisted putty exercises along with thermal modalities showed improvements in inflammation, tenderness, joint pain, hand strength, range of motion and activities of daily living (ADLs) while others [9, 10] found changes in range of motion with or without finger dexterity and no changes in strength. Two studies [11, 12] assessed the effects of exercise on joint stiffness. The first study [11] demonstrated no short or long term benefits, while the other [12] reported reduced morning stiffness with an evening home program.

A single blind randomized controlled trial [13] studied the effects of three different therapeutic approaches over a six month period in 67 individuals affected with rheumatoid arthritis. The first group (n=21) received a home program on joint protection advice, added with a set of tendon gliding and strengthening exercises for the hand. The program included flexion, extension exercises for the fingers, thumb and wrist; radial finger walking (fingers moving towards the radius only thus avoiding exacerbating ulnar deviation); pinch grip exercises; strengthening for the intrinsic and thenar eminence muscles; and wrist extensor muscle groups with a 'Thera-tubes' resistance band. The second group (n=24) received joint protection with hand mobility exercises, including wrist flexion, extension, circumduction, pronation and supination, radial deviation, abduction of all finger joints, thumb opposition and inter-phalangeal flexion to the maximal possible range. The third group (n=22) received joint protection advice alone. The primary outcome measure was the Arthritis Impact Measurement Scale-2 (AIMS-2). The AIMS-2 is a questionnaire on health status used to measure treatment outcomes in arthritis studies. Secondary measures were the Jebsen hand function test, grip force, pinch force, summated finger flexion of the dominant hand and disease activity. Improvements of AIMS-2 scores of upper limb function and key pinch strength of the dominant hand was demonstrated in the first group that received a combination of joint protection advice, mobility and strengthening hand exercises compared to the other two treatment groups. The other outcomes did not differ significantly. This study presented limited evidence on the interventions due to limitations such as a small sample size, risk of random errors and unknown effects of medication use or other hand therapies.

A clinical controlled trial [14] tested the effects of an intensive home program in the treatment group (n=30), while the control group (n=30) received mobility hand

exercises over a 14 week period. The theoretical basis for this study was that grip strength predicts hand function and it is necessary to incorporate intensive exercises against resistance in hand therapy programs. It was assumed that improving grip strength would reduce activity limitations and improve functional independence. The control group received a set of concentric isotonic exercises against mild resistance (soft dough) which included ulnar deviation of the wrist (with fingers flexed), flexing the fingers into a fist, extending the fingers, touching the tip of each finger with the thumb, rolling a ball with the palm on the table with extended fingers, radial finger walking with the four ulnar fingers moving towards the thumb and abduction of the thumb with the inter-phalangeal joint flexed. In addition to the above, the following were performed without resistance: Volar and dorsal flexion of the wrist, pronation and supination of the hand and forearm, opposition of the thumb and flexion of the inter-phalangeal joint of the thumb. Each exercise was repeated three times. The exercises for the treatment group were almost identical to the control group and included thumb opposition performed against resistance. Exercises that included touching the tip of each finger with the thumb and rolling a ball with the palm on the table were removed, as these do not influence grip force. Also, each exercise was repeated 10 times, but the radial finger walking was repeated five times. The control group performed their exercises at their own convenient timings while the treatment group performed five days per week. The primary outcome measure was grip strength and was tested using the Grippit instrument. Secondary outcome measures were hand pain, joint mobility, self-rated hand function, grip ability test (GAT), modified Health Assessment Questionnaire (MHAQ) and patient global assessments of pain, fatigue and disease activity using visual analogue scales (VAS). Grip strength improved in the treatment group. Joint mobility, GAT, MHAQ showed few

significant differences in improvements between the two treatment groups. This study concluded that the intensive home program significantly improved hand strength. However, studies [7, 14] do not support the effects of either mobility exercises or intensive hand exercises in improving hand function in people affected with rheumatoid arthritis.

A study [15] evaluated the effects of a 12 week exercise program comprising Flatt's hand exercises and gentle resisted exercise with therapeutic putty in 20 women with rheumatoid arthritis compared with 20 age matched healthy controls. Finger flexion, extension force, Grip Ability Test, DASH questionnaire, ultrasound measurements for muscle cross-sectional area, muscle thickness, pennation angle and contraction pattern (change in shape of the muscle and time from start to maximal contraction) were the outcome measures. The study showed significant improvements in extension and flexion force in both groups after six and twelve weeks. Both groups showed significant improvements in Grip Ability Test scores after six weeks. After 12 weeks, the rheumatoid arthritis group showed significant improvement in DASH score, while the control group did not show any improvements. After six weeks of hand exercise therapy, the cross-sectional area of the extensor digitorum muscle in the rheumatoid arthritis group increased, while no improvements were reported in the control group. However, after 12 weeks, cross-sectional area increased significantly in both groups. The pennation angles did not increase after hand exercise therapy. After six weeks, muscle thickness improved in the control group while no improvements were noted in the rheumatoid arthritis group. After 12 weeks, maximal contraction time and the muscle shape increased significantly in both groups. The cross-sectional area of extensor digitorum muscle showed significant difference between the 2 groups before, but after six weeks no significant difference was



observed between the groups. The study has shown significant improvements in the Grip Ability Test and DASH scores. The Grip Ability Test is a quick test of hand function and includes only three tasks to represent all of the tasks encountered in daily living. The Grip Ability Test is also less sensitive to detect changes and has no published normative data, while the DASH measure is subjective. The grip force and ultrasound outcome measures did not demonstrate evidence of adequate psychometric properties for their use in a population with rheumatoid arthritis. The study did not clearly describe the exercises prescribed for the rheumatoid arthritis treatment group. The other limitations were that the control group was neither a patient group, nor had a home program for effective comparison.

One of the other included studies [7] had a large sample size of 100 and a very short treatment period of three weeks with the control group receiving no treatment at all. Flatt's hand exercises and balanced resistive exercises using therapy putty to include finger abduction and adduction were prescribed with five repetitions each for 20-30 minutes, along with modalities such as therapeutic heat or cold, faradic hand baths and thermal baths. The study variables included inflammation, tenderness, joint pain, hand strength, range of motion and ADLs. Over three weeks of exercising, there were significant improvements favoring the treatment group in all of the variables except joint size and erythrocyte sedimentation rate (ESR). There was a non-significant worsening of symptoms in the control group. However, the control group did not receive any treatment, while the treatment group received nearly one hour of exercises on a daily basis. Also, the combination of physical modalities might have influenced leading to overlapping of therapeutic effects. Therefore, it is inconclusive whether the treatment group benefited by the exercises alone.

Another study [11] looked into the short term (one session) and long term (many sessions over six weeks) effects of various physiotherapeutic home exercise programs on reducing the joint stiffness of finger joints in 12 controls and 18 people affected with rheumatoid arthritis. The techniques used were: hot wax baths, pulsed ultrasound (1Megahertz) alone, wax baths plus pulsed ultrasound and exercise. The exercises were gentle passive finger flexion /extension plus active exercises with soft rubber objects. Metacarpo-phalangeal joint stiffness of the right index finger was measured by a computer controlled metacarpo-phalangeal joint arthrograph. The study demonstrated higher stiffness levels in people with rheumatoid arthritis compared to the controls. But it did not provide sufficient details on the soft rubber objects used for exercising, number of repetitions, or frequency. In short-term, wax plus ultrasound produced a statistically significant reduction in stiffness. Wax, ultrasound alone or exercise did not produce short or long term effects.

The effects of long term home exercise programs were evaluated in a clinical trial [8]. The control group did not receive any hand exercises and the test group was prescribed with six exercises as follows: 1) finger extension 2) finger abduction/adduction 3) roll and unroll a bath towel 4) roll and unroll a paper roll 5) metacarpo-phalangeal flexion and extension and 6) proximal inter-phalangeal flexion and extension. The outcome measures were grip and pinch strength measured using a sphygmomanometer and flexion /extension of metacarpo-phalangeal and proximal inter-phalangeal joints measured with a goniometer. Grip strength was considered to be the indirect measure of hand function in this study. On study completion, grip and pinch strength significantly improved in test group but deteriorated in the control group. Metacarpo-phalangeal extension was significantly lost in both groups; however the test group showed less

statistical loss of metacarpo-phalangeal extension than the control group. Metacarpo-phalangeal flexion showed no difference in both groups. Changes in proximal inter-phalangeal flex/extension were not significant in both groups. The exercises were clearly described and compliance was also monitored over the whole study period. The test group did not reach statistical significance in the loss of proximal inter-phalangeal motions compared to the control group. No performance based tests or self-reports were used in this study to measure hand function. Controversies still exist over considering grip strength as the best predictor of finger hand function. With these two limitations, it could be concluded that the study findings did not demonstrate sufficient evidence for hand exercises in improving hand function in people with rheumatoid arthritis.

The effects of Flatt's hand exercises and wax therapy was studied in a 4 week randomized trial [10] on 52 people affected with rheumatoid arthritis. They were assigned into four groups (G1, G2, G3 and G4). The groups received the following home programs: G1-wax therapy followed by hand exercises; G2-hand exercises only; G3-wax therapy only; and G4-no intervention. G1 and G2 used soft exercise dough to allow optimal resistance during hand exercises. They were also additionally prescribed with gentle shoulder flexion, abduction and rotation movements. Each exercise was repeated five times per session for around 20 minutes of total duration. For wax therapy, both hands were dipped into 47-50 degrees of hot wax for five times. Bilateral finger flexion, extension, Sollerman grip function test for the dominant hand, bilateral grip strength, pain during resisted motion of the dominant hand during performance of each subtest of Sollerman test, pain during non- resisted motion of both hands and stiffness of both hands were the study variables. Sollerman grip function test measures grips that are needed for certain ADLs such as eating, driving, personal hygiene and writing. The test includes

subtests that represent common handgrips, (volar, transverse volar, spherical volar; and pinch positions: pulp, lateral, tripod and five fingers) and activities such as using a key; picking up coins from a flat surface; writing with a pen; using a phone; and pouring water from a jug. The time taken, level of difficulty displayed and the quality of performance using the correct pinch or grip position are considered while scoring. Performance is graded on a five point scale from zero (task cannot be performed at all) to four (task is completed without any difficulty within 20 seconds and with hand-grip of normal quality). An overall comparison between the four groups revealed significant improvements in flexion deficits in G1 and G2. Sollerman test items significantly improved in G1 compared to other groups. Pain with non-resisted motion improved in G2 and G3. No significant effects were observed for wax therapy in any of the groups. Stiffness reduced immediately after intervention in all four groups, but was not significant. Additionally, no significant improvements in grip strength were observed among groups. Grip function was considered to be the indirect measure of hand function in this study. Though the study has demonstrated improvements in a performance based outcome measure, the sample size is small and no self-reported hand function measure was used to compliment the objective findings.

Another study [16] compared the effects of a combination of mobility exercises and isometric hand strengthening exercises over a 4 month period on 18 people with rheumatoid arthritis. With metacarpo-phalangeal in extension, range of motion exercises included: 1) Proximal and distal phalangeal joints flexion and 2) Squeezing of interossei. Isometric exercises included: strengthening of finger flexors, extensor digitorum communis and dorsal and palmar interossei. No exercises for thumb were included. Bilateral grip strength, range of motion, fist closure and hand function during four

common daily tasks with dominant hand were the study variables. Grip strength improved in 28 out of 35 numbers of hands evaluated in 18 people and bilateral finger range of motion (proximal and distal inter-phalangeal) improved significantly compared to their initial values. Six out of 18 people improved in terms of performing the four functional tasks. None of the study outcome measures were reliable and valid in rheumatoid arthritis population. The four functional tasks evaluated in this study were: opening a screw top jar, lifting a dish weighing 0.9 kilograms, writing with a pencil and picking up a small object. This evaluation had no standardized protocol or scores to rate performance. Instead it measured how many people were able to perform all the four tasks. Also, these tasks do not adequately represent the ADLs and no self-reports were used to measure hand function. There is no clear consensus that improvements in impairments such as grip strength or finger range of motion translate into improvements in hand function abilities. It could be concluded that the study findings did not demonstrate sufficient evidence for the effects of hand exercises in people with rheumatoid arthritis.

In summary, there are no adequately powered randomized trials that provide strong evidence on the therapeutic effects of joint mobility or strengthening exercises in rheumatoid arthritis [6, 17].

A brief outline of the studies that evaluated the effects of conventional exercise programs in people with rheumatoid arthritis is presented in Table 6.

**Table 6: Outline of clinical studies that examined conventional hand exercise programs in rheumatoid arthritis**

Study	Intervention	Outcomes	Results
Sofia Brorsson et al, 2009 N=40 women, Control group (CG): 20 Study group (SG): 20	Flatt's hand exercise regimen Study duration: 6 weeks	Grip strength Hand function (Grip ability test) DASH measure	Both groups improved in grip strength and GAT. Study group improved in DASH
Aud Ronningen et al, 2008 N=60; CG, n=30, SG, n=30	Gentle concentric isotonic hand exercises (vs.) Intensive home program Study duration: 14 weeks	Grip and pinch strength Joint mobility Pain Functional ability (Visual analogue scale)	SG: Significant differences in grip strength and pain
O'Brien et al, 2005 N=67 into 3 groups G1: n=21, G2: n=24 G3: n=24	G1: Joint protection (JP) advice, Mobility and Strengthening Exs. G2: JP + Stretching exercises, G3: JP alone Study duration: 6 months	Hand function (Arthritis Impact Measurement Scale-2, Jebsen hand function test) Grip and key pinch strength Summated flexion score	G1: AIMS-2 reduced by 1 point, Improvement in key pinch No other significant changes
Buljina et al, 2001 N=100, CG : n=50 SG : n=50	Control group: No treatment SG: Combination of therapeutic modalities with hand mobility exercises and balanced resistive exercises using putty Study duration: 3 weeks	Articular index Grip strength Pain Range of motion (ROM) ADL (1-6 point scale)	SG improved in ROM, ADL but No improvements in pain and articular index control group –No improvements

Study	Intervention	Outcomes	Results
Brighton et al, 1993 n=44 female clients CG, n=22 SG, n=22	control group: No exercise SG: ROM exercises Study duration: 4 years	Grip and pinch strength  Range of motion	control group improved Both groups showed, *decreased metacarpo-phalangeal extension * Improved Pinter-phalangeal extension
Hoenig et al, 1993 N=57, divided into 4 groups All exercises demonstrated to all patients	G1: Range of motion (ROM) hand exercises G2: Strengthening exercises G3: ROM + Strengthening G4: No treatment Study duration: 3months	Grip strength ROM Joint circumference Pain, Stiffness, Hand articular index Dexterity test	G1,G2,G3 improved G2 improved in Pinter-phalangeal No change Not reported G1 decreased G3 improved
Delhag et al, 1992 N=52 divided into four groups	G1: Wax therapy + active hand exercises, G2: Active hand exercises, G3: Wax therapy + Exercises, G4: No treatment Study duration: 4 wks	ROM, pain, stiffness, Sollerman test Grip strength	Wax + exercise improved ROM Active exercise alone improved stiffness
Schaufler et al, 1978 N=18; No control group	ROM +Isometric strengthening exercises Study duration: 4months	Grip and pinch strength Task performance, ROM	Significant increase in strength and ROM
McLaughlin and Reynolds et al, 1973 N=20	ROM exercises Opp. Hand as control Study duration: 6 wks	Function, grasp size, grip, pinch strength, ROM	No significant difference between exercised and non-exercised hands

### **2.3. Effects of conventional hand exercises on people with hand osteoarthritis**

A 2005 systematic review [18] on the effectiveness of pharmacological and non-pharmacological therapies of osteoarthritis hands included 31 randomized controlled trials published between 1966 and 2004. The review found moderate evidence in favour of splints for first carpo-metacarpal osteoarthritis; yoga, occupational and spa therapies in managing hand osteoarthritis. The major findings were that there were very few randomized controlled trials evaluating the multidisciplinary management of hand osteoarthritis. The published studies also presented major methodological limitations such as inadequate description of randomization, concealment and failed intention to treat analysis, lack of consistent case definitions and standardized outcome measurements. None of the studies focused solely on hand exercises as an intervention for hand osteoarthritis. Development of consensus guidelines for design and conduct of trials to evaluate possible treatment options for people with hand osteoarthritis was recommended. A further updated version [19] of the above review included more randomized controlled trials published between August 2004 and February 2008 and included a total of 44 studies. Evidence on strength training exercises [20] was added to the previous results. The EULAR (European League against Rheumatism) recommendations [21] based on available research evidence and expert consensus for the management of hand osteoarthritis included joint protection advice, local heat application with hot packs or wax therapy or ultrasound before exercise therapy, topical non-steroidal anti-inflammatory drugs (NSAIDs) and splints for basal thumb joint and oral analgesics. The EULAR recommendations for assessment and exercises in hand osteoarthritis concluded that any specific hand exercises, such as finger range of motion exercises, grip, pinch



strength exercises and thumb muscles strengthening was limited to level 4 expert opinion. It recommended the need to determine the appropriate type or combination of hand exercises in people with hand osteoarthritis.

An umbrella overview [22] included four high quality systematic reviews [18, 21, 23 and 24] that focused on non-pharmacological and non-surgical home exercise programs for people diagnosed with hand osteoarthritis according to the American College of Rheumatology (ACR) classification criteria. The treatment outcomes were pain, joint stiffness and function. There was some evidence for topical capsaicin and limited evidence on basal thumb splint on pain relief. One randomized controlled trial [25] favored improvements in function by the combined effect of exercise and joint protection advice compared to joint protection alone. The overview confirmed very little evidence for conservative management of hand osteoarthritis due to the paucity of research. The review also concluded that there is insufficient high-quality evidence regarding non-pharmacological and non-surgical home exercise programs for hand osteoarthritis.

A recent systematic review [26] included all randomized controlled trials and cohort studies published between 1986 and 2009 on conservative treatments such as splinting, heat modalities, hand exercises, joint protection advice, adaptive equipment provision for hand osteoarthritis. Six 2b (individual cohort studies including low quality randomized controlled trials) studies [27,28,20,29-31], three level 3 cohort studies [25, 31, 32] that evaluated the effects of exercises in a total of 369 people with hand osteoarthritis reported moderate levels of evidence for hand exercises in improving grip strength, range of motion, hand function and pain relief. A 2011 systematic review [33] focused on ten studies on rehabilitative home exercise programs on pain, function and

physical impairments in people with hand osteoarthritis. Out of ten, three studies were based on exercise treatments, two on laser and heat and one each for massage, splints and acupuncture. Clinical studies [20, 25 and 28] on home exercise programs in people affected with hand osteoarthritis were included in the review. With major limitations in the included studies such as heterogeneity of exercise prescription and dosage, the review concluded that hand exercises had no effect on pain, stiffness and hand function. A brief outline of systematic reviews on conservative management of hand osteoarthritis is presented in Table 7.

**Table 7: Outline of systematic reviews in conservative management of hand osteoarthritis.**

Systematic reviews	Conclusions
Ye, Kalichman, L, D & Bennell, 2011 Seven randomized controlled trials, two crossover trials, one quasi-randomized controlled trial on various rehabilitative home programs	Hand exercises have no effect on pain, stiffness and hand function
Ingvild Kjekken, 2011 3 randomised controlled trials	No specific recommendations regarding design of home exercise programs have been published
Valdes & Marik, 2010 randomized controlled trials and cohort studies published between 1986-2009	Moderate evidence to support hand exercises on improving grip strength
Moe RH, Kjekken, 2009 Reviews on the non-pharmacological and non-surgical home programs	Very little evidence for conservative management
Zhang et al., 2007 EULAR (European League against Rheumatism) multidisciplinary evidence-based recommendations	Direct evidence for exercise alone is lacking Any specific hand exercise prescribed is limited to level 4 expert opinion

A randomized controlled trial [30] studied the effects of yoga therapy for hand osteoarthritis in a treatment group (n=9) for a period of ten weeks while the control group (n=7) did not receive any treatment except drug therapy. Therapy consisted of stretching and strengthening exercises. Pain, strength, motion, joint circumference, tenderness and self-reported hand function were included as study variables. Except for hand function in the control group, all variables showed improvements in both groups. Significant improvements in all variables were reported in the group that received yoga while improvements in the control group were non-significant.

A non-randomized trial [31] compared the effects of strength training exercises in the treatment group (n=9) with the control group (n=10) for six weeks. In the treatment group, isometric resisted exercises for hand and forearm muscles were performed at 40-60% of maximum voluntary contraction; isotonic strengthening from low intensity of 40% of 1-Repetition Maximum (RM), 10 to 15 repetitions progressed to moderate intensity of 60% 1-RM, six to eight repetitions and other specific exercises such as grabbing and releasing rice inside a bag, progressive pinch grip lifting of a sand bag using all fingers and wrist roll exercises using a polyvinyl pipe. The control group did not receive any treatment. Grip, pinch strength, finger range of motion and joint pain were the study variables. Jamar grip and pinch gauge for grip and pinch strength, goniometer for range of motion and a six point scale (zero-no discomfort, six-extreme discomfort) for joint pain were used as outcome measures. Compared to the control group, grip strength and range of motion significantly improved in the treatment group while pain and pinch strength showed no differences. However, the findings are less generalisable due to small sample size. Also the control group was not an active comparator for the treatment group. The study does support resisted hand exercises in improving hand strength, but did not

measure hand function through validated objective or subjective measures. A 2002 randomized trial [25] studied the effects of joint protection and home hand exercises on hand function in people with hand osteoarthritis. The primary variable was grip strength while pain and global hand function were secondary variables. Outcomes were measured using Martin Vicorimeter, Health assessment questionnaire (HAQ) and Visual Analogue Scale (VAS) for pain and global hand function. Twenty people in the control group received oral and written information on joint protection education such as using larger joints and assistive devices; avoiding stress or vibrations to the finger joints etc. Twenty people in the experimental group received instructions on joint protection, along with a home hand exercise program. The home program consisted of making a fist, making a small fist (flexing the proximal and distal inter-phalangeal joints only), flexing the metacarpo-phalangeal joints alone, touching the tip of each finger with the tip of the thumb, 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 metacarpo-phalangeal joint with the tip of the thumb. Participants were instructed to exercise with both hands 10 times a day for three months. Study findings revealed a statistically significant increase in grip strength in both hands in the experimental group, while no changes were noted in the control group. Global hand function showed improvement in a higher number of people in experimental group than the control group. The HAQ scores and global pain did not change significantly. This short term study concluded that a combination of joint protection advice and home hand exercises was effective in improving hand function in people with hand osteoarthritis. In another randomized controlled trial [29], two forms of splints and thumb exercises were tested for efficiency in forty people with osteoarthritis of the thumb. A novel thermoplastic thumb

strap splint designed by Wajon was worn by the experimental group for two weeks and the splint was removed only during personal hygiene activities. After two weeks, palmar abduction against gravity was performed five times for three sessions daily and was gradually increased in repetitions. A short opponens splint covering the metacarpophalangeal joint was worn by the control group and a pinch exercise using a very soft foam block was advised starting from five repetitions three sessions a day and gradually increased till sixth week. Both groups were advised about joint protection and home hand exercises. Both groups improved and showed no differences in pain, pinch strength and hand function. The study is also limited with combination of home exercise programs and does not provide evidence whether the exercises were beneficial or the splints. A two year follow up study [34] on 55 people with radiographic hand osteoarthritis studied the effects of whole body strength training and gripping exercises on hand function, pain and strength. A structured strength training program three times per week included a set of warm up, general strength training for the whole body and a gripping exercise performed on a hand gripper machine. The number of sets and repetitions progressed based on participant responses to strength training. Pain and isotonic and isometric grip strength increased considerably while the self-reported hand function measured by AIMS-2 showed no significant changes. However, it is unclear whether the strength gains were purely from the gripping exercises alone because some of the general body strengthening exercises required gripping the bars tightly. The other major limitation was that the study did not have a control group for fair comparison between programs. Hence, the study results do not contribute to strong evidence.

A controlled cross over trial [28] was conducted on 46 people with hand osteoarthritis. The purpose of the study was to assess the effects of a home program and a

placebo non-medicated hand cream (Sham treatment) in order of sixteen weeks each, with a wash out period of 16 weeks in between. Hand exercises were prescribed based on earlier work [25] and consultations of occupational and certified hand therapists. A set of mobility and strengthening hand exercises, such as making a full fist, making a small fist, flexion of metacarpo-phalangeal joints of 2<sup>nd</sup> to 5<sup>th</sup> digits, squeezing of soft ball, finger spreading and return to neutral, key pinch and fingertip pinch with the soft ball, thumb opposition and making an ‘okay’ sign was provided. Each exercise was performed ten times during the first four weeks, progressed to 12, then 15 and finally to 20 in the last four weeks. There were very moderate improvements in secondary variables of grip and pinch strength not translated to improve the physical function sub scale of Australia Canada (AUSCAN) questionnaire, the study primary outcome measure in both groups. The intervention was not effective in improving dexterity as no changes were detected by Purdue peg board test.

The 2011 ACR recommendations [35] for the use of non-pharmacologic and pharmacologic therapies on hand osteoarthritis, hip and knee did not include ‘exercise’ for hand osteoarthritis but suggested joint protection advice, assistive devices, thermal modalities, trapezo-metacarpal splints and use of oral and topical NSAIDs, Tramadol and topical capsaicin. A brief outline of the clinical trials that evaluated hand exercises in hand osteoarthritis is presented in Table 8.

**Table 8: Outline of clinical studies that examined conventional hand exercise programs in hand osteoarthritis**

Study	Intervention	Outcomes	Results
Rogers et al, 2009 N=46	Home based programs versus Sham treatment Study duration: 16weeks	Hand function (Physical function subscale of Australia Canada (AUSCAN) hand index) Grip and pinch strength Peg board dexterity	Home program modestly improved hand strength. Change in AUSCAN scores showed no difference between groups
Lefler & Armstrong et al, 2004 N=19	SG: Strength training CG: Normal activities Study duration: 6 weeks	Grip, pinch strength Finger ROM Pain	Grip strength and ROM increased after exercise
Stamm et al, 2001 N= 40	CG: Information on OA SG: Joint protection +home based programs Study duration: 3months	Grip strength Disability (Health assessment questionnaire) Pain, global hand function (VAS)	SG: 25% increase in grip strength 65% of SG improved in global hand function
Garfinkel et al, 1994 N=25	SG: Supervised yoga and relaxation techniques Study duration: 10 weeks	Circumference of finger joints Finger ROM Grip strength Joint tenderness & Pain	Pain and joint tenderness decreased and grip increased after yoga



## **2.4. Current recommendations and practices in exercise therapy for people with arthritis of the hands**

A very recent review [36] recommended the use of active or active-assisted exercises for maintaining or improving joint range of motion. The exercises were to be performed within the physiologic limits of the affected joint and not allowing any compensatory trick movements. Isometrics and low to moderate load (40-70% of 1 repetition maximum), high repetition (8-15 repetitions) isotonic strength training exercises were also suggested for preventing muscle wasting, weakness and risk of contractures.

A 2012 Dutch survey [37] evaluated current physical therapy practices in management of people with rheumatoid arthritis, which included responses from 233 physiotherapists. The study reported that exercise therapy and patient education were always prescribed by most (70%) of the physiotherapists in their clinical practices. However, details of the type of exercises prescribed for people with rheumatoid arthritis were not provided.

To date, a standard evidence based hand exercise program is not available due to limited high quality trials in rheumatoid arthritis and hand osteoarthritis. Current clinical practices are based on professional agreement of applying exercise therapeutic techniques and clinical knowledge on arthritis disease characteristics. The general theoretical basis includes maximizing function by maintaining or improving joint range of motion and strength of surrounding muscles. A combination of active or active assisted finger range of motion exercises and strengthening exercises with equipment such as therapeutic putty, finger exercise rings, finger gripper and soft medicine balls are often followed.

## **2.5. Exercise motivation in people with arthritis**

Patient motivation is one of the most significant factors reported in literature in relation to the exercise or activity behavior [38]. No studies discussing the role of motivation in performing hand exercises in people with arthritis were identified. A few studies on general exercise or physical activity programs in people with rheumatoid arthritis or other chronic conditions are discussed here. In a cross sectional study, approximately 50% of 107 randomly selected individuals with chronic diseases reported poor motivation as one of the factors for regular exercising [39]. A narrative review on the benefits of exercise in arthritis conditions highlights the lack of enjoyment and motivation negatively influencing exercise behavior [40]. In another cross sectional study involving 176 individuals with rheumatoid arthritis, lack of motivation was found to be strongly associated with inactivity. The study recommended development of interventions to increase motivation and improve physical activity. Lack of motivation has also been seen in relation to inactivity in other chronic conditions such as cancer and type 2 diabetes mellitus [41]. Another study reports 45-60% of non-compliance reported in people with arthritis [42]. A qualitative study nested within a randomized controlled trial interviewed twenty participants who had undergone a home exercise program for an osteoarthritis knee. One of the major themes evolved for compliance and non-compliance in those participants was motivation which depended on participants' attitudes towards the symptoms, severity of arthritis symptoms, ability to accommodate the exercise program in everyday routine, and knowledge about the arthritis condition [43]. A cross sectional study [38] on 643 rheumatoid arthritis patients employed autonomous regulation or intrinsic motivation, one of the constructs of self-determination theory in which

patients consider the target health behavior as their own chosen personal goal and not forced by others. On identifying the relationship between physical activity and autonomous regulation, the study findings indicated higher levels of physical activity associated with autonomous regulation. The study further suggested that patients should be intrinsically motivated by the health care members, using motivational interviewing to facilitate patient decisions for a behavioral change.

## **2.6. Task-oriented training program for people with arthritis of the hands**

### **2.6.1. Theoretical basis**

Rheumatoid arthritis or osteoarthritis affecting the hands and wrists profoundly affects the individual's abilities to engage in daily activities of self-care, work and leisure. Activities of daily living, such as manipulating objects, turning a door knob, picking up coins, holding a credit card require dexterous and coordinated finger hand function [44]. Dexterity quantifies and judges both ability and disability by measuring the quality of movement as the hand interacts with common objects of daily life [45]. A cohort study [46] on geriatric women reported that dexterity is the best predictor of independence in daily life activities. Difficulties in many gross/fine dexterous activities, such as opening jar lids, turning door knobs or keys, gripping small objects between finger tips and holding heavy objects are well documented in rheumatoid arthritis [47, 48] and hand osteoarthritis [49, 50]. Importance of dexterity has also been highlighted by the domain 'fine finger use' in the recently developed ICF core sets for both rheumatoid arthritis and osteoarthritis. With dexterity being an important component of hand function [45], the guiding principle is to include coordinated and skilled finger hand movements for

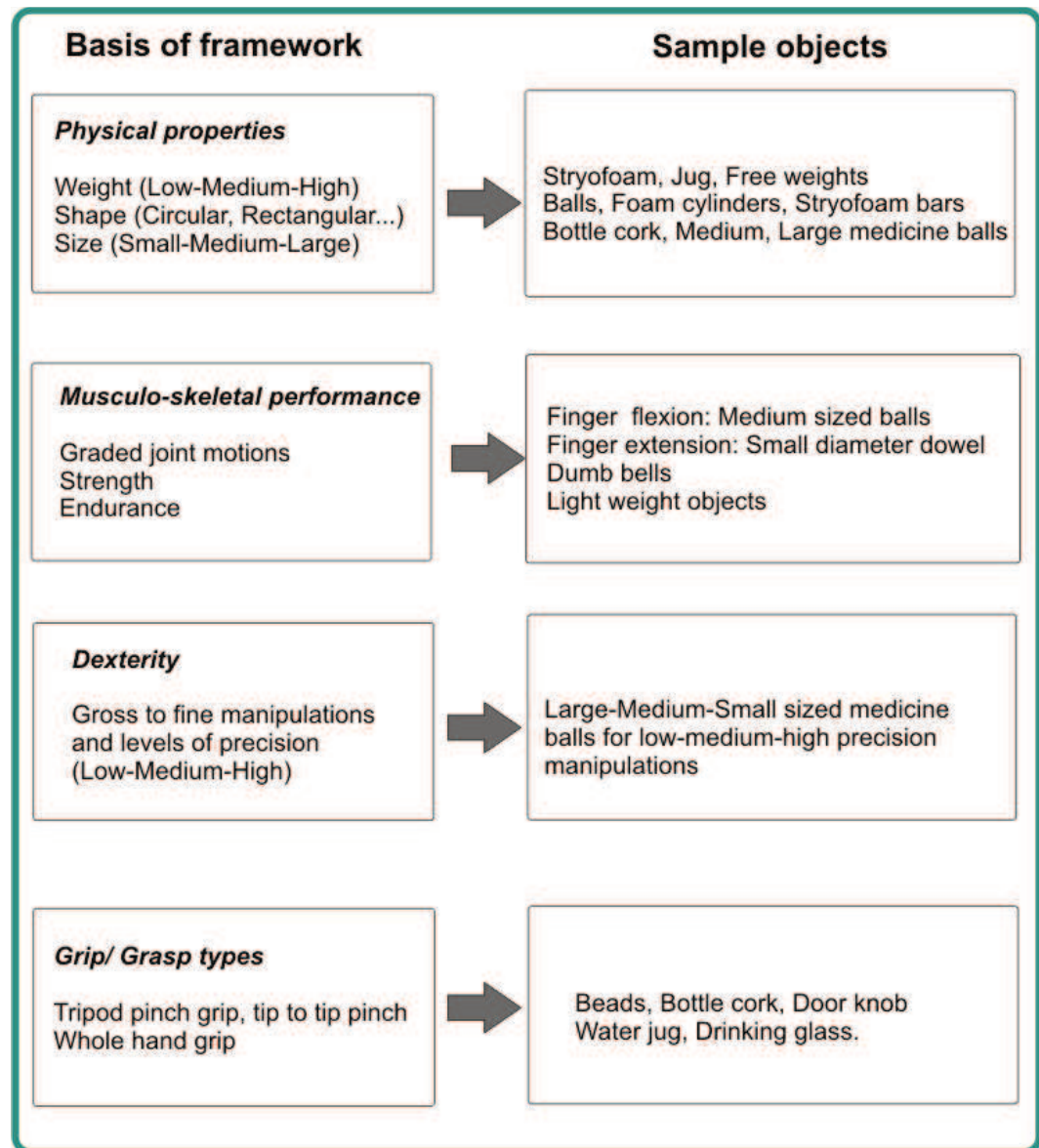
improving hand function [51]. Performing the conventional hand exercises does not sufficiently transfer performance to most of the daily life tasks which require complex combinations of fine finger movement patterns. In contrast, if fine finger movements are trained, co-ordination, precision and skill levels will improve [51] and these abilities could be effectively transferred to perform most activities of daily living. In a randomized controlled trial [52] on 36 young adults with hand injuries, a conventional home exercise program that included passive, active range of motion and hand strengthening exercises was compared to training with 25 different therapeutic activities that mimicked activities of daily living (ADL) such as using a spoon; rolling a cylinder; locking and unlocking door key; and turning a page. Improvements in hand function were noted in the group that received therapeutic activities mimicking ADL. The study suggested that a hand exercise rehabilitation program should incorporate training of coordinated movements for efficient hand use in daily life. Building on this concept, a training program adapting the principles of functional, task-oriented approach [61] was designed. The program was also based on clinical knowledge of rheumatoid arthritis and osteoarthritis, theory based knowledge on the content of various hand function measures and common activity limitations reported in arthritis clinical studies, and inputs provided by people with arthritis of the hands.

The task-oriented approach focuses on acquisition of skills with repetitive training to increase endurance and intensity of practice [53, 54]. The graded joint mobility, endurance and muscle strength training involved in practicing functional movements of common tasks are expected to efficiently transfer in performing functionally relevant tasks of daily living. Task practice in natural home environment settings enables people to function more independently and to use common objects of daily life [55, 56]. The task-

oriented training approach has been found effective in gait retraining, sit to stand transfers, reaching tasks and upper limb function recovery in people with spinal cord injury, traumatic brain injury, Parkinson' disease and total hip replacements [54, 57]. A few examples of task-oriented upper limb tasks include: opening and closing jars, using a spoon and grasping or picking up an object.

In the task-oriented training program, common object manipulation tasks were trained targeting therapeutic goals such as graded finger mobility, precision, repetition and endurance and resistance and strength of the hand muscles [58]. A functional framework (Figure 5) has been developed in selecting therapeutic objects to attain personalized treatment goals.

Figure 5: A functional framework for selecting ‘therapeutic’ objects.



The selection of therapeutic objects for task-oriented training can be based on the following:

a) Object's physical properties: Size, Shape and Weight & Grip and Grasp Types

Objects ranging from light to heavy weights, such as Styrofoam to free weights can be instrumented by the motion sense mouse, as required. Low, medium, heavy free weights (dumb bells) are selected for progressive strengthening of wrist muscles. Gross dexterous movements, involving the palm and fingers, can be trained using large size objects. Medium precision movements involving the use of three or four fingers could be trained by medium size objects, while very fine manipulation skills are practiced with small size objects, involving two fingers only. The program also allows manipulation of objects of any shape (cylindrical, spherical, conical, rectangular objects etc.).

b) Musculoskeletal performance: Joint mobility, strength and endurance

If the goals are to strengthen hand/wrist muscles, heavier object manipulation tasks may be trained to improve hand strength. Light weight objects that do not elicit pain are selected for repeated movements to improve endurance. Some objects require less grip force while some require a strong grip. Thus, for an individual with reduced grip strength, medium size and light weight objects would be selected.

c) Dexterity

Depending on each individual's level of impairments, needs and treatment goals, personalized training is planned focusing on manual dexterity training. Examples: Gross dexterous functions including hand, wrist and forearm or fine dexterous functions such as small, delicate object manipulations within the hand.

#### d) Grip/grasp types

Depending on training needs to improve dexterity, joint mobility or strength, objects would be manipulated with two fingers (using tip to tip, pad to side or pad to pad grasp), three fingers (using tip to tip, pad to pad or oblique palmar grasp), four fingers (using tip to tip or pad to pad grasp), or the whole hand (using spherical, cylindrical, disc or lumbrical grasp) with or without wrist, elbow or shoulder joint motions.

In summary, objects of daily life were selected on the basis of their physical properties, function and task goals. For example, small objects such as a bottle cork, golf ball, door key, beads or bottle caps were selected to train fine manipulation and precision skills which emulate various dexterous activities of daily living. Gross manipulation of objects such as medium or large size balls, light weight flat boards, medium or large size scissors, water jug, coffee mug, drinking glass and foam cylinders emulate manipulation of medium to large sized objects that requires various degrees of finger mobility. Manipulation of objects such as medium diameter paper rolls and sponge cylinders were used to target extension at metacarpo-phalangeal and inter-phalangeal joints. These tasks would emulate handling of objects requiring finger extension. Light weight styrofoam cylinders were used to target free wrist flexion and extension motions while dumb bells were used for strengthening wrist flexors and extensors. These tasks emulate many functional activities of upper limb in daily life requiring free wrist mobility or grip strength [58].

A few examples of functional tasks training that can be performed with computer gaming are presented in Table 9.



**Table 9: Examples of functional tasks training**

Opening/ closing of salad tongs
Up/ down tilting of coffee mug/ drinking glass
Up/ down tilting of plate or flat board
Rolling dowels of various diameter sizes
Simulated pouring activity with a jug
Rolling of small, medium, large sized beads/bottle caps
Simulated turning of door knob/ handle/key
Simulated opening/ closing of jar lids
Simulated cutting with scissors
Simulated using of screw driver
Simulated steering wheel activity
Simulated in-hand manipulations of medium/small sized spherical objects
Gross manipulations of objects such as pool noodles, large size sports balls, table punching balls or dumbbells

The task-oriented training program can be explained using the ICF model terminology. The program focus on improving hand related impairment variables (body functions), and activity limitations and participation restrictions (activities and participation). Reduced grip strength, endurance and finger and wrist joint motions are targeted with components of musculoskeletal performance such as strength, endurance and graded joint motions training. Fine and gross dexterous tasks and activities encountered in daily life situations are targeted by repetitive training of such tasks involving the use of two fingers, three fingers and whole hand. The three main activities and participation categories of the ICF; the fine finger use, hand and arm use and lifting and carrying objects which have been prioritized in the comprehensive core sets for the rheumatoid and osteoarthritis populations are also emphasized in the task-oriented training program. The program thus differs from conventional exercise programs which are focused only on impairment variables (body functions).

#### **2.6.2. Task-oriented training coupled with computer gaming**

The task-oriented training was performed through a computer gaming platform which included motion sense mouse (universal game controller), common objects of daily life and commercially available computer games.

##### **2.6.2.1 Motion sense mouse (Universal game controller)**

A standard sized motion sense mouse (Gyratron air mouse, Elite) was used to seamlessly transform many diverse objects, utensils, tools into computer input devices. Thus an instrumented object is emulated as a traditional computer mouse ready for 'exergaming' the hand. The motion sense mouse is a commercial, plug and play, standard USB

driven computer mouse (Figure 6) and costs around \$80.00 per unit. Many objects used in daily life can be directly instrumented with the mouse using Velcro strips, while a few small objects require a slightly modified structural set up using a dowel and a wooden block.

**Figure 6: Gyration Elite Motion Sense Mouse**



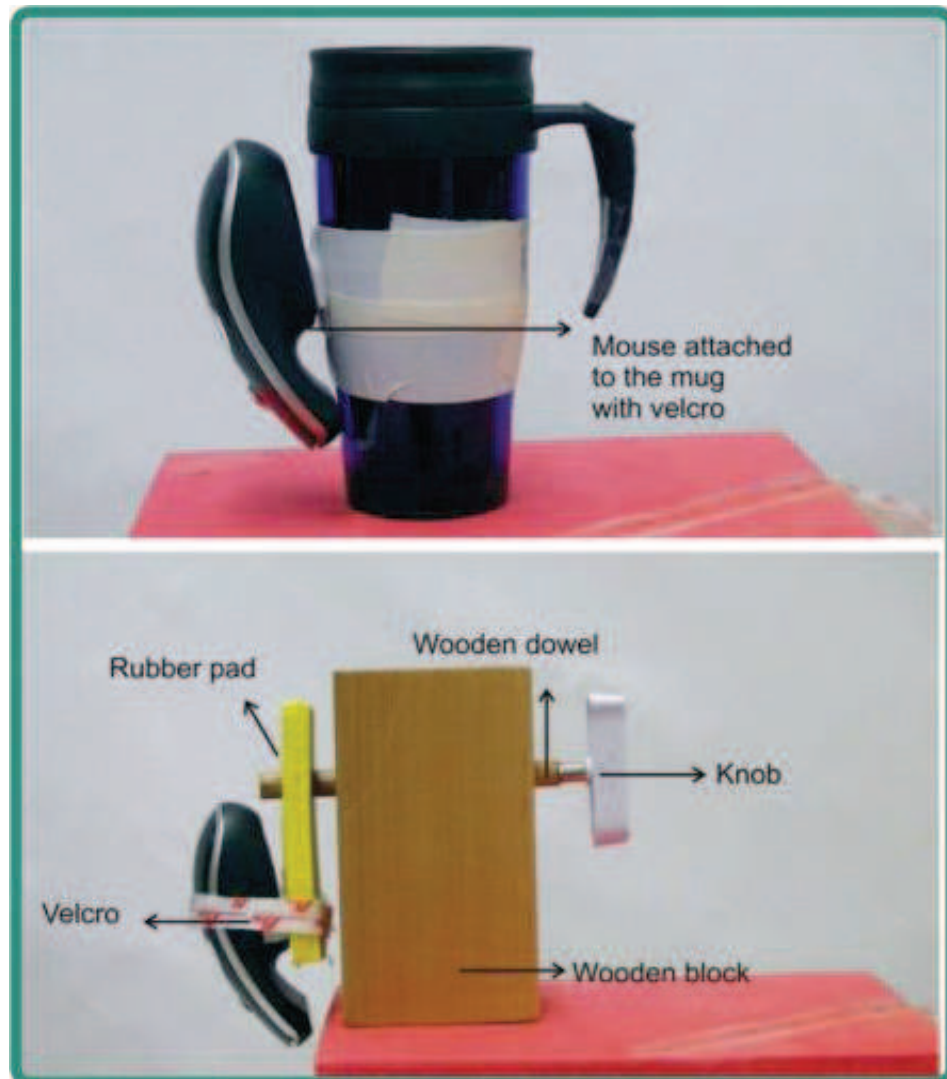
#### 2.6.2.2. Common objects of daily life

Common objects of daily life have different physical, functional and ergonomic properties. Taking advantage of these properties (e.g., size, shape, weight, etc.), objects could be selected to train dexterity (fine and gross), graded joint motions, endurance and strength. A wide range of common objects that could be instrumented with the motion mouse are illustrated in Figure 7. Figure 8 shows a coffee mug instrumented with the motion sense mouse using Velcro strips, and a knob instrumented using a modified structural set up.

**Figure 7: Common objects that could be instrumented with the motion sense mouse.**



**Figure 8: Instrumentation of objects**



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### 2.6.2.3 Commercially available computer games

Any commercially available computer game that requires mouse movements in X or Y or both axes could be used with the gaming platform. Commercially available computer games are inexpensive, engaging, interesting, motivating and easy to use with the tremendous potential as rehabilitation application. Computer games provide a wide range of precision levels, movement speeds, amplitudes and directions. Added features such as distracters, reaction times, strategies, game difficulty levels and visual-spatial and cognitive challenges compliment for more fun and motivation. There are also a wide variety of choices available for selecting an appropriate or preferred game to suit a client's level of hand functional abilities. Approximately 50-60% of commercial games require play movements in X or Y directions, while the remaining games need to be played in both axes. The following are to be considered during the selection of commercially available computer games: 1) it is important to identify games that suit the individual preferences and the wide range of commercial games makes this possible. Games should be simple, easily understood, engaging and motivating and should be well balanced with respect to skill, chance and strategy. Skill should be able to bring the best of the required rehabilitative movements, while chance and strategy keeps the client motivated, and 2) Computer games are typically episodic events with a wide range of movement amplitudes, speeds and precision levels. Random ordering of 'n' trials of x tasks increases task variability and this leads to a better performance than a single task practiced repeatedly. For the present study, a variety of inexpensive games from Big Fish Games ([www.bigfishgames.com](http://www.bigfishgames.com)) was used. This site has a diverse collection of over 400

high-quality computer games in all genres. Around 65 computer games have been tested and found suitable for the present study.

The task-oriented training program was targeted to improve hand function during everyday tasks requiring dexterity functions and strength. The random manipulative movements with each object task were used to control the motion of the computer game cursor.

## **2.7. Interactive computer games in rehabilitation**

Since 1980, commercially available interactive computer games have been used for therapeutic purposes in different patient populations [59-75]. Game based rehabilitation approach provides people with interesting play opportunities in unlimited virtual scenarios and motivation to complete a task or many trials [71]. It is also reported that computer games are fun and enjoyable [69, 71] and are intrinsically motivating, engaging and pleasurable [71]. The use of interactive computer games in geriatric rehabilitation is increasing [73-75]. A recent randomized controlled trial [75] studied the effects of interactive gaming exercise on balance impairment in older adults with balance and mobility limitations. The experimental group received sixteen sessions of dynamic balance exercise coupled with three different computer games, while the control group received a typical physiotherapy program generally prescribed for people with balance impairments. Balance, confidence during balance, mobility, spatio-temporal gait parameters and dynamic balance performance were the study outcome measures. Findings demonstrated significant improvements in post treatment balance performance scores for both groups and change scores were significantly greater in the experimental group compared with the control group. Another study [67] evaluated the feasibility of

commercially available interactive computer games coupled with manipulation of diverse range of objects in improving finger hand function in three cases of incomplete cervical spinal cord injury, left cerebrovascular accident and left hemiplegic cerebral palsy. Common objects were selected for their ergonomic and therapeutic values on the basis of client impairments, functional ability and personal needs to target training of spatial temporal movement accuracy, movement efficiency and endurance. All objects were instrumented with a miniature motion sensor and the object motions were synced with the motion of the game sprite permitting interactive game play. Participants attended 15 one hour sessions and the Jebsen-Taylor hand function test, passive and active range of motion were the outcomes. A computer based custom tracking was used to quantify fine finger manipulation skills by comparing the reference and user motion trajectories through an overall movement performance index. Post-treatment, the time taken to complete Jebsen hand function test was considerably reduced, range of motion and movement performance were considerably improved. Task specific repetitive training of finger hand movements using computer games produced positive effects in improving finger hand function in all the three neurological cases. The study used random computer games with different levels of movement amplitudes, precision levels or speeds. This task variability during movement practice was said to contribute to retention of the task learning.

Interactive computer games have gradually started to complement classic rehabilitation approaches in various fields of rehabilitation. Recent advancements in computer and gaming technology have further led to the availability of hundreds of commercial games at an affordable cost.



## **2.8. An overview of the Arthritis Hand Function Test (AHFT) and the DASH questionnaire**

The Arthritis Hand Function Test is a performance based test for measuring hand function [76-79]. It has 11 items relating to four sub-scales of strength, dexterity, applied strength and applied dexterity. Assessments of grip and pinch strength, and peg board dexterity involve the strength and dexterity sub-scales. The applied strength and dexterity sub-scales involve some common tasks of daily living, such as carrying a tray and lacing a shoe. The AHFT has demonstrated adequate test retest reliability with Intra-class correlation coefficients ranging between 0.53 to 0.96 in twenty individuals with rheumatoid arthritis [78] and between 0.7 and 0.96 in twenty-six individuals with osteoarthritis [77]. Face or content validity has been tested by five occupational therapists. The test has also demonstrated convergent validity showing moderate correlations with self-report measures such as Michigan Hand Questionnaire (Spearman  $\rho=0.3-0.65$ ), Dreiser functional index for hand osteoarthritis (Spearman  $\rho=0.44-0.57$ ) and Cochin hand function disability scale (Spearman  $\rho=0.52-0.64$ ) in forty individuals with hand osteoarthritis.

The DASH questionnaire [80-83] assesses the client reported measure of upper limb function ability in daily activities. It contains 30 core disability/symptoms items covering three constructs of the ICF such as body functions, activity limitations and participation restrictions. Twenty-one items relate to identifying the level of difficulty in performing common day to day activities, such as opening a tight jar and carrying objects, five items relate to body functions such as pain, tingling and stiffness, and four items relate to social activities, sleep and work. The DASH measure has excellent test retest

reliability with an Intra-class correlation coefficient of 0.97 in 102 individuals with rheumatoid arthritis. Validity has been demonstrated with strong correlations with Pearson correlation coefficient  $r=0.88$  with the HAQ, 0.7 with Short Form-36 and 0.85 with the AIMS-2 questionnaire [80]. The measure also demonstrated excellent test retest reliability with an Intra-class correlation coefficient of 0.96 in 200 individuals with different wrist/hand or shoulder problems [81].

## **2.9. An overview of mixed methods research**

Quantitative and qualitative research methods represent two different ends on a continuum [84] in conducting research, in which mixed methods research (a combination of quantitative and qualitative methods) occupy the middle of the continuum. Quantitative research involves testing objectives by examining the relationship between the study variables [85]. Strategies of inquiry in quantitative research include true experimental designs, such as randomized controlled trials; quasi-experimental or non-randomized designs, such as single subject studies; and non-experimental designs such as surveys. Data is collected in numerical terms using performance based measures or self-reports; analyzed and interpreted using statistical test procedures. Quantitative research follows the assumptions of post-positivist philosophical worldview which emphasize on evaluation of causes influencing outcomes as in experimental studies. Qualitative research involves exploring and understanding of the nature of occurrences or a phenomenon [86]. Strategies of inquiry in qualitative research include narrative research, phenomenology, case studies, ethnography and grounded theory. Text data is collected in natural settings through open-ended questions or interviews. Additional forms of data include observations, audiovisual materials and documents. Information gathered through

such multiple sources is analyzed by generating codes and themes to represent the larger perspective of the research problem. Qualitative research follows the assumptions of the social constructivist world view which emphasizes developing subjective meanings of personal, cultural or historical experiences or views of individuals; ‘the meanings’ essentially addressed by social interactions with other community members.

Mixed methods research involves the combined use of quantitative and qualitative research methods. Johnson et al, 2007 [87] defines mixed methods research as, “research in which a researcher or team of researchers combines elements of qualitative and quantitative research approaches (e.g., use of qualitative and quantitative viewpoints, data collection, analysis, inference techniques) for the purposes of breadth and depth of understanding and corroboration”.

An expanded definition was further provided by Creswell & Plano Clark [88] as, “It is a research design with philosophical assumptions as well as methods of inquiry. As a methodology, it involves philosophical assumptions that guide the direction of the collection and analysis and the mixture of qualitative and quantitative approaches in many phases of the research process. As a method, it focuses on collecting, analyzing and mixing both quantitative and qualitative data in a single study or series of studies. Its central premise is that the use of quantitative and qualitative approaches, in combination, provides a better understanding of research problems than either approach alone.

They [88] list the main characteristics of the mixed methods research as follows:

- a) Collecting quantitative and qualitative data depending on the research questions
- b) Mixing or linking data from both methods either to build over one another or embed within one another

- c) Setting priority to either one or both research methods
- d) Using both methods in the same study or in multiple phases of a study
- e) Utilizing research paradigms and philosophical world views to guide the study

Mixed methods designs help to achieve different objectives [85, 88, 89] in a single study, offset the weaknesses and compliment the strengths of each other method, help to gain broader understanding of the research problem, tends to be more practical and free to choose the methods as required by the study purposes, provides strong data evidence through the process of data triangulation rather than using a single method alone [89] and encourages the use of 'Pragmatic' philosophical worldview over the rigidly associated paradigms specific to quantitative and qualitative research methods [88].

Five purposes of using mixed methods research identified by Rossman and Wilson [90] were, 1) Corroboration-triangulating the data from different sources on the same research problem 2) Complementation-complimenting or elaborating findings from one method with the other 3) Expansion- using different research methods to assess different research questions and improve breadth of inquiry 4) Initiation-suggesting directions for future studies and 5) Development-findings from one method to guide another research method [91].

Since the late 1970s, debates were on about mixing quantitative and qualitative research approaches because each had their own paradigms and data collection methods. Reichardt & Cook [92] suggest that different paradigms and methods are compatible, if each research method is considered for its advantages. A dialectical perspective proposed by Green & Coracelli [93] maintains viewing mixed methods research preferably as a 'method'. Teddlie & Tashokkori, 2003 & 2009; and Macy 2003 [94-96] added that research questions should be more emphasized than debating on theory or paradigm used

for each research method. In 2009, Teddie & Tashokkori [94] proposed ‘pragmatism’ as the philosophical basis of the mixed methods research. According to this paradigm, both research methods may be used in a study with more focus set on the research questions, thoughts on ‘what works best’ and appreciating knowledge gained from each research method.

The pragmatic worldview allows use of multiple research methods, collects different forms of data and follows different types of analyses. Three strategies of inquiry are used in mixed methods research: 1) sequential mixed methods, where a study may begin with a quantitative method followed by a qualitative method and vice versa 2) concurrent mixed methods, where both forms of data are collected simultaneously and 3) transformative mixed methods where the researcher uses a theoretical framework to guide the mixed methods study procedure.

In spite of its many advantages, mixed method research poses major challenges such as being expensive in terms of time, resources, expertise and efforts. The mixed methods researcher must be skillful and familiar with data collection and analysis procedures of both research methods and should have a good understanding of other essential features of mixed method designs [88]. Mixed methods research still being a relatively new field provides challenges with respect to issues such as writing up and publishing in academic research journals

## **2.10. Pilot clinical trials**

Pilot trials are considered to be small scale versions of subsequent fully fledged trials. Some operating definitions of pilot studies provided in the published research literature are as follows: Moore et al., 2011 [97] defines them as, “preparatory studies

designed to test the performance characteristics and capabilities of study designs, measures, procedures, recruitment criteria and operational strategies that are under consideration for use in subsequent, often larger study”. Arnold et al., 2009 [98] defines as ‘stand-alone trials’ with specific study objectives, methodology and randomization procedures. Porta et al., 2008 [99] defines as “a small scale test of procedures and methods to be used on a large scale”.

The main purposes of conducting pilot studies are to: 1) assess the potential for successful implementation of the proposed study and to reduce threats to its validity [100], 2) contribute to the development and design of a future study [97], 3) inform the design and conduct of the large trial [98] , 4) predict the feasibility and acceptability of a protocol design, identify unpredicted harm, and to guide effective use of available resources [101], and 5) evaluate implementation of a novel intervention [102]. In addition to the above, a comprehensive typology developed by Thabane et al, 2010 [103] suggested four major domains such as assessments of study process, resources used, management and clinical outcomes. Some of the feasibility outcomes assessed are the recruitment rates, participant retention rates (study process); time taken to administer a self-report questionnaire or conduct a performance based test (resources); with management of data and study personnel (management) and determining the effects of the interventions studied using statistical analyses (clinical outcomes).

Pilot studies are considered an important first step in planning large randomized controlled trials [100], however they warrant further large sample sized studies for appropriate statistical significance testing of study [101]. Pilot studies are often not expected to have a large sample size [100, 104] or statistical power for considering statistical significance of study findings [101]. A review on current practice and editorial

policy of pilot studies by Arian et al, 2010 [105] reported that only 10 out of 54 studies included in the review performed a pre-study sample size calculation. Some areas in which pilot studies could substantially contribute [106] are in: 1) identifying practical problems that may slow down or prevent completion of a large trial 2) providing practical and realistic estimates of human resources, time, and equipment required for study completion 3) providing new insights on new interventions 4) evaluating different study recruitment strategies 5) field testing of novel interventions and 6) informing any revisions to be considered in study procedures or interventions in order to proceed to the large size study successfully. Additionally, pilot studies provide opportunities for exploring study participants' opinions on therapy programs through self-report questionnaires, open ended individual or focus group interview questions.

A few examples of pilot randomized trials with sample sizes ranging between 19 and 45 are included [107-119]. Any previously published pilot trials or protocols involving exercise programs for people with rheumatoid or osteoarthritis of the hands has not been identified.

## **2.11. Phenomenology strategy of qualitative inquiry**

Phenomenology is a term derived from Greek; 'logos' defined as 'the science of', giving the meaning 'the science of a phenomenon'. Phenomenology identifies the meaning of the lived experiences of several individuals around a central concept or a phenomenon. A phenomenon is the 'object' of human experience; a few examples would be undergoing a surgery, grief process or anger. The whole 'essence' of lived experiences of the participants with the phenomenon is captured by asking two broad questions: 1) What have you experienced in terms of the phenomenon, and 2) What context or

situations influenced your experiences with the phenomenon [85]. Two types of phenomenological approaches are discussed in the literature: Hermeneutic phenomenology, and empirical, transcendental or psychological phenomenology. Hermeneutic phenomenology described by van Manen [120] emphasizes more on researcher interpretations in understanding the meaning of the lived experiences of the participants on a phenomenon.

## **2.12. Focus group interviews**

Lederman defines a focus group as, “ a technique involving the use of in-depth group interviews in which participants are selected because they are a purposive, although not necessarily representative, sampling of a specific population, this group being ‘focused’ on a given topic”. Focus groups would provide a diverse range of responses and hence generate rich qualitative data [121]. Some of the other reasons for the focus group method were: 1) focus group sessions would allow active interactions between group members and enhance discussion, 2) focus groups would provide more insights into the research questions than the interviews conducted on an individual basis [121-124], and 3) focus group sessions would save time and resources compared to conducting individual based interviews.

## **2.13. Summary**

This chapter discussed the available evidence on the effectiveness of conventional hand exercises in people with rheumatoid arthritis or hand osteoarthritis, current exercise recommendations for people with arthritis of the hands, motivation with exercise programs, exercise compliance, the AHFT and the DASH hand function outcome



measures, task-oriented training program for people with arthritis of the hands, interactive computer games in rehabilitation, overview of the mixed methods research, pilot clinical trials, phenomenological strategy of qualitative inquiry, and focus group interviews.

## **Chapter 3: Methodology**

### **3.1. Introduction**

This chapter describes the study rationale, objectives and research questions, study design, study protocol, measurement instruments and data analyses procedures for both quantitative and qualitative research methods.

### **3.2. Study rationale**

Activity limitations and restricted participation in home, work, family and community life results from joint pain, fatigue, joint damage, stiffness and swelling, reduced range of motion and hand muscle strength in people with rheumatoid arthritis or hand osteoarthritis. Dexterity skills in handling and manipulating objects with fingers and hand are important for almost all activities of daily life such as, dressing, grooming, eating, use of utensils and participation in play, hobbies and chores. These activities require manipulation of objects with a wide range of physical properties (size shape, weight, inertia) and often require a high degree of precision where small deviations in timing or endpoint positioning and orientation of the object leads to complete disruption of performance. Difficulties in performing simple tasks of daily life, such as buttoning, cutting with a knife, carrying things, picking up small size objects or coins etc., have been widely reported in people with rheumatoid arthritis or hand osteoarthritis.

In spite of the moderate evidence available on the effectiveness of conventional hand exercises in people with rheumatoid arthritis or hand osteoarthritis, the theory

behind prescribing exercises is to maximize function by improving joint mobility and muscle strength and preventing the occurrence of joint deformities. It should be noted that most of the exercise programs prescribed for people with rheumatoid arthritis or hand osteoarthritis either include joint mobility or strengthening exercises or a combination of both with or without the additional use of thermal modalities. However, other components of hand function such as dexterity or skills training are not usually included in hand exercise rehabilitation programs. Similarly, it would also be important to include task-oriented training with manipulation of common objects of daily life for efficient transfer of skills into activities of daily living. Another significant factor to be overcome in long-term management of chronic diseases such as arthritis is the low compliance with exercise programs. Support strategies to facilitate client engagement and motivation during exercising is also lacking in arthritis hand rehabilitation. As a result, there is a definite need to develop programs and supportive rehabilitation platforms to maximize functional independence, encourage client participation and motivation and improve/maintain long-term outcomes in people with arthritis of the hands. A novel home based task-oriented training program has been designed for improving hand function in people with arthritis of the hands. Functional tasks of daily living, especially the fine dexterous tasks were trained repetitively using common objects of daily life through a computer gaming platform. The training was coupled with computer gaming for increased client motivation and engagement during exercise sessions. The therapeutic purposes of the novel program were to train fine and gross finger/hand manipulation skill, graded finger mobility and hand muscle strength and endurance.

The training program has been described in a few previous studies [58, 67 and 70]. However, no studies have been conducted to evaluate the program in people with arthritis of the hands. Therefore, a mixed methods study combining both quantitative and qualitative research methods was planned. A pilot study was undertaken to describe the feasibility of conducting a full randomized controlled trial in terms of study procedures, resources and home exercise programs and the effects of home exercise programs on study outcomes. In addition to the pilot trial, it was of much interest to explore study participants' perceptions of the home exercise programs in real practice settings. It was believed that the subjective reports provided by the participants would help in understanding the content and delivery of home programs, practicalities and other issues related with the training program from participants' perspective. Phenomenological research is the qualitative strategy of inquiry used to describe lived experiences of individuals on a common phenomenon [123, 125, and 126]. A pilot phenomenological qualitative study was proposed to gain deeper understanding of the experiences of participants in both groups with their respective home programs.

### **3.3. Objectives and research questions**

The objectives of the pilot randomized controlled trial are: 1) to describe feasibility assessment in terms study procedures, resources, management and clinical outcomes of the home exercise programs, and 2) to obtain preliminary data on the therapeutic effectiveness of task-oriented training program in people with rheumatoid arthritis or hand osteoarthritis.

The research questions included, 1) would the trial be feasible in terms of study procedures, resources used, management and clinical outcomes of the exercise programs, and 2) could a preliminary estimation of therapeutic effectiveness of task-oriented training program be done in twenty people with rheumatoid arthritis or hand osteoarthritis?

It was expected that the study procedures, resources and management would be feasible. Also, the experimental group receiving the task-oriented training program would show improvements in performance based and self-reported hand function measures (AHFT, DASH and the game based hand function assessment application) as compared to the control group receiving conventional hand exercises.

The objectives of the phenomenological study were to explore the lived experiences of the study participants who completed their respective home exercise programs in the pilot randomized controlled trial. The broad research questions were “What were the experiences of the study participants with the home exercise programs and on what context were the experiences based upon?”

### **3.4. Study Design**

The present study (Part II of the thesis) adopted an embedded mixed methods model [92, 95]. With this model, one major research method (quantitative or qualitative) serves primarily to drive the study procedures and another minor method (quantitative or qualitative) serves ‘secondary’ to support them. The secondary research method is given less priority and embedded within the primary method. The secondary research method also addresses different research questions than the primary method. So this model has

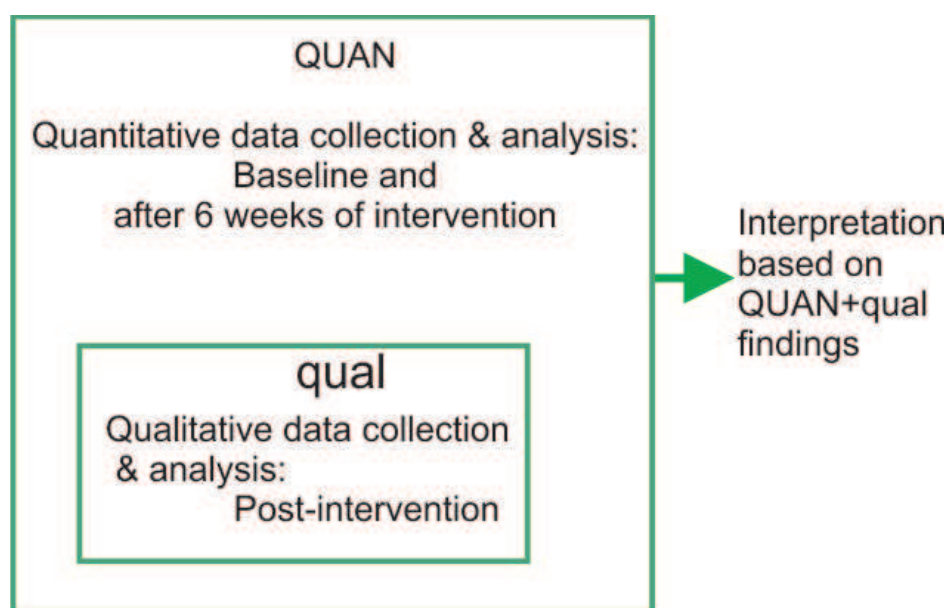
the scope of achieving various objectives and answering different research questions by generating data from both primary and secondary methods, than with the a primary method alone. This model was also preferred because it allowed simultaneous collection of data from both research methods, which is less expensive in terms of available time. The model provides two different types of data in the same study, thus widening its scope with both approaches of inquiry. In this study, an experimental randomized controlled trial was undertaken as a primary strategy of inquiry. A secondary phenomenological study to gain deeper understanding of both group participants' experiences with their respective home exercise programs was conducted along the trial.

Factors such as timing, weighting and mixing are some of the important aspects considered in a mixed methods study design. 'Timing' refers to whether quantitative and qualitative data were collected simultaneously or sequentially in a study. In this study, qualitative data was collected alongside the pilot trial or at simultaneous time points during the study period. Participants who consecutively completed their home exercise programs in the pilot randomized controlled trial phase were invited to participate in the qualitative study. 'Weighting' refers to the degree of priority given to any one approach. The quantitative method was given priority and the qualitative method was supporting the additional need of getting a different perspective (participants' experiences) on the home programs. 'Mixing' refers to mixing, integrating or connecting quantitative and qualitative data which may occur either during data collection, data analysis, discussion stages or during all stages of the study. According to Creswell [85], the mixing of the data in an embedded model could be done in two ways: 1) integrating information from both research methods and comparing the data over one other, or 2) presenting information from each method separately and providing an overall summary without any

comparisons. In the present study, complete integration of data from both methods may not be possible, as each method has its own specific objectives and different research questions. Hence, the priority will be towards emphasizing the ‘mixed approach’ rather than mixing the data [85]. According to Teddlie & Tashakkori, 2009 [94], studies which use both research approaches, but fail to integrate them, fall under the category of ‘quasi-mixed methods’ design. The present study therefore followed a quasi-mixed methods design in which data from each of the research methods was considered separately. The final interpretation was based on the summary of findings from both methods.

An illustration of the embedded mixed methods model used in this study is presented in Figure 9. ‘Quan’ and ‘qual’ are shortened forms of the ‘quantitative’ and ‘qualitative’ research methods. Priority of the quantitative research method over the qualitative method is shown by capitalizing its shortened term as QUAN. Boxes indicate the quantitative and qualitative data collection and analysis procedures. The embedded mixed methods model is denoted by the notion ‘QUAN (qual),’ which means that the small qualitative study is embedded within the large quantitative study.

**Figure 9: Embedded Mixed Methods Model.**





### **3.5. Study protocol**

#### **3.5.1 Ethics approval**

The pilot trial and the qualitative study protocol were approved by the University of Manitoba Human Research Ethics Board, Bannatyne campus (Ethics Reference number: H2012:182).

#### **3.5.2. Study participants**

People with rheumatoid arthritis or hand osteoarthritis residing in the city of Winnipeg were invited to participate in the study. Men and women between the ages of 30 and 60 years and diagnosed with rheumatoid arthritis according to the American College of Rheumatology (ACR) 1987 classification criteria or hand osteoarthritis according to ACR criteria, were included during the early months of study recruitment. Other criteria included willingness to provide informed consent, owning a home computer and having basic working knowledge of computers. An additional screening on self-reported hand function ability with the Disabilities of Arm, Shoulder and Hand (DASH) questionnaire was conducted. A hypothetical DASH score range between 25 and 50 out of the maximum score of 100 was selected to include individuals presenting with the perception of a moderate level of difficulty in performing common activities of daily life. The DASH score criterion was also used to include people presenting with a homogeneous baseline level of self-reported symptoms and level of difficulty in activities and participation, irrespective of the type of arthritis.

People were excluded if they presented with any of the following features: 1) severely deformed finger joints which have become fixed without any possible joint

motion 2) neurological conditions of the dominant side upper limb 3) recent trauma in the wrist or hand 4) upper limb surgeries in the previous six months 5) co-existing hand conditions in the dominant hand 6) problems with vision or hearing 7) recent changes in drug regimen (disease modifying anti-rheumatic drugs (DMARDs) or corticosteroids <3 months) and 8) DASH scores < 25>50. People aged above 70 years were excluded in order to minimize the presence and effects of other co-morbid conditions associated with the aging process. Additionally, if feasibility of the computer game based exercise program was found to be unsuccessful in the 30 to 70 years age group, it is less likely to be successful in people above 70 years. Any diagnosis of major diseases of lungs, heart or liver might have a functional impact on an individual's day to day life, was also considered an exclusion criterion.

A revision in participant age and DASH score inclusion criteria was undertaken during the later course of the study to improve the study recruitment rate. Participants aged between 30 and 70 years and DASH self-report scores ranging between 0 and 75 (representing none to severe levels of difficulty in hand function during a variety of everyday tasks) were considered for participation.

### **3.5.3. Recruitment**

Recruitment tools such as A-4 sized advertisement posters and business card sized information cards were used. Recruitment strategies included distributing advertisement posters through mass electronic mails, attending phone call inquiries, making direct visits to rheumatology offices and posting in the Winnipeg Free Press newspaper, official webpage and Facebook page of the Arthritis Society, Manitoba/Nunavut Division and Winnipeg Kijiji website. Information about the study was made available to the public in

all major locations of Winnipeg, such as religious centers, fitness centers, community centers, physiotherapy offices, patient waiting areas in general Hospitals and rheumatology clinics and senior homes.

Volunteers with rheumatoid arthritis or hand osteoarthritis who were interested in participating in the study contacted the investigator via electronic mails or phone calls. They were screened for eligibility with background questions related to the study participation criteria and the DASH questionnaire score range. Initial screening, pre and post-intervention assessments, home program training sessions of the pilot trial and data collection sessions of the qualitative study were conducted at the Rehabilitation Hospital in Winnipeg. Participants performed their respective six week hand exercise program at their homes.

#### **3.5.4. Sample size and statistical power calculation**

Assuming a 20% change in the scores of peg board dexterity and applied dexterity from a previously published data of arthritis hand function test in 40 patients with rheumatoid arthritis aged between 22 and 76 years [127], a sample size of 20 was considered for the pilot trial with a moderate effect size of 0.5-0.6 and statistical power of 55-73%, two tailed 95% CI. Post hoc statistical power analysis was conducted for the total number of 16 participants enrolled in the study. Power calculation was done using an online statistical calculator available at, [http://www.statisticalsolutions.net/pss\\_calc.php](http://www.statisticalsolutions.net/pss_calc.php). It was also proposed that both group participants who completed their six week home program would be invited to participate in the qualitative study. Table 10 shows the power calculations conducted for the pilot trial.

**Table 10: Power calculation for the pilot trial**

AHFT dexterity scores	Mean	SD	20% improvement in mean score	Effect size	Power for n=20	Power for n=16
Peg board dexterity (seconds)	51.07	17.67	40.86	.6	0.73	0.64
Applied dexterity (seconds)	153.01	65.95	122.41	.5	0.55	0.5

### **3.5.5. Randomized controlled trial design**

The pilot randomized controlled trial was a single center; assessor blinded trial with a parallel group design. Participants were randomly assigned to control or experimental group in equal allocation ratio. The trial was registered with ClinicalTrials.gov (available at <http://clinicaltrials.gov/show/NCT01635582>).

### **3.5.6. Randomization, allocation concealment and blinding**

The sequence for the randomization procedure was generated by referring to computer-generated group numbers. Sequentially numbered, opaque sealed envelopes were used for the allocation concealment. Each cover was opened only after the participant details were written on the envelope after the baseline assessment session. A staff member who was not involved with the trial generated the random numbers, did the allocation concealment and kept them until the end of the study. Two senior physiotherapists and the study investigator were involved in delivering the home exercise programs. The study investigator was also involved in study recruitment and coordinating appointments for participant assessment and individual training sessions. An independent

assessor blinded to the group allocations evaluated the study outcomes at baseline (Pre-intervention) and six weeks later (Post-intervention).

### **3.5.7. Baseline assessment session**

A pre-intervention assessment session was conducted for approximately 50-60 minutes which included: 1) Documentation of participant demographics such as age, gender, occupation, type of arthritis, number of years since diagnosis and individual specific problems with hand function during tasks of daily living 2) Observation of fine/gross finger abilities on handling different objects of daily life and 3) Hand function evaluation with the AHFT, the DASH questionnaire and computer game based hand assessment application .

### **3.5.8. Home exercise programs**

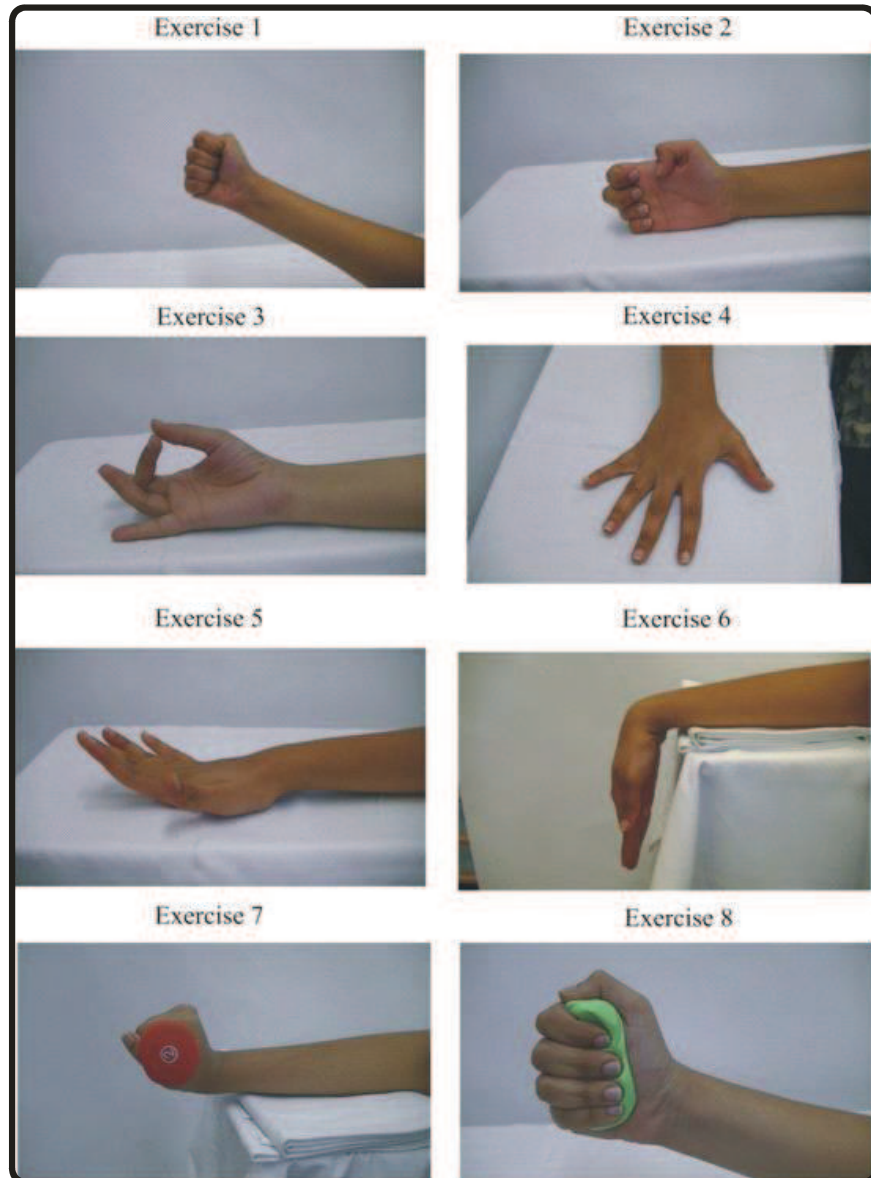
#### **3.5.8.1. Control group: Conventional hand exercises**

The home exercise program for the control group included a conventional hand exercise program based on previous studies [1, 7, 9, 10, 15, 25, and 28], targeted to improve finger range of motion and hand strength. The exercises are illustrated in Figure 10.

- 1) Making a full fist by flexing the metacarpal phalangeal, proximal inter-phalangeal and distal inter-phalangeal joints of all fingers
- 2) Making a small fist by flexing only the proximal and distal inter-phalangeal joints of all fingers
- 3) Touching the tip of each finger with the tip of the thumb (thumb opposition)

- 4) Spreading the fingers as much as possible and closing them
- 5) Raising the fingers as much as possible
- 6) Flexing and extending the wrist
- 7) Strengthening of wrist muscles with a dumbbell (2lb)
- 8) Hand intrinsic strengthening with 85 grams medium-resistance therapeutic putty

**Figure 10: Conventional Hand Exercises**



### 3.5.8.2. Experimental group: Task-oriented training with computer gaming

The home exercise program for the experimental group included the task-oriented training program designed for people with arthritis of the hands. Clinical judgments based on a detailed review of baseline AHFT and the DASH questionnaire scores, self-reported problems in fine/gross finger abilities on handling different objects of daily life guided the selection of objects for task training. Participants were asked to prioritize 2-3 tasks perceived as difficult to do. The tasks prioritized by them were considered for training and either real life objects manipulations or closely simulated manipulation tasks were chosen for individual training. In the present study, fine finger skills training with a wooden dowel and a golf ball, and wrist mobility training with a light weight flat wooden board was given for all the experimental group participants. In addition to these objects, approximately two to three objects personalized to individual needs and preferences were included in the home exercise program. For example: one participant reported opening of jar lids and lifting heavy objects as her major limitations. The participant was trained with the opening and closing of a jar lid and wrist strengthening with a dumb bell. Another participant who reported difficulty with picking up small and large things was trained with additional personalized objects, such as a bottle cap, and medium and large size medicine balls. The task-oriented training program included the following components:

- 1) Fine finger manipulations
- 2) Gross finger-hand manipulations
- 3) Wrist mobility exercises
- 4) Resisted (Low to Moderate) exercises for wrist flexors and extensors



A few examples of object manipulation tasks training are presented below:

1) Fine finger manipulations with small objects and precision grips

The following object manipulation tasks involving only the fingers emulate various dexterous activities of daily living. The purpose is to improve fine manipulation and precision skills.

1a. Involving thumb, index and middle fingers (3 finger grip)

An object (such as a bottle cork) is rolled up and down or left to right and vice versa using three point pinch involving pad of thumb and pad of fingers. The task includes the following joint motions: thumb opposition, inter-phalangeal flexion, index finger abduction, metacarpo-phalangeal flexion and flexion or extension of the inter-phalangeal joints of the index and middle fingers with ulnar and radial deviations at the wrist. The other fingers may be flexed or extended and the wrist is usually kept in mid prone position. Functional uses: These movements are considered most functional and emulate manipulations of small pieces of food, delicate objects, writing and many other fine hand activities.

1b. Involving thumb and index finger (two finger grip)

An object (Example: a door key) is held between the pad of the thumb and radial aspect of the flexed index finger. With other fingers in flexed position, the key is turned up/down or left/right directions. The movements involve simultaneous carpo-metacarpal thumb rotation, partial thumb opposition and adduction, metacarpo-phalangeal and inter-phalangeal flexion (Proximal inter-phalangeal > Distal inter-phalangeal) of index finger and a few degrees of forearm supination/pronation with the wrist in neutral position. Functional uses: These movements emulate activities such as opening a door or pulling up/down the zipper while dressing.

1c. Involving pad to pad of thumb and index or middle fingers

Objects such as a small size cube block or a wooden dowel (Figure 11) are manipulated by securing between the pads of the thumb and index or middle finger with a two point pinch. The task includes the following joint motions: thumb opposition, inter-phalangeal flexion and extension, metacarpo-phalangeal flexion and ulnar and radial deviation at the wrist. The other fingers may be flexed or extended. The movements associated with the manipulation are performed randomly to play a computer game that requires cursor movements in X axis. Functional uses: These movements emulate manipulation of fine food items or small toys and objects.

**Figure 11: Manipulation of a dowel**



1d. Involving tip of thumb and tip of index or middle finger

Some fine objects, such as small beads, require to be manipulated between the tips of thumb and index or middle finger. Such an object is rolled left and right with thumb opposition and flexion, metacarpo-phalangeal flexion, proximal and distal inter-phalangeal flexion and adduction of index or middle finger. The other fingers may be in flexion or extension with the wrist in neutral position allowing a few degrees of ulnar and radial deviations. Functional uses: These movements emulate manipulation of very fine, small and delicate objects or activities such as doing up buttons.

2) Gross finger hand manipulations with medium- large objects & power grasps

These would involve the use of the whole hand and palm with finger abduction/adduction, flexion and extension of metacarpo-phalangeal, proximal and distal inter-phalangeal joints and wrist, forearm motions.

2a. Objects such as a plate or book are manipulated using a lumbrical grip (Figure 12). With forearm in supination and wrist flexing and extending, the thumb secures the object firmly by opposition, adduction and extension across the palmar surface of the other fingers. Random up and down and left and right movements with the board are used to play a computer game that requires cursor movements in X and Y axes.

Functional uses: These movements emulate holding and manipulating objects, such as books or plate either in horizontal or vertical planes in day to day life.

**Figure 12: Manipulation of a flat board**



2b. Spherical objects are manipulated with whole hand (Figure 13). With the wrist in neutral, the objects are rotated left and right involving ulnar/radial deviations, finger abduction/adduction and metacarpo-phalangeal and inter-phalangeal flexion. Random rolling movements to right and left directions are used to play a computer game that requires cursor movements in X axis. Spreading of fingers increases with large size objects, while more degrees of flexion at metacarpo-phalangeal and inter-phalangeal joints is required with even smaller objects.

Functional uses: These movements emulate manipulation of spherical, round objects in daily life.

**Figure 13: Manipulation of a medium size sports ball**



2c. Objects such as a mug or water jug can be manipulated using an oblique palmar grasp. With forearm in mid prone and wrist in neutral, a liquid pouring activity is simulated. The object is secured obliquely across the palm with all the fingers. The extended thumb stabilizes the movements, while the fingers are in slight flexion at metacarpo-phalangeal and full flexion at inter-phalangeal joints.

Functional uses: These movements would transfer to real activities, such as pouring a liquid from a jug or a carton.

2d. Cylindrical objects, such as a drinking glass, are tilted up down using a cylindrical grip. Figure 14 shows manipulation of a soup can using oblique palmar grasp. Random up and down tilting movements (simulating a pouring activity) are used to play a computer game that requires cursor movements in Y axis.

Functional uses: These movements emulate manipulation of drinking glass or using different cooking utensils/ cylindrical objects.



**Figure 14: Manipulation of a soup can**



2e. Objects such as a standard, large scissors is opened and closed using a

functional scissoring grasp to simulate scissoring action. With forearm in mid prone and wrist in neutral, the thumb, middle and ring fingers are placed in the scissors loop, while other digits are flexed into the palm. The thumb is extended and middle and index fingers are flexed at metacarpo-phalangeal, proximal and distal inter-phalangeal joints. All three fingers are stabilized near the distal inter-phalangeal joints.

Functional uses: These movements emulate activities such as cutting paper, cloth, hair, etc.

2f. Objects such as paper rolls, sponge foam cylinders, medicine balls are rolled up and down to encourage finger extension of all digits. With the forearm in pronation and thumb in abduction, the palm is placed on the object. The rolling maneuver encourages extension of fingers at metacarpo-phalangeal and inter-phalangeal joints.

### 3) Wrist mobility exercises using light weight objects

Holding a medium sized styrofoam bar, the wrist is moved into flexion, extension and ulnar/radial deviations. These movements emulate many functional activities of upper limb in daily life requiring free wrist movements such as eating, dressing, lifting and carrying etc.

### 4) Wrist flexors and extensors strengthening using dumb bells

With the same position as for wrist mobility, dumb bells are used to strengthen wrist muscles (Figure 15). These exercises emulate many open chain functional activities of upper limb in daily life requiring grip strength, such as carrying, handling heavy objects.

**Figure 15: Wrist muscle strengthening with a dumb bell**



The program was coupled with computer gaming and the random manipulative movements with each object task were used to control and play the computer game. The movements accompanied by each object manipulation task were pilot tested to make sure

that the movements were easy to execute and serve the purpose of accomplishing the task without any deficits or difficulties. By this way, it was ensured that task training with every different object was performed in a consistent manner. Experience gained from previous hand function studies, repeated testing different objects with a variety of games, peer discussions, and clinical knowledge were utilized to match the appropriate game for each of the object manipulation tasks. A number of computer games by different genres, such as adventure, matching, and action were used in the present study. Among this collection, some games required narrow arc (left  $\leftrightarrow$  to right or up  $\leftrightarrow$  down) of mouse pointer motions, approximately covering 10-15 centimetres on the computer screen. Some games required moderate coverage between 1/3 and 2/3rds of the screen, while some required full arc of mouse pointer motions in X or Y axes covering the breadth or width of the computer screen. It was ensured that training of a manipulation task with a specific object closely fits the amplitude of the motions required to play a game. For example, rolling manipulations with a bottle cap requires a short arc of left  $\leftrightarrow$  to right motions. These movements were trained by selecting a game that required a closely similar arc of fine mouse motions. One of the Big fish games, 'Aqua-ball' was chosen to train rolling manipulations with a bottle cap. Another example, manipulation of a flat board that required wrist flexion and extension go well with a game 'Feeding frenzy' which would allow free up and down mouse pointer motions through the full height of the computer screen. For each object task, a collection of tested games of the same genre was provided to ensure uniform provision among the experimental group participants. The collection had a minimum of two to three games of the same genre with different play scenarios in order to facilitate fun and excitement with training.

### **3.5.9. Home exercise program training sessions**

Within seven to ten days after the baseline assessment session, participants attended three individual training sessions on their respective home exercise program for approximately 60-75 minutes each time. A standardized training protocol (Table 11) was followed to ensure equal attention for all participants. Care was taken that all participants understood the purpose of every exercise and did them correctly with the required number of repetitions or minutes of computer game play. All of the participants were also encouraged to ask questions and clarify any questions regarding their home programs. A mock home exercise session was conducted during the third training visit to ensure that the participants had clearly understood what they were supposed to do and that they would be able to manage their home program on their own. The study staff maintained a record of participants' attendance during all training sessions. An overview of the topics covered during the training sessions is presented in Table 11.

**Table 11: Home exercise program training protocol**

Sessions	Control group	Experimental group
Session one	<p>Brief overview of study procedures Explanation of conventional hand exercises and how it would help people with arthritis Introduction to the exercises; equipment used and therapeutic purpose of each exercise</p> <p>5-10 minutes for questions</p>	<p>Brief overview of study procedures Explanation of task based approach and how it would help people with arthritis Introduction to functional tasks; equipment used; and therapeutic purpose of each task training Demonstration of 2-3 tasks coupled with computer gaming</p> <p>5-10 minutes for questions</p>
Session two	<p>Demonstration of eight finger mobility and strengthening exercises Participants' self-demonstration Information on exercise dosage (number of repetitions; sessions per week) Information on 'adverse symptoms' Demonstration on completing the exercise diary</p> <p>5-10 minutes for questions</p>	<p>Demonstration of 4-5 object tasks with computer games Information on mouse placement over objects; and installing computer games Information on training dosage (minutes of play; sessions per week) Information on 'adverse symptoms' Demonstration on completing the exercise diary</p> <p>5-10 minutes for questions</p>
Session three	<p>A brief review of the exercise program A mock session simulating original home exercise session Feedback and suggestions on the session 5-10 minutes for questions Provision of home program accessories</p>	<p>A brief review of the training program A mock session simulating original home exercise session Feedback and suggestions on the session 5-10 minutes for questions Provision of home program accessories</p>

### 3.5.10. Six week home exercise program

On completion of the training sessions, both groups were provided with their respective home exercise program protocols. The control group was provided with medium-resistance therapeutic putty (85 grams) and a dumbbell as home exercise program equipment. The rationale dosage for the conventional exercises is tabulated in Table 12.

**Table 12: Exercise rationale and dosage for the control group**

Rationale	To improve or maintain finger range of motion To improve or maintain grip and intrinsics strength
Type of exercises	Isotonic concentric and eccentric exercises (muscle contractility , extensibility)
Number of repetitions (0-2 weeks of the exercise program)	Each exercise held 5 seconds and repeated five times. Grip strengthening with 50-80% 1RM, one set of 8 repetitions
Number of exercise sessions per week (0-6 weeks of the exercise program)	4
Time taken to complete each exercise (0-6 weeks)	Ranges between 2-4 minutes
Duration of each exercise session (0-2 weeks of the exercise program)	15 minutes
Principles of progression	Overload principle Intensity increased with more repetitions
Rest period	1-2 minutes rest in between each exercise

The experimental group was provided with a package that included the Gyration Elite motion sense mouse unit, a set of personalized objects and commercial computer games, accessories such as spare Velcro strips, wooden dowel and block and the computer game based hand function application. The motion sense mouse unit included the mouse, a charger and a 2.4 Giga-Hertz Universal Serial Bus (USB) receiver. The rationale and dosage for the task-oriented training is tabulated in Table 13.

**Table 13: Training rationale and dosage for the experimental group**

Rationale	To improve or maintain finger dexterity skills To facilitate graded joint mobility To improve or maintain grip strength
Type of exercises	Functional training with isotonic concentric and eccentric contractions (muscle contractility , extensibility)
Number of personalized objects (0-2 weeks of the exercise program)	3-4, each object task trained 2-3 minutes of game play
Number of repetitions (0-2 weeks of the exercise program)	Grip strengthening with 50-80% 1RM, one set of 8 repetitions, <1 minute of game play
Number of exercise sessions per week (0-6 weeks of the exercise program)	4
Time taken to complete each task training (0-6 weeks)	Ranges between 2-4 minutes
Duration of each exercise session (0-2 weeks of the exercise program)	15 minutes
Principles of progression	Overload principle Intensity increased with more objects
Rest period	1-2 minutes rest in between each object task



The following joint protection instructions were provided to both group study participants in order to exercise the finger joints efficiently without leading to any undesirable flare of joint pain or stiffness.

- ‘Respect the pain’-participants were asked to perform the exercises or the functional tasks only up to the limits of pain during their training or home exercise sessions
- In case of pain or stiffness during the home sessions, the number of exercise repetitions or minutes of game play should be reduced. If pain or stiffness continued, exercises to be discontinued and study staff to be contacted
- ‘Activity pacing’- participants were asked to perform their home exercise sessions once in a day, 4 times per week & were also instructed to allow rest period between exercises
- Participants were asked to maintain good sitting posture during exercising in order to avoid any episodes of back strain
- Participants were asked to avoid prolonged sitting posture and the home exercise sessions were performed not more than 25 minutes
- Participants were asked to avoid excessive pinching forces, carry heavy objects, extreme ulnar deviation position during exercising
- Muscle strengthening exercises were prescribed with low load and high repetitions for both group
- Overall, the home exercise programs were performed within pain free limits, without overloading of finger joints, and, using simple exercise equipment

A personal exercise diary was given to both groups to document the duration of each home session, changes in medication or any difficulties experienced with exercising.

When participants started their home exercise program, they informed the commencement date to the study staff. A record was maintained for each participant to ensure regular monitoring through weekly telephone calls. Both groups were asked to perform their home exercise programs for 15-25 minutes, four times per week for six weeks. Exercise support was provided for both groups through weekly telephone calls till the end of sixth week. Progression or modification of home exercise programs was made every two weeks for both groups, according to each individual's need and abilities. If participants experienced any adverse symptoms such as increased pain, stiffness or discomfort during or after exercises, they were asked to report to the study staff. When no symptoms were reported, progression was followed as in Table 14.

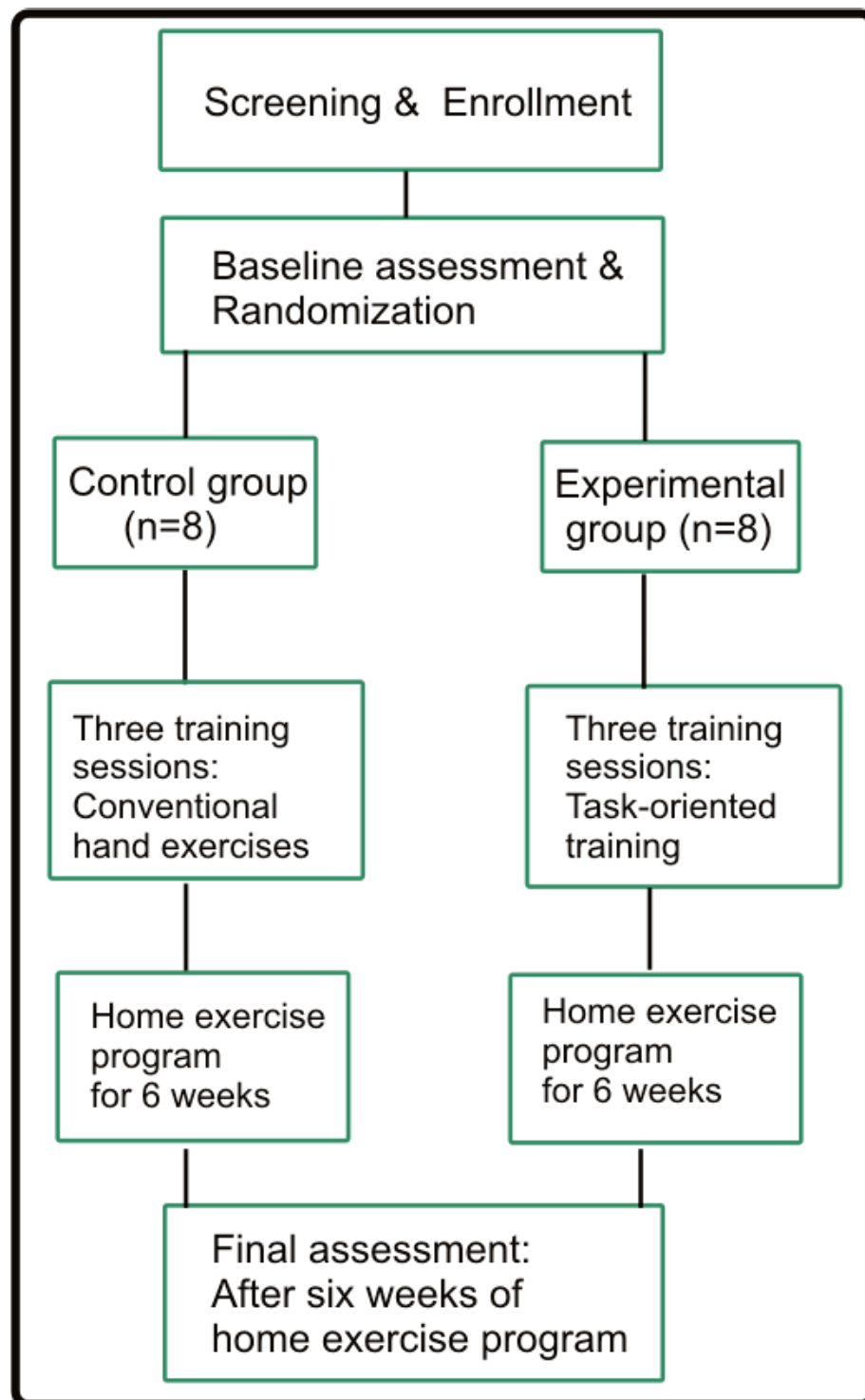
**Table 14: Home exercise program progression plan for both groups**

Groups	Progression goals	0-2 weeks	3-4 weeks	5-6 weeks
Control group	Number of repetitions	5	8	12
Experimental group	Personalized objects	3-4	4-5	4-5
Both groups	Hand strength training (50-80% of 1RM) *RM-Repetition Maximum	8 repetitions	15 repetitions	20 repetitions
Both groups	Exercise duration (minutes)	15	20	25

In the event of any symptoms being reported, it was proposed that the treatment parameters be modified by reducing the number of repetitions or minutes of play. Any

occurrence of increased pain or stiffness that continued over one week was considered to be an adverse event. In that case, the intervention may be discontinued and the participant may be referred to his/her general practitioner. The study staff maintained a record of the number of weekly reminders and progression plans communicated with each participant. Reporting of adverse events was proposed to include details such as severity, duration and appropriate steps taken for participant safety. A final (Post-intervention) assessment session was conducted to evaluate the study outcomes at the end of the sixth week. The sequence of events in the pilot randomized controlled trial is illustrated in Figure 16.

**Figure 16: Sequence of events in the pilot randomized controlled trial**



### 3.5.11. Focus group interviews

A qualitative investigation on the experiences of the study participants with their respective exercise programs was conducted analogous to the trial. The present study adopted the empirical, transcendental or psychological phenomenology described by Moustakas, 1994. This approach places more emphasis on participants' experiences and views around a phenomenon rather than the interpretations of the researcher. The process is called 'Epoche' or bracketing, where the researcher sets aside his or her preconceptions and attempts to perceive everything as new. To achieve this, deliberate efforts were taken through discussions with the other study staff to identify and sideline principal investigator's personal ideas and attitudes in regard to the home exercise programs and clinical knowledge of arthritis conditions. Guided by the phenomenological research and study questions, interviews with groups of multiple individuals who had experienced the same phenomenon were planned. A criterion based sampling was followed to recruit participants for this qualitative study. Criterion sampling infers that all individuals considered for inclusion in a study should have experienced the same phenomenon. Participants' willingness to provide written informed consent for their participation was another criterion. The control and experimental group participants who completed their respective six week home program in the pilot trial were invited to participate in the focus group interviews. Participants, who were interested in participating in the interviews, agreed to provide their written informed consent. A total of seven participants from both groups agreed to participate and were recruited into two focus groups. One group was formed with control group participants, (n=4); and another with experimental group, (n=3) respectively.

The interview sessions were coordinated with each focus group and were conducted in a quiet conference room at the Rehabilitation Hospital in Winnipeg. All of the participants provided their written informed consent before the interview. Demographic details such as age, gender, arthritis diagnosis and number of years since diagnosis were collected. An interview guide with a list of agenda and semi-structured interview questions was used to lead the interview session. The focus group questions were developed from a broad research question narrowed down to a few sub-questions. All of the questions were open ended in order to elicit detailed responses from the study participants. The broad question was, ‘What were your experiences in performing the hand exercises for six weeks’. Probing sub-questions were pre-determined through a detailed discussion with the study staff and were considered relevant in accordance with the study purpose. The questions focused on collecting participants’ perceptions relating to 1) content and delivery of the home exercise programs 2) personal and environmental factors in doing their home sessions and 3) recommendations or modifications for improving the home exercise programs. Finally, participants were asked to provide an overall summary of their experiences with the home exercise program.

Each interview session was conducted by a facilitator and a note taker for approximately one hour. The note taker commenced each interview session and explained the study purpose, interview process, interview data usage, study participant rights and the guiding rules for the interview. The guiding rules emphasized: 1) respectful interactive environment 2) free opinions of the participants 3) assurance of data confidentiality 4) equal participation and representation by all participants and 5) ‘only one person talks at a time’. The participants were also informed that pseudonyms will be used to protect their privacy and confidentiality during data transcription and analysis

procedures. After the interview, a few minutes were allotted for informal interaction between the study investigator, note taker and the participants.

### **3.6. Measurement instruments and procedures**

The feasibility assessment was planned on the basis of experiences gained from previous projects on people with arthritis of the hands. In regard to the study process, it was expected that twenty participants would be recruited in a one year period. However, it was difficult to predict participant retention, exercise compliance and follow-up rates as the trial involved piloting of a novel exercise program. Except for the DASH scores, participation criteria were similar to previously conducted assessment studies in people with arthritis of the hands. Hence the trial participation criteria were assumed suitable and feasible. The management of study resources was expected to be feasible, as study equipment and accessories, performance based outcome measures, and software was readily available with the research team. Preliminary data on study outcome measures from twenty study participants was expected to be collected. Evaluation of between and within group effects of the interventions was proposed for statistical testing.

#### **3.6.1 Study process**

The following information were recorded to describe the study recruitment process: 1) number of interested volunteers contacted 2) number of volunteers who were assessed for eligibility 3) number of volunteers who met or did not meet the study participation criteria 4) number of volunteers who were enrolled in the study 5) number of drop outs during the study period and 6) number of participants who stayed in the study from the time point of enrolment till the final assessment session

Any difficulties experienced by the study participants and study staff during the informed consent process, data collection sessions with the AHFT, DASH and object manipulation tasks testing and exercise training sessions were tracked. Attendance of study participants for assessment and exercise training sessions was also tracked. A list of home exercise equipment and accessories was prepared for each study participant. When participants informed their start date of their home exercise program, the study staff maintained a record with specific dates and participant preferred timings to make the weekly reminder calls.

Through the weekly telephone communication, any clarifications sought by the study participants with regard to their home exercises, reporting of adverse symptoms or events and corrective actions taken were regularly tracked.

### **3.6.2 Resources**

Assessment of resources included administration of study procedures and time taken for completing the performance based AHFT, DASH questionnaire, object manipulation tasks, consent form and exercise training sessions. The DASH, object manipulation tasks and the custom computer game have been administered on 65 people with arthritis hands in earlier projects. Practicalities learnt from those previous experiences were helpful in informally assuming the feasibility of procedures and number of hours required for assessment and training sessions. Psychometric information on the AHFT test and the DASH questionnaire were additionally referred for estimating the approximate time required for its administration and scoring. Home exercise equipment, including the motion sense mice, objects of daily life, dumbbells, therapeutic putties, big



fish games collection and other accessories were available for use from previous projects of the research team.

### **3.6.3. Management**

A record of study participants' demographic information was maintained. The AHFT data was entered into a data collection form for each participant and each of the completed DASH questionnaires was scored. Grip and pinch strength graphs collected from the Biometrics hand dynamometer unit were saved as electronic text files. Performance measures during the object manipulation tasks testing with the game based hand function application were collected and saved as electronic text files. All of the electronic text files were named with unidentifiable participant study codes and recorded in two separate password protected computers. Demographic information and study outcomes data were entered in a Microsoft excel master data sheet. When the participants returned their exercise log diaries after six weeks, the number and duration of completed home exercise sessions were entered in the master data sheet. All of the study related paper documents, and a USB memory stick with the backup copy of the master data sheet, were safely secured in a locked cabinet.

### **3.6.4. Clinical outcomes**

The Arthritis Hand function Test (AHFT) and the Disabilities of Arm, Shoulder and Hand (DASH) questionnaire were the primary outcome measures. The AHFT [76-79] is an 11 item performance based test that measures grip and pinch strength, peg board dexterity, applied dexterity and applied strength in people with arthritis. Grip strength of the dominant hand was evaluated using a computerized hand held dynamometer

(Biometrics isometric hand dynamometer G100, Biometrics Ltd., UK) instead of AHFT grip apparatus. The following grip testing position recommended by American Society of Hand Therapists (ASHT) was adopted [128, 129]. Participants were seated in a comfortable straight back chair without arm rests, feet flat on floor, shoulder adducted and neutrally rotated; elbow flexed at 90 degrees, forearm in mid-prone position and wrist between 0 and 30 degrees of extension. The instrument use was demonstrated to participants prior to testing. With the dynamometer held vertically, participants were instructed to grip it as hard as possible without any jerk. Three consecutive attempts, with ten seconds rest in between, were conducted to minimize fatigue. Grip strength was recorded in kilograms and the best score out of three attempts was used for analyses. In the same testing position, three point pinch strength (pinching between thumb, index and middle finger tips) and two point pinch strength (pinching between thumb and index finger tips) were measured in kilograms using the pinch meter (Biometrics Precision Pinch meter P200, Biometrics Ltd., UK). The peg board dexterity test [130] involves measuring the time taken to place and remove nine pegs into nine holes. Applied dexterity was the sum total of time taken in seconds to complete each of the following tasks: Lacing a shoe, tying a bow, fastening and unfastening four buttons, fastening / and unfastening two open safety pins, cutting putty into four pieces with a knife and fork and manipulating four coins by picking them up with the dominant hand and dropping through a slot in a coin box. Applied strength was measured by counting the total number of cans lifted in a tray and volume (liters) of water lifted in a pitcher.

The level of perceived difficulty in performing the everyday tasks, such as carrying a heavy object, using a knife to cut food, wash the back or make a bed is rated by the clients using a five point one to five Likert scale of the DASH questionnaire. A scale

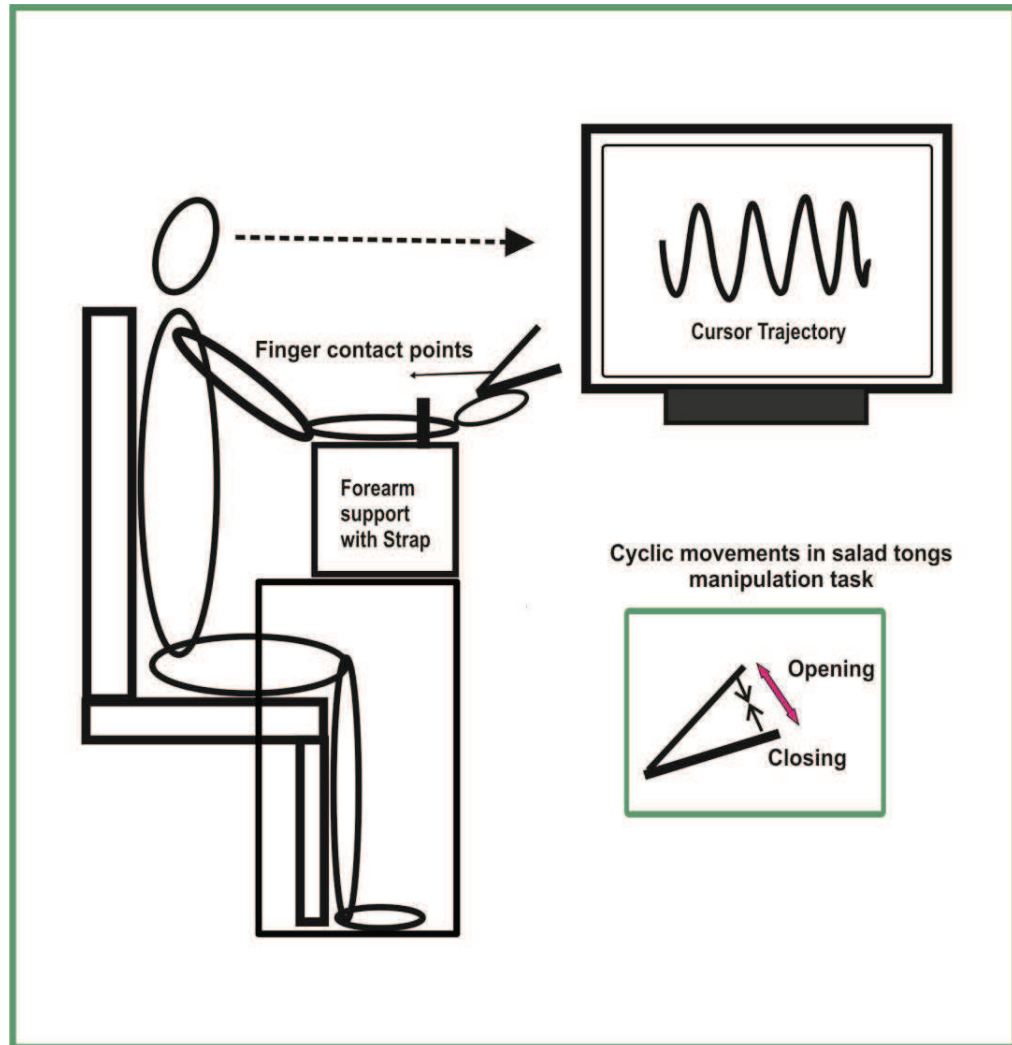
of one refers to no difficulty, two- mild difficulty, three- moderate difficulty, four-severe difficulty and five-Unable to do. The disability/symptom score is measured using the formula:  $[(\text{sum of 'n' responses}) - 1] \div n \times 25$ , where 'n' is the number of responded items. The DASH disability and symptoms scores range between 0-100. Higher scores indicate greater self-reported disability. The DASH outcome measure and scoring norms are available for downloading and printing from the link <http://www.dash.iwh.on.ca>.

The custom computer game based hand function assessment application with either of its custom tracking or a random paddle based game modes, objectively evaluates task performance during object manipulation tasks. The application was used as an exploratory outcome measure in the pilot trial. As the study involved training of object manipulation tasks performed with computer gaming, the application was considered appropriate to evaluate the training effects. The application [58, 131] was used as an exploratory outcome measure to measure task performance and pain and stiffness (pre-task and post-task) during selected manipulation tasks with three objects: salad tongs, jug and a turning knob. These objects were selected to represent a diverse range of manipulation tasks requiring different functional requirements of handling. To ensure that there is no practice effect, these three objects were not included in the experimental group home program. The application has two different modes: 1) Predictable custom tracking and 2) Episodic (random) game.

Predictable custom tracking protocol: A predictable, sinusoidal custom tracking with configurable amplitude and frequency provides a method to present a controlled visual input to guide a motor task. A custom software program has been created to move an on- screen cursor (a bright colored ball) either horizontally or vertically in a predictable sinusoidal pattern. Participants were comfortably seated in front of a computer

monitor positioned at eye level to perform the object manipulation tasks. The arm was positioned at approximately 60 degrees of shoulder flexion, internally rotated with the elbow flexed and forearm fully supported on a styrofoam pad. A strap near the wrist allowed friction free hand movements and avoided any vertical forearm motion during manipulation tasks. A wide range of objects, utensils or applications can be instrumented with a miniature (8mm in diameter) multi axis motion sensor (Mini-bird model 800, Ascension Technology, Burlington, VT, USA) that precisely measures the 3D spatial position and orientation. The motion sensor and interface records linear and angular object motions during the tasks. The static resolution of the Mini-bird is 0.5mm (linear) and 0.1 degrees (angular) within 30.5 cm of the transmitter. An object instrumented with the Mini-bird sensor is manipulated to play any of the two game modes in X or Y axes. An object (e.g., salad tongs) held with a tripod grip and moved in concert with a sinusoidal moving visual target on the computer screen (Predictable tracking) is illustrated in Figure 17. The bottom insert shows the salad tongs to track the visual target moving upward and downward respectively.

Figure 17: Predictable custom tracking with a salad tongs



The computer software records and saves the co-ordinates of the target cursor motion and the linear/angular coordinates of the user motion at the sampling rate of 100 Hz. For the predictable custom tracking (sinusoidal) game mode, the frequency of the visual target motion was set at 0.5 Hz and the onscreen amplitude was 15 cm. These parameters were selected to represent the natural movements experienced in daily activities and without time constraints. Participants played the predictable tracking with the salad tongs. They were instructed to track the vertical up and down movements of the colored ball on screen by rhythmically opening and closing the salad tongs. The task duration was 20 seconds, which produced approximately 12 movement cycles. The position coordinates of the on-screen moving target cursor and the 3D position and orientation coordinates of the Mini-bird motion sensor (actual object motion) were synchronously logged and saved to a file.

Participants played the random game with two objects; a turning knob and a jug. They were asked to turn the knob back and forth thus simulating a turning activity and tilt the jug up and down as in liquid pouring activity. Each task was tested for 90 seconds respectively.

The application is also embedded with two separate 11-point numerical verbal rating scales for measuring joint pain and stiffness before and after any manipulation task performed in predictable or episodic gaming modes. The pain scale ranges from 0 (no pain) to 10 (unbearable) and stiffness from 0 (none) to 10 (cannot move). Verbal descriptors are added in both scales for ease of participant reporting. The scales popped in sequence on computer monitor before and after playing each game for a predetermined time (20 seconds in tracking protocol and 90 seconds in random mode). Participants were asked to verbally rate their pain and stiffness intensity before and after each manipulation

task. The study staff recorded them respectively, which were automatically saved along with the user motion data.

The coordinates collected by the computer game based application during object manipulation tasks were processed using custom analysis routines written in Mat lab (The Math Works, Natick, MA) and then exported for offline analysis. Out of the 12 cyclic movements collected with sinusoidal tracking, the first two cycles were excluded to ensure that the participant started to move concurrently with the target motion. The last two cycles were removed to avoid factors such as fatigue and loss of attention. The middle portion of the cycles was considered for analysis after using a fourth order dual pass Butterworth low pass filter of 6 Hertz to eliminate noise signals. Based on the known target trajectory and the participant's actual motion, coefficient of determination (CoD) was calculated to represent task performance (Figure 15). The sinusoidal bold lined wave form represents the user trajectory and the lighter shaded sinusoid is the performance waveform for a manipulation task. The Y-axis is the relative amplitude excursion on the screen and the X-axis is time in seconds. The co-efficient of determination provides the degree of precision of object manipulation synchronous to visual target tracking. Co-efficient of determination values range between 0 and 1, with negative values as well. Co-efficient of determination values near to one closely fit the user motion signals of each task with the target cursor motion, while negative values explain the least fit of task data sets.

Figure 18 shows the reference trajectory of the custom tracking protocol. The Y-axis represents the relative amplitude excursion on the screen and the X-axis is time in seconds. The plot shows an arbitrary line drawn in up and down directions to represent amplitude consistency. For amplitude consistency in both directions, co-efficient of

variation % (CoV %) of the average movement amplitude for directions maxima to minima and vice versa were computed.

**Figure 18: Amplitude consistency during the predictable tracking task**

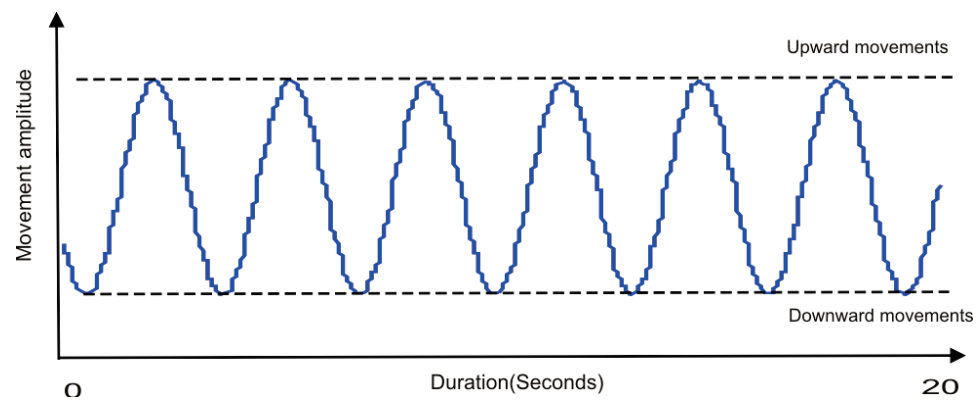
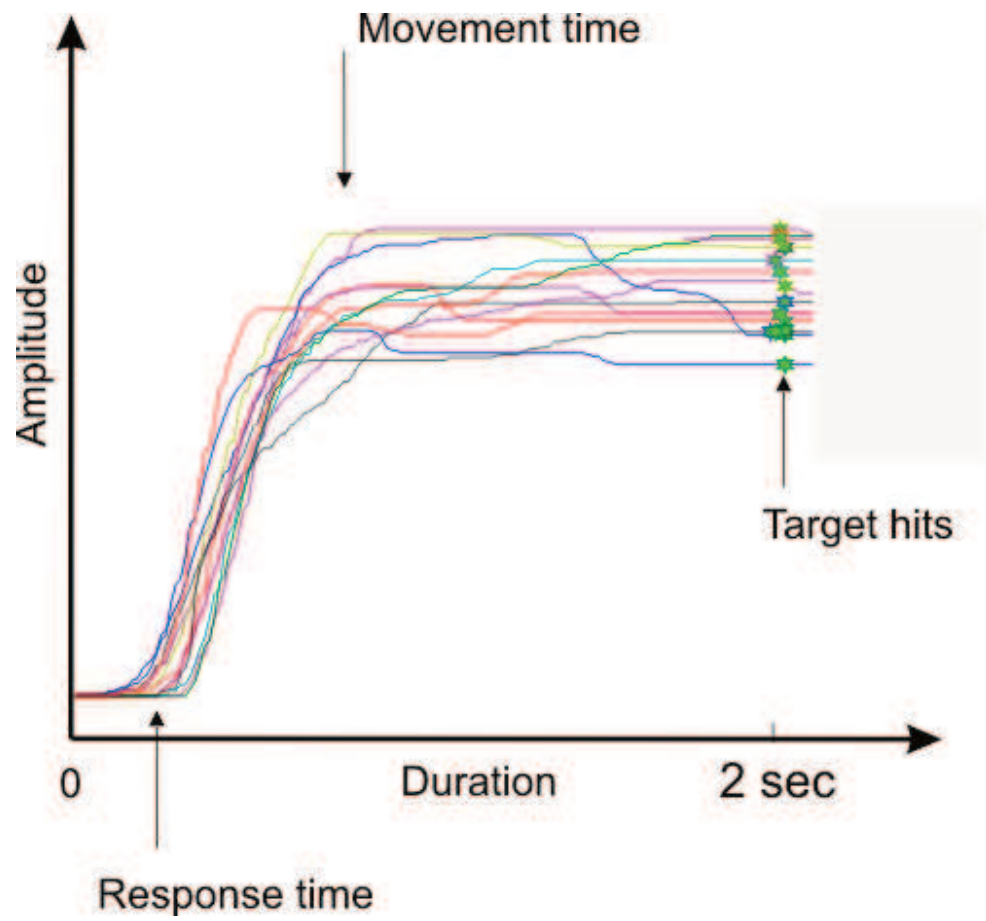




Figure 19 shows the variables analyzed from sorted gaming trajectories during an episodic gaming session of approximately two minutes. Different features of the player's movements provide a basis for objective quantification of variables such as success rate (number of target hits), average motor response time-the time from the appearance of the target to start of the movement, and average movement time-90% rise time between movement onset and end of the game movement. The outcome variables of the application are tabulated in Table 15.

Figure 19: Variables of the episodic game



**Table 15: Outcome variables of the computer game based hand assessment application**

Game modes	Variables
Predictable tracking	<p>Task performance: Co-efficient of determination</p> <p>Movement skill: Amplitude consistency</p> <p>Pre / post task pain and stiffness</p>
Episodic (Random)	<p>Success rate: Number of target hits</p> <p>Movement skill:</p> <p>Average motor response and movement time</p> <p>Pre / post task pain and stiffness</p>

### 3.6.5. Exercise compliance

Study participants logged their completed home sessions in a personal exercise log diary. Those reports were used to measure compliance. The average number of completed home sessions out of 24 total sessions in six weeks was calculated in percentages. On completion of the home exercise program, the number of completed home exercise sessions and approximate duration of each session was retrieved from the exercise log diaries.

A list of feasibility outcomes described is presented in Table 16.

**Table 16: Feasibility outcomes described in the pilot trial**

Feasibility domains	Feasibility outcomes
Study process	Number of volunteers been contacted Number of volunteers assessed for eligibility Number of volunteers who met or did not meet the study criteria Total number of volunteers who were enrolled in the study Number of drop outs during the study period Number of participants who retained till the end of the study Study inclusion criteria Informed consent process Conducting data collection sessions Conducting exercise training sessions Weekly reminder calls to the study participants Recording of adverse events or adverse symptoms
Resources	Time taken to administer the study outcome measures Provision of home exercise equipment, computer games, motion mice and other accessories
Management	Managing study related documents Data entry in data collection sheets and Microsoft excel sheets Storage of data files along with a backup copy Maintaining additional home exercise program equipment for replacements
Scientific outcomes	Baseline and final study outcomes data using the AHFT, DASH questionnaire and computer based hand function assessment tool. Exercise compliance (total number of completed exercise sessions) Average duration of completed home exercise sessions

### **3.7. Data analyses procedures**

#### **3.7.1. Statistical data analyses**

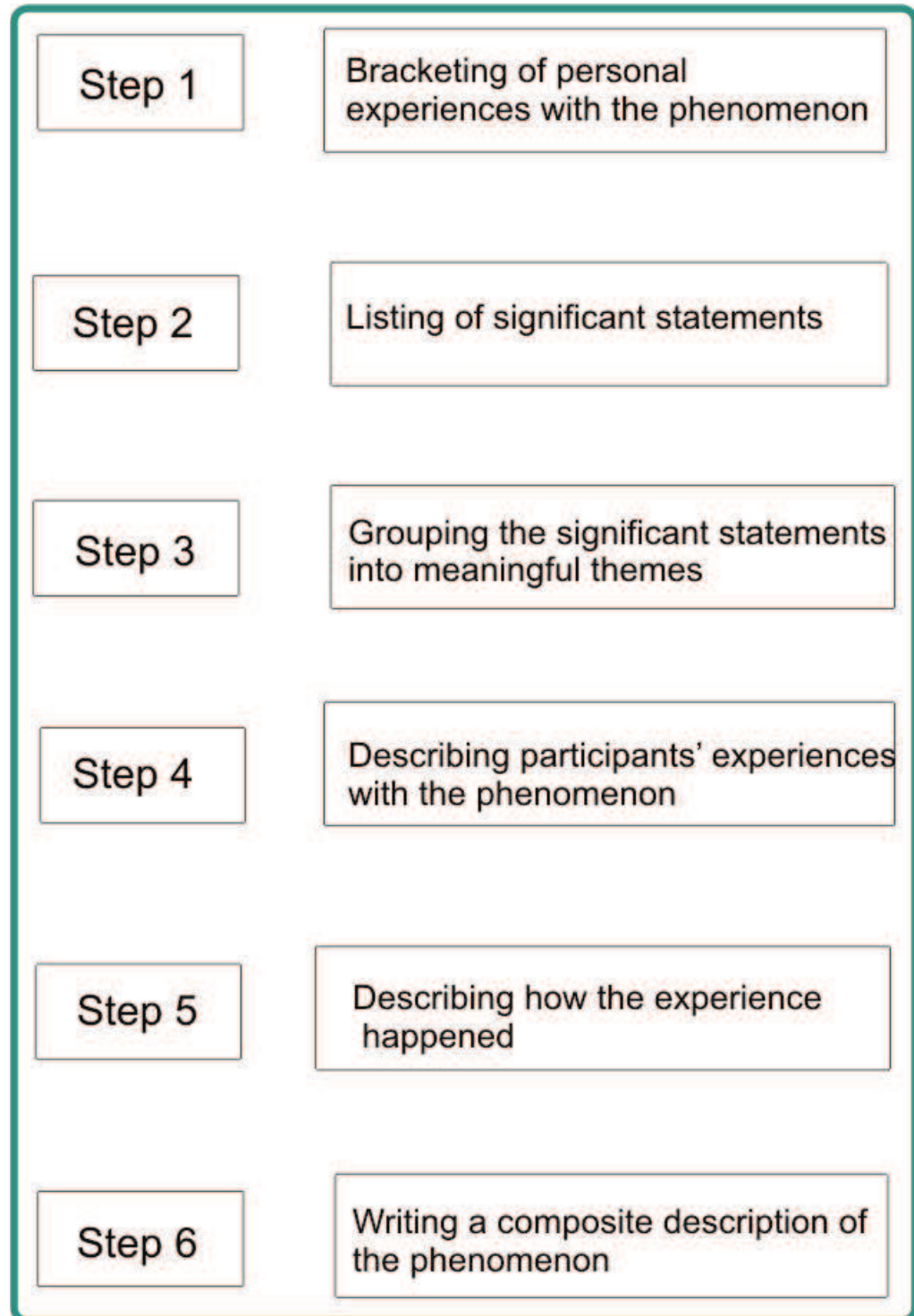
Normality of all the data were tested using Shapiro Wilk's test and appropriately reported as Mean (Standard deviation) or Median (Inter quartile range). Independent samples student 't' test or Mann-Whitney 'U' statistics was used to compare the demographic variables and baseline outcomes between groups. Data from all randomized participants were included by following last observation carried forward method, in order to minimize missing data. A mixed model repeated measures analysis of variance (ANOVA) testing was done to evaluate between and within subject effects and any interaction effects of the interventions. Both groups were considered as fixed factors and the assessment time points were the random factors. Wilcoxon signed rank test was used to evaluate the pre to post differences in pain and stiffness associated with three object manipulation tasks (salad tongs, turning knob and jug) in both groups during baseline and final assessment sessions. Mann Whitney U statistic test was used to compare the change scores of pain and stiffness with three object manipulation tasks between control and experimental group at final assessment session. Owing to the small number of participants enrolled in the study (n=16), data will be interpreted and discussed by comparing the mean values of the study outcomes.

#### **3.7.2. Qualitative data analyses**

Focus group interview audio files from the qualitative study were transcribed verbatim in the English language and saved as Microsoft word documents. The transcribed interview text was the primary unit of data analysis. The steps informed by a

simplified Stevick- Colaizzi Keen structured method [132, 133] for analyzing the phenomenological data was used for analysis. Steps in phenomenological data analysis are illustrated in Figure 20.

**Figure 20: Steps in phenomenological data analysis**



The first step of data analysis is ‘Epoche’ or bracketing , which targets to set aside the investigator’s personal opinions and attitudes while exploring the experiences of the study participants. This process is performed through conscious efforts of the investigator in order to practice a fresh view on the transcript text. Though this step could not be performed to the full extent, the focus of analysis will then be more directed towards the views of the study participants. The second step involves developing a list of significant statements from the transcript text. Each statement is required to be meaningful, non-repetitive and equally prioritized, the phenomenon being called ‘horizontalization’ of the data. The third step involves deriving formulated meanings from the statements which will then be clustered to themes. Themes which are identified as an expression of the latent content of the text will be reported as textural and structural descriptions. Textural description is a description on ‘what’ the study participants’ experienced with the phenomenon. Textural description is usually accompanied with verbatim examples of participants’ own words and sentences. In structural description, the investigator reflects on the context and setting in which the phenomenon was experienced. The final step of analysis includes a composite summary of both descriptions to provide the essence of ‘what’ the participants’ experienced with the phenomenon and ‘how’ they experienced the phenomenon.

### **3.8. Summary**

This chapter discussed the study rationale, objectives and research questions, study design, study protocol, measurement instruments and data analyses procedures for quantitative and qualitative research methods. The next chapter (Chapter 4) will present the findings of the randomized controlled pilot trial and the embedded qualitative study.



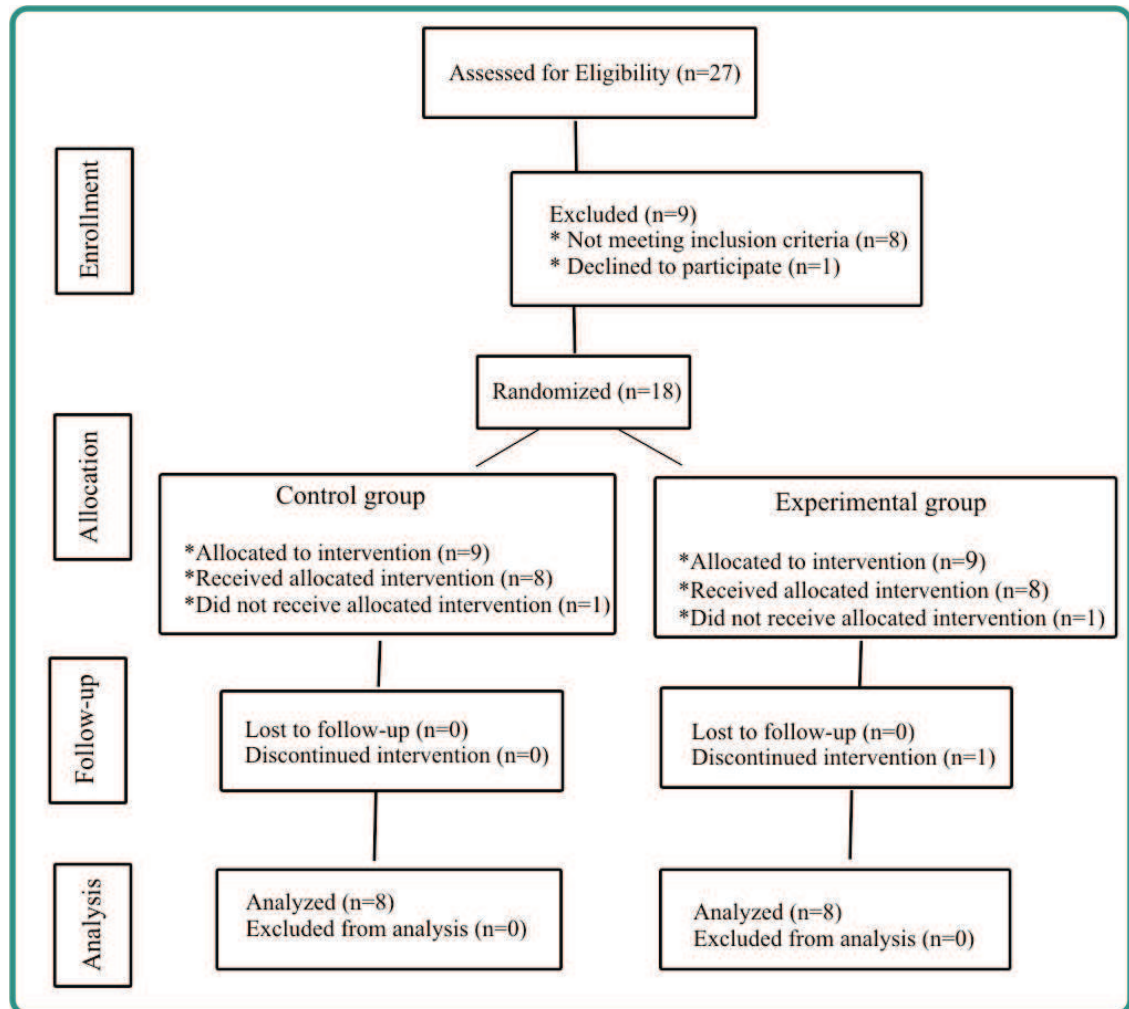
## **Chapter 4: Results**

### **Section 4a: Results of the pilot randomized controlled trial**

#### **Section 4a: 1. Participant flow**

Figure 21 shows the CONSORT flow chart [116] for this study. Out of 27 volunteers screened for eligibility, 68% were randomized and 32% were excluded and 84% of those randomized were retained till the final assessment conducted six weeks after the interventions.

**Figure 21: CONSORT flow chart for the pilot trial**



## **Section 4a: 2. Feasibility assessment**

Feasibility of the trial is described using the model proposed by Thabane et al [103] in conducting pilot studies. According to the model, pilot trials should include testing of four domains: process, resources used, human and data management and home programs. 'Process' assessment involves evaluating feasibility of key study processes, a few examples such as participant recruitment rates, dropout rates, eligibility criteria and participant retention rates. Pilot trials should also test feasibility of resources, such as time taken to complete study questionnaires and other resource problems reported over the study period. Feasibility of issues, such as data storage and data entry, intervention safety, data variance and estimation of effect size are to be considered additionally.

### **Section 4a: 2.1. Study process**

Recruitment commenced in July 2012 and was proposed to achieve the target sample size of 20 by May 2013. It took an extra ten months than the stipulated duration to enroll 16 volunteers in the study, reaching 80% of the proposed target.

Eligible volunteers who attended the baseline assessment session were briefed on the entire study procedure and expectations were thoroughly explained. They were then asked to read through the informed consent document. All volunteers were able to make informed decisions on their participation after reading the consent form, understanding it and clarifying with the study staff any questions they had. Those who were willing to participate in the study were then asked to sign the informed consent document. At baseline, study outcomes were assessed prior to randomization and group allocation

procedures. In assessing the study outcomes, a standardized protocol was followed during pre and post intervention assessment sessions.

All participants were able to perform the 11 items of the arthritis Hand Function Test and answer all 30 items of the DASH questionnaire. All three object manipulation tasks (salad tongs, turning knob and jug) evaluated with the computer based application were completed, except with two control group participants who were evaluated with salad tongs and turning knob during both assessment sessions. Both of them found it difficult to hold the jug and play the episodic game for 90 seconds. All participants demonstrated a 100% attendance rate during both assessment sessions.

A total of 45 one hour training sessions were conducted at the Rehabilitation Hospital and both group participants attended all three of their individual training sessions of their home exercise program. Instructions were provided to the experimental group on, a) downloading the computer games from [www.bigfishgames.com](http://www.bigfishgames.com) website b) placing the motion sense mouse on various objects and c) understanding the dynamics of different computer games assigned for their home exercise program. All participants demonstrated 100% attendance rate during their training sessions. Participants were able to attend their assessment and training sessions as appointments were flexible and conveniently scheduled in consultation with them.

During the third training session, participants were provided with written exercise protocols and sufficient exercise accessories to complete their home programs. None of the participants reported shortage of any accessory items during their six week home program. The process of sending weekly reminders and exercise progression instructions to both group participants through phone calls was feasible as well.

All participants managed to perform their home exercise programs on their own for six weeks. Wrist exercise with a dumbbell was modified with reduced number of repetitions for two control group participants who reported difficulty in doing it. They were comfortable with the reduced repetitions. The experimental group participants also managed to treat and play the computer based hand assessment application as an additional choice of computer game. When participants required any clarification on their home program procedures, (a few examples, such as choice of games in the experimental group; or number of exercise repetitions in the control group) they contacted the staff through phone calls. Efforts were taken to respond to participants' concerns in a prompt manner. All participants were able to self-report their home sessions in their log diaries.

Two participants in the control group reported pain while exercising the wrist muscles with the 2lb dumbbell. The number of repetitions with the dumbbell was therefore reduced and then progressed incrementally. There were no further complaints from them. No participants in the experimental group reported any symptoms, such as pain or stiffness during or after the task-oriented training. None of the participants from both groups reported any adverse events throughout their home program.

The study demonstrated excellent rates of participant retention through the stages of a six week home exercise program to the final assessment session. Retention rates were 100% in the control group and 87.5% in the experimental group. One participant from the experimental group dropped out from the study during her third week of home program for reasons related to a family member's sickness.

#### Section 4a: 2.2. Resources

The average time taken to complete the informed consent process was between 20 and 25 minutes. Participants were able to complete the AHFT between 20 and 25 minutes and the DASH questionnaire between 10 and 15 minutes. The outcome assessor took approximately five minutes each for scoring the AHFT and the DASH questionnaire respectively. Approximately 15 minutes was taken to test the three manipulation tasks using the computer based application. Overall, the total duration of each assessment session ranged between one hour and one hour and 10 minutes. Training sessions for both groups ranged between one hour and one hour and 15 minutes, slightly more than the initially proposed one hour.

The experimental group underwent task-oriented training with different object manipulations, coupled with playing a variety of computer games. Objects provided to them were those commonly used in daily life, easy to purchase and also inexpensive. The cost of the Gyration Elite motion sense mouse was approximately eighty dollars and it was affordable to provide each experimental group participant to take one home for their home program. In case of any damage or technical issues being reported, five additional units were maintained for replacement. The computer games were readily available from the research team's user account with the "Big fish games" games company. The website was safe to use in Windows and Mac computer systems. Around 65 varieties of games were made available for the study participants to choose, download and play for unlimited time. Games were colorful, interesting, non-violent and suitable for all ages. The experimental group reported no difficulties in downloading games as they have been instructed stepwise on 'how to download games' during their training sessions. The

computer based application was also easy to install in any computer system and therefore no difficulties were reported. All of the equipments and infrastructure used in this project were a part of a previously funded project and no additional costs were incurred.

#### Section 4a:2.3. Management

It was feasible to enter the data in hard and soft copies. Anonymous codes were assigned for each participant to maintain data privacy. All of the study related documents were stored in locked cabinet and a password-protected computer. A back up of study data was also maintained in a Universal Serial Bus flash drive and kept in the locked cabinet. Raw data was entered in an Excel master worksheet and was used for final analyses.

#### Section 4a: 2.4. Clinical outcomes assessment

Demographic characteristics of participants of both groups and study outcome variables are summarized in Tables 14 and 15. Except for the number of years since diagnosis was made, all variables passed the Shapiro-Wilk normality test ( $p>0.05$ ). Based on distribution, data was appropriately described as Mean (Standard deviation) or Median (Inter quartile range). Independent student 't' test or the Mann Whitney U test was used to demonstrate any differences in baseline variables between groups. No significant differences ( $p>0.05$ ) were seen between the control and experimental group in age, gender, disease duration, arthritis Hand Function Test, DASH scores and measures of the computer game based hand function assessment application. Significance level ( $p<0.05$ , two tailed) for each baseline variable is presented in Table 17. At baseline, study

participants also self-reported the most important difficulties encountered during their everyday activities. They are presented in Table 18.



**Table 17: Baseline characteristics of study participants**

Baseline study variables	Control (n=8)	Experimental (n=8)	Significance 'p' value
Participants' age (Years)	61.2 ± 8.8	55.2 ± 8	0.174
Participants' gender (Male/Female)	2/6	1/7	0.554
Number of years since diagnosis	12 ± 12	9 ± 10	0.607
Arthritis Hand Function Test			
1) Grip strength (Kilograms)	4.3 ± 1.95	4.8 ± 1.53	0.582
2) 2 pinch strength (Kilograms)	2.4 ± 0.76	2.55 ± 1.12	0.766
3) 3 pinch strength (Kilograms)	2.9 ± 0.516	3.07 ± 1.43	0.788
4) Peg board dexterity (Seconds)	29.81 ± 3.71	28.64 ± 6.4	0.662
5) Total applied dexterity (Seconds)	103.55 ± 18	94.04 ± 20.5	0.340
Applied dexterity items			
a) Lacing a shoe (Seconds)	9.05 ± 2.4	9.94 ± 3.25	0.545
b) Tying a bow (Seconds)	12.9 ± 9.2	9.52 ± 4.24	0.353
c) Fastening/Unfastening 4 buttons (Seconds)	33 ± 11.92	28 ± 6.9	0.324
d) Fastening/Unfastening 2 safety pins (Seconds)	13.55 ± 4.3	9.8 ± 3.15	0.066
e) Cutting putty (Seconds)	23.62 ± 7.2	23.53 ± 8.61	0.982
f) Manipulating coins into a slot (Seconds)	11.38 ± 5.2	13.25 ± 5.20	0.483
6) Applied strength			
a) Number of cans lifted in a tray	7.87 ± 2.7	8.5 ± 1.93	0.602
b) Volume of water (Liters) lifted	1.7 ± 0.51	1.81 ± 0.33	0.611
DASH scores (0-100)	35.52 ± 14.91	27.46 ± 17.81	0.343

**Table 18: Baseline variables of the exploratory computer game based application**

Baseline variables of computer game based application	Control (n=8)	Experimental (n=8)	Significance 'p' value
Custom tracking protocol			
a) CoD (0-1)	0.65 ± 0.20	0.71 ± 0.20	0.566
b) CoV% of amplitude consistency –Downward movements	11 ± 7	10 ± 12	0.93
c) CoV% of amplitude consistency –Upward movements	12 ± 8	16 ± 18	0.59
Episodic game			
a) Success rate			
Turning knob	89.6 ± 9.4	92.25 ± 2.54	0.480
Jug	77 ± 33	88.7 ± 7.2	0.375
b) Average response time			
Turning knob	0.65 ± 0.40	0.54 ± 0.24	0.533
Jug	0.65 ± 0.41	0.6 ± 0.2	0.700
c) Average movement time			
Turning knob	0.53 ± 0.34	0.57 ± 0.32	0.805
Jug	0.59 ± 0.38	0.62 ± 0.1	0.857

At baseline, study participants also self-reported the most important difficulties encountered during their everyday activities. They are presented in Table 19.

**Table 19: Self-reported limitations in everyday activities**

<p>Control group (n=8)</p> <p>Participants diagnosed with rheumatoid arthritis (n=5)</p> <p>Perceived difficulty with hand strength  Picking up small things; Cutting; Handling door knobs  Opening lids; Lifting heavy objects  Carrying medium-large size objects; Turning door knobs  Opening small bottle caps; Opening tight lids or old fashioned door knobs</p> <p>Participants diagnosed with hand osteoarthritis (n=3)</p> <p>Opening eye drops bottle, ointment tubes, jars and doors; Picking up papers; Buttoning  Putting socks; Tight pinching between finger tips  Writing; Holding a pen; Wringing; Opening a jar</p>
<p>Experimental group (n=8)</p> <p>Participants diagnosed with rheumatoid arthritis (n=4)</p> <p>Fine finger skills; Picking up small, large things  Opening tight jars or taps  Opening tight jars  Difficulty with fine skills, holding cups, opening jars</p> <p>Participants diagnosed with hand osteoarthritis (n=4)</p> <p>Opening jars; Heavy lifting; Carrying soup cans; Squeezing  Opening jars; Manual work with application s; Holding keys  Opening door knobs or jar lids; Carrying things  Pressing a doorbell; Holding large size jars; Twisting hand movements</p>

Figure 22 presents the histograms for group means and standard deviations for the grip and pinch strength items of the AHFT in both groups.

**Figure 22: Grip and pinch strength**

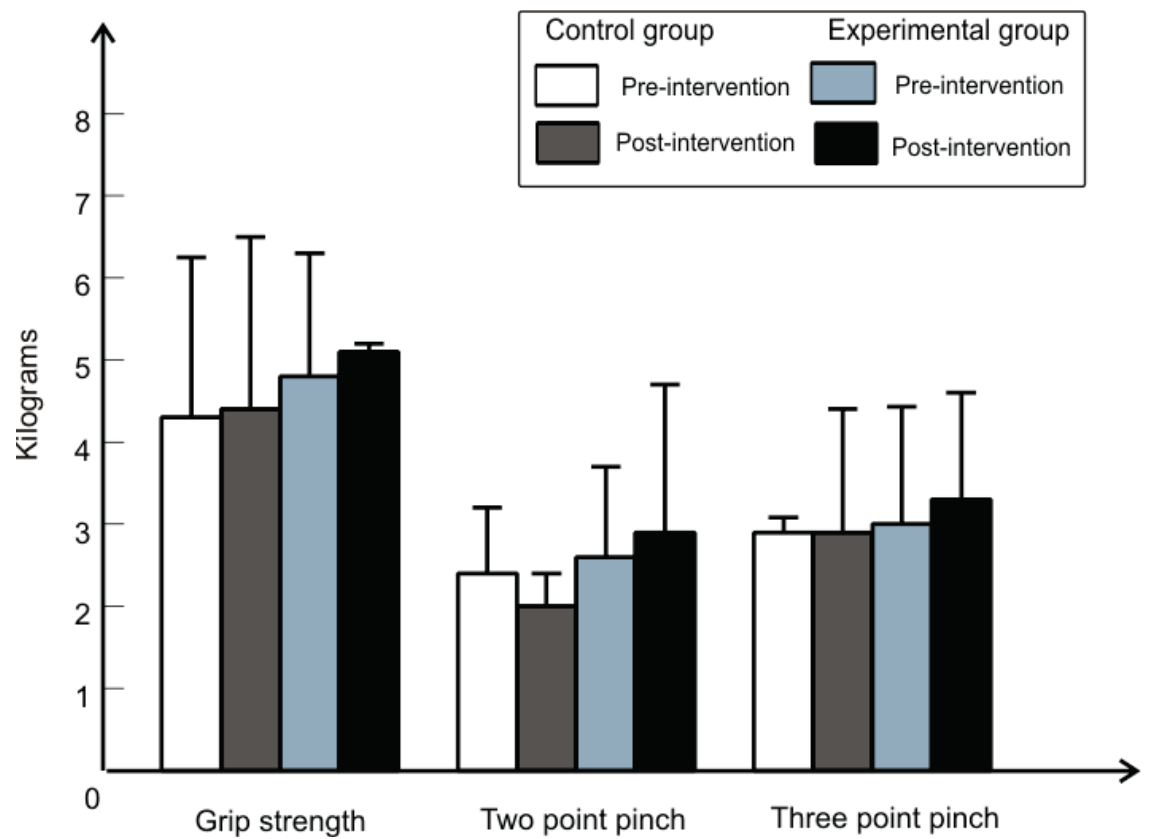


Figure 23 presents the histograms for group means and standard deviations for the peg board dexterity item of the AHFT in both groups.

**Figure 23: Peg board dexterity**

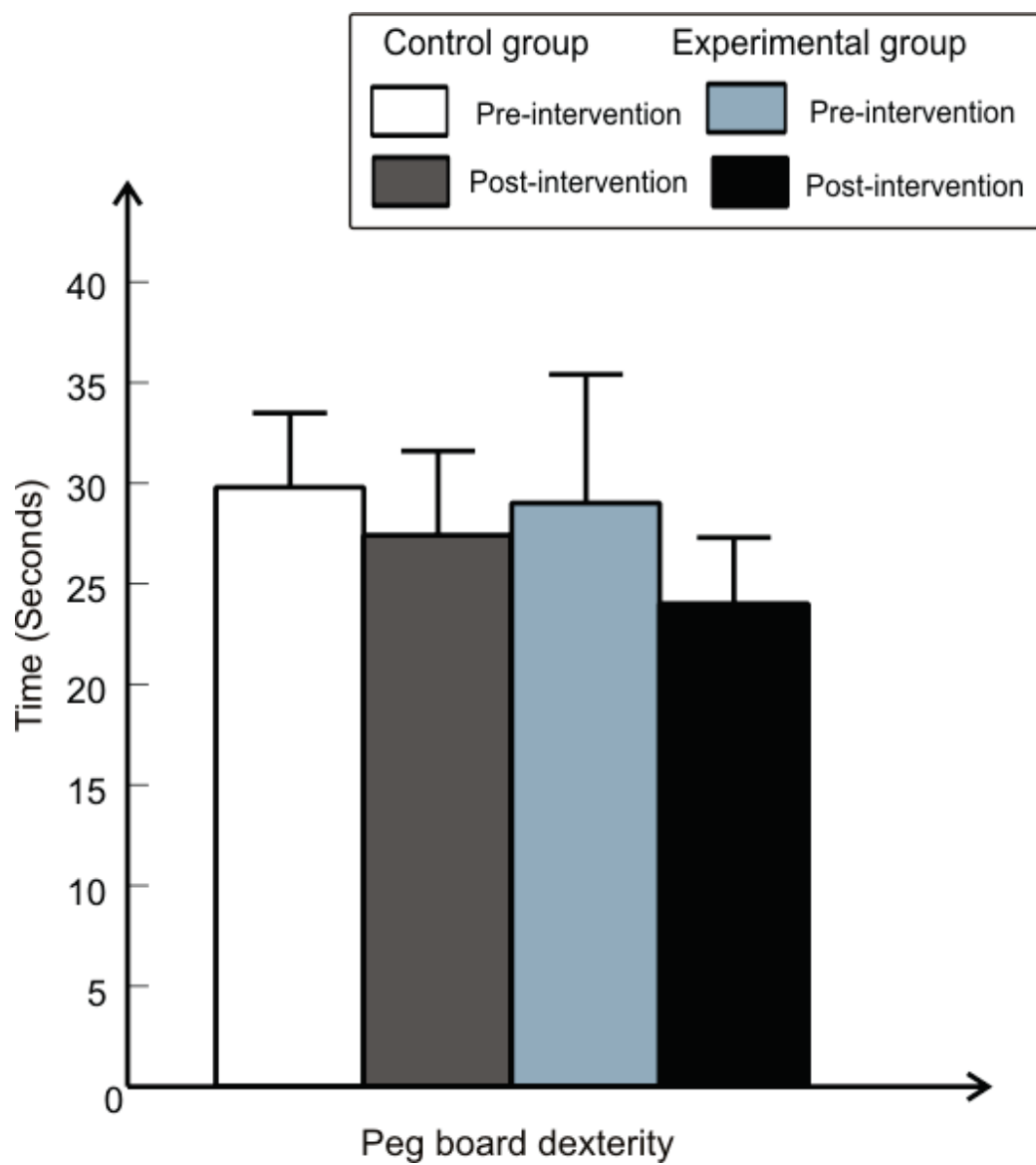


Figure 24 presents the histograms for group means and standard deviations for each task of the applied dexterity subscale of the AHFT in both groups.

**Figure 24: Six tasks of the applied dexterity item**

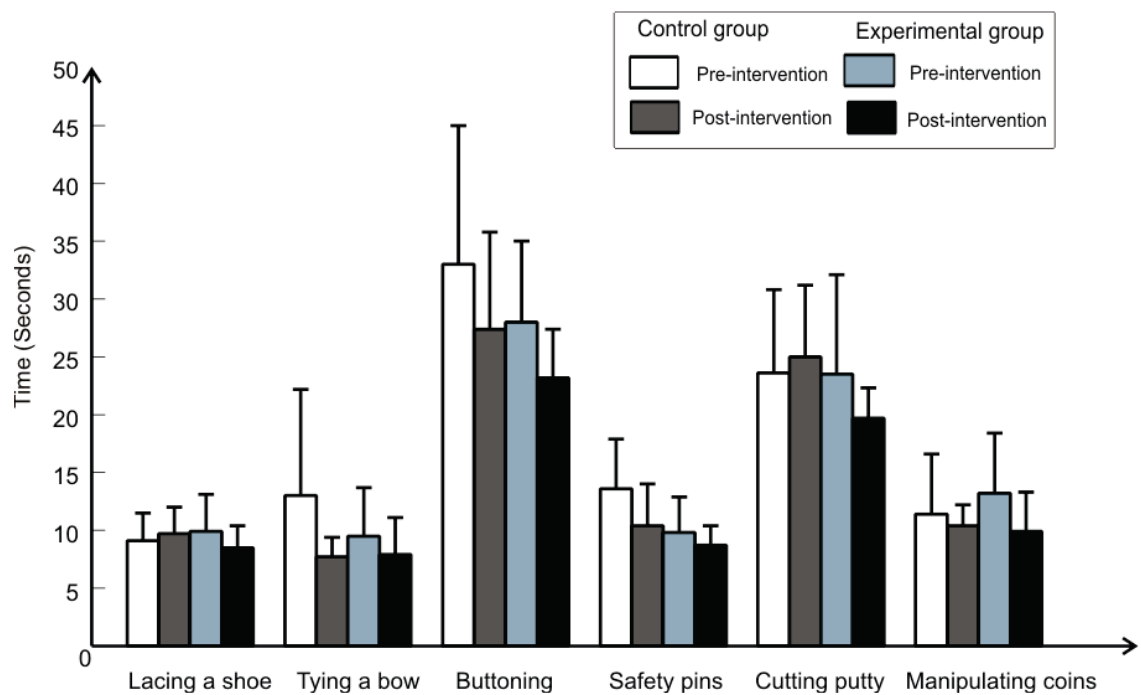
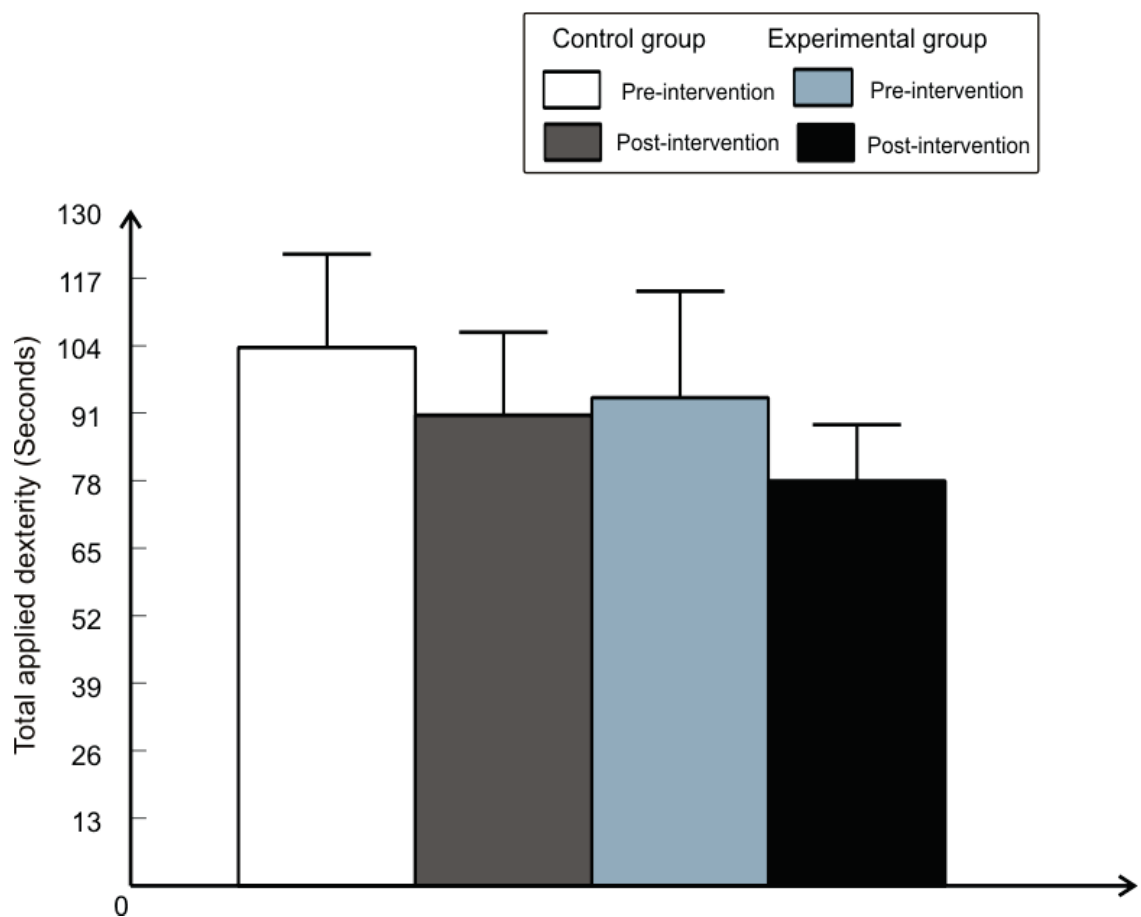


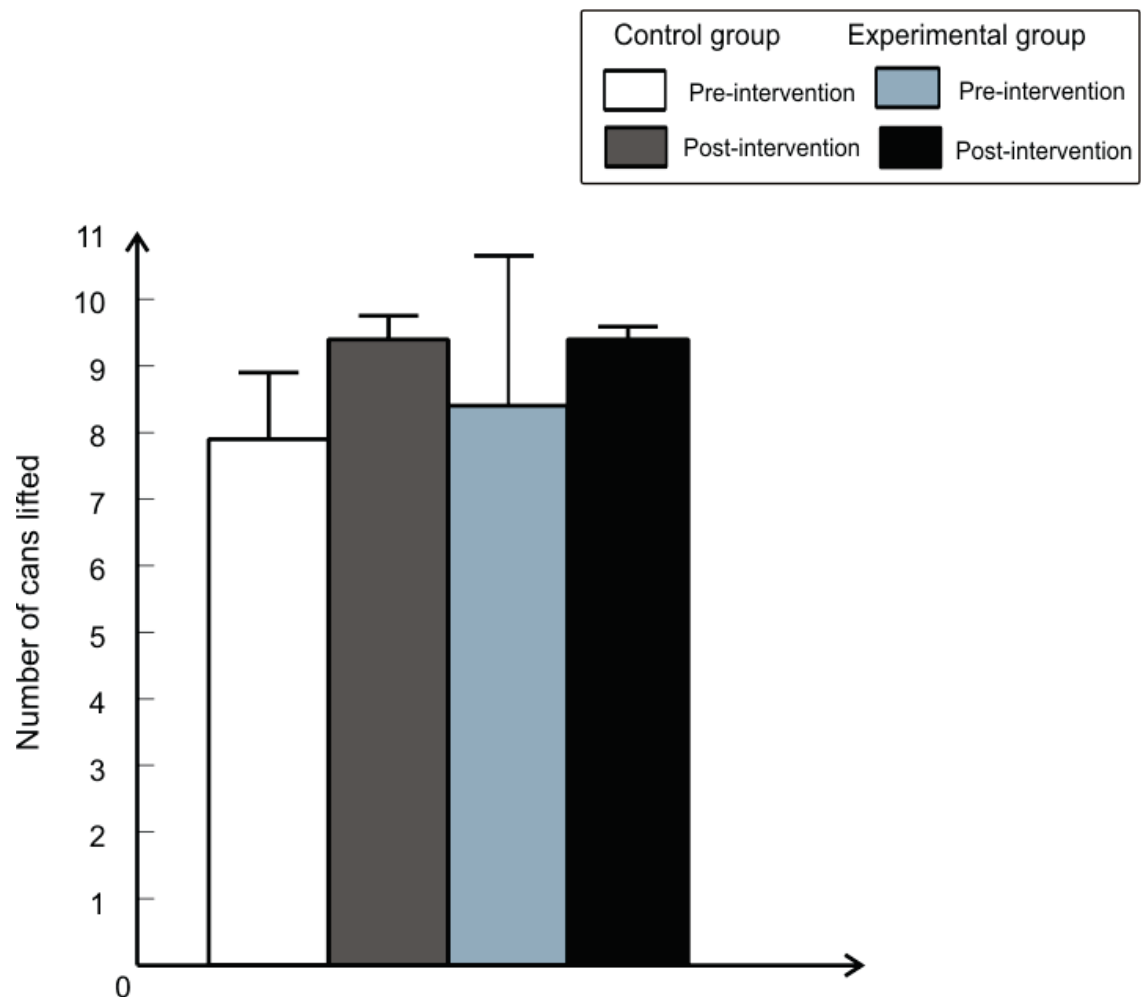
Figure 25 presents the histograms for group means and standard deviations for the total applied dexterity of the AHFT in both groups.

**Figure 25: Total applied dexterity**



Figures 26 and 27 presents the histograms for group means and standard deviations for the two tasks (number of cans and volume of water lifted) of the applied strength subscale of the AHFT in both groups.

**Figure 26: Number of cans lifted**





**Figure 27: Volume of water lifted**

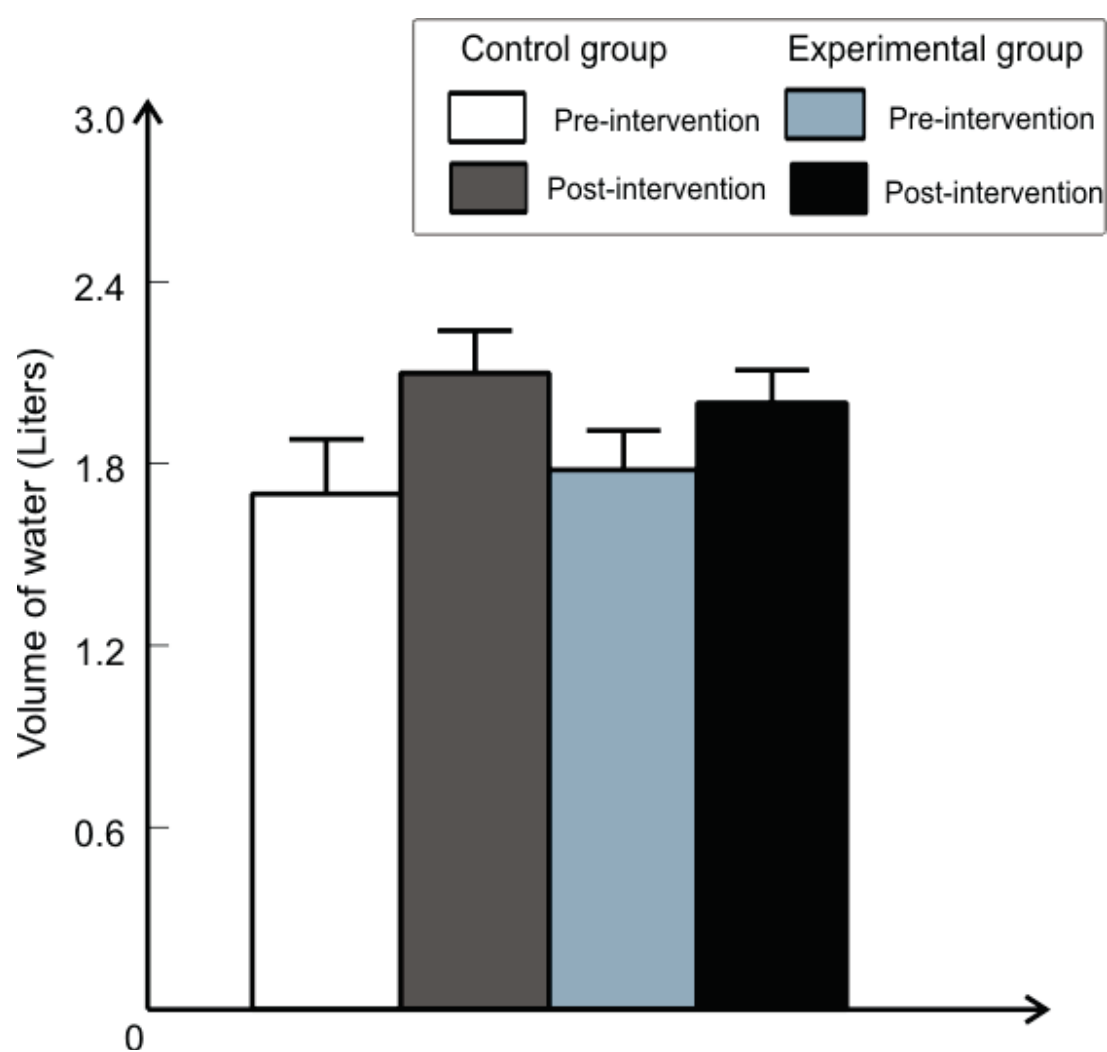


Figure 28 presents the histograms for group means and standard deviations for the DASH scores in both groups.

**Figure 28: DASH scores**

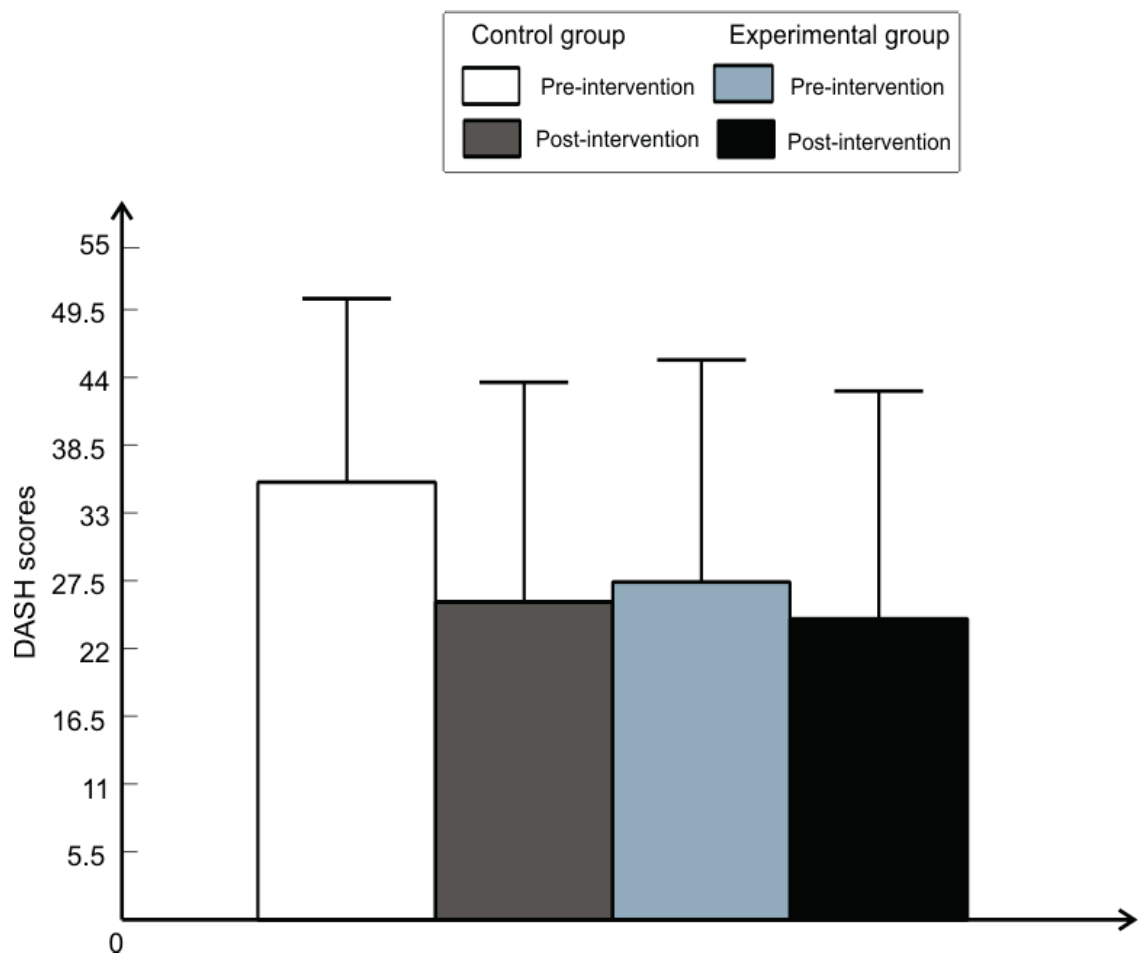


Figure 29 presents the histograms for group means and standard deviations of the predictable tracking task performance in both groups.

**Figure 29: Performance measure of the predictable tracking task**

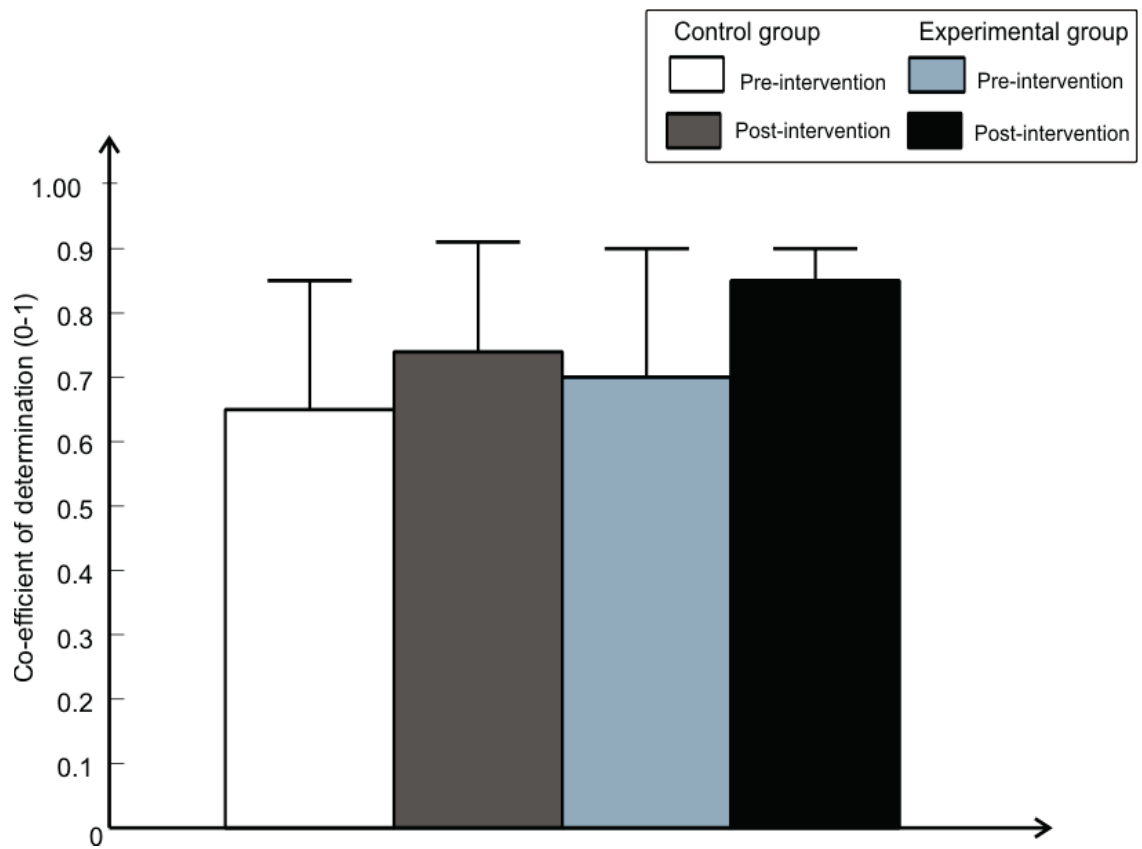


Figure 30 presents the histograms for group means and standard deviations of co-efficient of variation % of the amplitude consistency of the predictable tracking task (upward and downward movements) in both groups.

**Figure 30: CoV % of the amplitude consistency of the predictable tracking task**

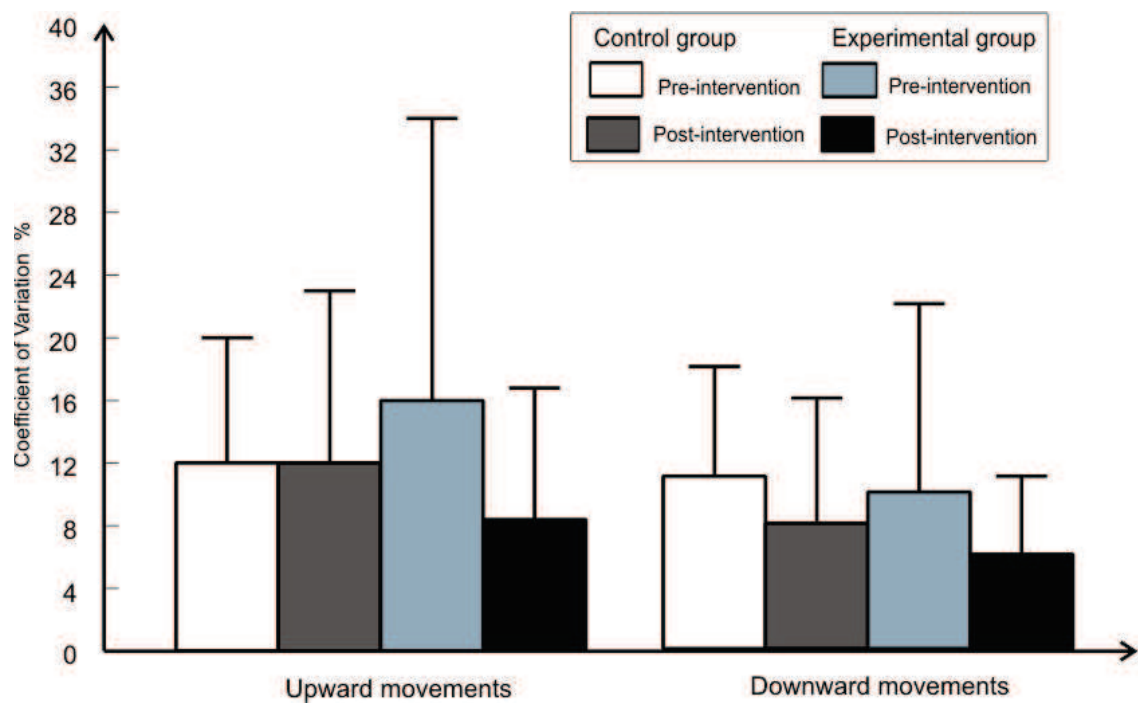


Figure 31 presents the histograms for group means and standard deviations of the success rates of the random game tasks in both groups.

**Figure 31: Success rates for the random game tasks**

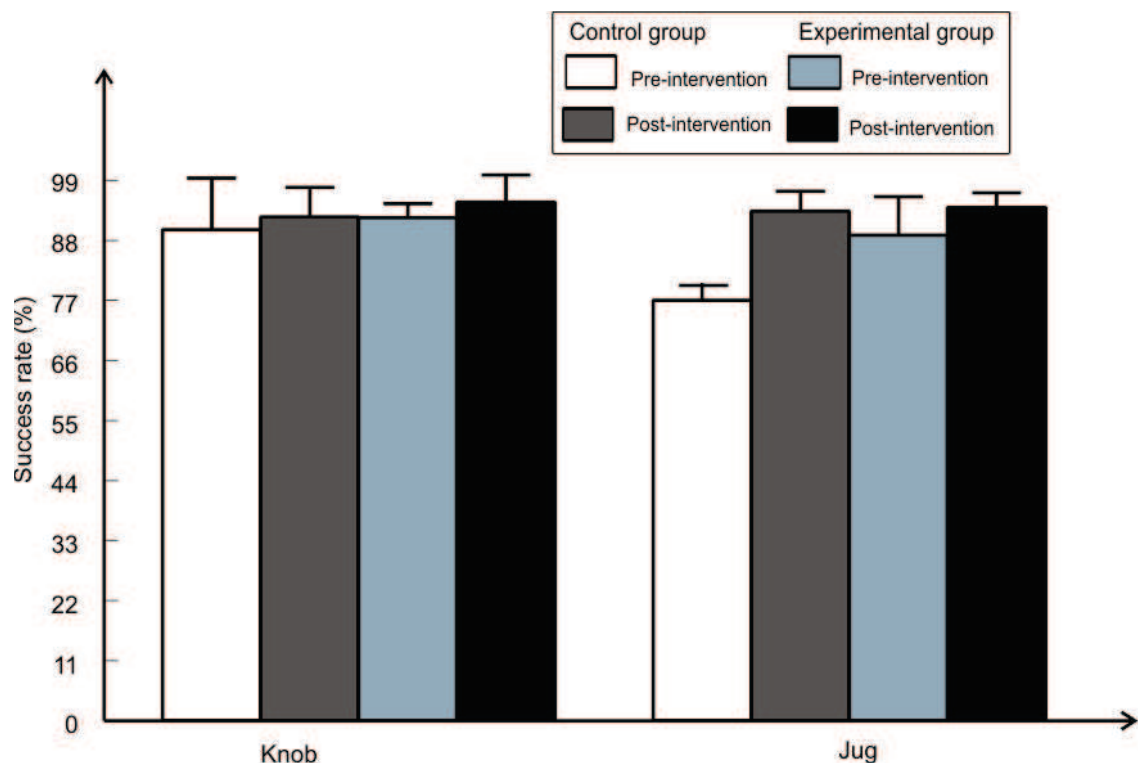


Figure 32 presents the histograms for group means and standard deviations of motor response and movement time of the random game tasks in both groups.

**Figure 32: Average motor response and movement time for the random game tasks**

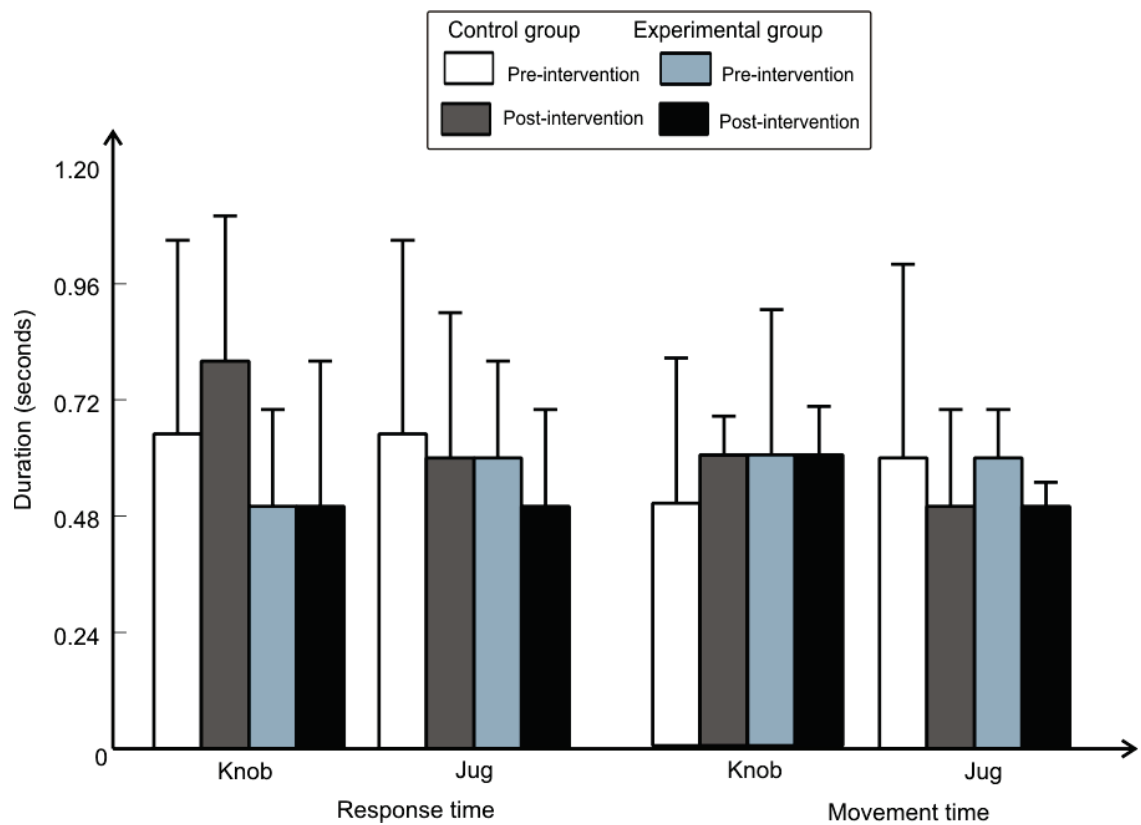


Figure 33 shows the box and whisker plots for pre and post intervention self-reported pain and stiffness scores before and after performing each object manipulation task (salad tongs, turning knob and jug) in both groups during baseline assessment session. Y axis represents the pain scores. The top and bottom of the boxes represent the upper and lower quartiles and median is presented as the middle line. The top and bottom whiskers represent the maximum and minimum values.

**Figure 33: Pre and post task pain and stiffness- Baseline session**

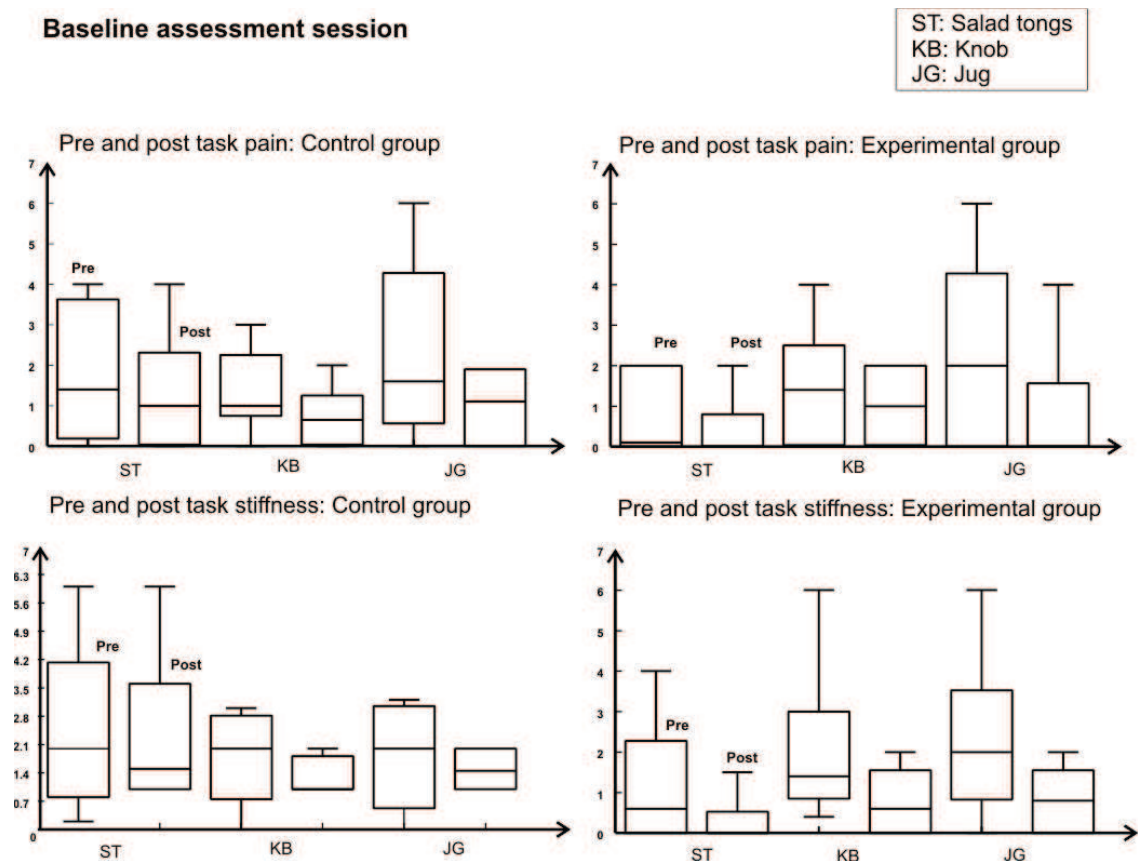


Figure 34 shows the box and whisker plots for pre and post intervention self-reported pain and joint stiffness levels before and after performing each object manipulation task (salad tongs, turning knob and jug) in both groups during final assessment session. Y axis represents the stiffness scores. The top and bottom of the boxes represent the upper and lower quartiles and median is presented as the middle line. The top and bottom whiskers represent the maximum and minimum values.

**Figure 34: Pre and post task pain and stiffness-Final session**

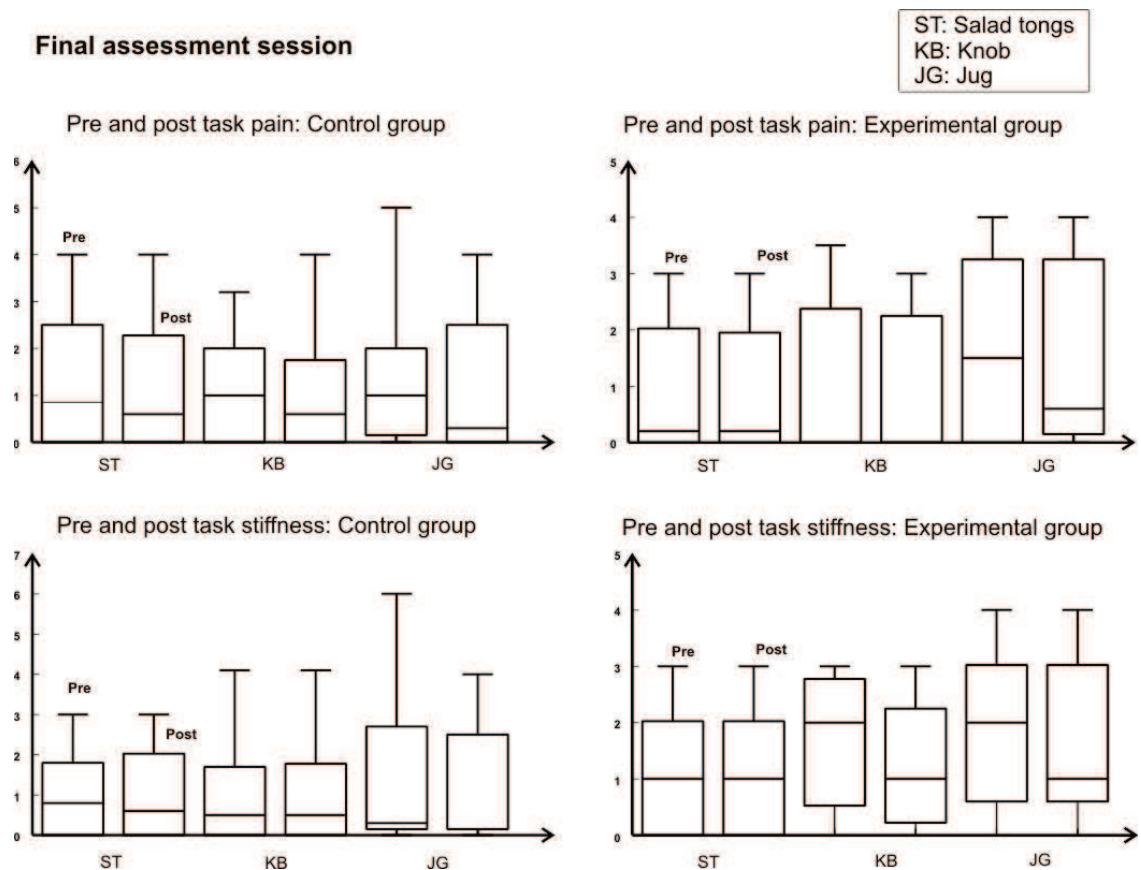




Table 20 presents the results of the mixed model ANOVA on AHFT and DASH scores, pre to post intervention. Except for within subject differences in the time taken to complete the peg board dexterity and total applied dexterity in favour of the experimental group, all other variables were non-significant. No interaction effects were noted.

**Table 20: AHFT and DASH outcomes, pre to post intervention**

Hand function outcome variables	Random effects factor: Within subjects	Fixed effects factor: Between subjects	Interaction
Grip strength	$p= 0.240$ $F=1.545$ $\eta_p^2= 0.123$	$p= 0.353$ $F= 0.940$ $\eta_p^2= 0.079$	$p= 0.701$ $F= 0.155$ $\eta_p^2= 0.014$
Two pinch strength	$p= 0.920$ $F= 0.087$ $\eta_p^2= 0.001$	$p= 0.374$ $F= 0.858$ $\eta_p^2= 0.072$	$p= 0.398$ $F= 0.772$ $\eta_p^2= 0.066$
Three pinch strength	$p= 0.773$ $F= 0.087$ $\eta_p^2= 0.007$	$p= 0.626$ $F= 0.250$ $\eta_p^2= 0.020$	$p= 0.763$ $F= 0.095$ $\eta_p^2= 0.008$
Peg board dexterity	$p= 0.023$ $F= 6.518$ $\eta_p^2= 0.318$	$p= 0.176$ $F= 2.027$ $\eta_p^2= 0.126$	$p= 0.378$ $F= 0.830$ $\eta_p^2= 0.056$
Applied dexterity	$p= 0.010$ $F= 8.929$ $\eta_p^2= 0.389$	$p= 0.126$ $F= 2.655$ $\eta_p^2= 0.159$	$p= 0.748$ $F= 0.107$ $\eta_p^2= 0.008$
DASH scores	$p= 0.163$ $F= 2.171$ $\eta_p^2= 0.134$	$p= 0.485$ $F= 0.514$ $\eta_p^2= 0.035$	$p= 0.519$ $F= 0.438$ $\eta_p^2= 0.030$

' $p$ ' value= Probability of statistical significance;  $F$  (F-statistic) = variance between groups/ variance within groups;  $\eta_p^2$  = Effect size.

Table 21 shows the results of the mixed model ANOVA in the game based hand function variables, pre to post intervention. There were no between and within subject differences, or interaction for any of the outcomes derived from the game based hand function assessment application.

**Table 21: Game based hand function outcomes, pre to post intervention**

Outcome variables of the custom computer game	Random effects factor: Within subjects	Fixed effects factor: Between subjects	Interaction
Tracking protocol: a) CoD	$p=0.128$ $F=2.642$ $\eta_p^2=0.169$	$p=0.183$ $F=1.983$ $\eta_p^2=0.132$	$p=0.641$ $F=0.228$ $\eta_p^2=0.017$
a) Amplitude consistency CoV% -Down movements	$p=0.3$ $F=1.163$ $\eta_p^2=0.082$	$p=0.532$ $F=0.412$ $\eta_p^2=0.031$	$p=0.977$ $F=0.001$ $\eta_p^2=0.00$
b) Amplitude consistency CoV% -Upward movements	$p=0.398$ $F=0.763$ $\eta_p^2=0.055$	$p=0.922$ $F=0.01$ $\eta_p^2=0.001$	$p=0.494$ $F=0.496$ $\eta_p^2=0.037$
Episodic game: a) Success rate  Turning knob   Jug	$p=0.111$ $F=2.963$ $\eta_p^2=0.198$   $p=0.138$ $F=2.602$ $\eta_p^2=0.206$	$p=0.373$ $F=0.861$ $\eta_p^2=0.067$   $p=0.338$ $F=1.012$ $\eta_p^2=0.092$	$p=0.975$ $F=0.001$ $\eta_p^2=0.00$   $p=0.425$ $F=0.692$ $\eta_p^2=0.065$
b) Average movement time  Turning knob   Jug	$p=0.374$ $F=0.852$ $\eta_p^2=0.066$   $p=0.275$ $F=1.334$ $\eta_p^2=0.118$	$p=0.182$ $F=2.003$ $\eta_p^2=0.143$   $p=0.786$ $F=0.077$ $\eta_p^2=0.008$	$p=0.075$ $F=3.791$ $\eta_p^2=0.240$   $p=0.734$ $F=0.122$ $\eta_p^2=0.012$
c) Average motor response time  Turning knob   Jug	$p=0.862$ $F=0.032$ $\eta_p^2=0.003$   $p=0.212$ $F=1.780$ $\eta_p^2=0.151$	$p=0.600$ $F=0.290$ $\eta_p^2=0.024$   $p=0.564$ $F=0.355$ $\eta_p^2=0.034$	$p=0.501$ $F=0.481$ $\eta_p^2=0.039$   $p=0.751$ $F=0.106$ $\eta_p^2=0.010$

' $p$ ' value= Probability of statistical significance;  $F$  (F-statistic) = variance between groups/ variance within groups;  $\eta_p^2$  = Effect size.

Table 22 shows the Z statistics and ‘*p*’ values of the Wilcoxon signed rank test in comparing the pre and post task pain scores for each object manipulation task in each group during the baseline assessment session. No significant differences were seen after each object manipulation task in each group.

**Table 22: Comparison of pre and post task pain for the object manipulation tasks- Baseline session**

Objects	Baseline session Control group		Baseline session Experimental group	
	Pain (pre <sup>*</sup> ) (post <sup>*</sup> )	Significance	Pain (pre) (post)	Significance
Salad tongs	1.4 (3.25) 1(1.7)	Z=-1.461 <i>p</i> = 0.144	0.15 (2) 0(0.37)	Z=-1.342 <i>p</i> = 0.180
Turning knob	1 (1) 0.65(0.95)	Z=-1.826 <i>p</i> = 0.068	1.4 (1.95) 1(1.95)	Z=-1.069 <i>p</i> = 0.285
Jug	1.6 (3) 1.1(1.9)	Z=-1.214 <i>p</i> = 0.225	2 (3.75) 0(0.75)	Z=-1.89 <i>p</i> = 0.059

Table 23 shows the Z statistics and ‘*p*’ values of the Wilcoxon signed rank test in comparing the pre and post task pain scores for each object manipulation task in each group during the baseline assessment session. Except for stiffness associated with the knob and jug manipulation tasks in the experimental group, no significant differences were seen in both groups.

**Table 23: Comparison of pre and post task stiffness for the object manipulation tasks-Baseline session**

Objects	Baseline session Control group		Baseline session Experimental group	
	Stiffness (pre)	Significance (post)	Stiffness (pre)	Significance (post)
Salad tongs	2 (2.5) 1.5(1.7)	Z=-0.378 <i>p</i> = 0.705	0.65 (1.75) 0(0.2)	Z=-1.841 <i>p</i> = 0.066
Turning knob	2 (1.75) 1(0.75)	Z=-0.966 <i>p</i> =0.334	1.4 (1) 0.65(1.38)	Z=-2.201 <i>p</i> =0.028
Jug	2 (2.3) 1.45(1.07)	Z=-0.677 <i>p</i> = 0.498	2 (1.64) 0.85(1.4)	Z=-2.032 <i>p</i> =0.042

Table 24 shows the Z statistics and ' $p$ ' values of the Wilcoxon signed rank test in comparing the pre and post task pain scores for each object manipulation task in each group during the final assessment (Post intervention) session. No significant differences were seen after each object manipulation task in each group.

**Table 24: Comparison of pre and post task pain for the object manipulation tasks-  
Final session**

Objects	Post intervention session Control group		Post intervention session Experimental group	
	Pain (pre) (post)	Significance	Pain (pre) (post)	Significance
Salad tongs	0.85 (1.95) 0.6(1.7)	$Z=-1.342$ $p=0.180$	0.2 (1.75) 0.15(1.5)	$Z=-0.730$ $p=0.465$
Turning knob	1 (1.5) 0.6(1)	$Z=-0.816$ $p=0.414$	0.15 (2) 0.1(2)	$Z=-1.342$ $p=0.180$
Jug	1 (0.8) 0.3(1.9)	$Z=-0.184$ $p=0.854$	1.5 (2.8) 0.65(2.9)	$Z=-0.730$ $p=0.465$

Table 25 shows the Z statistics and ‘*p*’ values of the Wilcoxon signed rank test in comparing the pre and post task pain scores for each object manipulation task in each group during the final assessment session. No significant differences were seen after each object manipulation task in each group.

**Table 25: Comparison of pre and post task stiffness for the object manipulation tasks-Final session**

Objects	Post intervention session Control group		Post intervention session Experimental group	
	Stiffness (pre) Stiffness (post)	Significance	Stiffness (pre) Stiffness (post)	Significance
Salad tongs	0.8 (1.25) 0.5(1.7)	$Z=-0.447$ $p=0.655$	0.8 (1.7) 0.8 (1.6)	$Z=-1.414$ $p=0.157$
Turning knob	0.45 (0.875) 0.5(0.95)	$Z=-0.447$ $p=0.655$	2 (2) 0.6(1.38)	$Z=-1.473$ $p=0.141$
Jug	0.3 (1.4) 0.2(1.8)	$Z=-1.095$ $p=0.273$	2 (1.97) 1(2)	$Z=-1.089$ $p=0.276$

Table 26 shows the Z statistics and ' $p$ ' values of the Mann-Whitney test in comparing the change scores of pain and stiffness for each object manipulation task between control and experimental groups during the final assessment session. No significant differences between groups were seen.

**Table 26: Between group comparison of change scores of pain and stiffness for the object manipulation tasks-Final session**

Change scores of pain (Pre to post task)	Mann Whitney test between groups	
	Baseline	Final
Salad tongs	$Z= 0.00$ $p= 0.9$	$Z= -0.121$ $p= 0.90$
Turning knob	$Z= -1.1$ $p= 0.271$	$Z= -0.128$ $p= 0.89$
Jug	$Z= -0.735$ $p= 0.463$	$Z= -0.427$ $p= 0.669$
Change scores of stiffness (Pre to post task)		
Salad tongs	$Z= -0.685$ $p= 0.494$	$Z= -0.829$ $p= 0.407$
Turning knob	$Z= -0.536$ $p= 0.592$	$Z= -1.08$ $p= 0.277$
Jug	$Z= -1.063$ $p= 0.288$	$Z= -0.060$ $p= 0.952$



Table 27 shows the percentages of reduction in pain and stiffness before and after performing an object manipulation task during baseline assessment session. Reduction in pain was seen in both groups. There was a prominent reduction in stiffness ranging between 54-100% in the experimental group.

**Table 27: Reduction in pain and stiffness pre to post task during baseline session**

Object tasks	% reduction in pain (pre to post task)		% reduction in stiffness (pre to post task)	
	Control	Experimental	Control	Experimental
Salad tongs	28.5	15	25	100
Knob	40	28.5	50	54
Jug	31	100	27.5	57.5

Table 28 shows the percentages of reduction in pain and stiffness before and after performing an object manipulation task during final assessment (Post-intervention) session. Reduction in pain was seen in both groups, except for an increase in pain with knob manipulation in the experimental group. There was a prominent reduction in stiffness ranging between 50-70% with knob and jug manipulations in the experimental group.

**Table 28: Reduction in pain and stiffness pre to post task during final session**

Object tasks	% reduction in pain (pre to post task)		% reduction in stiffness (pre to post task)	
	Control	Experimental	Control	Experimental
Salad tongs	29.4	25	37.5	No change
Knob	40	33	-10	70
Jug	70	57	33	50

The mean scores of the clinical outcomes pre and post intervention were compared between the groups in a straight forward fashion and are described below:

#### The Arthritis Hand Function Test

The grip strength scores did not show notable increase in either group. The two and three point pinch strength scores increased by 14% and 9% in the experimental group, while no changes were seen in the control group.

The time taken to complete the peg board dexterity task decreased by 17.5% in the experimental group compared to 8% of the control group.

The total time taken to complete the six tasks of the applied dexterity decreased by 17% in the experimental group compared to 12.5% of the control group. Except for two tasks, lacing the shoe and cutting the putty of the applied dexterity sub-scale, the control group consistently showed reduction in time to complete the other individual tasks. The experimental group showed reduction in time taken to complete all of the individual tasks. The reduction in time to complete fastening and unfastening two safety pins was 23% in the control group and 11% of the experimental group. The reduction in time to complete the coin manipulation task was 27.8% in the experimental group compared to 8.8% in the control group. The reduction in time to complete the buttoning task was 17% in both groups.

An observed 16% increase in the number of cans lifted was noted in the control group compared to 9.6% of the experimental group. Similarly, an observed 19% increase in the volume of water lifted was noted in the control group compared to 9.5% of the

experimental group. The improvements in the volume of water lifted were significant within the study participants.

#### The DASH questionnaire

Self-reported hand function disability measured by the DASH scores decreased by 9.7 and 3.7 points in the control and experimental groups respectively.

#### Computer game based hand function assessment application

The increase in performance (CoD) scores of the tracking protocol in both groups were closely similar, while amplitude consistency showed excellent improvements by 47.5% change in upward and 40% in downward movements in the experimental group. A increase of 17% in the success rate of the jug manipulation task was noted in the control group compared to 6% of the experimental group. No changes were seen in the experimental group with the average motor response and movement time for the knob task. The decrease in the average motor response and movement time for the jug task in the experimental group was 16% and 14.5% respectively. In the control group, the average motor response and movement time for the knob task increased by 19% and 12%. The jug task showed 16% decrease in the average movement time.

Reduction in pain and stiffness levels after performing each of the three object manipulation tasks during both assessment sessions were consistent with the object manipulation tasks in both groups.

## Summary

To summarize, both groups showed a reduction in the time taken to complete four individual tasks (excluding lacing a shoe and cutting putty tasks in the control group) of the applied dexterity and the total time to complete all six tasks. The applied strength items, DASH questionnaire scores, and most of the variables of computer based hand function application also increased in both groups. The experimental group increased in two and three point pinch strength and amplitude consistency of the predictable tracking task. The decrease in the pegboard dexterity and total applied dexterity durations was better in the experimental group, while the control group was better in the DASH questionnaire scores. A consistent reduction in pain and stiffness were noted in both groups after performing the salad tongs and jug manipulation tasks during baseline and final assessment sessions.

### **Section 4a: 2.5. Exercise compliance**

Both group participants were asked to complete four sessions per week for six weeks, each session ranging between 15 and 25 minutes. By the end of sixth week, the mean average ( $\pm$  SD) duration of each home session in the control group was 16 ( $\pm$  4.1) minutes and 23 ( $\pm$  4) minutes in the experimental group.

The mean average ( $\pm$  SD) number of completed home sessions self-reported by the control group was 23.5 ( $\pm$  0.53) and 21.1 ( $\pm$  3.8) by the experimental group.

## **Section 4b: Results of the embedded qualitative study**

### **Section 4b: 1. Demographic characteristics of focus group-1**

The first focus group was formed with four volunteers who had completed six weeks of home based conventional hand exercises during the pilot trial. The program included six exercises for finger and wrist mobility and two exercises for wrist and intrinsic strength. The demographic characteristics of the focus group participants are presented in Table 29.

**Table 29: Demographic characteristics: Focus group 1**

Participant code	Age	Sex	arthritis type
Participant #1	70	Female	rheumatoid arthritis
Participant #2	62	Female	rheumatoid arthritis
Participant #3	70	Male	rheumatoid arthritis
Participant #4	62	Female	hand osteoarthritis

### **Section 4b: 2. List of significant statements**

Table 30 presents selected significant statements reported by the focus group. Four common themes emerged from the focus group interview.

**Table 30: Selected significant statements informed by the Focus group 1**

Significant statements	Emergent themes
<p>They (exercises) seem to be appropriate for exercising the hand  I didn't feel I was not doing something  I think that they were useful, when I was doing it.  The exercises seemed to be reasonably well designed  It (exercises) was a good experience and all together doing it  I could certainly handle what was asked.  It wasn't too much to worry but I think it was enough to do some good  I did them as they were write out  Number of times a week was fine</p>	<p>Theme 1</p> <p>The exercise program was appropriate and doable</p>
<p>I did had the opportunity to relax, because it was only 20 minutes, it was no problem  I think exercising is boring and so little motivation is really important. That was an advantage having a structured program. There was enough structure and so that reasonably motivated to complete the program and that was the good thing  Journalizing was very very important keeping it useful  I thought it was wonderful that we could do something proactive. I liked the idea of being involved in that. That was a motivation in itself to do the program. I thought it had a lot of value for me!  I think I found it a positive thing to do and felt like I was doing good for myself and also being involved in the study  There is no other kinds of support...might be useful and I was attracted to this as an idea, because it provide some extra care  Sure, that (weekly reminders) helped with the motivation as well. I mean I think that all that was appropriate, I think, it was done, the way progression plan was laid out  The fact that I could either email the (study investigator) or pick up the phone if I need (study investigator) sure was wonderful.  If you needed help, it was there.  I think it is sound important to keep in touch. That was great  That (progression through phone calls) was great that way I could tell my concerns  It was good to know that (study investigator) was watching and say it felt like you were involved with someone who is keeping track of how you are doing and gave us a chance of something to say that was required that something down</p>	<p>Theme 2</p> <p>Facilitators of participation</p>
<p>I could feel that they (exercises) were stretching my hand and that was a good thing, especially working the wrist with the weight and also working with the putty seemed to be really good. I could sense that good things were happening with the hand</p> <p>When I did, it (exercises) was most beneficial</p> <p>the squeezing of the putty was great</p> <p>The exercises didn't cause me any problem, or pain or stiffness particularly.</p> <p>My hands felt better after I had done because it was looser and seemed to be working... So much, so much better</p> <p>I think it needed the weight to get exercise my wrist I believe were stronger at the end of the exercises. I remember that I lifted more water at that final testing , I held lot more water in the jug</p>	<p>Theme 3</p> <p>Perceived exercise benefits</p>

<p>I just liked the way the hands felt after it and I know that it was good</p> <p>Because of the stage of my arthritis, it (exercises) was controlled well, certainly involves hands and wrists primarily, I think the exercises were good and effective</p> <p>I can't think of any way that it could have been...because it worked very well...obviously we did all the exercises</p> <p>There certainly is a value; however it depends on where your disease is at. Because some would find it difficult and we have to wonder are we doing more damage than good, because we don't know!</p> <p>It would say there's great value, when your joints have not been very compromised</p>	
<p>I obviously had some difficulty with some of them (exercises)</p> <p>At the beginning they were okay, I found them quite hard in the later mainly because I have wrist problems. The wrist ones was quite not difficult but harder than it had been</p> <p>You know, it such an individual thing, it's so subjective because you are dealing with a disease mainly , but it affects people in many different ways and at many different times</p> <p>It is difficult to have 'one size fits all' so I think we do the exercise and we take from what we can.</p> <p>I don't think I had any problems keeping up with the (progression) or, I think I could have handled somewhat more</p> <p>I was finding the weight and the putty too strong</p> <p>I had problems was with the wrist and not with the flexion without the weights...but with the weights.</p> <p>I couldn't even reach the fourth finger</p> <p>The fine thing I just I got frustrated...my hand wasn't .I don't know what you could do with that</p>	<p>Theme 4 Perceived exercise difficulties</p>



### **Section 4b: 3. Textural description**

Textural description of the interview includes brief explanation of the focus group themes and a few key quotes supporting each of them:

Theme 1: The exercise program was appropriate and doable.

All four participants reported that the exercises were appropriately designed and practically doable without any difficulty.

Participant #2, 62/F: “They seem to be appropriate for exercising the hand.”

Participant #3: 70/M): “I could certainly handle what was asked. It wasn’t too much to worry but I think it was enough to do some good.”

Participant #4, 62/F: “I think that the exercises themselves were good.”

Theme 2: Facilitators of participation

Some important factors that were instrumental towards participating in the home program were identified from the focus group interview. Two participants (Participant #1: 70/F; Participant #2: 62/F) reported that participating in the study made them ‘feel good about themselves’. They perceived that they made a good choice by benefiting themselves with exercising their arthritis affected joints. One participant (Participant #3: 70/M) found it as a good opportunity to deal with his arthritis pain and also mentioned that the structure of the exercise program motivated them to continue with the exercises. Additional factors such as the 20 minutes of exercise duration, exercising in home settings, communication with the study investigator, weekly reminders, logging of each exercise session and regular monitoring by the study staff were identified important in

facilitating full participation. The focus group shared common consensus acknowledging the weekly reminders and journalization as motivators in completing their exercise sessions.

Participant # 1, 70/F: “I thought it was wonderful that we could do something proactive. I liked the idea of being involved in that. That was a motivation in itself to do the program. I thought it had a lot of value for me”!

Participant #4, 62/F: “I think I found it a positive thing to do and felt like I was doing good for myself”.

Participant #3, 70/M: “This program gave me a chance to do something about . It’s tough to deal with”.

Participant #2, 62/F: “Having that to write down every single time, journalizing was very very important keeping it useful”

### Theme 3: Perceived exercise benefits

Three participants (Participant #2: 62/F; Participant #3: 70/M; Participant #4: 62/F) described the exercise program as beneficial. One of them (Participant #3: 70/M) felt that the fingers seemed easy to move and loosened after exercising the wrist and hand. Two participants (Participant #2: 62/F, Participant #4: 62/F) perceived great benefits of the strengthening exercises with putty and dumbbell. One of them (Participant #2: 62/F) also reported that the felt changes were obvious and that she was able to lift more weight (lift more volume of water in a pitcher: arthritis Hand Function Test Applied strength test) during the post intervention assessment session.

Participant #2: 62/F: “I think it needed the weight to get exercise my wrist. I believe they were stronger at the end of the exercises. I remember that I lifted more water at that final testing; I held lot more water in the jug”.

Participant #3: 70/M: “Because of the stage of my arthritis, it (exercises) controlled well, certainly involves hands and wrists primarily, I think the exercises were good and effective”.

Another participant (Participant # 1, 70/F) opinionated that the exercises would tend to be effective with least compromised arthritis joints.

Participant #1: 70/F: “There certainly is a value; however, it depends on where your disease is at. It would say there is great value, when your joints have not been very compromised”.

The same participant also added it would be more ‘subjective’ to conclude if the hand exercises were beneficial, because of the varied presentation of arthritis symptoms.

Participant #1: 70/F: “It’s such an individual thing, it’s so subjective because you are dealing with a disease mainly , but it affects people in many different ways and at many different times... one week ‘fine’, next week ‘Oh My God!’ ... It just varies with because the disease will flare up or just be contained for one day... you know it is difficult to have ‘one size fits all’ so I think we do the exercise and we take from what we can”.

#### Theme 4: Perceived exercise difficulties

The focus group identified three different types of difficulties with the home program. They were: difficulty in doing certain exercises, progressing with the exercises and visualizing each exercise method while doing them. Two participants (Participant #2: 62/F; Participant #4: 62/F) reported that they had difficulties with wrist muscle

strengthening exercise using the dumbbell. One of them (Participant #2: 62/F) also reported mild difficulty doing the thumb opposition movements. Another one (Participant #1: 70/F) reported problems with doing more repetitions with the dumbbell during the last weeks of the exercise program. One participant (Participant #3: 70/M) reported no issues with any of the exercises and the exercise progressions as well.

Participant #2, 62/F: “I had the same issues as you had JN (Participant #1: 70/F), is the wrist where I had problems was with the wrist and not with the flexion without the weights...but with the weights. That’s the one that did cause pain”.

Participant #3, 70/M: “I don’t think I had any problems keeping up with the (progression) or, I think I could have handled somewhat more”!

#### **Section 4b: 4. Structural description**

It is evident that most of the focus group participants experienced the phenomenon by acknowledging the benefits of home program, irrespective of the stage or levels of discomfort they were having with arthritis. Therefore, even with a few difficulties reported, all of them were able to agree with one another that the exercises did benefit them. However, one participant (Participant #1: 70/F) also had alternate views on benefits of exercises which might have reflected in context with her arthritis related knowledge and previous experiences with episodes of arthritis exacerbations, pain and stiffness. This participant was able to relate the unpredictable nature of arthritis symptoms with exercising. In her point of view, it may not be true that exercises had an effect when the nature of disease itself is not under control. A suggestion made by this participant to consider including the non-dominant hand while exercising would further demonstrate how her experiences living with arthritis has made her recognize the importance of

exercising both sides than prioritizing the dominant side alone. Other contexts in which the phenomenon might have been experienced were the participants' enthusiasm and motivation gained from regular reminders and journalization procedures. These were reflected in the interview quotes how participants felt some purpose in doing the exercises and how they were able to do them as instructed. The pilot randomized controlled trial findings which demonstrated an average of 23.5 completed exercise sessions (for a total of 24 recommended sessions) are in favor in these contexts.

#### **Section 4b: 5. Composite description**

The essence of participants' experiences was that the home based conventional hand exercises were appropriate and beneficial. Factors such as home environment, participant motivation and commitment played important roles with study participation in spite of a few minor difficulties in doing a few exercises in the program itself.

#### **Section 4b: 6. Demographic characteristics of focus group-2**

The second focus group was formed with three volunteers who had completed six weeks of home based task-oriented training program during the pilot trial. The program included task-oriented training via manipulation of different objects of daily life. Objects were selected based on each participant's needs and abilities and training goals such as graded finger, hand, and wrist mobility, strength, precision or endurance. The demographic characteristics of the focus group participants are presented in the Table 31.

**Table 31: Demographic characteristics: Focus group 2**

Participant code	Age	Sex	arthritis type
Participant #5	66	Female	hand osteoarthritis
Participant #6	58	Female	rheumatoid arthritis
Participant #7	59	Female	rheumatoid arthritis

#### **Section 4b: 7. List of significant statements**

Table 32 presents selected significant statements reported by the focus group. Four common themes emerged from the focus group interview.

**Table 32: Selected significant statements informed by the Focus group 2**

Significant statements	Emergent themes
<p>I liked the lack of pressure on me- do this certain times  It was very well explained when it started.  If there is any questions, help was right there...  I think It was very well progressed and it was very well done  I liked the 3-4 times a week, I think if it was physically too much and just been hard to pop it in.  I appreciate the assistance especially at the start of the home program.  The program in general, I thought was quite well set up  I think the length of the program was manageable  The six week program plan worked out for me</p>	<p>Theme 1</p> <p>The program was appropriate, flexible and doable</p>
<p>My hands could feel the workout when I was done, it was enough  Doing it several times, it's so much more beneficial to the hands  I think the object selected did what it was supposed to do  I can't say I really got fed up with doing anything, I think it was very beneficial.  I guess it built up strength overtime and I got little easier  I think for me, the good part was it made you more aware of the problems you have, not that we don't know some on daily basis but we have them.</p>	<p>Theme 2</p> <p>Perceived training benefits</p>
<p>It always became little more challenging with the levels  I would say the gaming makes it much more interesting and I would continue with that  I was little nervous about playing computer games, I found that by playing games and doing exercises, that was a good way to exercise, it takes your mind off.  I can see the gaming being much more centered to the person keep you doing it.  We had fun.  Some of the things where I used the weight I had the mouse on there I enjoyed those because I had no problems with the mouse and everything worked well</p>	<p>Theme 3</p> <p>Games 'engaged' the sessions</p>
<p>The whole Velcro thing was not always easy either.  The mouse was annoying.  Other ones I enjoyed doing them and I definitely got stronger and you know, the mouse and everything worked well, but that turning thing I found very hard on my fingers  The mouse was hard for me to turn on, it was difficult, not impossible but not easy  Lifting the tin can was most difficult exercise plus the game I played, you have to raising and lowering it many times, a lot so that by the end of  Exercise with the weight was difficult but by the time it was easier  It must have got easier because you know you are playing more extended games longer, so and you could do it near the end whereas in the beginning it was harder.  I got better when I was I was doing it.  Anything... that was little awkward, but I know it worked well once you got used to it.  Once you get used to it and then it moves smooother.</p>	<p>Theme 4</p> <p>Some difficulties with object instrumentation</p>

#### **Section 4b: 8. Textural description**

Four themes emerged from the focus group of three participants who had completed six weeks of task-oriented training in the pilot trial. Textural description involves brief explanation on each theme with a few supportive quotes.

Theme 1: The program was appropriate, flexible and doable.

All of the participants agreed that the task-oriented training program with computer gaming was appropriately designed in terms of the intensity, frequency and study duration and was quite flexible to be done at their own convenience

Participant #5, 66/F: “I felt that it was very well explained to begin with and if there is any questions, help was right there...”

Participant #6, 58/F: “I thought that the intensity was alright, it didn’t, it was short enough that you didn’t get bored with anything but enough that you had feel that you do it...”

Participant #7, 59/F: “The number of times was flexible. I think flexibility is important”.

Theme 2: Perceived training benefits

The focus group also perceived that the exercise program was beneficial and helping their hands in better ways.

Participant # 6, 58/F: “I could feel ... my hands could feel the workout when I was done, it was enough”. “I enjoyed doing them and I definitely got stronger and you know”.

Participant #5, 66/F: “I got better when I was I was doing it.”

Participant #6, 58/F: “I can’t think of anything bad....it was long enough period to do that was supposed to do, but it was short enough period that you though to say okay that’s just



fine, because its only x number of times, you know. I can't say I really got fed up with doing anything, I think it was very beneficial."

### Theme 3: Games 'engaged' the sessions.

Participants reported that playing computer games helped them engage with their sessions and even listed some of their very favorite games. There was strong consensus that everyone enjoyed playing a different variety of games, some which were also challenging.

Participant #5, 66/F: "I would say the gaming makes it much more interesting.... I would like to do it...it distracts you, doesn't it?"... "I can see the gaming being much more centered to the person keep you doing it"... "The one with the pigs and the wolves (Big fish games: Brave piglet) Just..... (Laughs) that was very challenging..."

Participant # 6, 58/F: "I would say my favorites were the birds (Big fish games: Birds Town) and the marbles (Big fish games: Jar of marbles) one."

### Theme 4: Some difficulties with object instrumentation

Participants did report that instrumenting the dowel and block set up with the mouse and removing/attaching the Velcro strips to be difficult and sometimes frustrating. In contrast, exercising with a few objects such as dowel, soup can and dumb bell were challenging. However participants acknowledged that they were able to manage them in due course of their consecutive home sessions.

Participant # 6, 58/F: "I was thinking that was the block and yeah now (laughs)....it was a little awkward to use"... "You have to un-Velcro, then try and turn all around...And

these fingers are not very strong and so then, you know, the whole Velcro thing was not always easy either.”

Participant #5, 66/F: “Like (Participant # 6, 58/F) said, transferring the mouse with the Velcro from thing to thing got a little awkward sometimes.”

Participant # 6, 58/F: “Some of the things where I used the weight I had the mouse on there I enjoyed those because I had no problems with the mouse and everything worked well. But some of the equipment I had to use (dowel and block setup)...and then it was Frustrating.”

Participant #5, 66/F: “I found the finger one...hard compared to the ball (Participant # 6, 58/F: Yes, Definitely), it was supposed to get some finer motor skills. Initially I believe that it would have been harder, but once you got used to the fine movement, it was a little better”. Anything fine... that was little awkward, but I know it worked well once you got used to it.

Participant # 7, 59/F: “The dowel exercise was little frustrating, but once you being doing the program, that helped. I worked it out”.

#### **Section 4b: 9. Structural description**

Participants reflected with mixed feelings on their experiences with the six week task-oriented training program. Though the group greatly agreed on domains such as the content of the program, computer games, number of sessions per week and availability of the staff in assisting with information at times of need, they were also concerned with issues such as instrumenting the dowel with the mouse and usage of Velcro to attach and detach things. These two procedures seemed to generally be difficult for all the participants. On the other hand, the group was aware of the benefits of the repeated task

training with gaming. It should also be noted that though the group reported difficulty with certain object manipulation tasks such as dowel, soup can and dumbbell, the group managed to practice them efficiently as sessions went by. A strong sense of commitment might have motivated the participants in taking their time to, 1) set up the objects before every home session, 2) learn the dynamics of a variety of computer games, 3) practice coupling tasks training with the computer games, 4) power charge the motion sense mouse every home session and 5) manage repetitive task practice for 15 to 25 minutes every session. Based on the transcript texts, the main context in which participants perceived the program was inclined towards both benefits of the program and practical difficulties they faced with instrumenting the dowel and using the Velcro.

#### **Section 4b: 10. Composite description**

The essence of participants' experiences with task-oriented training program, included appropriateness and practicality of the training program, perceived benefits from training and a few practical difficulties faced with object instrumentation.

#### **Section 4b: 11. Issues of consensus in both groups**

All participants from both focus groups unanimously agreed that they felt good doing exercises at home. Factors such as time limitations, discomfort and difficulties with transportation and car parking were the major factors in preferring home exercises to making clinic visits. 'Benefiting from exercises' was also commonly agreed among both group members. Table 33 presents a few key issues in which the first focus group with participants who had completed conventional hand exercises had general consensus with

each other. They agreed that weekly reminders were of great help and also emphasized video illustrations of hand exercises over written exercise protocols.

**Table 33: General consensus: Focus group 1**

Topics	Example quotes
Exercising at home	<p>“I love to prefer to do it from home, because just to pull off from that car parking that just kills me...bumpy and icy, artificial sand...you know. I loved doing at home and plus I could fit it into my schedules ....because some days I am busy some days, I could really fit in”!</p> <p>“This was much less time and I am not controlled by environment”.</p>
Weekly reminders	<p>“That’s a good thing. Yeah yeah yeah yeah! I mean that’s a good compromise that we were that ....you know, (investigator) was keeping track of .... Keep us all straightened out”.</p> <p>“I think the reminders were great”.</p>
‘Benefits to self’	<p>“I also knew that there was benefit to the exercises”.</p> <p>“This program gave me a chance to do something about rheumatoid arthritis. It’s tough to deal with.”</p>
Video illustrations of exercises	<p>“It (A video) would be even better, I think. For a lot of people, the video is a good idea!”</p>

Table 34 presents some main issues in which the second focus group with participants who had completed task-oriented training had general consensus among them. All of them agreed that computer games were fun and suggested choosing a small sized motion sense mouse for task training.

**Table 34: General consensus: Focus group 2**

Topics	Example quotes
Exercising at home	<p>“It was more less stressful doing at home than trying to do it doing somewhere else”</p> <p>“I would say it’s definitely easier doing at home, if I have to take about driving for 40 minutes to come and then parking and then exercising once a week...”</p>
‘Benefits to self’	<p>“I mean that arthritis everywhere, for me it’s always my hands are of biggest concern, if I can’t ....use my hands then it’s ....going to be pretty taxed. So I was quite able to do something that, you know, could help me”</p> <p>“And it gave you different ways of looking and doing things....other things, like if you are having trouble with something ...small, try...putting something over, you know, to use things in meager little bit different ways...”</p>
Games were fun and engaging	<p>“I used all the games you suggested at first, you know, but then I got favorites”.</p> <p>“It must have got easier because you know you are playing more extended games longer.”</p>
Small mouse for instrumentation	<p>“That’s (a small size mouse) much better, because the mouse just blocks things!”</p>

## **Overarching summary of findings**

This quasi-mixed methods pilot study included a pilot randomized controlled trial and a phenomenological qualitative investigation to evaluate two home exercise programs (a novel task-oriented training program and conventional hand exercises) in people with arthritis of the hands.

Findings from the pilot trial indicated feasibility in terms of, 1) study procedures such as informed consent, outcome assessments, training sessions and participant retention rates and 2) intervention (both groups) based features such as participant training sessions on their home exercise programs, exercise support, progression and monitoring of study participants through phone calls, intervention safety and compliance rates. With regard to the difficult recruitment process, a slight modification in the inclusion criteria and an extension of recruitment period were required. However, only 80% of the targeted sample size was reached.

Findings from the qualitative study provided preliminary evidence on appropriateness, practicality and acceptance of the task-oriented training program. Computer games motivated and engaged the participants throughout the study period. Setting up the motion sense mouse on one particular object and use of Velcro strips were identified to be practically difficult but not impossible. Participants did report that they felt the training program was beneficial to their hands. Similarly, the conventional hand exercises were perceived appropriate and doable. Participants who did conventional hand exercises perceived the weekly reminders and logging of exercise sessions as good motivators for exercising. Wrist exercises with the dumbbell were found to be difficult for a very few participants and they required a slow progression plan.

Participants from both groups (n=7) who took part in the qualitative study strongly agreed on the following topics: 1) Exercising from home was easy, convenient and less stressful 2) ‘Benefits to self’ was the main reason for participation 3) Willingness to continue the home exercise programs even after the study period 4) Ease of communication with the study staff 5) Perceived their home exercise programs as ‘meaningful’ and 6) Home exercise program training sessions were well explained and well presented.

With initial evidence from both research methods, the task-oriented training program was found to be appropriate, feasible and acceptable. Participants acknowledged that the training program was appropriate in its content. They also perceived it to be doable within their daily routines which reflected in the average number of completed home sessions reported in the trial phase. Participants’ perceptions on finding the program purposeful and compliance rate demonstrated in the trial complement each other on acceptability of the intervention. Participants also described that the computer games motivated them to engage with their home sessions. This fact was further supported by the average duration of home exercise sessions presented in the trial findings. Participants’ perceived benefits were also found to match with improvements seen in study outcomes (the DASH and applied dexterity scores) after six weeks training.

A check list on the feasibility of trial procedures is presented in Table 17. The columns indicate which of the data sources (‘QUAN’ or ‘qual’ methods) helped in informing feasibility of procedures.

A check list on the features of home exercise programs evaluated by both research methods is presented in Table 35. The columns indicate which of the data sources (‘QUAN’ or ‘qual’ methods) helped in informing feasibility of the programs.

**Table 35:A check list on the feasibility of trial procedures**

Study process, resources and data management	QUAN	qual	Feasibility
Participant recruitment procedures	✓		Requires revision
Study inclusion criteria	✓		Requires revision
Informed consent process	✓		✓
Assessment sessions (Pre& Post intervention)	✓		✓
Study outcome measures	✓		✓
Randomization procedures	✓		✓
Fixing appointments for three home exercise program training sessions	✓		✓
Participant training for home exercise programs	✓		✓
Provision of home exercise program accessories	✓		✓
Maintaining additional home exercise program equipment for replacements	✓		✓
Data collection, entry and storage	✓		✓
Weekly reminders	✓	✓	✓
Responding to participant queries	✓	✓	✓
Informing treatment progression plans	✓	✓	✓
Appointments for the final assessment session	✓		✓
Attendance at assessment and home exercise program training sessions	✓		✓
Study dropout rates	✓		✓
Participant retention rates	✓		✓



A check list on the features of home exercise programs evaluated by both research methods is presented in Table 36. The columns indicate which of the data sources ('QUAN' or 'qual' methods) helped in informing feasibility of the programs.

**Table 36: A check list on the features of home exercise programs**

Home exercise programs: Conventional hand exercises & Task-oriented training	QUAN	qual
Orientation to the program	✓	✓
Demonstration of exercises/ tasks to the participants	✓	✓
Answering participants' questions related to the program	✓	✓
Planning of treatment progressions	✓	
Appropriateness of the program	✓	✓
Feasibility of the program at home settings	✓	✓
Acceptance of the program	✓	✓
Treatment safety with the program	✓	
Beneficial effects of the program	✓	✓
Compliance with the program	✓	✓
Difficulties encountered with the program		✓
Participants' recommendations to the program		✓

## **Chapter 5: Discussion**

The primary purpose of this quasi-mixed approach pilot study was to describe the feasibility of a pilot randomized controlled trial involving a novel task-oriented training program and to obtain preliminary data on therapeutic effectiveness of the program in people with rheumatoid arthritis or hand osteoarthritis. The task-oriented training program was compared with a conventional hand exercise program that included finger mobility and hand muscle strengthening exercises. Study participants did their respective program for six weeks from their home settings. The effects of both programs were evaluated through a performance based hand function measure, self-report questionnaire on hand function ability, exercise log diary and a computer game based hand function application . The secondary purpose of the study was to learn about participants' experiences with their respective home exercise program, through a qualitative investigation conducted along with the pilot trial.

### **5.1. Participant recruitment**

A main feasibility target of the study was to enroll twenty eligible participants within a one year period. Though it was strongly believed that the estimated target would be met, only 11 were enrolled during that period. An extension of ten months was required to reach a total of 16 participants. Therefore, the study recruitment process was unsuccessful relating to issues such as extension of recruitment period and costs. Recruitment of participants is quite often one of the most challenging tasks reported in many clinical trials [134-137]. A 2009 review [138] reporting participant recruitment and

retention in 133 randomized controlled trials concluded 21% of the studies did not meet their recruitment target at randomization, while another recent review [136] on 73 trials published between 2002 and 2008 reported 55% studies did not meet their initially specified sample size and 30% of the trials received time extension to recruit its targeted sample. It also seems that the present study suffered Lasagna's principle, which states that the number of eligible volunteers available for participation in a research study is usually over estimated [139-141].

One important strategy that helped the participant recruitment process, was the study investigator directly meeting people [140, 142, 143] affected with arthritis and explaining about the study. Some of the volunteers were contacted in health fairs and public presentations were identified eligible for the study and accounted for 33% of its total recruitment. Around 26% of participants reported that they heard about the study through newspaper or website advertisements. Direct and regular contact with the offices of rheumatologists and orthopedic surgeons did help the process with 14% of recruitment completed through this avenue. Other enrolled volunteers were recruited through the study advertisements posted at their local fitness centers or Physiotherapy clinics. Regular scheduled meetings with other members of the research team also helped in identifying the nature of recruitment difficulties and all possible strategies to boost up recruitment.

A major limitation identified in the study recruitment process was the original inclusion criterion of including people whose baseline DASH scores were between 25 and 50 for a total score of 100. This range allowed inclusion of volunteers who self-rated between mild and moderate difficulty of hand function during common tasks of daily living. During the early recruitment period between July 2012 and December 2012, five volunteers were excluded based on this criterion. There were also instances when two

volunteers aged above 60 years were excluded during initial screening. Learning that the narrow DASH score range and age influencing the recruitment, the DASH score range was modified to include participants scoring between 0 and 75. The age range was also widened to include participants between 30 and 70 years. These modifications were made in order to improve the study recruitment rate, as well to improve the generalizing of findings. A total of six participants, four participants aged above 60 years and two participants whose DASH scores were above 50 were then recruited in the study. The revisions made to the inclusion criteria helped the recruitment process. Modifications made in study protocol in order to facilitate recruitment process are often experienced in conducting clinical trials. In a 2006 review [144] which included 114 trials, 10% of studies have been reported to change their original study inclusion criteria and 50% studies extending their recruitment period in order to improve recruitment rates.

In the present study, a few additional factors such as study design, transportation difficulties, time limitations, and financial incentives for study participation are assumed to have influenced the study enrolment. However, no conclusions can be made as these factors were not formally evaluated.

**Study design:** The study procedure required a total of five visits (two (baseline and final) assessment and three exercise training sessions) to the study site and a commitment of approximately 1.15-1.30 hours per visit. Perceived difficulties with scheduling or attending the sessions due to time limitations might have influenced some interested volunteers' decision to participate in the study [138,143,145].

**Transportation:** It is speculated that the distance between home and the study site [142] and transportation difficulties in winter months might have also influenced participation. A three armed randomized controlled trial [143] identified from its 134

consented participants that distance between the residence and the study setting was a major factor in determining study participation. In another way, this possibility was demonstrated in the present study, as three enrolled volunteers mentioned that they were residing or working within a 1 km radius around the study site.

Payment for participation: Any form of financial incentive was not planned for the present study. It was clearly explained in the consent form that there will be no payment or reimbursement for any expenses related to taking part in this study. No details of incentives were included in the posters, flyers or newspaper advertisements. Participants were clearly informed about these details after which they provided their consent to participate in the study. In spite of many studies that identified financial incentives as one of the reasons for participation [142, 143, 145-147], there are few other studies that report incentives may not be completely helpful in recruiting study participants. One study [143] mentioned that its participants said that they would have taken part in the study even if they were not paid for participation. Another survey analysis [148] of 78 studies conducted in primary care research in Netherlands supported that financial incentives do not play an influential role in participant recruitment. In the present study, five volunteers were recruited from the study site premises and three volunteers residing or working in the nearby areas of the study site. Therefore, parking and transportation was easy and convenient for them to attend the assessment and training sessions. For a few participants, vehicle parking or transit charges were paid upon request to cover the expenses for attending the assessment and training sessions.

## **5.2. Other study procedures**

Study procedures, such as informed consent, pre and post intervention assessment sessions, home program training sessions, provision of home program instructions and accessories and delivery of home exercise programs were feasible with no major difficulties throughout the whole study period. Ethical considerations such as participants' understanding, voluntariness and disclosure of all necessary information were met in obtaining consent from the participants [142, 149].

Communication through phone calls provided the participants with opportunities to let the study staff know any of their concerns or questions regarding their home programs. The study staff also perceived it as an excellent platform to keep track of each participant's weekly reminders and progression plans. Thus the participants were regularly monitored, though unsupervised. One study identified two strategies such as communication and support relating to successful participant retention [137].

## **5.3. Clinical outcome measures**

In regard to the study outcome measures, the AHFT was preferred over other performance based hand function measures for the following reasons: 1) other performance based hand function measures, for example, Grip Ability Test do not test a variety of dexterous tasks commonly encountered in daily life. In addition to standard peg board dexterity test, the AHFT evaluates some common dexterous tasks of functional importance. A few examples are tying a bow, lacing a shoe, manipulating coins and fastening and unfastening safety pins, 2) the AHFT also evaluates grip, pinch and functional strength. Grip strength is often considered an important outcome of hand

rehabilitation program and has been evaluated in most of the hand exercise studies involving rheumatoid and osteoarthritis populations [7,8, 10, 13, 14, 16, 28, 30, and 31]. In regard to pinch strength, it is a prerequisite that adequate strength is required for three and two point pinch functional grasps. Functional strength testing of holding a tray and pouring water from a jug, represent some common challenging tasks in everyday life faced by people with arthritis of the hands. None of the other performance based hand function measures include traditional and functional testing of dexterity and strength, 2) the AHFT is one of the very few performance based hand function measures that has been validated for use in rheumatoid and osteoarthritis populations, and 3) administration and respondent burden to complete the AHFT is minimal. The approximate time for administration and scoring were 20 and five minutes respectively.

The DASH questionnaire was preferred over other upper limb self-report measures for the following reasons: 1) the questionnaire items focus on impairments, activity limitations, and participation restrictions, which are the constructs of the International Classification of Functioning Disability and Health (ICF) taxonomy model. Thus, the questionnaire would allow an overall assessment of the intervention effects in terms of the three health outcome domains, 2) compared to other upper limb self-report questionnaires, the DASH has excellent psychometric proprieties in a wide variety of upper limb conditions [150-154] , 3) it is also being extensively used in clinical practice and research in a wide variety of wrist and hand disorders [153], 4) the DASH questionnaire has demonstrated high responsiveness with a standardized response mean of 1.37 closely similar to the PRWHE in 60 people who had undergone three months of hand therapy for different wrist and hand conditions [154], and 5) administration and

respondent burden to complete the questionnaire is minimal. The approximate time for administration and scoring were 10-15, and  $\leq$  five minutes respectively.

#### **5.4. Home exercise programs**

Feasibility, acceptability and appropriateness of the content of both home exercise programs were complimented by quantitative and qualitative research methods. Participants described that the programs were well designed and meaningful. They accepted their home exercise programs and adhered to the recommended dosage (frequency, intensity and duration) till the end of study period. Acceptability of the task-oriented training program was further supported by the low dropout rates. Home exercise sessions were perceived to be doable and participants preferred them to exercising at clinic settings.

One important factor identified in both focus groups was that participants were very well aware of the benefits of exercising their arthritis affected joints. This is supported in two qualitative studies in people with rheumatoid arthritis [155, 156]. Another large scale qualitative study that involved comparing the aspects of daily functioning in people with different rheumatological conditions, identified some concepts such as impaired hand function, reduced levels of dexterity and fine finger use, independence in self-care activities and opening of doors described by 25 people with rheumatoid arthritis and 56 people in hand osteoarthritis [157]. These findings are also in accordance with the participant self-reported difficulties documented at baseline.

It was difficult to draw evidence from published literature to explain many of the findings of the present study. No published qualitative studies that explored participants' experiences on receiving hand exercises were available. Also, the task-oriented training



program is relatively a new intervention of its own kind and further studies are warranted in different patient populations.

### **5.5. Preliminary estimation of therapeutic effects of the interventions**

Since statistical inferences on the therapeutic effects of the interventions are limited by the small sample size, a straight comparison of the mean scores of the clinical outcomes will be used to discuss the pre to post intervention changes in each group.

Pre to post intervention, grip strength did not show notable changes in either group. The conventional hand exercise program received by the control group had a major proportion of exercises (six out of eight) for joint mobility and two exercises for strength training. The strength training levels in most of the control group participants ranged between 40-60% of one Repetition Maximum (1RM) of wrist muscles. The therapeutic putty was also of moderate resistance in challenging the intrinsic muscle work. With light to moderate intensity levels of strength training, these reasons might explain why improvements in grip strength were not seen in the control group. On the other hand, task-oriented training received by the experimental group involved practice of fine and gross dexterity skills. Training with a dumbbell was suggested for a very few participants who expressed difficulty in lifting objects such as a liquid jug, cans etc at baseline. Therefore, an increase in grip strength was least expected in the experimental group. Though a 14% increase in grip strength between groups post-intervention is observed, it should be noted that the baseline grip values were comparatively greater in the experimental group than the control group. There was a minimal increase of 5% from baseline grip values in the experimental group at six weeks.

Pre to post intervention, some increase in two point pinch strength with 14%; and three point pinch strength with 9% was seen in the experimental group. Similarly, a comparison between groups post-intervention, favored the experimental group. These findings could be explained by the task-oriented training program which primarily involved repetitive training with small objects requiring pinch grip between two (thumb and index) or three (thumb, index and middle) finger tips. The control group did not receive exercises of such kind, except for the gentle thumb opposition for mobility.

Pre to post intervention, the control group demonstrated an encouraging increase in both tasks of applied strength item of the arthritis Hand Function Test. The average increase in the number of cans lifted was 1.5 and the volume of water lifted in a pitcher was 0.5 liters. It was also anticipated that the observed increase in grip strength will linearly relate to applied strength. However, the reverse was noted in this group. One possible reason is that grip strength is a measure of maximal voluntary effort with the dominant side hand muscles, while applied strength tasks do not require maximal grip force for execution. Lifting cans in a tray was a bimanual task and lifting a pitcher with water involved the slow step wise addition of water volume.

In contrast, the experimental group took less time to complete six tasks of the applied dexterity item and peg board dexterity item of the arthritis Hand Function Test. The average reduction in total time was 15 seconds to complete the six applied dexterity tasks and five seconds to complete the peg board dexterity test. Post-intervention, the average difference noted between both groups' duration was 13 seconds for completing the applied dexterity tasks and 3.8 seconds for the peg board dexterity test. The task training program was guided by the principle that home exercise programs should incorporate training of dexterity skills. Around 85% of common tasks of daily life

demand a variety of finger and hand dexterous functions rather than grip strength [81].

The main components of the task training program, such as fine and gross dexterity skills (Examples: rolling manipulations between two or three fingers, manipulation of different sized balls and soft objects) which require adequate pinch force may have had an effect on improving dexterity.

Perceptions on hand function ability in common tasks of daily living as measured by the DASH questionnaire increased in both groups. These results are analogous to participants' reports during their focus group sessions perceiving their home exercise programs helping them. Improvement in the DASH scores from baseline to six weeks was more evident in the control group. The difference was 9.7 points, which is comparable to the minimal detectable change at the 95% confidence level (Minimal Detectable Change<sub>95</sub>; MDC<sub>95</sub>) range between 8-17 points calculated in six different study populations, <http://dash.iwh.on.ca/faq> .

Pre to post intervention, increase in skill and task performance measures with three different object manipulation tasks (salad tongs, turning knob and jug) were better in the experimental group. Manipulation of these tasks required fine to gross levels of finger/hand dexterous functions. Task-oriented training with a variety of object manipulations further supports the 'training specific effects' between skills training and observed improvements in the experimental group.

During both pre and post intervention assessment sessions, a consistent decrease in pain and joint stiffness were noted after performing salad tongs and jug manipulation tasks in both groups. These findings are consistent with current practice in the use of mobility exercises for the management of pain and stiffness affecting larger joints such as hip, knee and shoulder [158-160] in individuals with osteoarthritis or rheumatoid arthritis.

## **5.6. Exercise compliance**

No formal criteria to delineate compliance and non-compliance were initially set in this study. Guided by another study [161] which defined non-compliance below 80%, both groups were found to be compliant. The number of completed home sessions is more favorable towards the control group. The experimental group completed 88% of the total recommended home exercise sessions compared to 98% of the control group. A few reasons might be the inclusion of missing data from the experimental group participant who dropped out after starting her home program and two other participants who missed a few sessions for very brief illnesses (not related to arthritis) during the study period.

Compliance measured with self-report methods such as exercise log diaries are reported to be feasible and cost-effective methods [162]. The control group participants highlighted the use of exercise diaries in motivating them to do the exercises regularly. As both home exercise programs had optimal session duration and frequency, participants were able to schedule their home sessions and complete them. This is explained by the available published evidence that compliance is better if the exercise programs fit into participants' daily routine [137,162,163]. Weekly reminders helped participants comply with their exercises, without forgetting [137,163]. Increased compliance is also reported if participants perceived their exercises to be meaningful [163] and if they were confident that the exercises would benefit them. In this study, instructions during training sessions [164, 140] to keep participants well informed about the purpose of each exercise/task training and to manage their home exercise programs on their own would have helped compliance.

The average duration of each home exercise session in the experimental group was approximately seven minutes more than the control group. The extra duration reported by the participants who received task-oriented training could be related to the ‘engaging’ nature of interactive computer games. Some previous studies have also reported the advantages of random task practice which is easily possible with the random features of the computer games such as amplitude, speed, direction or difficulty levels. It is also well documented that the computer games are challenging, motivating and more fun [67, 69 and 75].

### **5.7. Strengths and limitations**

No published studies with a mixed methods design in evaluating exercise programs in people with arthritis of the hands have been identified. The present study will be a first attempt in evaluating two home exercise programs (a novel task-oriented training program and conventional hand exercises) in people with arthritis of the hands, using quantitative and qualitative research methods. The design employed more insights and opinions on both home exercise programs.

The number of participants in the pilot trial and qualitative study were very low due to recruitment difficulties. Both phases predominantly involved Caucasian females with rheumatoid arthritis or hand osteoarthritis. So findings from both methods may not be generalized to other ethnic women. Study findings could also not be generalized in males with arthritis of the hands due to a very low representation of males in the present study.

### **5.7.1. The pilot randomized controlled trial**

Internal validity of the pilot trial was maintained by following rigorous randomization and concealed allocation procedures for assigning home exercise programs to the participants, thus reducing participant selection bias. Outcome assessors were blinded to participants' group allocation and hence detection bias was minimized. Clinical outcomes were assessed using measures that have excellent psychometric properties of content validity, test retest reliability and construct validity in rheumatoid arthritis and hand osteoarthritis populations. Replication of home exercise program protocols is made possible from their detailed descriptions. The study also presented features of generalizing in terms of adopting a variety of participant recruitment methods and flexible inclusion criteria with modified DASH score and age ranges for participation. Another major strength was that the pilot study did not intend to draw statistical conclusions on the effects of home exercise programs from its small sample. As an alternative, conservative interpretation of observed changes in clinical outcomes was made and discussed.

As the study sample included few participants with either rheumatoid arthritis or hand osteoarthritis, the preliminary data presented may not be specifically representing either of the populations. The study relied on self-reports to determine participants' hand function ability levels and did not employ any formal disease activity measures to evaluate the baseline disease activity. Also, the degree of finger deformities was not objectively quantified. The study was of short duration and the long term effects of home exercise programs on clinical outcomes and compliance were not evaluated.

A major limitation of the present study is its small sample size with low statistical power. Therefore, the study poses a common risk of underpowered studies; the type II error where the probability of identifying a difference between groups is reduced when a difference actually exists (missed hits). This would lead to a phenomenon referred as ‘absence of evidence is not evidence of absence’, which means that null effects are noted just because of lack of statistical power making it difficult to identify a true difference [165, 166]. It has also been said that underpowered studies would also increase type I error where the probability of falsely assuming the significance when a difference doesn’t actually exist (false hits). For these reasons, the preliminary statistical findings on the therapeutic effects of the exercise programs should be considered with more caution.

However, with evaluation of feasibility as one of the study purposes, the proposed sample size is considered sufficient [167, 18]. It has also been widely mentioned that pilot studies do not need a large sample size, nor a prior sample size calculation. A review [164] on 79 pilot trials from the United Kingdom Clinical Research Network (UKCRN) and the International Standardized Randomized Controlled Trial Number (ISRCTN) registers reported sample sizes ranging from 8 to 114 study participants per arm. The review also recommended justification of sample size though the estimates are often considered preliminary and uncertain in pilot studies.

With no clear definition available for underpowered studies, a conventional 80% of statistical power is usually followed [166]. Underpowered studies are often justified in cases of piloting the feasibility of the interventions [169]. It has been said that a trial should have a minimum of 50% power [169], and one of the common reasons for low power studies is related to recruitment issues [169]. Though stand alone, low power

studies have limited utility in demonstrating evidence and suffer from publication bias [169], they could substantially contribute to knowledge by pooling of data in meta-analyses [164]. A 2013 study [170] which reviewed 14, 886 meta analyses of the Cochrane reviews found 10, 492 of them had included underpowered (<50%) studies.

### **5.7.2. The phenomenological study**

The embedded phenomenological study supported the trial and provided participant perspectives on experiencing the home exercise programs in real world circumstances. The findings from this study added, complimented and strengthened the findings of the pilot randomized controlled trial. In order to have reliable and accurate data for analysis, the transcript texts were checked by comparing them with the audio recordings and also by reading the transcript texts several times. Along with interview data, observations and field notes recorded by the note taker served as additional sources of information.

However, there are some specific limitations pertained to the qualitative portion of the study. Firstly, the total number of participants in each focus group was very low. Published qualitative literature evidence suggests at least five to eight participants for an ideal focus group [121-124]. The study was able to recruit 'mini focus groups' [171] with a maximum of three to four participants. Secondly, the study sample predominantly included Caucasian female participants. Only one Caucasian male from the control group of the trial participated in the interview. The other group which included participants from the experimental group of the trial had three Caucasian female participants alone. So the results are specific to this small number of predominantly white female participants and hence cannot be generalized or transferred to other ethnic females or males with arthritis



of the hands. Thirdly, either a member checking by taking the results back to the focus group participants or a peer debriefing method might have further helped in validating the findings for accuracy. Fourthly, in spite of bracketing myself from my pre-defined conceptions on people with arthritis of the hands and content of both home exercise programs, there are possibilities of bias I might have brought into the study findings.

### **5.8. Recommendations for the future study**

The main findings of this quasi-mixed methods pilot study described feasibility of conducting a randomized controlled trial on a task-oriented training program in people with arthritis of the hands. Preliminary evidence from focus group interviews with the participants who underwent task-oriented training supports the acceptability, feasibility and appropriateness of the program. The study also identified a few problem areas in the trial protocol and some features of the task-oriented training program. It is important to address these problems and find possible solutions before planning for a future definitive trial.

The task-oriented training program trial was unsuccessful in reaching its recruitment goal of twenty participants during the proposed one year time period. It was recognized that the recruitment process was impacted by narrow inclusion criteria of the DASH scores and age range of eligible participants. The following amendments in the original trial protocol may be considered for successful participant recruitment of the future trial:

1. Revision of inclusion criteria
2. Enhancing the recruitment strategies

### **5.8.1. Revision of inclusion criteria**

Some previous studies have reported that liberal inclusion criteria help in study recruitment rates. In the present study, the original inclusion criteria of DASH scores between 25 and 50 at baseline and participants' age between 30 and 60 years could be revised to DASH scores between 0 and 75 and participant age between 30 and 70 years. The pilot trial also managed to recruit six participants based on the new inclusion criteria thus supporting revision requirements. In a future trial, implementing the revised inclusion criteria might be of help in identifying more eligible participants and may increase the probability of participants being randomized.

### **5.8.2. Additional recruitment strategies**

Apart from the types of recruitment strategies followed in the pilot trial, a few other additional strategies might be considered to enhance participant recruitment. They are, 1) appointing separate personnel for recruitment [137, 143] allocating adequate funds for recruitment expenses [143] 3) providing participants with financial incentives such as gift cards or cash for their participation or reimbursing the transportation charges for every visit made to the study setting [137] 4) identifying large gatherings involving people with arthritis and arranging for direct personal meetings with them [137, 143] 5) developing more contacts with local clinicians and therapists and 6) considering a multi-center study [143]

In terms of the features of the task-oriented training program, participants identified two difficulties in real life practice settings: 1) instrumentation of the dowel and block setup with the motion sense mouse for finger fine skills training and 2) frequent

removal and attachment of the Velcro strips while shifting from one object to another object task training. Focus group participants also preferred the use of the small size motion sense mouse over the standard sized one. A mini size motion sense mouse (2 x 2 inches), which is under development, would be a possible solution for both these problems. A modified set up with dowel and block may then not be needed for instrumenting small size objects, as they could be instrumented by direct placement of the motion sense mouse over them. Additionally, the small size mouse could be attached to the body parts, which would permit practice of a greater number of functional tasks, such as those involving unilateral or bilateral whole upper limb movements.

#### **5.9. Sample size calculation for the future study**

Before evaluating the efficacy and effectiveness of the task-oriented training program through a large trial, an intermediate evidentiary study would be highly recommended. In order to obtain estimates of data variance and effect size, it would be of benefit to conduct a multi-centered intermediate randomized controlled trial for more evidence on the task-oriented training program.

The peg board and total applied dexterity baseline scores of all study participants were pooled for estimating the sample size for the future study. A 10% increase in peg board and applied dexterity duration was assumed. Power and sample size calculations were done using an online statistical calculator available at, [http://www.statisticalsolutions.net/pss\\_calc.php](http://www.statisticalsolutions.net/pss_calc.php). A proposed sample size calculation for the future study is presented in Table 37.

**Table 37: Sample size calculation**

Baseline data of the present study n=16	Mean	SD	Assumed improvement in mean score	Effect size	Power	Estimated sample size
Peg board dexterity (seconds)	29.22	5.1	26.3 (by 10%)	0.6	0.8	24
Applied dexterity (seconds)	98.8	19.25	89 (by 10%)	0.5	0.8	31

## Chapter 6: References

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## **Synthesis discussion**

### **Implications of the thesis work**

Part I of the thesis work presented evidence on the test retest reliability and convergent validity of a computer game based hand function custom tracking protocol in people with arthritis. According to the ICF framework, the impact of a health condition on an individual can be classified through body structures and functions and activities and participation which are further influenced by environmental and personal factors [1]. Measurement of function and life-role participation interact [2] and many agree that we should measure at each level in order to determine which interventions that result in gains in task skills and function, also result in sufficient improvements in life role participation [2, 3]. For example, how and to what extent does increased strength, or movement quality of fine/gross object manipulation tasks improve an individual's ability to manage housework, go shopping, use an ATM card or participate in various leisure and social activities. The computer game based hand assessment application provides a standardized method to evaluate task performance during any object manipulation task. This approach allows one to focus not only on body functions and structures, but to include goals and outcomes related to activity (carrying out tasks) and participation (involvement in life situations); and movement precision, which is a critical factor for efficient performance. Many different objects of daily life can be used, and thus performance with different types of manipulation tasks can be objectively quantified with the application. Knowledge of the object properties and functional demands allows therapists to target specific treatment goals such as mobility, strength, speed, accuracy or

endurance. In this way, the application can also be used for task-oriented training with real life objects to improve hand function. This innovative approach provides a highly flexible and personalized assessment and treatment application for people with arthritis affecting the hands.

A report [4] from the National Institutes of Health (NIH) emphasized the need for research to assess the effectiveness and optimal timing, intensity, and duration parameters of rehabilitation interventions. Few studies have directly tested the contribution of the total amount and specificity of practice related to improved function. Therefore, there is a need to develop tools to identify and delineate outcomes and parameters of rehabilitation programs, which could be used to track changes over time and make informed decisions about efficacy and dose response relationships [5, 6]. In addition, hand function cannot be graded with just one task, therefore multiple objects with varied sizes, shapes, weights and functional demands and precision should be included.

The enabling factors of the novel home based task-oriented training program in Part II of the thesis work include the following: (a) it involves an innovative therapy grounded on technological developments (b) it includes the constructs of the ICF, thus focussing on activities and participation abilities of the individual with arthritis hands (c) provides flexible and personalized functional training based on individual abilities and treatment needs (d) uses available inexpensive technologies and real life objects and e) it involves an emerging treatment approach which is to combine therapeutic activities with computer games thus making exercise and rehabilitation interactive, engaging and enjoyable.

## **Future directions**

The overall findings on the custom computer game custom tracking protocol and the task-oriented training program have contributed with valuable evidence on the applicability of the game based application protocol; new clinical knowledge and discussion on the preliminary analysis of therapeutic effects, compliance and delivery of the task-oriented training program, and feasibility factors to be considered for planning a future trial. These findings will guide future studies that will be designed to evaluate additional objects with varying physical and anatomical requirements for a broader application of the application. They will also support the applicability of using the Tele-rehabilitation platform (TRP) to deliver home based exercise programs and facilitate cost effective long-term outcomes in people with arthritis, stroke, spinal cord injury and children with neuro-developmental disorders. The platform where treatment and assessment will be integrated in future studies is highly attractive for several reasons: (a) saves time and cost effective, (b) promotes access to client centered home based hand therapy programs, irrespective of barriers, such as geographical distances, costs of travelling and chronic disability issues (c) provides feedback for client and health care providers, (d) aids in tele-monitoring, tele-consultation and tele-support on the hand exercise program (e) documents volume of practice with measures of intensity, duration and client compliance and (f) allows tracking of change within each treatment session and over time (trend analysis). Therefore, it is possible for delivering exercise therapy with embedded assessment (monitoring) and feedback (support) to function in the home and community settings. This would streamline services, leverage clinician time, and permit extended, regular practice at times that are more convenient for the population. Validated

data analysis methods of the custom computer game will be embedded with the exercise program to provide objective, reliable, verifiable, contextual information and electronic records about performance and capacity of each person during each use (assessment and/or treatment session). This is important because evidence-based practice requires objective outcomes which can identify those combinations of exercise and activities that are most effective. In the distant future, a function registry will also be integrated with the TRP. The registry will link people with arthritis hands, researchers in hand function and other health care members. The electronic measures and outcomes of the clients could be accessed and shared by health care members through a content management system. This would improve communication between different users of the framework, (e.g. researchers, health care providers, policymakers and members of the public) and maximize knowledge mobilization and continuum of care. For the purpose of evidence based multidisciplinary management, the registry will incorporate clinical practice guidelines, expert mentoring, self-reporting questionnaires, informal client education and web links to evidence resources.

### **Knowledge translation**

Knowledge translation plan for this thesis work is guided by the Canadian Health Services Research Foundation framework [7]. The dissemination goals would include presenting the findings to the target audience, such as the physiotherapists, hand therapists, occupational therapists, clinicians, researchers in hand rehabilitation and individuals with arthritis. The knowledge translation activities would include, 1) presenting the study findings at clinical meetings 2) publishing in peer-reviewed

academic research journals and 3) developing plain language summaries of findings for the Arthritis Society newsletter and Winnipeg newspapers.

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## Conclusions

Computer based technologies have provided health care providers with exciting possibilities for innovative treatment and assessment tools. Without doubt, Tele-rehabilitation technologies will play a leading role in supporting the future health care systems. However, there is a need to develop and validate assessment and treatment frameworks that bring structure to the process to allow a systematic exploration of all available possibilities. The findings of the thesis work have provided preliminary evidence on the applicability of the computer game based hand function assessment application and the novel task-oriented training in people with rheumatoid arthritis or hand osteoarthritis, upon which future work will be undertaken in these patient populations.

## Appendix 1: Informed consent form for the pilot randomized controlled trial



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## RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

### **Title of Study:**

Task-oriented training with computer gaming in people with Rheumatoid arthritis or Hand osteoarthritis: A quasi-mixed methods pilot study.

### **Protocol number:** “ \_\_\_\_\_ ”

### **Principal Investigator:**

Cynthia Swarnalatha Srikesavan, PhD graduate student, C/O Dr. Tony Szturm, PhD, Department of Physical Therapy, RR106-771 McDermot Avenue, University of Manitoba,

### **Co-Investigators:**

Dr. Tony Szturm, PT, PhD, Department of Physical Therapy, University of Manitoba, RR319 - 800 Sherbrook Street, Winnipeg, Manitoba, 787-4794

Dr. Barbara Shay, PT, PhD, Department of Physical Therapy, University of Manitoba, RR323 - 800 Sherbrook Street, Winnipeg, Manitoba, 787-2756

You are being asked to participate in a Clinical Trial (a human research study). Please take your time to review this consent form and discuss any questions you may have with the study staff. You may take your time to make your decision about participating in this clinical trial and you may discuss it with your regular doctor, friends and family before you make your decision. This consent form may contain words that you do not understand. Please ask the study doctor or study staff to explain any words or information that you do not clearly understand.

### **Purpose of Study**

This Clinical Trial is being conducted to study the effects of two different home based exercise programs in people affected with Rheumatoid arthritis or Osteoarthritis in their hands. You are being asked to take part in this study because you are aged between 30



## Task-oriented training with computer gaming in people with Rheumatoid arthritis or Hand osteoarthritis: A quasi-mixed methods pilot study.

and 60 years, diagnosed with rheumatoid arthritis (RA) or Osteoarthritis (OA) of the hands, own a home computer and have basic working knowledge of computers and are willing to give written informed consent. This research is being done because it is not known on what is the most effective hand exercise treatment for people with RA or OA. A total of thirty participants will participate in this study.

### **Study procedures**

You will be randomized into one of two treatment groups. "Randomized" means that you are put into a group by chance, like flipping a coin. You will have an equal chance of being placed in either group. The two groups will receive two different exercise programs both involving gentle mobility and strength exercises for the hand and wrist.

The study investigator will be assigning an anonymous code instead of using your name to protect your privacy and maintain confidentiality of information.

### **If you take part in this study, you will have the following tests and procedures:**

You will be screened by a simple questionnaire about your daily hand function. It is the 'Disabilities of Arm, Shoulder and Hand' (DASH) questionnaire and it rates your ability to perform 30 items of daily activities such as, turn a key; prepare a meal; write etc.

After screening, you would be assessed at two time points for approximately 45 minutes per session: Before the start of the exercise program and at the end of sixth week in the clinical research laboratory of Dr. Szturm, RR 345, 3<sup>rd</sup> floor, Rehabilitation Hospital, Health Sciences Center, Winnipeg. All tests will be conducted by an independent assessor who does not know which group you are in. In an emergency, this information will be made available.

### **First session:**

During your first visit, an assessment session will be conducted which includes the following:

1. Documentation of details such as your age, sex, occupation, diagnosis, disease duration, current medications.
2. Documentation of any specific problems during specific tasks of daily living experienced by you.
3. Administration of a hand function test. You will be tested for your dominant hand grip and pinch strength. You will also be asked to perform tasks such as placing 9 pegs into 9 holes and removing them, tying a shoelace, fastening buttons, using safety pins, cutting with a knife and fork, manipulating coins, pouring water, and lifting a tray of soup cans. The time taken to complete each task will be recorded.
4. Completion of DASH questionnaire

Task-oriented training with computer gaming in people with Rheumatoid arthritis or Hand osteoarthritis: A quasi-mixed methods pilot study.

5. Manipulation of four common objects of daily living such as a coffee mug, salad tongs etc. You will be asked to hold and move the object by tracking a bright colored ball on a computer screen for twenty seconds. Your ability to accurately move the object in concert with the ball movements will be measured.
6. Self rating of pain and stiffness levels on two separate scales

Once the first assessment is completed, the hand exercises you need to perform will be described and demonstrated. After your first visit, you will be asked to participate in the following sessions of the study:

### **Training sessions**

You will be asked to attend three additional Physiotherapy sessions each lasting approximately 45-60 minutes. Cynthia Swarnalatha Srikesavan will be conducting these sessions within 7-10 days before the start of study at RR 345, 3<sup>rd</sup> floor, Rehabilitation Respiratory Hospital, HSC. The co-investigators will be supervising the whole process. It will be seen to that the exercises are clearly demonstrated to you during these sessions. You will also be provided opportunities to discuss and ask any questions regarding the exercise programs. You will be provided with a paddle game based hand function assessment tool to record your pain and stiffness levels before and after each exercise session.

### **Home exercise sessions**

After the training sessions, a list of clearly illustrated hand exercises will be given to you. A personal exercise diary will also be provided to log your exercise sessions, duration, medication use and any discomfort experienced due to exercising.

You will be asked to perform your specific exercise program at home for 10-15 minutes, 4 times per week for six weeks. You will be asked to play the hand function assessment game for 20 seconds at the beginning and end of each exercise session to automatically record and save your pain and stiffness levels. This will be transferred to a USB memory stick or sent directly through email to the study investigators.

After you have done your home program for one week, the study investigator (Cynthia) will telephone you to check on your exercise performance, answer any questions or help you with any difficulties you may have in performing your exercises or operating the computer games. She will contact you every week by phone to help you progress your exercises safely and answer any concerns or questions you have about your exercises.

### **Final Session**

You will be asked to attend for a final follow-up assessment at the end of the 6<sup>th</sup> week. You will be asked to return the exercise session data files (saved to a USB memory stick or emailed), exercise diary and any of the equipment used during the study.

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On completion of the 6 week exercise program, you will be invited to take part in a group interview to discuss the experiences you had on receiving the specific hand exercise program. Other study participants who received the same hand exercises are expected to take part in the interview along with you. The interview will be for approximately 2 hours and will be held at RR 345, 3<sup>rd</sup> floor, Rehabilitation Hospital, Health Sciences Center. The whole interview session will be audio taped. You will be given a separate form to give your written consent for participation in the interview process. Your identity will be protected and your privacy will be maintained. All the information discussed and shared during the interview will be kept confidential and safely protected.

You can stop participating at any time. However, if you decide to stop participating in the study, we encourage you to talk to the study staff first. If you are interested in the results of the study you may contact the Principle Investigator at the end of the study.

### **Risks and Discomforts**

While participating in the study, there is a risk of increased discomfort in either of the two exercise programs. The risk would not be any greater than would be expected during performance of daily activities or other regular exercise.

The assessments may seem strenuous. You will likely feel tired after the assessment. When starting the home exercise program, you may experience an increase in your symptoms. Some people may experience some frustration if they feel they are unable to do all the exercises well. All precautions will be taken to minimize and prevent the possibility of increasing discomfort during your home exercise program. You will be given written instructions and you will be shown how to safely do your exercises

### **Benefits**

By participating in this study, you will be providing information to the study staff that will show the effects of two different home based exercise programs for the treatment of hands affected with Rheumatoid arthritis or Osteoarthritis. There may or may not be direct medical benefit to you from participating in this study. We hope the information learned from this study will benefit other people affected with Rheumatoid arthritis or Osteoarthritis in the future.

### **Costs**

All clinic and professional fees, diagnostic and laboratory tests which will be performed as part of this study are provided at no cost to you. There will be no cost for the study treatment that you will receive.

### **Payment for participation**

You will receive no payment or reimbursement for any expenses related to taking part in this study.



### **Confidentiality**

Information gathered in this research study may be published or presented in public forums; however your name and other identifying information will not be used or revealed. Despite efforts to keep your personal information confidential, absolute confidentiality cannot be guaranteed. Your personal information may be disclosed if required by law. Medical records that contain your identity will be treated as confidential in accordance with the Personal Health Information Act of Manitoba. All records will be kept in a locked secure area and only the principal staff will have access to these records. The University of Manitoba Health Ethics Research Board may review records related to the study for quality assurance purposes. No information revealing any personal information such as your name, address or telephone number will leave the University of Manitoba.

### **Voluntary Participation/Withdrawal from the Study**

Your decision to take part in this study is voluntary. You may refuse to participate or you may withdraw from the study at any time. Your decision not to participate or to withdraw from the study will not affect your other medical care at this site. If the study staff feels that it is in your best interest to withdraw you from the study, he/she will remove you without your consent. We will tell you about any new information that may affect your health, welfare, or willingness to stay in this study.

Participants who are students or employees of either The University of Manitoba or Health Sciences Centre or individuals associated professionally with any of the staffs can be assured that a decision not to participate will in no way affect any performance evaluation of potential participants.

### **Medical Care for Injury Related to the Study**

You are not waiving any of your legal rights by signing this consent form or releasing the staff from their legal and professional responsibilities

### **Questions**

You are free to ask any questions that you may have about your treatment and your rights as a research participant. If any questions come up during or after the study or if you have a research-related injury, contact any one of the study staff: Cynthia Swarnalatha Srikesavan (204) 330-0302 or Dr. Tony Szturm (204)787-4794 or Dr.Barbara Shay (204)787-2756. For questions about your rights as a research participant, you may contact The University of Manitoba Biomedical Research Ethics Board at (204) 789-3389. Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

### **Statement of Consent**

I have read this consent form. I have had the opportunity to discuss this research study with Cynthia Swarnalatha Srikesavan or Dr. Tony Szturm or Dr. Barbara Shay. I have had my questions answered by them in language I understand. The risks and benefits have been explained to me. I believe that I have not been unduly influenced by any study team member to participate in the research study by any statement or implied statements. Any relationship (such as employee, student or family member) I may have with the study team has not affected my decision to participate. I understand that I will be given a copy of this consent form after signing it. I understand that my participation in this clinical trial is voluntary and that I may choose to withdraw at any time. I freely agree to participate in this research study. I understand that information regarding my personal identity will be kept confidential, but that confidentiality is not guaranteed. I authorize the inspection of any of my records that relate to this study by The University of Manitoba Research Ethics Board, for quality assurance purposes.

By signing this consent form, I have not waived any of the legal rights that I have as a participant in a research study.

**Participant signature** \_\_\_\_\_ **Date** \_\_\_\_\_  
(Day/month/year)

**Participant printed name:** \_\_\_\_\_

I, the undersigned, have fully explained the relevant details of this research study to the participant named above and believe that the participant has understood and has knowingly given their consent

**Printed Name:** \_\_\_\_\_ **Date** \_\_\_\_\_  
(Day/month/year)

**Signature:** \_\_\_\_\_

**Role in the study:** \_\_\_\_\_

**Relationship (if any) to study team members:** \_\_\_\_\_



## Appendix 2: Informed consent form for the focus group session



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## RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

### **Title of Study:**

Task-oriented training with computer gaming in people with Rheumatoid arthritis or Hand osteoarthritis: A quasi-mixed methods pilot study.

**Protocol number:** “ \_\_\_\_\_ ”

### **Principal Investigator:**

Cynthia Swarnalatha Srikesavan, PhD graduate student, C/O Dr. Tony Szturm, PhD,  
RR319 - 800 Sherbrook Street, Winnipeg, Manitoba,

### **Co-Investigators:**

Dr. Tony Szturm, PT, PhD, Department of Physical Therapy, University of Manitoba,  
RR319 - 800 Sherbrook Street, Winnipeg, Manitoba, 787-4794

Dr. Barbara Shay, PT, PhD, Department of Physical Therapy, University of Manitoba,  
RR323 - 800 Sherbrook Street, Winnipeg, Manitoba, 787-2756

You are being asked to participate in a group interview session following the 6 week hand exercise program you received. Please take your time to review this consent form and discuss any questions you may have with the study staff. You may take your time to make your decision about participating in this interview and you may discuss it with your regular doctor, friends and family before you make your decision. This consent form may contain words that you do not understand. Please ask the study staff to explain any words or information that you do not clearly understand.

### **Purpose of Study**

This group interview is being conducted to study your experiences in performing the hand exercise program prescribed for arthritis. You are being asked to take part in this interview as you have completed the 6 week hand exercise program and indicated your willingness to participate in the group interview session. 14 other participants who



## Task-oriented training with computer gaming in people with Rheumatoid arthritis or Hand osteoarthritis: A quasi-mixed methods pilot study.

performed the same hand exercise program are expected to participate in the interview with you.

### **Study procedures**

The interview session will be an informal open discussion on how you felt about the hand exercise program. The interview will be for approximately 2 hours and will be held at RR 345, 3<sup>rd</sup> floor, Rehabilitation Hospital, 800 Sherbrook Street. The study investigator and a note taker will be present during the session. The study investigator will lead and coordinate the interview, while the note taker will record non-verbal actions and group dynamics. The whole session will be audio taped and then transcribed to a paper copy.

The session will start with a debriefing orientation on issues such as the study purpose, your rights as a study participant and the ground rules for the interview. A wall chart listing all the rules will be hung in a clearly visible and readable place. It will emphasize the following: 1) respectful interactive interview environment, 2) free opinions of the participants, 3) assurance of data confidentiality, 4) equal participation and representation by all participants and 5) only one person will talk at a time.

After the debriefing, you will be introduced to the rest of the group which will then be followed by questions on the experiences you had performing the hand exercises. You are encouraged to state your frank opinions, feelings and ideas during the discussion on topics such as how you felt about your hand function, content of the hand exercise program and pain or any discomfort during exercising. You will also be asked to share any suggestions/recommendations on the hand exercises you performed.

A ten to fifteen minute break will be taken after 45 minutes of the interview. After approximately 2 hours, the session will finish with a debriefing and acknowledging everyone for their time and sharing of experiences.

The interview will be audio recorded and transcribed later. The study investigator will assign an anonymous code instead of your name to protect your privacy and maintain confidentiality of information.

You can stop participating in the interview at any time. However, if you decide to stop participating, we encourage you to talk to the study staff first. If you are interested in the results of the interview, you may contact the principal investigator at the end of the session.

### **Risks and Discomforts**

There is a risk of discomfort while sharing your experiences with others in the group environment. You may feel that you are over disclosing your personal thoughts and feelings. We cannot promise or ensure complete confidentiality, as we do not have control over what participants may disclose after leaving the interview session.

## Task-oriented training with computer gaming in people with Rheumatoid arthritis or Hand osteoarthritis: A quasi-mixed methods pilot study.

However, precautions will be taken by requesting all the participants to keep the details within themselves and not to share with any outside individuals.

Precautions will be taken to minimize any physical discomfort during the session and a few minutes of break time with light refreshments will be allotted half way through the interview.

### **Benefits**

By participating in this study, you will be providing information to the study staff about your experiences on performing the hand exercise program for six weeks. There may or may not be direct benefit to you from participating in this study. We hope the information learned from this study will benefit other people affected with Rheumatoid arthritis or Osteoarthritis in the future.

### **Costs**

There will be no cost for participating in this group interview.

### **Payment for participation**

You will receive no payment or reimbursement for any expenses related to taking part in this study.

### **Confidentiality**

Information gathered in this research study may be published or presented in public forums; however your name and other identifying information will not be used or revealed. Despite efforts to keep your personal information confidential, absolute confidentiality cannot be guaranteed. Your personal information may be disclosed if required by law. Medical records that contain your identity will be treated as confidential in accordance with the Personal Health Information Act of Manitoba. Audio tapes and transcripts will be kept in a locked secure area and only the study staff will have access to these records. The aggregate interview data will be used for presentation and publication purposes. Audio tapes will be destroyed and transcripts will be shredded, once the analysis is done.

The University of Manitoba Health Ethics Research Board may review records related to the study for quality assurance purposes. No information revealing any personal information such as your name, address or telephone number will leave the University of Manitoba.

Task-oriented training with computer gaming in people with Rheumatoid arthritis or Hand osteoarthritis: A quasi-mixed methods pilot study.

### **Voluntary Participation/Withdrawal from the interview**

Your decision to take part in this interview is voluntary. You may refuse to participate or you may withdraw any time. Your decision not to participate or to withdraw from the interview will not affect your other medical care at this site. If the study staff feels that it is in your best interest to withdraw you from the interview, they will remove you without your consent.

Participants who are students or employees of either the University of Manitoba or the Health Sciences Centre or individuals associated professionally with any of the staff can be assured that a decision not to participate will in no way affect any performance evaluation.

### **Medical Care for Injury Related to the Study**

You are not waiving any of your legal rights by signing this consent form or releasing the staff from their legal and professional responsibilities

### **Questions**

You are free to ask any questions that you may have about your rights as a research participant. If any questions come up during or after the interview or if you have a research-related injury, contact any one of the study staff: Cynthia Swarnalatha Srikesavan (204) 330-0302 or Dr. Tony Szturm (204) 787-4794 or Dr. Barbara Shay (204) 787-2756. For questions about your rights as a research participant, you may contact The University of Manitoba Biomedical Research Ethics Board at (204) 789-3389. Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions

**Statement of Consent**

I have read this consent form. I have had the opportunity to discuss this interview with Cynthia Swarnalatha Srikesavan or Dr. Tony Szturm or Dr.Barbara Shay. I have had my questions answered by them in language I understand. The risks and benefits have been explained to me. I believe that I have not been unduly influenced by any study team member to participate in the interview by any statement or implied statements. Any relationship (such as employee, student or family member) I may have with the study team has not affected my decision to participate. I understand that I will be given a copy of this consent form after signing it. I understand that my participation in this interview is voluntary and that I may choose to withdraw at any time. I freely agree to participate in this interview. I understand that information regarding my personal identity will be kept confidential, but that confidentiality is not guaranteed. I authorize the inspection of any of my records that relate to this study by The University of Manitoba Research Ethics Board, for quality assurance purposes.

By signing this consent form, I have not waived any of the legal rights that I have as a participant in a research study.

**Participant signature** \_\_\_\_\_ **Date** \_\_\_\_\_  
(Day/month/year)

**Participant printed name:** \_\_\_\_\_

I, the undersigned, have fully explained the relevant details of this research study to the participant named above and believe that the participant has understood and has knowingly given their consent

**Printed Name:** \_\_\_\_\_ **Date** \_\_\_\_\_  
(Day/month/year)

**Signature:** \_\_\_\_\_

**Role in the study:** \_\_\_\_\_

**Relationship (if any) to study team members:** \_\_\_\_\_

### Appendix 3: List of abbreviations



- 1) RA: Rheumatoid arthritis
- 2) OA: Osteoarthritis
- 3) TRP: Tele-rehabilitation platform
- 4) DASH: Disabilities of Arm, Shoulder and Hand questionnaire
- 5) HAQ: Health Assessment Questionnaire
- 6) AHFT: Arthritis Hand Function Test
- 7) ANOVA: Analysis of variance
- 8) ICC: Intra-class correlation coefficient
- 9) HLA-DR4: Human leucocyte antigen DR4
- 10) ICF: International Classification of Functioning, Disability and Health
- 11) JHFT: Jebsen Hand Function Test
- 12) SODA: Sequential Occupational Dexterity Assessment
- 13) GAT: Grip Ability Test
- 14) AIMS 2: Arthritis Impact Measurement Scale 2
- 15) ADL: Activities of daily living
- 16) NHPT: Nine hole peg test
- 17) IP: Inter-phalangeal
- 18) MCP: Metacarpo-phalangeal
- 19) CoD: Co- efficient of determination
- 20) SEM: Standard error of measurement
- 21) SD: Standard deviation
- 22) SPSS: Statistical package for the social sciences
- 23) HAQ-DI: Health Assessment Questionnaire-Disability index



- 24) IQR: Inter-quartile range
- 25) ATM: Automatic teller machine
- 26) NIH: National institutes of health
- 27) MHAQ: Modified Health Assessment Questionnaire
- 28) VAS: Visual Analogue Scale
- 29) ESR: Erythrocyte sedimentation rate
- 30) JP: Joint protection
- 31) ROM: Range of motion
- 32) NSAIDs: Non- steroidal anti inflammatory drugs
- 33) EULAR: European league against rheumatism
- 34) ACR: American College of Rheumatology
- 35) RM: Repetition maximum
- 36) AUSCAN Index: Australia Canada Index
- 37) Quan: Quantitative
- 38) Qual: Qualitative
- 39) DMARDs: Disease modifying anti-rheumatic drugs
- 40) CI: Confidence interval
- 41) USB: Universal serial bus
- 42) ASHT: American society of hand therapists
- 43) CoV: Co: efficient of variation
- 44) CONSORT: Consolidated standards of reporting trials
- 45) MDC95: Minimal detectable change 95
- 46) MCID: Minimal clinically important difference