A comparative study to determine the immediate effects of paraffin wax and moist heat therapies on pain, joint range of movement and grip ability in adults with rheumatoid arthritis affecting the hands.

A mini dissertation submitted in partial fulfillment of the requirements for the degree of Master of Hand Rehabilitation

In the

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Declaration

I, Thirusha Ramsudh, hereby declare that the work on which this mini dissertation is based is my own original work (except where acknowledgement and references indicate otherwise) and that neither the whole work, nor part thereof has been, is being or will be submitted for another degree at this or any other university.

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Abbreviations and Operational Definitions

ACR – American College of Rheumatology

ANOVA - analysis of variance

CMCJ – carpometacarpal joint – the joint at the base of one's thumb

Cox – Cyclooxygenase

DIPJ – distal interphalangeal joint – the furthermost joint in one's finger

DMARDS – disease modifying anti-rheumatic drugs

DOH – Department of Health

GAT – Grip Ability Test

Group 1 – wax group

Group 2 – heat group

HANDSPLD – left hand span difference

HANDSPRD – right hand span difference

ILDIPJD – left index finger distal interphalangeal joint difference

ILMCPJD – left index finger metacarpophalangeal joint difference

ILPIPJD – left index finger proximal interphalangeal joint difference

IPIPJDD – index finger proximal interphalangeal joint difference between hands

IPJ – interphalangeal joint – the two furthermost joints in one's fingers and the most distal joint in the thumb

IRDIPJD – right index finger distal interphalangeal joint difference

IRMCPJD – right index finger metacarpophalangeal joint difference

IRPIPJD – right index finger proximal interphalangeal joint difference

KZN – KwaZulu-Natal

LDIPJ – little finger distal interphalangeal joint

LLDIPJD – left little finger distal interphalangeal joint difference

LLMCPJD – left little finger metacarpophalangeal joint difference

LLPIPJD – left little finger proximal interphalangeal joint difference

LRDIPJD – right little finger distal interphalangeal joint difference

LRMCPJD – right little finger metacarpophalangeal joint difference

LRPIPJD - right little finger proximal interphalangeal joint difference

MANOVA – multivariate analysis of variance

MCPJ – metacarpophalangeal joint, the knuckle joint in the hand

MLDIPJD – left middle finger distal interphalangeal joint difference

MLMCPJD – left middle finger metacarpophalangeal joint difference

MLPIPJD – left middle finger proximal interphalangeal joint difference

MRDIPJD – right middle finger distal interphalangeal joint difference

MRMCPJD – right middle finger metacarpophalangeal joint difference

MRPIPJD – right middle finger proximal interphalangeal joint difference

MTx – methotrexate

NPRS – numerical pain rating scale

NPRSD – numerical pain rating score difference i.e. NPRS (pre) – NPRS (post).

NSAIDS – non-steroidal anti-inflammatory drugs

OPP - measure of ability to connect little finger and thumb

OT – Occupational therapy

Paperc – paper clip task i.e. time taken to put paper clip into an envelope.

PapercD – paper clip task difference i.e. Paperc (pre) – Paperc (post)

PIPJ – proximal interphalangeal joint – the joint between the furthermost joint and the knuckle in one's finger

Pour - time taken to pour water from 1 litre jug into 200 millilitre cup

PourD - pour task difference i.e. Pour (pre) – Pour (post)

RA – rheumatoid arthritis

RF – rheumatoid factor

RLDIPJD – left ring finger distal interphalangeal joint difference

RLMCPJD – left ring finger metacarpophalangeal joint difference

RLPIPJD – left ring finger proximal interphalangeal joint difference

RMCPJ – ring finger metacarpophalangeal joint

ROM – range of movement

RRDIPJD – right ring finger distal interphalangeal joint difference

RRMCPJD – right ring finger metacarpophalangeal joint difference

RRPIPJD – right ring finger proximal interphalangeal joint difference

Sock - time taken to put sock into non-dominant hand using dominant hand

SockD = Sock (pre)- Sock (post)

SPSS - Statistical Package for the Social Sciences

TENS – transcutaneous electrical nerve stimulator

THERMOTHERAPY – the therapeutic application of heating and cooling physical agents

THIPJ – thumb interphalangeal joint

THIPJDD – thumb interphalangeal joint difference between hands

THLIPJD – left thumb interphalangeal joint difference

THLMCPJD – left thumb metacarpophalangeal joint difference

THMCPJ – thumb metacarpophalangeal joint

THRIPJD – right thumb interphalangeal joint difference

THRMCPJD – right thumb metacarpophalangeal joint difference

UKZN – University of KwaZulu-Natal

Abstract

Physiotherapists use many treatment modalities in the management of rheumatoid arthritis of the hand. Two commonly used heating modalities are moist heat and paraffin wax therapy. The aim of this study was thus to compare the immediate effectiveness of moist heat therapy and paraffin wax therapy in the management of the rheumatoid hand.

A quantitative, pretest – posttest design was used to compare the effects of paraffin wax and moist heat therapy on pain, joint range of movement and grip ability in adults with stage II rheumatoid arthritis, affecting the hands. One hundred and fifteen subjects at a district/regional provincial health care institution in the Ethekwini metro district were randomly allocated to two groups. Fifty six subjects in Group 1 were treated with paraffin wax therapy, using the drip-wrap method and active hand exercises and in Group 2, fifty nine subjects were treated with moist heat therapy and active hand exercises. Pre- and posttest measurements were taken in all subjects. Pain was measured using the numerical pain rating scale and intrinsic hand joint range of movement was measured using a metal short arm goniometer and the dorsal approach. Hand span and grip ability were also measured.

Results revealed that both treatment modalities were effective in helping moderate pain, increase joint range of movement and improve grip ability in the adult rheumatoid hand. Paraffin wax improved joint range of movement significantly more than moist heat therapy in 25% of joints ($p \leq 0.05$). Right hand span was also significantly improved ($p=0.013$) by the application of wax. No statistically significant differences were found between the effects of paraffin wax and moist heat therapy on pain and grip ability however the findings of this study suggest clinical significance as both modalities improved pain perception and grip ability in the rheumatoid hand.

CHAPTER 1

Introduction, Significance and Purpose

1.1 Introduction

Rheumatoid arthritis (RA) is a systemic, autoimmune disorder characterized by inflammation of the synovial membrane lining of the joints (Mody and Cardiel, 2008). Chronic symmetrical synovitis of the hands, wrists and feet are hallmark features of this disease. Accompanying the classic articular hallmark features of RA are a host of peri- and extra-articular features such as tenosynovitis, dermal manifestations (e.g. dermatitis), vasculitis, ocular disease, rheumatoid nodules, lung and cardiac disease etc. (Khurana and Berney, 2005). A painful condition, rheumatoid arthritis can lead to progressive joint damage, decreased functional capacity resulting in deteriorating quality of life and a shortened life expectancy (Kavuncu and Evcik, 2004).

O'Brein, Jones, Mullis and Mulherin (2006) estimated that the hands and wrists are affected in about 80% to 90% of patients with RA. The wrist, metacarpophalangeal (MCPJ) and proximal interphalangeal (PIPJ) joints of the fingers and the MCPJ and carpometacarpal joints (CMCJ) of the thumb are most commonly affected, with the distal interphalangeal joint (DIPJ) being affected due to mechanical imbalances at the proximal joints. Patient symptoms include joint pain and stiffness, loss of range of movement (ROM) and reduction in muscle power and grip strength. Anecdotal feedback from patients living with RA at the researcher's health care facility, suggests that the hand pain and stiffness is probably the most debilitating effect of RA, affecting the individual's ability to perform their activities of daily living and reducing their independence (Hammond, 2004), thus negatively impacting on quality of life. Pain control and improving hand joint mobility is therefore the primary focus of physiotherapy in the researcher's hand clinic and was the focus of this study.

Prescribed drug therapy usually includes corticosteroids to control acute inflammation, nonsteroidal anti-inflammatory drugs (NSAIDs) for relief of pain and stiffness, and disease modifying antirheumatic drugs (DMARDs) to reduce inflammation and delay progression of the disease. Despite the advances in pharmaceutical development, there are no current drug therapies that lead to long

term remission for all patients with RA. Rehabilitation, inclusive of physiotherapy, thus plays an important role in the overall management of RA, managing the physical, psychological, social and functional consequences of the disease (O'Brein et al, 2006).

The prevalence of RA in rural South Africa is approximately 0.67% and in urban South Africa, 0.9% (Mody and Cardiel, 2008). In the South African public health care system, these patients may initially seek treatment for their symptoms at primary health care facilities, which are usually staffed by nurses and general medical practitioners. Here, patients identified with RA, are referred to district and regional hospitals for continuation of treatment.

At the district and regional hospitals, patients with RA have access to a multidisciplinary team of medical and paramedical professionals to assist in the holistic management of the disease. The multidisciplinary team approach of managing RA is aimed at controlling disease activity, improving functional and vocational ability and improving psychosocial health. Team members include the rheumatologist, orthopaedic surgeon, pharmacist, physiotherapist, occupational therapist, clinical psychologist, social worker, dietician, clinical nursing specialist and the patient.

1.2 Background

Physiotherapy forms an integral part of the multidisciplinary team. There were 238 physiotherapists working in the public health sector in Kwazulu-Natal in 2012, equating to 2.54 therapists per 100 000 patients according to statistics provided by the Health Systems Trust. The physiotherapy department at the researcher's health care facility, a provincial district/regional hospital, has 7 physiotherapists providing services to a catchment area with a population of over 1.5 million people (Census, 2011). This department sees approximately 25 patients with RA a month. These patients are accommodated in the daily hand clinic which has a maximum booking of 5 patients per clinic due to human resources and time constraints. The hand clinic is a general clinic rendering services to patients with hand pathology including fractures, dislocations, soft tissue injuries, digital amputations and neurological

conditions. On average, 107 patients per month receive treatment at this clinic. Patients with acute orthopaedic or soft tissue conditions are given priority. Since RA is a chronic condition, patients with RA, are at best, reviewed twice a month, given the availability of appointments. Viewed in this context, it is imperative that RA patients receive the best possible services within the available resources. Since 80% to 90% of RA patients have hand involvement affecting their ability to carry out their activities of daily living (O'Brein et al, 2006), the importance of effective rehabilitation to help maintain the individual's independence is imperative.

Physiotherapists have been using physical agents for centuries to treat rheumatologic diseases however; there is still much debate on the efficacy of physiotherapy in the management of rheumatoid arthritis (Bulgina, Taljanovic, Avdic and Hunter, 2001). Local heating modalities have been shown to increase pain and tenderness thresholds of joints in those with subacute and chronic RA. In addition, it has been found to reduce hand stiffness and prepare the area for therapeutic exercises (Ayling and Marks, 2000).

Today, physiotherapists have many heating modalities at their disposal. The choice of modality in clinical practice is often dictated by availability, the clinical condition, therapist knowledge, time constraints and to a limited extent, patient preference. Most physiotherapists use some sort of thermotherapy to reduce muscle pain and joint stiffness prior to exercise (Hammond 2004). Informal anecdotal feedback from colleagues in other provincial health care facilities indicate that paraffin wax therapy and moist heat therapy are the most commonly used heat modalities in treating rheumatoid arthritis of the hands, as is recommended in literature (Maritz, 2008).

Paraffin wax therapy is a superficial heating modality. The application of wax can be a cumbersome and time consuming process. Patients need to be agile enough to immerse their hands in the wax bath. Depending on the mode of application, the hands remain immersed for a period of time or, are repeatedly dipped and then wrapped in insulating material. The hand remains in contact with the wax for approximately 10 to 15 minutes. Most public sector physiotherapy departments have a specific treatment area designated for paraffin wax application due to the size of the wax bath, and the potential hazards of manoeuvring it between different treatment areas.

In comparison, the application of a moist heat pack is relatively easier. Heat packs, heated in a hydrocollator, can be applied to the body part being treated with a layer of insulation material between the heat pack and the skin. Heat packs can be applied in any treatment setting and is not dependent of the mobility/agility of the patient.

In view of the differing application methods, it seems as though moist heat therapy should be the treatment of choice given the time constraints and limited physical manpower required. In daily clinical practice at her health care facility, the researcher observed that even though both paraffin wax and moist heat are used interchangeably for RA patients, most patients indicate a preference for wax over moist heat. Patients report better pain control and flexibility with wax. The premise that paraffin wax therapy produced better pain relief and joint flexibility was the motivation for this study to determine if one modality was indeed more effective than the other.

Hawkes, Care, Dixon and Wright (1986) and Buljina et al (2001) compared the effects of thermotherapy modalities such as paraffin wax, thermal baths, faradic hand baths, ice massage and therapeutic ultrasound, as well as exercise therapy, on hand function in patients with rheumatoid arthritis. Even though these are modalities used in the management of RA, direct comparisons between modalities could not be made as multiple treatments were done on a single patient, making it difficult to ascertain the effectiveness of a single modality. Hence the need for a study to compare modalities directly was established.

1.3 Problem Statement

Hand pain in the RA patient can hinder adherence to exercise programmes resulting in joint stiffness and muscle weakness over time. Poor muscle power and joint mobility impacts negatively on functional ability thus reducing independence. Given the large number of patients seen at the hand clinic, together with the human resources and time constraints at the particular health care facility where the researcher is employed, the need for establishing the most effective treatment modality to help moderate symptoms in RA patients, was essential as hand function

is reported to be of utmost importance in daily life (Jones, Hanley, Mooney, Rand, Spurway and Eastwood, 1991).

Immediate treatment outcomes following heat applications were investigated because heat has been shown to have a short term effect, raising pain thresholds right after application only. Heating agents provide short term analgesia that is sufficient to increase tolerance for manual therapies and exercise (Welch, Brosseau, Casimiro, Judd, Shea, Wells and Tugwell, 2002). There is limited evidence of any benefits of heat applications on long term pain relief, joint flexibility and impact on disease process (Curkovic, Vitulic, Babic-Naglic and Durrigl, 1993). In addition, paraffin wax baths followed by exercises, have only been shown to have short term beneficial effects on pain and joint flexibility (Welch et al 2002).

Uncertainty still exists in the selection of heating modalities in the management of RA. A dearth of literature and evidence based practice in this regard has established the need for research into the effectiveness of these modalities. A direct comparison between the effects of the most commonly used heat modalities in provincial health care facilities was therefore warranted. This study sought to directly compare the immediate effects of paraffin wax therapy and moist heat therapy, on pain, joint range of movement and grip ability in the adult rheumatoid hand. Better pain management could lead to more efficient compliance with the exercise programmes, which form an essential part of treatment programmes (Schwellnus, Patel, Nossel, Dreyer, Whitesman and Derman, 2010). Compliance with exercise programmes will help maintain joint flexibility and muscle strength thereby improving functional ability and independence.

The uncertainty demonstrated in modality selection is compounded by other challenges faced by physiotherapists in the public sector. The researcher failed to source any relevant literature on the experiences of the South African public sector physiotherapist however anecdotal evidence gathered from discussions with colleagues at other facilities cite inadequate number of physiotherapists employed in the public sector, aging physiotherapy equipment and building infrastructure and lack of physical resources as some of the major problems facing physiotherapy service delivery. This coupled with the high number of patients seen, emphasises the need

for evidence based practice techniques to work more efficiently and effectively within the limited resources.

1.4 Aim and Objectives

The local effects of heat therapy that are particularly sought by therapists are pain relief, reduction of muscle spasm, increased joint range of movement and improved flexibility (Maritz, 2008). These effects are especially beneficial in patients with RA of the hands as it serves to prepare the patient for other techniques such as exercise programmes. If a patient's pain is well controlled and hand stiffness is eased, exercise programmes should be easier to execute.

Since both paraffin wax and moist heat therapies provide these effects, the primary aim of the study was therefore to compare these modalities to ascertain if either of them produced a superior outcome on hand pain, joint movement and grip ability.

The objective of the study was to evaluate and compare the effects of paraffin wax therapy and moist heat therapy on:

- pain;
- joint range of movement of the metacarpophalangeal, proximal and distal interphalangeal joints;
- hand span; and
- grip ability.

Grip ability in this regard referred to a series of timed tasks such as pouring water from a 1 litre jug into a 200 millilitre cup, putting a sock over the non-dominant hand and putting a paper clip onto an envelope. The researcher used this test to ascertain if the modalities being investigated had any effect on dexterity of the hands. The patients targeted for this study were adult patients between the ages of 18 and 50 years with a confirmed diagnosis of RA and specifically affecting the hands.

1.5 Significance

Paraffin wax therapy and moist heat therapy are the two heat modalities most commonly used in the management of RA at provincial health care facilities. A literature search revealed that to date, no direct comparison between the effects of these modalities on pain, joint movement and grip ability has been established. Hence these two modalities are used interchangeably at the researcher's health care facility, the use of which is largely dependent on the therapist's preference, availability of resources and to a lesser extent, the patient's preference. Modality choice however should be based on clinical presentation, availability of resources and evidence based practice for more cost effective treatment outcomes. This study sought to compare the effects of moist therapy and paraffin wax therapy on patients presenting with RA of the hand. The most effective modality can then be included in treatment programmes allowing for more effective alleviation of symptoms, thereby promoting functional independence in patients living with RA.

Furthermore, clinicians can use information generated from this study to help guide equipment choices when purchasing new equipment. This can be of particular benefit in the primary health care setting. The Kwazulu-Natal Department of Health (DOH) has placed a priority on decentralisation of services with the establishment/upgrading of primary health clinics as a major focus. According to the Department's Annual Performance Plan for 2013/14 – 2015/16, 55 new and replacement clinics are planned in the long term infrastructure upgrade plans (pages 232-232). The Rehabilitation Programme (a component of DOH) assists with advice on furnishing these clinics with appropriate equipment to provide rehabilitation services. Information generated in this study could help assist this process.

1.6 Chapter Overview

Chapter 2 – Literature Review: providing information on the following:

- basic anatomy of the hand;
- epidemiology, etiology, pathology and clinical manifestation of rheumatoid arthritis;

- the multidisciplinary approach to rheumatoid arthritis management, emphasising the rehabilitation component and review of the current literature and research on the treatment methods available within the scope of practice of the physiotherapist. Also included, is a review of previous research similar and related to this study.

Chapter 3 – Methodology: details the research methodology, including subject recruitment, the procedure that was followed by the researcher and the methods used to analyse the data collected to address the objectives of this study.

Chapter 4 – Results: This chapter presents the results and an analysis thereof.

Chapter 5 – Discussion: This chapter presents a discussion and will interpret the results.

Chapter 6 – Limitations, recommendations and conclusion. This chapter provides insights into the sampling limitations experienced by the researcher and suggestions for future studies.

CHAPTER 2

Literature Review

The literature review has been divided into subsections to provide an overview of the subject matter relating to the researcher's study. The first subsection provides a basic overview of the anatomy of the hand. The second subsection provides more information on rheumatoid arthritis and the current trends in management of the disease process including an emphasis on the scope of the physiotherapist.

2.1 Overview of the Structural Anatomy of the Hand (Menon, 2008)

"*The human hand is the most developed prehensile organ amongst all living creatures*" (Menon, 2008). It is capable of performing a wide range of gross motor and fine precision movements due to a combination of extrinsic and intrinsic muscle action, in tandem with a highly developed sense of touch. The hand comprises of the wrist, the metacarpus and the digits. All the intrinsic joints are synovial in nature and are stabilized by strong ligaments.

The five metacarpophalangeal joints are condylar joints between the distal heads of the metacarpals and the proximal phalanges. These joints allow for flexion, extension, abduction, adduction, circumduction and limited rotation. The interphalangeal joints are hinge joints and allow for flexion and extension.

The action of the muscles of the anterior and posterior compartments of the forearm allow for wrist abduction, adduction, flexion and extension as well as digital flexion and extension. Digital movement is further enhanced by the intrinsic muscles of the hand which allow for fine precision movement.

The hand derives its nerve supply from three major peripheral nerves i.e. the median, radial and ulnar nerves. Vascular supply to the hand is via the branches of superficial and deep palmar arches which originate from the ulnar and radial arteries.

Knowledge of anatomy is essential to the physiotherapist when clinically assessing and treating patients with rheumatoid arthritis of the hands. For instance, in this study, the assessment of joint range of movement necessitated an integration of

anatomical knowledge and goniometer placement for effective and reliable measurements with the goniometer. Knowledge of surface anatomy allows the therapist to identify structures that may be at risk. Knowledge of muscle action and planes of movement are also essential in designing appropriate exercise programmes for the hand.

2.2 Rheumatoid Arthritis

2.2.1 Epidemiology

Rheumatoid arthritis is the most common autoimmune disease worldwide, affecting approximately 1 to 1.5% of the worldwide population (Khurana and Berney, 2005). Even though the prevalence of RA increases with age, it can occur at any age (Firth, 2011). The incidence of RA rises sharply during adulthood and peaks during the ages of 40 – 60 years. RA occurs in all populations with women being predominantly affected with a female to male ratio of 2 to 4:1(Khurana and Berney, 2005).

Rheumatoid arthritis is less common in the developing world with a prevalence of <0.5% in South Africa. According to the African League of Associations for Rheumatology (AFLAR), the prevalence of RA in rural South Africa is 0.67% and in urban South Africa, 0.9% (Mody and Cardiel, 2008). The urban – rural gradient could be attributed to a delay in access to health care in rural populations. Furthermore in developing countries, RA is often unrecognized or inadequately treated due to factors such as limited public health care resources, cultural beliefs, lack of insight and education and the use of complementary therapies. All these factors may suggest that the actual prevalence could be higher than the reported prevalence. The female to male ratio in South African blacks is 6.9:1 with an average age onset of 36 years. The age of disease onset in Caucasian South Africans is 44.2 years (Mody and Cardiel, 2008).

2.2.2 Etiology

The cause of rheumatoid arthritis is unknown. Possible causative factors could

include environmental exposure, genetic predisposition, and infection; however there is no conclusive evidence to substantiate this (Lipsky, 2010).

2.2.3 Pathology

Occlusion of the microvasculature and proliferation of the synovial cells in the joint lining is the first sign of rheumatoid arthritis. As the process progresses, the synovium becomes oedematous and protrudes into the joint space as a result of hyperplasia and hypertrophy (Lipsky, 2010). This invasive tissue is referred to as pannus. The pannus invades the articular cartilage, subchondral bone and peri-articular structures much like an invasive tumour (Khurana and Berney, 2005). Destruction of the tissues invaded by the pannus is inevitable if the disease process is not managed timeously and effectively (seen in stages III, IV and V of the disease process).

2.2.4 Clinical manifestation

Rheumatoid arthritis can follow a monocyclic pattern (single cycle with remission of at least one year) in about 20% of RA patients, a polycyclic pattern (cyclic pattern with exacerbations and incomplete remission) in about 70% of patients and a more progressive pattern (continuously increasing joint involvement) in about 10% of patients (Munneke and De Jong, 2000).

It manifests as a chronic polyarthritis, beginning insidiously in most patients with systemic and vague musculoskeletal symptoms. Sudden acute onset occurs in about a third of patients affected with RA (Lipsky, 2010).

Symptoms include:

- fever,
- loss of appetite with subsequent weight loss in the early disease stages,
- malaise,
- generalised muscle pain and weakness,
- joint pain, swelling and tenderness,

- loss of joint range of movement and
- morning stiffness (greater than one hour duration).

Synovitis often occurs later in the disease process. Asymmetric joint involvement is not unusual initially with symmetric involvement developing as the disease progresses (Khurana and Berney, 2005). Extra-articular features of RA occur in approximately 40% of patients with RA. These include (Lipsky, 2010):

- rheumatoid nodules,
- anaemia,
- pulmonary complications,
- cardiac involvement,
- splenomegaly,
- Sjogren's syndrome,
- neuropathies,
- myopathies,
- vasculitis.

Four stages can be identified in the disease process.

- The acute phase or stage I is characterized by acute pain, joint swelling and inflammation which is warm when palpated.
- In the subacute phase or stage II, inflammation is less marked, pain is less severe, the pannus invades soft tissue causing decreased mobility, tenosynovitis is often present and no obvious joint deformities are present.
- The chronic phase or stage III, is marked by less pain and progressive joint deformities with soft tissue and bone involvement.
- The chronic inactive phase or stage IV is also known as the skeletal collapse and deformity stage and is characterized by joint instability, dislocation, spontaneous fusion and bony or fibrous ankylosis (Biese, 2002).

2.2.4.1 Hand Involvement

Symmetric hand involvement is often the hallmark of RA. Swelling of the MCPJs and PIPJs is common. The DIPJs of the digits are rarely involved directly, but rather as a consequence of mechanical imbalances at proximal joints. Persistent synovitis can lead to tendon and ligamentous laxity or damage; damage or weakening of the joint capsule; cartilage degradation and muscle imbalances. These factors result in the following characteristic changes noted in the rheumatoid hand (Lipsky, 2010):

- radial deviation of the wrist with ulnar drift of the MCPJs;
- palmar subluxation of the MCPJs;
- hyperextension of the PIPJ with compensatory flexion of the DIPJ resulting in a swan neck deformity;
- flexion on the PIPJ with hyperextension of the DIPJ resulting in a boutonniere deformity;
- hyperextension of the interphalangeal joint of the thumb with concurrent flexion of the thumb MCPJ resulting in the “Z” deformity of the thumb.

These deformities reduce general mobility, strength and prehensile ability of the hand which can have a significant impact on activities of daily living. People with RA report pain as a significant impairment that affects everyday life and impacts negatively on participation in the activities of daily living and independence (Ahlstrand, Bjork, Thyberg, Bjorn and Falkmer, 2012). This, together with joint stiffness and the characteristic hand deformities of RA, make pain management and joint mobility a priority of rehabilitation. The researcher thus sought to investigate the effects of commonly used pain moderating modalities on pain perception and joint mobility in this study.

2.2.5 Diagnosis

According to the revised criteria of the American College of Rheumatology (ACR) classification of RA (1987), a diagnosis of established RA is made if four of the following criteria are met (Firth, 2011):

- morning joint stiffness lasting for at least one hour;
- involvement of at least three or more joints;
- involvement of the hand joints;
- symmetric joint involvement;
- rheumatoid nodules;
- positive serum rheumatoid factor (RF factor) or
- radiographic changes.

As stated by Firth (2011), early stages RA are diagnosed according to new criteria formulated by the ACR and the European League Against Rheumatism. This includes:

Box 1 – Diagnosis criteria for RA.

- Synovitis in at least one joint in the absence of any other diagnosis
- A score of 6 or greater out of a possible 10 in the four domains listed below:

☐ Number and site of joints involved (score 0-5)

☐ Serological abnormalities e.g. rheumatoid factor (score 0-3)

☐ Elevated acute phase response e.g. C-reactive protein, erythrocyte sedimentation rate (score 0-1)

☐ Symptom duration (score 0-1)

Source: Firth, 2011

Integration of disease knowledge and patient presentation enables the therapist to assess the patient with RA appropriately and helps the therapist set realistic goals of rehabilitation together with the patient. An understanding of the pathophysiology of RA also assists the therapist in identifying the possible anatomical structures affected and/or at risk. This, together with knowledge of stages of disease presentation, will help the therapist formulate appropriate, goal orientated treatment plans. The treatment modalities selected will depend on disease activity and patient tolerance.

2.2.6 Management of Rheumatoid Arthritis

The broad aims of RA management are to control pain, preserve joint integrity by minimizing deformity, maintain or improve function, and delay the progression of the disease. Since RA is not a curative disease, many therapeutic interventions are used in combination to delay disease progression. This is achieved via a combination of drug therapy, rehabilitation, and lifestyle modification (Firth, 2011).

2.2.6.1 Drug Therapy

Despite the wide array of drugs now available, total remission of the disease may still not be possible (Khurana and Berney, 2005). Pharmacological therapy is usually a combination of analgesia, nonsteroidal anti-inflammatory drugs (NSAIDS), disease modifying anti-rheumatic drugs (DMARDS), biologic agents and immune-adsorption agents. Medications often used (Khurana and Berney, 2005) are listed in Table 1.

Table 1: Medications used in Rheumatoid Arthritis Treatment

Analgesia/ NSAIDS	Glucocorticoids	DMARDS	Biologic Agents	Immuno-adsorption Agents
Ibuprofen	Prednisone	Azathioprine	Etanercept	Prosorba
Tramadol		Hydroxychloroquine	Infliximab	
Cox 2 inhibitors		Methotrexate	Adalimumab	
Capsaicin		Sulphasalazine	Anakinra	
Narcotics		Leflunomide		
Acetaminophen		Gold salts		

2.2.6.1.1 Analgesia/Nonsteroidal anti-inflammatory agents (NSAIDs)

These drugs are often the first line of treatment, used to control pain and inflammation. They work well at controlling the signs and symptoms of the disease but do not affect the progression of the disease. Cyclooxygenase (Cox) inhibitors have also been shown to be as effective as NSAIDs but with fewer gastric events. Cox inhibitors, though effective, may cause an increased risk of cardiac events (Lipsky, 2010).

2.2.6.1.2 Glucocorticoid Therapy

Low dose oral glucocorticoids suppress the signs and symptoms of inflammation. Prednisone or prednisolone is often used. Kalla and Mohammed (2003) postulated that it may also retard the development of bone erosions. Intra-articular glucocorticoids can also provide symptomatic relief. Even though glucocorticoids provide prompt and effective symptomatic relief, long term use can have adverse effects such as osteoporosis, cataracts and an increased risk of infections. Knowledge of the sequelae of long term glucocorticoid therapy guides the therapist in the selection of appropriate treatment programmes for example; weight bearing activities will be emphasized in the osteoporotic patient.

2.2.6.1.3 Disease Modifying Anti-Rheumatic Drugs (DMARDs)

DMARDs play a pivotal role in managing RA. DMARD therapy improves the clinical presentation as well as slows down disease activity (Lipsky, 2010). Methotrexate (MTx) is often the first DMARD used, due to its affordability, tolerability and efficacy. It can be used in patients requiring combination therapy with other DMARDs. Patients need to be carefully monitored for drug toxicity. Hydroxychloroquine or chloroquine is effective in early RA. It is well tolerated and a relatively cheap drug, commonly used in developing countries. Sulphasalazine is also used as a first line DMARD in early disease. Combinations of DMARDS are used to treat early and established RA. "*A triple combination regime of methotrexate, chloroquine and sulphasalazine has been shown to reduce radiological progression of the disease*."

(Kalla and Mohammed, 2003). DMARDS are potentially toxic substances, careful monthly monitoring is therefore required to balance the therapeutic effects and the drug side effects.

Some DMARDS such as Leflunomide and Hydroxychloroquine are associated with an increased risk of peripheral neuropathy (Khurana and Berney, 2005). Physiotherapists must pay particular to attention to patients on these drugs and screen patients for any peripheral sensory or muscular dysfunction. With regards to this study, emphasis was placed on intact peripheral sensation prior to thermotherapy.

2.2.6.2 Rehabilitation

Rehabilitation in RA is a multidisciplinary approach including primarily the occupational therapist, physiotherapist and psychologist. These are the disciplines most often involved in rehabilitation at the researcher's health care facility.

2.2.6.2.1 Occupational Therapy

Occupational therapy (OT) aims to restore and compensate for a patient's limited physical function, improve or maintain psychological status, facilitate adaptations in the home and work environments and teach joint protection principles during the performance of activities of daily living.

Patients with RA are referred to the occupational therapist as soon as possible after diagnosis at the researcher's health care facility. The major focus of occupational therapy is self-management education and preservation of functional ability. This is achieved by maintaining limb function through a combination of joint protection principles, exercises, assistive device prescription where necessary, splinting, fatigue and pain management principles, and activity and environmental modifications (Hammond, 2010).

Despite the high profile of the role of the occupational therapist in RA management, there is limited evidence on the efficacy of occupational therapy interventions in

rheumatoid arthritis. Rapoliene and Krisciunas (2006) in an empirical study concluded that occupational therapy significantly improves the functional state of the hands in patients with rheumatoid arthritis. Their intervention of functional training of the upper extremities, hand exercises, advice on joint protection principles and lifestyle modification and prescription of splints and adaptive devices was found to improve self-care abilities. In contrast, Steultjens and associates' (2005) review of the effectiveness of comprehensive occupational therapy (which included exercises, lifestyle modification, and prescription of adaptive devices) in functional outcomes in RA, found limited evidence that comprehensive occupational therapy improved functional ability. However, the review did conclude that splinting reduced hand pain, increased grip strength but reduced dexterity.

Occupational therapists are also equipped to provide counselling services to help patients with RA cope with the sequelae of the disease and its impact on their social and mental well-being. This, together with advice on the disease process, lifestyle and activity modification, helps the RA patient holistically adapt to living an optimally fulfilling life.

2.2.6.2.1.1 Joint Protection Principles

Taking into consideration knowledge of joint alignment and mechanics, joint protection principles aim to modify everyday tasks so as to reduce effort and the load placed on joints. By conducting everyday tasks in an ergonomically and biomechanically sound fashion, pain and local inflammation should be relieved in vulnerable joints by relieving the stress on joint structures that may be compromised by the disease process (Hammond, 2004). This together with energy conservation techniques such as taking rest breaks during long tasks and planning activities, can help patients with RA cope better with activities of daily living (O'Brein and Backman, 2010).

2.2.6.2.1.2 Assistive Devices

The prescription of assistive devices which incorporate joint protection principles can increase independence by compensating for muscle weakness and joint stiffness. Assistive devices such as built-up knives and tap openers have been shown to reduce hand pain significantly in RA patients (Hammond, 2004). This, together with home modifications such as hand rails, ramps etc. help increase functional independence in the home environment.

2.2.6.2.1.3 Splints

The principle of splinting is to maintain joints in a biomechanically sound position to help prevent or correct deformities. This support of joints is expected to (Adams, 2010):

- help reduce or minimize pain,
- help control active inflammation in the acute stages by immobilizing joints,
- minimize joint contractures and maintain capsular and ligamentous integrity,
- increase joint stability and
- improve overall hand function by maintaining joint integrity

Hammond's systematic review (2004) of occupational therapy in RA did not find any evidence to support any long term beneficial effects of hand splinting on deformity prevention and preservation of functional ability. However it did support the use of splints to help ease pain and improve grip strength. Anecdotal feedback from patients living with RA at this facility indicates that functional resting splints are particularly helpful in relieving pain during acute inflammation by providing joint stability and rest.

2.2.6.2.2 Physiotherapy

The objectives of physiotherapy intervention in rheumatoid arthritis are to (Hammond, 2004):

- decrease pain,
- decrease joint swelling,
- decrease joint stiffness,
- increase range of movement (ROM),
- increase/maintain muscle strength,
- minimize or prevent deformity, and
- improve overall function.

Physiotherapy uses a combination of several modalities within a treatment session to achieve this. Electrical and physical agents (such as heat/cold modalities) are often used as an adjunct to manual therapies.

2.2.6.2.2.1 Exercise

Exercise programmes form an integral part of physiotherapy treatments (O'Brein and Backman, 2010). Active hand exercises have been shown to decrease joint tenderness, improve muscle strength, decrease stiffness and improve hand function, in addition to stabilizing joints and preventing traumatic hand injuries (Buljina et al, 2001). The overall aim of active hand exercises is to optimize hand function and maintain self-independence.

Hand exercises are prescribed to:

- improve muscle strength,
- improve joint flexibility,
- reduce muscle spasm,
- improve exercise tolerance and
- maximize joint stability.

Buljina and associates (2001) advocated a hand exercise programme suitable to the disease stage as standard practice. During the acute stage, gentle free active exercises focusing on range of movement, moderated with rest breaks, are preferable. Exercises in the subacute and chronic stages can be more robust but care should be taken to avoid excessive resistance exercises which may place undue strain of vulnerable joints. Daily exercise may help to maintain quality of life (O'Brein and Backman, 2010). O'Brien et al (2006) concluded that a combination of mobilizing and stretching exercises improved hand function and grip. Pain was described as a major barrier to exercise by most patients encountered by the researcher. Despite patients being counselled on the importance of hand exercises, compliance depended on the level of pain experienced by the patient. It is therefore essential that adequate pain control is achieved prior to exercise to improve compliance with exercise programmes. The physiotherapist can achieve adequate pain control with electrical and physical agents

The focus of this study was to investigate the effectiveness and to compare two pain relieving modalities commonly used by physiotherapists prior to hand exercises.

2.2.6.2.2.2 Electrical Modalities

Electrical modalities are often used for pain and inflammation modulation prior to exercise programmes. Commonly used electrotherapy modalities in RA include low level laser therapy, electrical stimulation therapies (transcutaneous electrical nerve stimulators (TENS), interferential therapy), shortwave therapy and ultrasound therapy. Aside from the laser, most health facilities in the public sector are equipped with these modalities, making it readily available for RA treatments. The choice of modality depends on the goals of therapy, the disease stage, time constraints and therapist's preference

Electrical stimulation has been shown to increase local blood flow, decrease local oedema, maintain tissue extensibility and modulate pain perception, amongst other physiological effects (Robertson, Ward, Low and Reed, 2006). These effects are beneficial to the patient with RA. The most commonly used electrical stimulation therapies in the public health sector are TENS and interferential therapy.

TENS units are small, portable machines that deliver a non-invasive electrical impulse via surface skin electrodes. All modes of TENS (conventional, burst, brief intense and modulation) have been shown to improve pain, however RA patients tend to prefer the conventional TENS application (Bearne and Hurley, 2010). TENS units are cost effective and readily available in public sector health facilities. RA patients at the researcher's facility have reported good pain relief with TENS. TENS units are small, lightweight and portable and can be easily applied to patients' hands. When thermotherapy is contraindicated, TENS is the electrical modality most often used for pain relief in RA patients at the researcher's facility.

2.2.6.2.2.3 Thermotherapy

Thermotherapy refers to the therapeutic application of heat or cold modalities. Heating modalities in the rheumatoid hand been shown to help relieve pain and improve flexibility (Brosseau, Wells, Tugwell, Egan, Dubouloz, Casimiro, Robinson, Pelland and McGowan, 2004).

This study focused on superficial heating modalities, hence the need to discuss the physiological and therapeutic effects of heat on local tissue. The physiological effects of superficial heat on local tissues are (Cameron, 2003):

- increased blood flow,
- increased collagen extensibility,
- reduced muscle tone,
- improved muscle strength and flexibility,
- accelerated tissue healing and
- increased pain thresholds.

The therapeutic effects of local tissue heating are (Cameron, 2003 and Robertson et al, 2006):

- pain moderation,
- relief of muscle spasm,
- facilitation of joint movement,

- aiding in resolution of chronic inflammatory states and
- increased exercise tolerance in some people.

Heat transfer is achieved via conduction (heat transfer by direct contact). Heat is conducted from the material of higher temperature (wax, heat pack) to the material of lower temperature (skin).This is achieved by direct collision between the faster moving molecules of the warmer material and the slower molecules of the cooler material, causing them to accelerate. Transfer of heat continues until the temperature and speed of molecular movement of both materials are equal. The rate of heat transfer depends on the temperature difference of the materials and their thermal conductivity. Materials with a higher thermal conductivity transfer heat more rapidly than those with a low thermal conductivity. Physical heating agents are therefore generally composed of materials with a moderate thermal conductivity. Insulation materials used between the physical agent and skin are of low thermal conductivity and slow down the rate of heat transfer, protecting the skin from thermal burns (Cameron, 2003).

The risk of thermal burns exists with heat applications. Skin temperatures above 45^0C can cause tissue damage, depending on the length of exposure. A temperature of 45^0C can be tolerated for approximately one hour before skin damage occurs (Robertson et al, 2006). If heed is taken of the contraindications to heat applications and it is applied in a controlled environment, the risk of sustaining a burn is minimal and is tantamount to the risk faced in everyday life.

Heat application contraindications are:

- impaired thermal sensitivity in the area being treated,
- impaired circulation,
- open wounds,
- devitalized tissue,
- skin infections,
- acute inflammation and

- confused patients.

2.2.6.2.2.3.1 Moist Heat Therapy

Commercially available moist heat packs are usually made of bentonite (a hydrophilic silicate gel) encased in canvas. Bentonite is capable of absorbing large quantities of water and can provide a considerable storage of heat energy. The packs are made in various sizes and are heated by being placed in a hydrocollator filled with water at a temperature of 75^0C to 80^0C which is controlled by a thermostat. Once heated, the heat pack is removed from the hydrocollator, drained of excess water and wrapped in a material such as towelling before being applied to the area being treated. Towels are used for insulation between heat packs and the skin. The towels trap air which has a low thermal conductivity, limiting the rate of heat transfer from the insulated heat pack (approximately 40^0C to 42^0C) to the skin (Robertson et al, 2006).

The advantages of moist heat packs are that it's inexpensive, easy to use, requires little active time with a clinician, requires a low level of skill for application and is safe as the packs start cooling on removal from the hydrocollator.

2.2.6.2.2.3.2 Paraffin Wax Therapy

Melted paraffin wax combined with a mineral oil (liquid paraffin), is also used for superficial tissue heating. Paraffin wax applications were first used in the 1920's to help alleviate pain in rheumatic conditions. It was thought to increase pain and tenderness thresholds in subacute and chronic RA, improve joint mobility and overall hand function. If applied in acute RA where acute inflammation has already caused an increase in joint temperature, paraffin wax therapy could potentially aggravate joint pain (Ayling and Marks, 2000). Hence paraffin wax therapy, as with other heating modalities, is contraindicated in the acute stage of RA.

Paraffin wax is often used in the treatment of RA hands in the absence of any contraindications, at the researcher's health care facility. Anecdotal feedback from patients is that it provides better pain relief than other heating modalities such as

moist heat packs, which are used when paraffin wax is not available. In a review of literature by the researcher, no direct comparison between paraffin wax therapy and moist heat therapy was found, hence the need for study comparing treatment outcomes with these two modalities.

Ayling and Marks (2000), in their review of paraffin wax in the rheumatoid hand, amongst other parameters, explored the effects of paraffin wax on hand tissue temperature. It was found that the skin temperature was raised approximately 5.8^0C in the drip-wrap method of paraffin wax application and fell to the initial values within 10 to 60 minutes post application. Paraffin wax applications raised skin temperatures to a greater extent than other heat applications such as hot water immersion. Muscle temperature also increased by approximately 4^0C, and joint capsule temperature by 5^0C with paraffin wax application. Increased temperature of the muscles and capsule were achieved at about 10 minutes post application and then declined rapidly.

They also found that paraffin wax failed to produce any long term effects on hand function and symptomatic benefits in RA. The most significant benefits were noted immediately after application with pain relief and milder joint stiffness sited as the most noted effects. In view of this finding, the researcher sought to investigate the immediate outcomes of moist heat therapy and paraffin wax therapy in RA as opposed to repeated interventions.

The wax is heated in a thermostatically controlled wax bath to 42^0C to 50^0C. The drip-wrap and the drip-immersion methods are used for treatment of the hands. The hand can be comfortably immersed in paraffin wax of approximately 50^0C without danger of tissue damage. This is because the wax in contact with the skin cools and solidifies, forming a thin layer of solid wax on the skin. The thermal conductivity of solid wax is low. This solid wax layer insulates the hand from the warmer surrounding molten wax. Once removed from the wax bath, the outside surface of the solid wax layer cools rapidly but its low thermal conductivity limits the loss of heat from the skin. The loss of heat is further delayed by the application of insulating material such as plastic and towels (Robertson et al, 2006).

The advantages of paraffin wax therapy are that it maintains good contact with irregularly contoured treatment areas and lubricates and conditions the skin. A disadvantage is that it is regarded as messy and time consuming to use (Cameron,

2003). The choice of modality ultimately depends on clinician's skill and knowledge, time constraints and the availability of resources.

Dellhag and Bjelle (1992) evaluated the effect of active hand exercise and wax bath treatments in RA patients. Wax baths alone had no significant effect on grip function, grip strength, and joint range of movement; however it provided pain relief and decreased stiffness immediately after application. Wax therapy combined with hand exercises showed significant improvement in ROM and grip function. The Ottawa Panel's review of literature (Brosseau et al, 2004) confirmed this view. Furthermore, the panel's review affirmed that the application of ice or hot packs had little effect on the measures of disease activity in RA when compared to a control group with no intervention. Parameters measured included ROM, joint swelling, grip force and hand function. Buljina et al (2001) asserts that wax packs, ice massage, thermal baths, faradic hand baths and exercise therapy had favourable short term effects on the rheumatoid hand. However, since all physical agents were administered to all patients in the test group daily, with treatment sessions 30 minutes apart, it is difficult to ascertain the effectiveness of each modality. A study by Hawkes et al (1986) comparing the effects of paraffin wax therapy, therapeutic ultrasound and faradic baths found that wax therapy yielded a significant increase in range of movement and decreased pain.

The literature review has thus far indicated that thermotherapy is beneficial in the management of RA. The benefits however, are not sustained but rather, are short term effects. Physiotherapists capitalize on these short term effects of improved pain control and flexibility, to help enhance compliance with exercise programmes. Paraffin wax and moist heat therapy are commonly used to help alleviate or moderate pain prior to exercise regimes. Thus far, no direct comparison studies have been done to compare the effectiveness of these two modalities. The researcher therefore sought to establish if paraffin wax therapy was more effective than moist heat therapy in improving pain, joint range of movement and grip ability in the rheumatoid hand.

2.2.6.2.2.4 Psychosocial Implications

Living with a chronic disease that impacts on quality of life can sometimes have devastating effects on a person. Psychological intervention has been advocated to help patients with RA develop coping mechanisms to deal with the sequelae of the disease process. Stress and self-management programmes offered by psychologists using cognitive behavioural therapy approaches have been successful in addressing depressed moods, anxiety, pain coping strategies and acceptance of the disease process and altered levels of function. Psychological intervention has been shown to help reduce feelings of helplessness, depression and fatigue in patients with rheumatic conditions (Hale and Treharne, 2010). Newly diagnosed RA patients at the researcher's health care facility receive individual counselling sessions initially before being introduced to group counselling sessions, where patients with RA get the opportunity to share their experiences of living with RA.

CHAPTER 3

Methodology

This chapter describes the research aim, hypotheses, research design, the sample and sampling procedure, the procedure of the study, including ethical considerations and data collection. It also provides an overview of the methods used for the data analysis.

3.1 Introduction

3.1.1 Research Aim

The aim of this study was to determine if paraffin wax therapy was more effective than moist heat therapy in relieving pain and in improving joint range of movement and grip ability in the adult rheumatoid hand.

3.1.2 Hypotheses

Hawkes et al (1986), as well as Dellhag and Bjelle (1992) have already shown that paraffin wax therapy provided pain relief and relieved joint stiffness immediately after application. Even though Bulgina and associates (2001) investigated the effects of heat and wax therapy on inflammation and functional status of the rheumatoid hand, both modalities were used on all subjects making it difficult to compare the modalities directly. The researcher failed to find any other studies that compared moist heat therapy and wax therapy directly. The researcher thus sought to compare these two commonly used modalities to establish if paraffin wax therapy produced more favourable results than moist heat therapy thus corroborating the anecdotal feedback from RA patients.

H_a:

i. Paraffin wax therapy and hand exercises will be more effective in decreasing pain in patients with rheumatoid arthritis affecting the hands, when compared

to patients receiving moist heat therapy and hand exercises.

ii. Paraffin wax therapy and hand exercises will be more effective in improving joint range of movement in patients with rheumatoid arthritis affecting the hands, when compared to patients receiving moist heat therapy and hand exercises.

iii. Paraffin wax therapy and hand exercises will be more effective in improving grip ability in patients with rheumatoid arthritis affecting the hands, when compared to patients receiving moist heat therapy and hand exercises.

H_0:

i. Paraffin wax therapy and hand exercises will be less effective in decreasing pain in patients with rheumatoid arthritis affecting the hands, when compared to patients receiving moist heat therapy and hand exercises.

ii. Paraffin wax therapy and hand exercises will be less effective in improving joint range of movement in patients with rheumatoid arthritis affecting the hands, when compared to patients receiving moist heat therapy and hand exercises.

iii. Paraffin wax therapy and hand exercises will be less effective in improving grip ability in patients with rheumatoid arthritis affecting the hands, when compared to patients receiving moist heat therapy and hand exercises.

3.2 Research Question

The research question in this study was:

Does paraffin wax therapy produce more favourable outcomes on pain, joint range of movement and grip ability in the adult rheumatoid hand than moist heat therapy?

3.3 Research Design

This quantitative research was a combination of an experimental and quasi-experimental, pretest-posttest research design, used to study the cause and effect relationship of paraffin wax therapy and moist heat therapy on pain, joint range of movement and grip ability in the rheumatoid arthritic hand. Even though randomization of subjects to the test groups was done, the research design was not purely experimental as there was no control group. Withholding treatment would have been deemed unethical; hence a combination of the two research designs was used.

Pretest - posttest designs are popular for evaluating the efficacy of interventions on dependent variables (Spector, 1981). Pretest measurements of the dependent variables provide a baseline against which posttest measurements can be compared. Differences between the pre- and posttest measurements can be attributed to the intervention. The subject therefore serves as his/her own control. This is valuable in the absence of a control group as was the case with this study. A flaw of this design is that the change in measurements may not always be attributed to the intervention alone (Spector, 1981). However, since the posttest measurements were taken immediately after the intervention and the researcher had control over the events occurring to the subject during the study, this threat of history and maturation on internal validity was minimized. Thus the chance of posttest changes occurring due to extraneous variables was minimized.

The same data gathering instruments were used on all subjects, with the same instructions, starting positions and independent rater for all subjects. This attempt at standardization helped maintain internal validity and reduce bias. Furthermore, all subjects were new to physiotherapy thereby negating the effect of sensitization to the instruments and modalities being investigated.

The Hawthorne effect, another limitation of the pretest- posttest design (Spector, 1981) and an external validity threat, was minimized by conducting the study in a designated region in an active treatment area to reduce the perception of being observed. The same furniture and equipment were used for all subjects. This was a study comprising of 2 groups, with 2 interventions. A single independent variable

(wax and heat) was manipulated in each group, thus maximizing the external validity of this study.

Table 2: Study Groups and Physiotherapy Intervention

Group 1	Pretest of	Intervention	Posttest of:
Paraffin wax therapy and hand exercises ("wax group")	• Pain • ROM • Hand span • Timed activities	• Paraffin wax therapy • Hand exercises	• Pain • ROM • Hand span • Timed activities
Group 2	**Pretest of**	**Intervention**	**Posttest of:**
Moist heat therapy and hand exercises ("heat group")	• Pain • ROM • Hand span • Timed activities	• Moist heat therapy • Hand exercises	• Pain • ROM • Hand span • Timed activities

3.4 Research Setting

The study took place at a regional/district health care facility in Chatsworth, in the EThekwini district in Kwazulu-Natal where the researcher is employed. This site was chosen as the researcher had established a good working relationship with the multidisciplinary team who had expressed an interest in this study. This site was also chosen as it has a large catchment area serving the population of Chatsworth, and the surrounding area, including regions to the west commencing from Yellowwood Park to Richmond. This health care facility is also a referral facility for numerous primary health care clinics and one district hospital in this catchment area. These factors were considered favourable in obtaining an adequate sample for this study. The study was conducted within a designated area in the outpatient section of the physiotherapy department. The research setting was kept constant throughout the

study with access to the instruments being restricted to the researcher and independent rater alone.

3.5 Sample

3.5.1 Sampling Procedure

Sampling is the process by which a portion of a larger group of potential subjects is examined and the results gained are used to make statements about the larger group (Acharya, Prakash, Saxena and Nigam, 2013). The researcher used purposive sampling to obtain her sample. Purposive sampling is a type of nonprobability sampling in which the researcher identifies a population in which possible subjects are most likely to meet the inclusion criteria of the study (Jupp, 2006). Purposive sampling is not the most ideal sampling method to achieve an unbiased sample as it is not representative of the entire population and limits generalization. Since the researcher sought to investigate the relationship between variables with a pretest - posttest design, as opposed to proportions of a total population, purposive sampling was deemed suitable. This was also the sampling method of choice due to financial and time constraints.

Purposive sampling was used at a single provincial health care facility in the Ethekwini metro district where the researcher had access to patients. A sample frame was identified of possible subjects meeting the inclusion criteria. Patients with suspected RA are referred to the medical outpatient and arthritis clinics by medical officers in casualty and the outlying clinics according to patient referral patterns. Patients attending these clinics were therefore most likely to meet the inclusion criteria. Following discussions with the internal physicians with a special interest in rheumatology at this facility, the researcher decided to also target the primary health care clinic situated on the outskirts of the facility premises and the casualty department of the health care facility.

Subjects with a confirmed diagnosis of rheumatoid arthritis affecting both hands were targeted for this study. Although a diagnosis of rheumatoid arthritis cannot be made with one specific test, diagnosis was confirmed by medical officers in the referring clinics, based on their clinical presentation and the following blood tests:

- elevated erythrocyte sedimentation rate (indicated the presence of an inflammatory process in the body);
- positive serum rheumatoid factor (a positive rheumatoid factor in people with arthritic pain is a strong indicator of rheumatoid arthritis) and
- C-reactive protein test (high levels of C-reactive protein indicate inflammation in the body).

Inclusion criteria were:

- patients with rheumatoid arthritis of the hands and/or wrists in disease stages II and III, who were referred for physiotherapy. However prior to commencing fieldwork, the researcher decided to limit the study to patients in stage II of the disease helping minimize disease presentation variables and standardize subject profiles;
- intact light touch, pin prick and hot and cold sensation of the wrists and hands;
- blood tests (mentioned below in subject recruitment);
- males and females of all races in the age range 18-50 years and
- the ability to read, write and follow instructions correctly.

Sensation was evaluated by assessing light touch with a cotton wool ball, pin prick with a safety pin, and hot and cold sensation with test tubes filled with hot and cold water respectively. The potential subject was asked to close his/her eyes and the researcher applied each of the above in turn to the ulnar and radial aspects of each hand, as well as to the dorsal area of the first web space of the hand. These specific areas were chosen as they are representative of sensory innervation by the 3 peripheral nerves in the hand (ulnar, median and radial nerves respectively). The subject was asked to identify what they felt in each instant. If the subject could feel all of the above, sensation was considered intact.

Subjects over the age of 50 years were excluded to minimize the effects of age related degeneration. It has been found that pressure/pain thresholds and grip strength decrease with age, especially over the age of 60 years due to sensorimotor impairment thus affecting hand function (Donat, Ozcan, Ozdirenc, Aksakoglu and

Aydinoglu, 2005). The potential subjects' ability to read, write and comprehend was gauged by asking them to read the patient information sheet and consent form. Their understanding of the documents and the study proposed was then gauged by a general discussion between the investigator and the potential subjects, on what would be expected of them should they agree or disagree to participate in the study. Subjects that understood the study, the expectations of them and the possible benefits and risks of participating, were included in the study. If potential subjects were unable to read and understand the patient information sheet and consent form, they were not included as this could have impacted upon their degree of co-operation in compliance with the requirements of the research process.

Exclusion criteria were:

- acute/active inflammation,
- stages I, III and IV rheumatoid arthritis,
- surgical intervention in the hands or wrists,
- sensory or vascular impairment of the hands and/or wrists,
- open wounds on the hands or wrists and
- inability to read and comprehend the process and instructions.

Heat therapy is contraindicated in active inflammation as heat has been shown to aggravate acute inflammation (O' Brein and Backman, 2010); subjects with stage I RA were therefore excluded. Even though the researcher had initially planned to include subjects in stage III of the disease process, prior to commencing field work, she decided to limit her study to subjects in stage II to help minimize variations that would have occurred during data analysis. Exclusion of subjects with stage IV RA was necessary, as they would have presented with joint instability, fixed deformities, skeletal collapse and joint ankylosis, all of which, would have limited the available range of joint movement. Subjects with surgical interventions such as joint arthrodesis and replacements were excluded as the available range of movement is dependent on the nature of the surgical procedures and implants. Subjects with sensory impairment were excluded to limit the possibility of sustaining thermal burns.

Subjects with vascular impairment were excluded as dissipation of heat would have been compromised, which in turn, could have led to thermal burns. Due to infection control purposes, subjects with open wounds were excluded. The paraffin wax experimental group required the hands to be dipped into molten wax which could have caused wound contamination (Robertson et al, 2006 and Cameron, 2003).

3.5.2 Subject Recruitment

The researcher attended two unit meetings each, of all the targeted clinics (primary health care, casualty, medical outpatients and arthritis clinics) and communicated the purpose of her study to all the medical practitioners servicing these clinics. Lists of the inclusion and exclusion criteria for the study (refer to Appendix A) were distributed to medical practitioners at these meetings. It was agreed that potential subjects identified by medical practitioners at the primary health care clinic and casualty department would be referred to the medical outpatient and arthritis clinics. The potential subjects would then be screened by the internal physicians at these clinics. If a diagnosis of RA was confirmed by clinical presentation and blood tests and the potential subject met the inclusion criteria for the study, they were then referred to physiotherapy.

The researcher then screened the potential subjects in the physiotherapy department on the day of referral. By using a checklist (Appendix B), the researcher obtained a suitable sample of subjects with rheumatoid arthritis affecting both hands. A statistician had been consulted to help determine sample size when writing the study protocol. He concluded that a sample size of 40 subjects per group (a total sample size of 80 subjects) was required to show statistical significance.

Subjects meeting the inclusion criteria were invited to participate in the study. Subjects received an explanation of the study. Voluntary participation, withdrawal and confidentiality were emphasized. Subjects were assured that a refusal to participate in the study would not impact on their physiotherapy treatment in any way. Willing subjects were given a patient information sheet (appendices C or D) and consent form detailing the study. If they understood and agreed to participate, they were asked to sign the informed consent form (appendices E or F). All subjects that

participated in the study did so on the same day they were referred and screened. This was done to avoid any changes in their clinical condition which may have rendered them ineligible for the study.

Subjects were then randomized into the 2 groups as noted in Table 2. Random group assignment improved internal validity, minimized selection bias and ensured that the groups were as equivalent as possible. This was achieved by the subject picking a folded piece of paper with a number of 1 or 2 written on it, from a packet occluded from his/her vision. The numbers were interpreted as: 1 – paraffin wax and exercise group (hereafter referred to as the "wax group"); and 2 – moist heat and exercise group (hereafter referred to as the "heat group"). Due to the nature of the treatments, blinding of the subjects was not possible.

3.6 Instrumentation

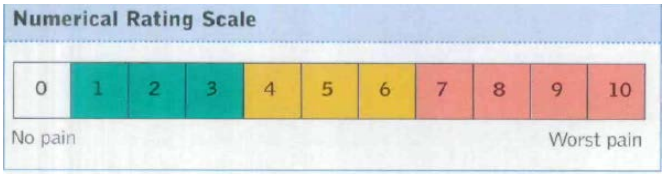
3.6.1 Pain

The ability to quantify pain is essential when caring for individuals with pain in order to monitor patient progress and analgesic effectiveness. Numeric pain rating scales have been shown to have test-retest reliability. They were the preferred scales of use in 33% of cognitively intact older minority adults when compared to a verbal descriptor pain scale and a revised face pain scale (Paice and Cohen, 1997). It has been found that the numeric pain scale had good sensitivity and generated data that can be easily analyzed statistically when compared to the visual analogue scale and the verbal rating scale (Williamson and Hoggart, 2005).The numeric pain rating scale is easy to understand and simple to use. It can be verbally administered to patients, thereby overcoming physical and visual impairments that may hamper the use of other pain scales such as the visual analogue scale (McLafferty and Farley, 2008). Pain evaluation was thus done using a numerical pain rating scale consisting of a set of numbers from 0 to 10, represented on a horizontal line, where 0 represented no pain and 10 represented worst pain.

Pain was assessed by asking the subject to rate his/her pain on a numeric pain scale as illustrated in Figure 1.

Figure 1: Numerical Pain Rating Scale

(McLafferty and Farley, 2008)



Key: 0 – no pain
1 to 3 (green) – mild pain
4 to 6 (yellow) – moderate pain
7 to 10 (red) – severe pain

3.6.2 Range of Movement (ROM)

The goniometer is commonly used in clinical practice to measure joint ROM. Gajdosik and Bohannon (1987) stated that although small errors in construction of goniometers may exist, the instruments generally are accepted as valid clinical tools. Both the lateral and dorsal approaches have been found effective in assessing joint ROM (Kato, Echigo, Ohta and Ishiai 2007). Validity of goniometer ROM measures is further enhanced by the therapists' anatomical knowledge, visual inspection skills and accurate alignment of the goniometer.

The same tester took all measurements as intratester reliability has been shown to be higher than intertester reliability (Innes, 1999). The same goniometer, starting positions and anatomical alignment of the goniometer were used as per appendix G for all measurements of digital flexion to maximize reliability. The American Academy of Orthopaedic Surgeons guideline for ROM notation was used. All movements were measured from a 0^0 starting point, with flexion being recorded as positive numbers and hyperextension beyond 0^0 as negative numbers (Cambridge-Keeling, 2002). The degree of flexion indicated the degree of joint mobility.

A linear measure of the distance between the midpoint of the tips of the thumb and the little finger on a tracing of the fully abducted digits was used to measure hand span in millimetres. Hand span illustrated the subject's ability to fully abduct the digits of the hand indicating extensibility of tissues in the researcher's opinion. Thumb opposition was assessed by asking the subject to touch the tip of the little finger with the tip of the thumb. Any deficit in opposition was evaluated by taking a linear measure in millimetres, between the centre of the tip of the thumb pad and the

centre of the tip of the little finger pad. Opposition also illustrated tissue extensibility and is a prerequisite for grip.

3.6.3 Grip Ability

Grip ability pretest and posttest was assessed using the Grip Ability Test (GAT). It has been shown to be reliable and sensitive to change in patients with RA (Dellhag and Bjelle, 1995). The test includes three tasks: putting a sock onto the non-dominant hand, putting a paperclip onto an envelope and pouring water from a filled one litre jug into a two hundred millilitre cup. The time in seconds taken to perform each task was recorded using a stopwatch. Even though the GAT does not assess overall activities of daily living and hand function, in the researcher's opinion, she thought it demonstrated the subject's ability to manipulate objects using precision and power grips. The researcher did not measure grip or muscle strength as it was unlikely that a single intervention would cause significant changes between pre-and posttest ratings.

3.7 Pilot Study

Prior to commencing data collection proper, a pilot study was conducted to validate the instruments used. Five subjects meeting the inclusion criteria were selected for the pilot study. These subjects were randomly allocated to either "Group 1" or "Group 2" by asking them to choose a piece of folded paper with either number 1 or 2 written on it from a packet occluded from their view. Three subjects chose number 2, representing the "heat group" and two subjects chose number 1 representing the "wax group".

All 5 subjects had pre-treatment measurements taken of:

- pain;
- the time taken to put a sock onto their non-dominant hand using their dominant hand;
- the time taken to pour water from a 1 litre jug into a 200 millilitre cup;
- the time taken to put a paperclip onto an envelope;

- linear measurement of opposition and hand span, and
- goniometric joint range of movement of all the intrinsic joints of the hand.

All measurements were captured on the data collection sheet (appendix H). Moist heat packs and paraffin wax therapy was applied to the subjects' hands as described in the fieldwork section (3.7.1). Three subjects had moist heat applied to their hands and two subjects had paraffin wax therapy applied. After the wax and heat treatments, all subjects observed a demonstration of the hand exercise programme (appendices I and J) and then executed the exercise programme under direct supervision. Upon completion of the hand exercise programme measurements of the above noted readings were again taken.

The pilot study served to test the instruments used for the study. The pain rating scales, timed hand activities and the goniometric and linear measurements were easy to use and suitable for the tasks at hand. It was not necessary to amend any of these tools or the method of application of the moist heat packs and wax therapy. The researcher then proceeded with data collection.

3.8 Data Collection Procedure

3.8.1 Fieldwork

Data collection was undertaken over a period of 8 months, commencing in July 2012 and concluding in February 2013. A total of 119 subjects met all the requirements of the study of which 115 subjects agreed to participate and signed informed consent forms. All 115 subjects successfully completed the study. There were no withdrawals.

External validity was enhanced by minimizing the Hawthorne effect. This was achieved by conducting the study in a designated part of the normal clinical area in the participating physiotherapy department. This minimized the subjects' perception of being part of a study. The experiment setting though in an active clinical area, was kept constant with the same furniture, equipment, tester and investigator. This maximized external validity and reliability.

Subjects were then randomized into the 2 groups as mentioned in Subject Recruitment (3.5.2). A baseline pretest assessment of the dependent variables was conducted by an independent rater to overcome bias and maximize reliability.

This consisted of:

- rating of pain using the numeric pain rating scale;
- goniometric measurement of joint range of movement of the intrinsic hand joints;
- linear measure of opposition;
- measurement of hand span using a tape measure on tracings of both hands and
- administration of the Grip Ability Test timed in seconds with a stopwatch.

All data was captured, together with biographical details, on the data collection sheet, appendix H. Each subject then received a treatment intervention depending on the group they were allocated to.

The treatment interventions in the groups were administered by the investigator and were as follows:

Group 1 – "Wax Group"

The drip-wrap method (Cameron, 2003) which is commonly used by therapists in daily practice, was used by the investigator to apply the paraffin wax as follows:

- The investigator checked the temperature of the wax using a thermometer. A therapeutic temperature of 45^0C was maintained.
- The subject removed all jewelry from the hands and washed their hands prior to commencement of treatment.
- The skin of the hands was inspected by the investigator for any contraindications.
- The subject was seated in straight back chair with both feet on the floor.
- The subject was informed that he/she would experience a moderate, comfortable heat with the wax application. Any uncomfortable sensations were to be reported to the investigator immediately.

- Prior to immersion, the temperature of the wax was checked with a thermometer for a second time to minimize the possibility of sustaining a burn.
- After being instructed not to touch the sides or bottom of the wax bath and with the fingers spread in a comfortable position that could be maintained during the dipping, the subject dipped each hand into the wax bath 8 times, waiting briefly for each layer to become opaque and solidify between dips, thus building up layers of wax forming a wax glove.
- The wax coated hand was then inserted into a plastic packet and then into a mitten which acted as insulation to slow the cooling of the wax.
- The hands were then rested on a hand table in front of the subject. The wax was left in place for 15 minutes.
- The subject thereafter peeled the wax off his/her hands.
- The subject was directly observed by the investigator during application of the paraffin wax to ensure safety and minimize the possibility of sustaining thermal burns.

On completion of the paraffin wax treatment, the hand exercise programme as illustrated in appendices I and J was demonstrated to the subject by the investigator. Instructions on how to perform the exercises were given to each subject. The subject then completed the stipulated number of repetitions of each exercise under the supervision of the investigator.

Following completion of the exercise programme, the subject's pain was rated immediately and posttest measurements were taken. All measurements were documented on the data collection sheet (appendix H) by the independent rater.

Group 2 – "Heat Group"

Moist heat was applied via hydrocollator heat packs which are available in most public sector physiotherapy departments. The researcher used the method of application that she uses in everyday practice. She standardized it for all subjects as follows:

- The temperature of the hydrocollator was measured with a thermometer by the investigator to ensure a temperature of 80^0C.
- The subject removed all jewelry from the hands and washed their hands prior to commencement of treatment.
- The skin of the hands was inspected by the investigator for any contraindications.
- The heated pack was drained of excess water before being wrapped in towelling. The towelling layer was 1cm thick to provide adequate thermal insulation. Thickness of towelling layer was measured with the Jamar® Medical Skinfold Caliper (model 5028)
- The temperature of the insulated pack was measured with a thermometer to ensure a therapeutic temperature of 40^0C to 42^0C.
- The subject was seated in straight back chair with both feet on the floor.
- The subject was informed that he/she would experience a moderate, comfortable heat with the heat pack application. Any uncomfortable sensations were to be reported to the investigator immediately.
- The investigator again measured the temperature of the insulated heat pack to ensure it was at the appropriate therapeutic level prior to application to the subject's hands.
- The insulated heat pack was placed over the subject's hands which were supported on a hand table in front of him/her. The duration of heat application was 15 minutes.
- The subjects were directly observed by the investigator during the treatment to ensure safety and to minimize the possibility of thermal burns (Robertson et al, 2006).

On completion of the moist heat treatment, the hand exercise programme as illustrated in appendices I and J was demonstrated to the subject. Instructions on how to perform the exercises were given to each subject. The subject then completed the stipulated number of repetitions of each exercise under the supervision of the investigator. Following completion of the exercise programme, the subject's pain was rated immediately and posttest measurements were taken. All measurements were captured on the data collection sheet by the independent rater.

3.8.2 Data Management

A total of 56 goniometric measurements, eight linear measurements, six timed task measurements and two pain scale ratings were taken on each subject. All measurements were recorded on the data sheet by the independent rater together subject biographical data such as age, race and hand dominance. The data collection sheets did not include any other personal information. Subjects were identified by a number. The data collection sheets and consent forms were kept separately. The consent forms did not include the subject number making it impossible to correlate a consent form to a data collection form thus ensuring confidentiality.

Data sheets which were collected from the independent rater on a daily basis, together with the consent forms, were kept in a locked cupboard in the researcher's office. Access to this cupboard was restricted to the researcher alone. On a weekly basis, the information from the data sheets was entered onto a Microsoft Office Excel 2007 worksheet by the researcher. Two separate worksheets were created, one for the wax group and one for the heat group. The researcher entered all data into the spreadsheet, double checking each entry to ensure accuracy. The spreadsheet was created in a folder on the researcher's personal laptop to which only she had access. Security was further enhanced by password protecting the spreadsheet. The password was only known to the researcher.

3.9 Data Analysis

On completion of fieldwork, the completed database was reviewed by a statistician from the College of Health Sciences at UKZN. The statistician imported the information from the Microsoft Office Excel 2007 spreadsheets into the IBM Statistical Package for the Social Sciences (SPSS) version 11.0 programme for Windows to generate an analysis report. Descriptive analysis of the demographic profile of the study sample was produced. These included an analysis of the age, race and gender profile of the subjects.

A comparative assessment of the effectiveness of the interventions was undertaken. The level of significance was set at 5%, (p-value ≤0.05). Hotelling's T-square test

was performed on the difference between pre- and posttest measurements of the numerical pain rating scale, the timed activities, joint range of movement and hand span. Analysis of Variance (ANOVA) tests were also performed on the above variables to establish the effects of intervention and age. Age range was categorized into three groups for this purpose: less than or equal to 36 years (≤36), 37 to 42 years and greater or equal to 43 years (≥43).

The effect of the intervention was analysed independently for each hand. A multivariate ANOVA (MANOVA) test was performed on the data of intrinsic hand joint measurements and hand span to determine if the intervention effects were significant. Comparison between the right and left hand mean differences in joint range of movement, hand span and grip ability were done to see if any significant differences existed between the hands. A comparison between the two different interventions was determined from the above conducted tests.

3.10 Ethics and Considerations

3.10.1 Consultation and Ethical Clearance

The CEO of the chosen health care facility was consulted. Permission was requested to conduct this study on the premises (appendix K). The head of the internal medicine department was consulted, to discuss the aims, possible benefits and sample frames for this study. He suggested the researcher discuss the study with his two physicians on staff, who had a special interest in rheumatology. Having obtained permission from the CEO (appendix L) to conduct the study, the researcher, being the Physiotherapy Manager at that health care facility, then sought permission from her direct supervisor, i.e. the Medical Manager. Permission to conduct the study was granted by all parties consulted, providing ethical clearance and permission from Department of Health head office was obtained.

Ethical clearance (Ref: BE194/11) was obtained from the Biomedical Research Ethics Committee at the University of KwaZulu-Natal (appendix M). Permission was subsequently granted by the Health Knowledge and Research Management Department (research division of the department of health's head office) on 27 June 2012 (appendix N).

Subjects were informed of the purpose of the study, taking care not to bias the subjects by indicating the researcher's aim of the study. The information sheet (appendices C or D) explaining the purpose of the study and the potential risks and benefits were given to each subject.

3.10.2 Safety Precautions

The risk of sustaining thermal burns during the study was minimized by:

- stringently applying the exclusion criteria;
- making sure equipment was serviced by the equipment agent before the study commenced;
- checking the temperature of the wax bath, the hydrocollator, and the insulated heat packs with a thermometer at the onset of the treatment session and again, immediately prior to application and
- directly observing the subjects during the heat applications.

The subjects were informed of the anticipated sensation of heat and were encouraged to report any adverse sensations to the researcher immediately. The risk of sustaining a burn could therefore be equated to the risk faced in everyday life. In the unlikely event of a thermal burn being sustained, ice packs were available to be immediately applied to the affected area to limit the extent/severity of the burn and the subject would have been taken to the casualty department of the health care facility. No thermal burns were sustained during this study.

Since subjects spent approximately two hours in the department, refreshments were provided. The pre- and posttest assessments were approximately 30 minutes apart which helped limit fatigue.

3.10.3 Confidentiality Issues

Subjects were assured of raw data confidentiality. However, subjects were given the option of having their data collection sheets attached to their physiotherapy outpatient files to monitor progress if they so chose. Furthermore, subjects were assured that their identity would not be revealed in any information presented or

published, as they would be grouped together with other subjects. Voluntary participation was emphasized and subjects were assured they could withdraw from the study at any time if they so chose without any negative impact on future physiotherapy treatment. Each subject was asked to sign a consent form prior to commencing the study (appendices E or F).

3.10.4 Reliability and Validity

The research setting and procedure was kept constant for all subjects. The instrumentation used in this study were validated tools in clinical practice and had a high test-retest reliability as noted in section 3.6.

Reliability was enhanced by using the same furniture, starting positions, intervention procedures and instructions and data gathering instruments on all subjects. All measurements were taken and recorded by the same independent rater to prevent inter-rater bias. The researcher applied the interventions to all subjects ensuring that the same procedure was followed with each subject, minimising variations in treatment applications. All subjects were treated and rated at approximately the same time of day i.e. midmorning between 10h30 and 12h30.

External validity threats were minimised by ensuring the Hawthorne effect was minimised and a single variable was manipulated in each study group. Threats to internal validity were minimised by the independent rater taking the posttest measurements immediately after the intervention to reduce the chance of extraneous variables influencing the outcome.

3.11 Summary

This pretest-posttest study investigated if paraffin wax therapy produced more effective outcomes than moist heat therapy in the rheumatoid hand. The study took place at a regional health care facility in Kwazulu-Natal after ethical clearance and permission was obtained from the University of Kwazulu-Natal Biomedical Ethics Research Committee and the Department of Health respectively. Subjects were identified via purposive sampling at the outpatient clinics and referred to physiotherapy where they were invited to participate in the study. All subjects were

informed of the purpose of the study and signed the relevant consent forms prior to participating in the study. Subjects were then randomized into the two test groups i.e. the wax group and the heat group where they received the respective intervention. Pre- and posttest measurements were taken by an independent rater in all subjects. Data generated from the study was analysed by a statistician from the College of Health Sciences at UKZN.

CHAPTER 4

Results

4.1 Descriptive Analysis

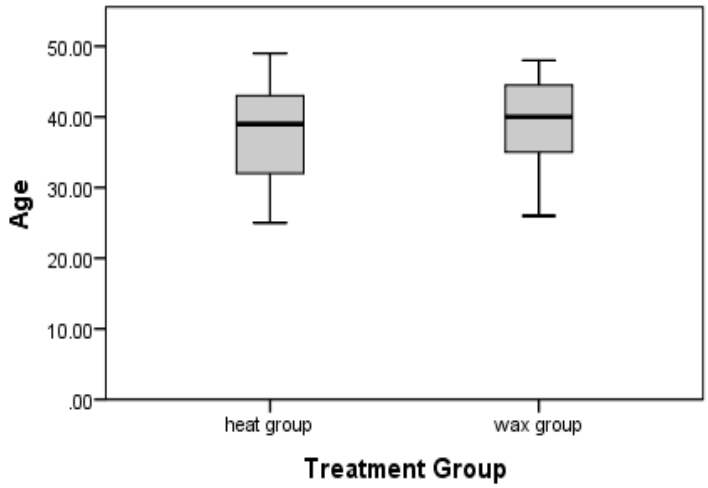
4.1.1 Demographic Information

The subjects were randomized into two groups. There were 56 subjects in the wax group and 59 subjects in the heat group. All subjects were in stage II of rheumatoid arthritis and participated in the study on the day of referral to physiotherapy to avoid changes in disease staging. The sample comprised African females and Indian male and females. Indian females constituted the majority. There were no Coloured (mixed race) or Caucasian subjects. The majority of the subjects were right hand dominant.

Table 3: Patient Demographics

	ETHNICITY				GENDER		DOMINANCE	
	INDIAN		AFRICAN		MALE	FEMALE	RIGHT	LEFT
WAX GROUP n = 56	49		7		16	40	51	5
	Male	Female	Male	Female				
	16	33	0	7				
	88%		12%		29%	71%	91%	9%
HEAT GROUP n = 59	42		17		13	46	54	5
	Male	Female	Male	Female				
	13	29	0	17				
	71%		29%		22%	78%	92%	8%
Total Sample n = 115	79%		21%		25%	75%	91%	9%

Figure 2: Box plot for age



In the above box plot, ages for the heat and wax groups are presented separately. In the heat group the lower age limit was 25 years and the upper limit was 49 years. The median age was 39 years indicated by the line within the shaded portion of the box and 50% of subjects fell within the range of 32 to 43 years as indicated in the shaded portion of the box.

In the wax group, the lower age limit was 26 years and the upper limit was 48 years represented by the whiskers of the box plot. As indicated above, the median age was 40 years, represented by the line within the shaded box and 50% of subjects fell within the range of 35 years to 44 years, indicated by the lower and upper limits of the shaded box.

As is evident when comparing both boxes, most subjects fell within the ages of 32 to 48 years in the entire sample. The youngest subject in the total sample was 25 years old, and the oldest, 49 years old. The median ages for both groups were similar: heat group - 39 years and wax group - 40 years. Hence it can be concluded that both groups were similar in age profile.

4.1.2 Pain

Pain was assessed using a numerical pain rating scale (NPRS) from 0 to 10, with 0 denoting no pain, and 10 the worst pain experienced by the subject. Tables 4 and 5 indicate the pre- and posttest NPRS scores for both groups.

Table 4: Pretest and Posttest scores: Wax Group

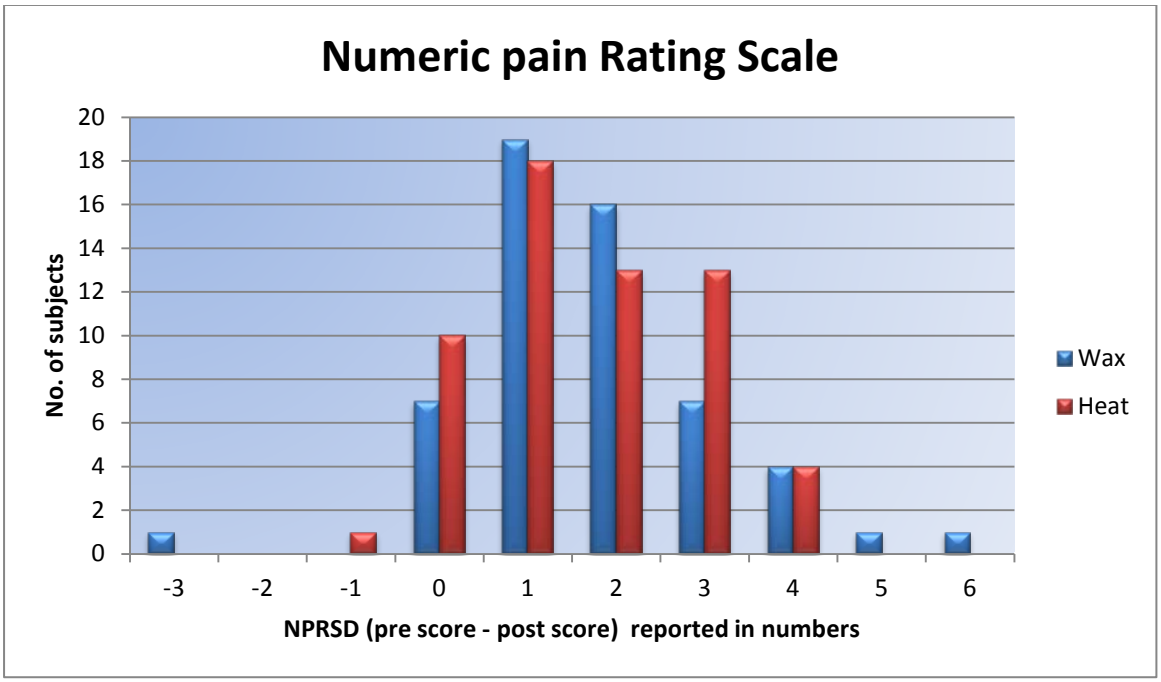
WAX GROUP	LOWEST	HIGHEST	MEDIAN
PRETEST SCORES	$^{3}/_{10}$	$^{9}/_{10}$	$^{6}/_{10}$
POSTTEST SCORES	$^{0}/_{10}$	$^{8}/_{10}$	$^{4.5}/_{10}$

Table 5: Pretest and Posttest scores: Heat Group

HEAT GROUP	LOWEST	HIGHEST	MEDIAN
PRETEST SCORES	$^{2}/_{10}$	$^{9}/_{10}$	$^{7}/_{10}$
POSTTEST SCORES	$^{1}/_{10}$	$^{9}/_{10}$	$^{5}/_{10}$

The tables above indicate that the lowest and highest scores were similar in both groups. Pretest scores minus the posttest scores, gave us the change in pain rating (ranging from -3 to 6). A positive score indicates a decrease in pain following the intervention, whereas a negative score indicates an increase in pain post intervention. The absolute frequency distribution of pretest minus posttest scores are illustrated in Graph 1.

Graph 1: Absolute frequency distribution of pretest minus posttest NPRS scores



Both modalities helped alleviate pain, as is evident from Graph 1. The difference in pre- and posttest scores in majority subjects ranged between one and three unit changes in both groups.

Table 6: Pain pretest minus posttest scores

NPRS Difference						
Treatment Group	Mean	N	Std. Deviation	Median	Minimum	Maximum
Heat group	1.6525	59	1.22564	2.0000	-1.00	4.00
Wax group	1.7143	56	1.44869	2.0000	-3.00	6.00
Total	1.6826	115	1.33333	2.0000	-3.00	6.00

The mean difference between pretest and posttest ratings in the heat and wax groups was similar. The highest change in pre- and posttest pain rating was noted in the wax group where one subject reported a pretest rating of $^{6}/_{10}$ and a posttest rating of $^{0}/_{10}$.

Table 7: Improvement in Pain

Improvement in Pain				
	YES	NO	INCREASE	TOTAL
WAX	48 (85.7%)	7 (12.5%)	1 (1.8%)	56
HEAT	48 (81.3%)	10 (17%)	1 (1.7%)	59
TOTAL	96 (83.5%)	17 (14.8%)	2 (1.7%)	115

The majority of the subjects in both groups reported an improvement in pain following the interventions. Only 2 subjects reported an increase in pain following the interventions, one in the wax group (pretest rating $^{3}/_{10}$, and posttest rating $^{6}/_{10}$) and one in the heat group (pretest rating $^{4}/_{10}$ and posttest rating $^{5}/_{10}$).

4.1.3 Grip Ability Test (GAT)

Pretest time minus posttest time gave us a score indicating the difference in time taken to complete the tasks (ranging from -3 to 9). A positive score indicates a decrease in time taken to complete the task following the intervention (regarded as an improvement), a score of 0 is indicative of no change between pre- and posttest times and a negative score indicates an increase in time taken to complete the task post intervention. Scores of 0 and below are referred to as “no improvement.”

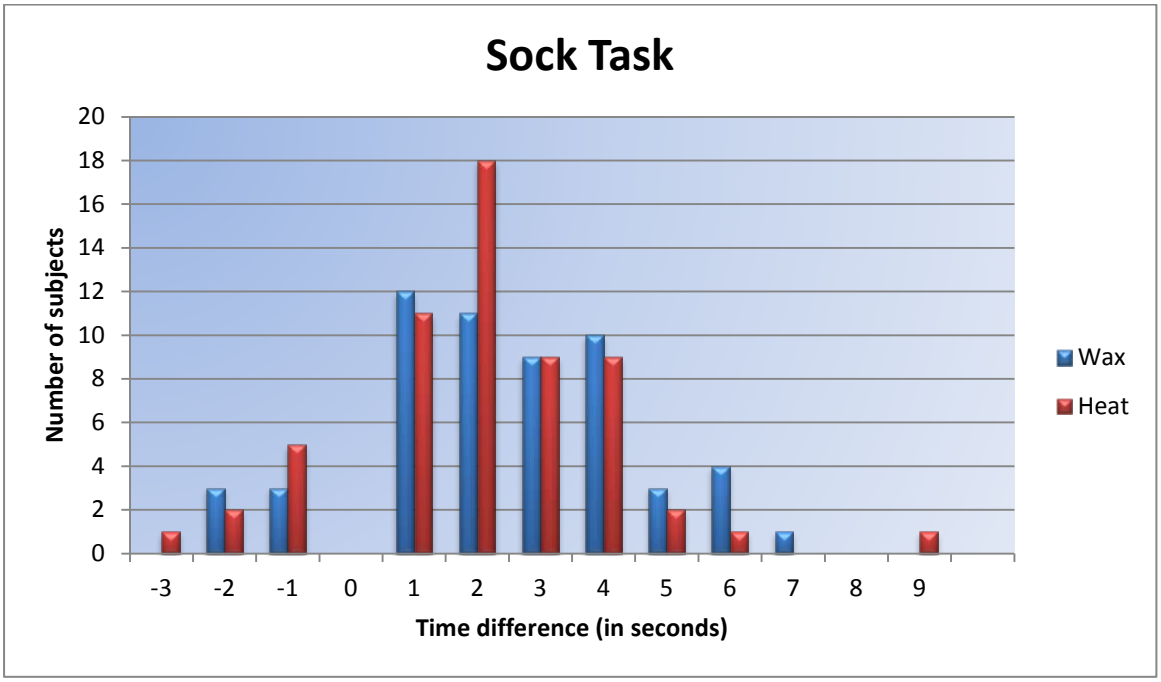
4.1.3.1 Sock task

As is evident from Table 8, majority of subjects in the sample completed the task in less time, post interventions, indicating an improvement in the task. The two groups were similar in this task.

Table 8: Improvement in Sock Task

Improvement in Sock Task			
	YES	NO	TOTAL
WAX	50 (89%)	6 (11%)	56
HEAT	51 (86%)	8 (14%)	59
TOTAL	101 (88%)	14 (12%)	115

Graph 2: Absolute frequency distribution of time differences in sock task



The highest change in pre- and posttest scores for this task was 9 seconds, noted in the heat group (15 seconds pretest and 6 seconds posttest). As is evident from the absolute frequency graph (Graph 2), most subjects completed the tasks in less time after the wax and heat applications. The highest frequency distribution was noted at time differences of 1 and 2 seconds. 23 subjects displayed a time difference of 1 second between pre- and posttest times (12 in the wax group and 11 in the heat group), and 29 subjects displayed a time difference of 2 seconds (11 in the wax group and 18 in the heat group). The mean and median values of the time difference

for both groups are reflected in Table 9 below. The wax group had a slightly higher mean time difference than the heat group.

Table 9: Time difference (in seconds) in sock task

Sock Task Difference						
Treatment Group	Mean	N	Std. Deviation	Median	Minimum	Maximum
Heat group	2.0678	59	2.02454	2.0000	-3.00	9.00
Wax group	2.4286	56	2.13079	2.0000	-2.00	7.00
Total	2.2435	115	2.07572	2.0000	-3.00	9.00

4.1.3.2 Paper clip task

Table 10 indicates that majority of the subjects in the sample took less time to complete the task after the interventions indicating an improvement.

Table 10: Improvement in Paper Clip Task

Improvement in Paper clip Task			
	YES	NO	TOTAL
WAX	47 (84%)	9 (16%)	56
HEAT	41 (69%)	18 (31%)	59
TOTAL	88 (77%)	27 (23%)	115

The highest change in pre- and posttest times for this task was 4 seconds, noted in both the wax and heat groups. The highest frequency distribution, as displayed in Graph 3, was again noted at time differences of 1 and 2 seconds. 44 subjects displayed a time difference of 1 second between pre- and posttest times (29 in the wax group and 15 in the heat group), and 37 subjects displayed a time difference of 2 seconds (13 in the wax group and 24 in the heat group).

Graph 3: Absolute frequency distribution of time differences in paper clip task

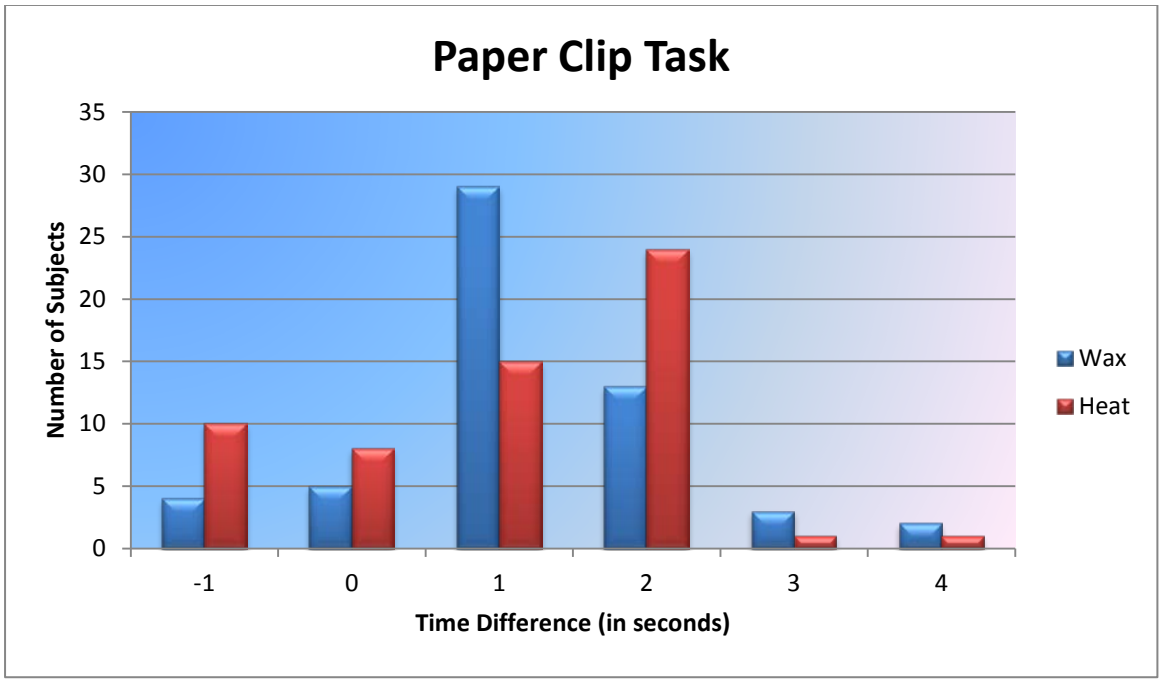


Table 11: Time difference (in seconds) paper clip task

Paper Clip Task Difference						
Treatment Group	Mean	N	Std. Deviation	Median	Minimum	Maximum
Heat group	1.0169	59	1.21046	1.0000	-1.00	4.00
Wax group	1.1607	56	1.14060	1.0000	-1.00	4.00
Total	1.0870	115	1.17403	1.0000	-1.00	4.00

The mean time differences between both groups in the paper clip task were similar as reflected in Table 12 above.

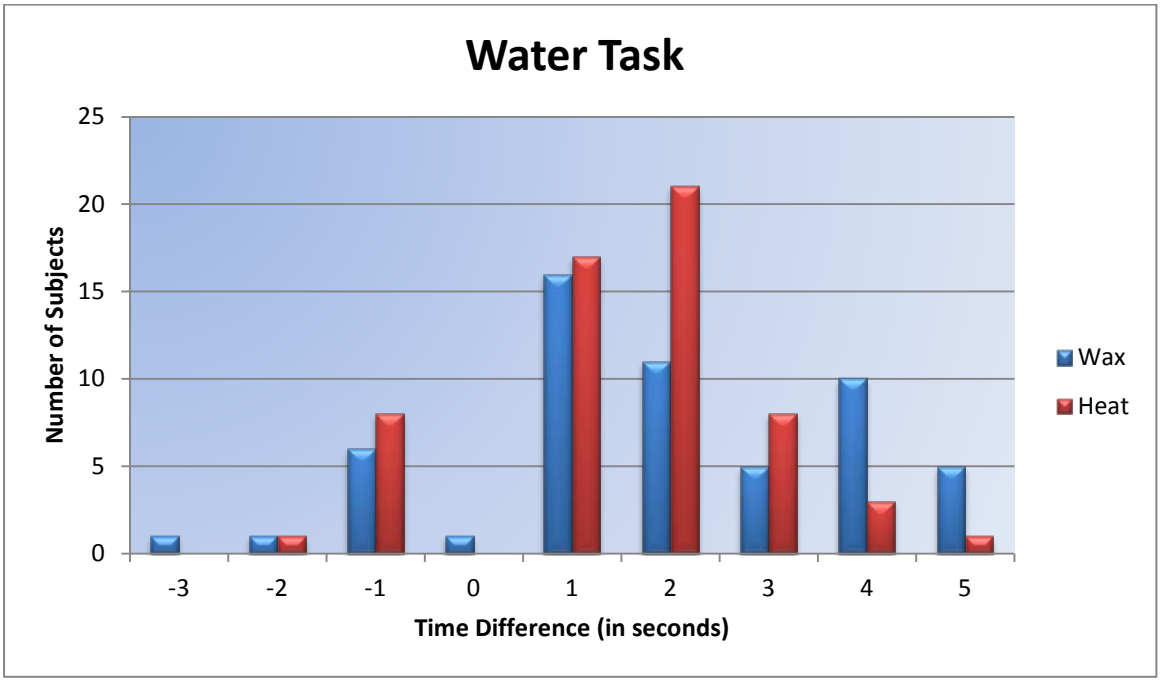
4.1.3.3 Water task

Table 12 reflects that majority of the sample completed the task in less time following the wax and heat applications indicating an improvement.

Table 12: Improvement in water task

Improvement in Water Task			
	YES	NO	TOTAL
WAX	47 (84%)	9 (16%)	56
HEAT	50 (85%)	9 (15%)	59
TOTAL	97 (84%)	18 (16%)	115

Graph 4: Absolute frequency distribution of time differences in water task



The highest difference in pre- and posttest scores for this task was 5 seconds, which was noted in both groups, 5 in the wax group and 1 in the heat group. Once again, majority of the subjects completed the task with a time difference of 1 and 2 seconds as is evident in the absolute frequency graph (Graph 4). 33 subjects displayed a time difference of 1 second between pre- and posttest times (16 in the wax group and 17 in the heat group), and 32 subjects displayed a time difference of 2 seconds (11 in the wax group and 21 in the heat group).

Table 13: Time difference (in seconds) water task

Water Task Difference						
Treatment Group	Mean	N	Std. Deviation	Median	Minimum	Maximum
Heat group	1.5085	59	1.44285	2.0000	-2.00	5.00
Wax group	1.9107	56	1.92851	2.0000	-3.00	5.00
Total	1.7043	115	1.70126	2.0000	-3.00	5.00

The wax group mean time difference was slightly higher than the heat group in this task as reflected in Table 13 above.

4.1.4 Joint Range of Movement

A total of 28 goniometric measurements were taken on the hands of each subject (a total of 3220 readings in the entire sample). Due to the large amount of data generated for this variable, descriptive tables of results of all goniometric measurements can be found in appendices O and P. Between 45% and 59% of subjects showed a 5^0 improvement of flexion at the MCPJ's and PIPJ's bilaterally in both groups. Improvement was not as marked at the DIPJ's where majority of subjects showed no change in ROM post intervention application in both groups.

Table 14: Joint range of movement changes

	MCPJ		PIPJ		DIPJ	
	Nil change	+ 5^0	Nil change	+ 5^0	Nil change	+ 5^0
HEAT	38.7%	45.7%	38.2%	46.4%	53%	34.3%
WAX	19%	57.6%	23.1%	58.6%	53%	35.5%

Analysis of the results will be discussed under hypothesis testing (4.2.2).

4.1.5 Hand Span

A composite measure of finger abduction and thumb web stretch (hand span) was obtained by taking a linear measure of the distance (in millimetres) between the

midpoint of the tips of the thumb and little finger from a tracing of the hand with all digits abducted.

Table 15: Hand span descriptive

Treatment Group		Right hand span difference	Left hand span difference
Heat group	Mean	2.5593	2.8305
	N	59	59
	Std. Deviation	5.68504	3.53871
Wax group	Mean	4.7321	4.1429
	N	56	56
	Std. Deviation	2.88249	3.67512
Total	Mean	3.6174	3.4696
	N	115	115
	Std. Deviation	4.65207	3.64985

As is evident from Table 15 above, both heat and wax resulted in improved hand span bilaterally post intervention. At a glance, it appears that the wax group has a greater mean difference than the heat group. This implies that wax produced a greater improvement in hand span bilaterally than heat.

4.2 Hypothesis Testing

Table16 reflects a summary of the response variables that were measured before and after receiving the wax or heat interventions.

Table 16: Response variables measured during the experiment

Variable	Description
NPRS	Numeric pain rating on scale 0 to10
Sock	Time taken to put sock into non-dominant hand using dominant hand
Paperc	Time taken to put paper clip into an envelope.
Pour	Time taken to pour water from 1 litre jug into 200 ml. cup.
MCPJ	Movement in the knuckles of each finger
IPJ	Movement in the second joint of the thumb
OPP	Measure of ability to connect little finger and thumb
PIPJ	Middle joint for all fingers except the thumb
DIPJ	Last joint for all fingers except the thumb
HANDSP	Distance from little finger to thumb with hand open

For each of the variables MCPJ, IPJ, OPP, PIPJ, DIPJ and HANDSP measurements were taken on both the left (L) and right (R) hands. MCPJ was measured on each of the five fingers (thumb-TH, index-I, middle-M, ring-R and little-L); IPJ and OPP were measured for the thumb only; and PIPJ and DIPJ were measured for all the fingers except the thumb. The difference between the pre- and post-measurements were calculated for each of the above mentioned variables.

For NPRS, sock, paperc and pour, the variable measuring the difference between the pre- and post-measurement is denoted by adding a D to the variable name e.g. NPRSD = NPRS (pre) – NPRS(post).

For each of the 5 measurements of finger joints the format of the variable name is (finger)(side)(variable), where “finger” is TH, I, M, R or L , “side” L or R and “variable” MCPJ, IPJ or OPP when the finger is the thumb and MCPJ, PIPJ or DIPJ when the finger is other than a thumb e.g. THRMCPJ refers to the MCPJ measurement of the right thumb, RLDIPJ refers to the DIPJ measurement of the left ring finger.

The hand span for the left and right hands are referred to as HANDSPL and HANDSPR respectively. For each of the finger joint variables and HANDSP a D is

added to the variable name to indicate a difference between the post and pre measurements.

The explanatory variables used in the study are intervention (heat or wax), gender and age. The dominant hand (left or right) was also recorded but due to too few left hand dominant patients (5 out of 115) this variable was not used.

4.2.1 Numeric Pain Rating Scale and Grip Ability Test

4.2.1.1 Success of Interventions

In order to determine if the interventions were successful on pain rating and the grip ability test, the pretest mean must be greater than the posttest mean, i.e. the mean of the difference between the pretest and posttest measurements will be greater than 0, indicating that the task was completed in less time after the intervention. Hotelling's T-square test was performed to test whether the means of NPRSD, sockD, papercD and pourD are jointly all equal to 0 versus the alternative that at least one of these means is not equal to 0. The test revealed $T^2 = 392.4955$ with a p-value of 2.2×10^{-16}, which suggests that at least one of the means is not equal to 0.

Table 17: Individual tests for zero mean for NPRSD, sockD, papercD and pourD

	NPRSD	sockD	papercD	pourD
T	13.533	11.59	9.928	10.743
p-value	0	0	0	0

From the above table it is clear that all the means are significantly greater than 0 implying that both wax and heat therapy applications were successful in reducing pain and in improving grip ability.

4.2.1.2 Effects of intervention and age on the pre minus the posttest differences for the numerical pain rating scale and grip ability

Analysis of variance (ANOVA) tests were performed on NPRSD, sockD, papercD and pourD to determine the effects of treatment and age by using interventions (heat and wax) and age (≤36, 37 to 42, ≥43) as factors. The findings are reflected in Table 18 below:

Table18: Results of ANOVA tests for NPRSD, sockD, papercD and pourD versus intervention and age

Variable/Source		Intervention	Age	Intervention x Age
NPRSD	F	0.042	1.76	0.93
	p-value	0.838	0.177	0.398
SockD	F	0.936	0.231	2.065
	p-value	0.336	0.794	0.132
PapercD	F	0.354	0.496	1.305
	p-value	0.553	0.61	0.275
PourD	F	1.058	3.18	0.625
	p-value	0.306	0.045	0.537

Only the effect of age on pourD was significant at 5% level of significance with a p-value of 0.045.

Table 19: Mean for pre minus post differences for age categories

Age	PourD Mean
<=36	2.03
37-42	1.13
>=43	2

This suggests that there is no statistical significance between the wax and heat groups on the mean differences of the numerical pain rating scale and the grip ability tasks. Therefore there is no basis to reject the null hypotheses i.e. paraffin wax therapy and hand exercises is less effective in decreasing pain in patients with rheumatoid arthritis affecting the hands, when compared to patients receiving moist heat therapy and hand exercises; and paraffin wax therapy and hand exercises is

less effective in improving grip ability in patients with rheumatoid arthritis affecting the hands, when compared to patients receiving moist heat therapy and hand exercises.

Age, however, had a significant effect on the above mentioned variables, with the 37 to 42 age category showing a slightly less improvement than the ≤36 and ≥43 age categories.

4.2.2 Range of Movement

4.2.2.1 Success of Interventions

The variable THOPPD (thumb, opposition, difference) was excluded as the value for this was zero in 114 out of 115 subjects. Hotelling's T-square test was performed separately on the 14 left and right hand finger measurements respectively to ascertain if the treatments were successful i.e. to determine if the mean of the difference between the posttest and pretest measurements was greater than zero. If the posttest measurement was greater than the pretest measurement, a gain in range of movement is suggested, proposing that the invention improved the range of movement. The test revealed $T^2 = 725.9671$ with a p-value of 2.2×10^{-16}, for the left hand and $T^2 = 905.9823$ with a p-value of 2.2×10^{-16} for the right hand, both suggesting that at least one of the means is not equal to 0.

Table 20: Individual tests for zero mean for the left hand finger measurements

	THLMCPJD	THLIPJD	ILMCPJD	ILPIPJD	ILDIPJD	MLMCPJD	MLPIPJD
T	6.441	9.868	10.408	11.994	5.729	10.779	9.594
p-value	0	0	0	0	0	0	0
	MLDIPJD	RLMCPJD	RLPIPJD	RLDIPJD	LLMCPJD	LLPIPJD	LLDIPJD
T	5.052	10.568	8.564	4.869	10.98	6.173	9.634
p-value	0	0	0	0	0	0	0

Table 21: Individual tests for zero mean for the right hand finger measurements

	THRMCPJD	THRIPJD	IRMCPJD	IRPIPJD	IRDIPJD	MRMCPJD	MRPIPJD
T	3.074	7.693	10.753	11.2	8.641	11.962	11.878
p-value	0.003	0	0	0	0	0	0
	MRDIPJD	RRMCPJD	RRPIPJD	RRDIPJD	LRMCPJD	LRPIPJD	LRDIPJD
T	6.93	12.032	9.734	1.24	10.06	9.779	4.599
p-value	0	0	0	0.217	0	0	0

From the above tables 20 and 21, it is clear that all the means are significantly greater than 0 thus implying that the treatments were successful. The hypothesis of a zero mean cannot be rejected for only one of the variables (RRDIPJD). The main reason for this is that this variable contains an outlier (a value of -35). If the outlier is disregarded and the test repeated the t-statistic is 2.412 with a p-value of 0.017 which does indicate that the hypothesis of zero mean can be rejected. Therefore both heat and wax significantly increased the range of movement at the intrinsic hand joints post intervention.

4.2.2.2 Effects of intervention and age on the post minus the pretest differences for joint range of movement

4.2.2.2.1 Left hand

A Multivariate ANOVA (MANOVA) was performed on the post minus the pretest differences for the fingers of the left hand. This test suggested that the effect of the interventions is the most significant of the effects.

Table 22: Results of MANOVA tests for left hand finger measurements versus intervention and age

Factor	Variable	F	p-value
Intervention	THLMCPJD	7.246	0.008
Intervention	THLIPJD	35.369	0
Intervention	LLMCPJD	4.034	0.047
Intervention	LLPIPJD	12.211	0.001
Age	RLPIPJD	6.434	0.002

Significant improvements in the post minus the pretest scores were found in the above mentioned variables, all with p-values ≤0.05 making it significant at the 5% level of significance. It can therefore be suggested that the interventions significantly improved the joint range of movement of the left thumb MCPJ and IPJ, and the left little finger MCPJ and PIPJ.

Table 23: Significant intervention effects for left hand finger measurements

Treatment	THLMCPJD	THLIPJD	LLMCPJD	LLPIPJD
Heat	2.37	2.12	2.88	2.63
Wax	5.89	6.61	4.2	5.45

The wax intervention resulted in significantly larger differences for the left thumb MCPJ and IPJ and the left little finger MCPJ and PIPJ differences as opposed to the heat intervention thus supporting the hypothesis that the wax intervention is more effective than the heat intervention in improving joint range of movement.

Table 24: Significant age effects for left hand finger measurements

Age	RLPIPJD
<=36	3.55
37-42	2.13
>=43	5.95

The difference is the smallest for the 37-42 age group and the largest for the >=43 age group.

4.2.2.2.2 Right hand

A Multivariate ANOVA (MANOVA) was performed on the data. This test suggested that the intervention effect is the most significant.

Table 25: Results of ANOVA tests for right hand finger measurements versus intervention and age

Factor	Variable	F	p-value
Intervention	THRIPJD	6.566	0.012
Intervention	IRPIPJD	4.182	0.043
Intervention	MRDIPJD	5.863	0.017
Intervention	LRPIPJD	6.517	0.012
Intervention × age	MRMCPJD	4.363	0.015

Significant improvements in post minus pretest scores were found in the above variables, all with p-values ≤0.05 making it significant that the 5% level of significance. It can therefore be suggested that the interventions significantly improved the joint range of movement of the right thumb IPJ, the right index finger PIPJ, the right middle finger DIPJ, the right little finger PIPJ and the right middle finger MCPJ.

Table 26: Significant intervention effects for right hand finger measurements

Treatment	THRIPJD	IRPIPJD	MRDIPJD	RRPIPJD	LRMCPJD	LRPIPJD	LRDIPJD
Heat	1.86	3.73	1.61	5	3.81	2.63	1.78
Wax	3.66	5.45	3.3	3.48	5.27	4.38	0.8

The wax intervention resulted in significantly larger differences for the right thumb IPJ, right index PIPJ, right middle DIPJ and right little finger MCPJ and PIPJ measurements. For the right ring finger PIPJ and right little finger DIPJ, heat resulted in significantly larger differences.

Table 27: Significant intervention × age effects for right hand finger measurements

Age	Intervention	MRMCPJD
≤ 36	Heat	5
≤ 36	Wax	3.33
37-42	Heat	2.39
37-42	Wax	5.59
≥ 43	Heat	4.06
≥ 43	Wax	4.76

For age > 36 the wax mean seems to be greater than the heat mean, while for age ≤ 36 the opposite is true.

4.2.2.3 Differences between the left and right hands

When Hotelling's T-square test was performed to test whether the means of the 14 left minus right hand differences are simultaneously equal to 0, it was found that $T^2 = 29.5882$ with a p-value of 0.008692. Hence, not all the means are equal to 0, i.e. there were differences between the left and right hand means for some variables.

Table 28: Individual tests for zero means of differences between left and right hand measurements

	t	p-value
THMCPJ	-2.439	0.016
THIPJ	-3.111	0.002
RMCPJ	2.348	0.021
LDIPJ	-2.122	0.036

In the table 28 a positive entry in the t column indicates that the mean of the left hand difference is significantly greater than that of right hand difference. A negative sign indicates the opposite (the mean of the right hand difference is significantly greater than that of left hand difference).

4.2.2.3.1 Effects of intervention and age on differences between left and right hand

Table 29: Significant effects of intervention and age on differences between left and right hands

Source	Variable	F	p-value
Intervention	THIPJDD	8.218	0.005
Intervention	IPIPJDD	4.901	0.029

An ANOVA conducted to examine the effects of interventions and age on differences between the right and left hands found a significant effect of intervention only with p-values ≤ 0.05 on the thumb IPJ difference and index finger PIPJ difference. There were no significant effects of intervention found on the other digits. Age did not have any significant effects on the variables tested.

Table 30: Significant intervention effects for differences between left and right hands

Intervention	THIPJDD	IPIPJDD
Heat	-0.25	-0.93
Wax	-2.95	1.34

In absolute value the wax difference is greater than the heat difference. This supports the hypothesis that wax therapy is more effective than moist heat therapy.

4.2.3 Hand span

4.2.3.1 Success of Interventions

Intervention success was tested using Hotelling's T-square test to test whether the means of the left and right hand span differences are simultaneously equal to 0, it was found that $T^2 = 113.08$ with a p-value of 2.2×10^{-16}. Hence, not both the means are equal to 0, i.e. the interventions have improved the hand span in at least one of the hands.

Table 31: Individual tests for zero means for the left and right hand span

	t	p-value	Mean Difference
HANDSPRD	8.339	0	3.617
HANDSPLD	10.194	0	3.47

Both the mean differences are significantly greater than 0 indicating that both interventions successfully improved hand span post intervention.

4.2.3.2 Effects of intervention and age on pre minus post differences for hand span

Table 32: Significant effects of interventions on left and right hand span differences

Source	variable	F	Sig.
Intervention	HANDSPRD	6.336	0.013
Intervention	HANDSPLD	3.257	0.074

An ANOVA performed on the data showed that intervention alone had a significant effect on the hand span differences. The interventions were significant at the 5% level of significance.

Table 33: Intervention means for left and right hand span differences

Intervention	HANDSPRD	HANDSPLD
Heat	2.56	2.83
Wax	4.73	4.14

For both hands the wax mean difference is greater than the heat mean difference thus supporting the hypothesis that paraffin wax therapy is more effective in improving joint range of movement, when compared to patients receiving moist heat therapy.

4.2.3.3 Differences between left and right hand span

The mean of the difference between the left and right hand span differences was not found to be significantly different from 0 (p-value = 0.695). Hence there was no difference in hand span between the right and left hands.

4.3 Summary

The results section presented the effects of the heat and wax interventions on pain, grip ability and range of movement of the finger joints. A descriptive overview of the changes in pain rating and grip ability post intervention was presented. Clinically both groups produced an improvement in the measured variables. The results also delved into the effectiveness of the interventions on the dependent variables and investigated the effects of the interventions and age on pain; grip ability and joint range of movement mean differences. The hypothesis that paraffin wax was more effective than heat in improving joint range of movement was supported by the results for particular joints. However there was no basis to reject the null hypotheses that paraffin wax therapy and hand exercises will be less effective in decreasing pain in patients with rheumatoid arthritis affecting the hands, when compared to patients receiving moist heat therapy and hand exercises; and paraffin wax therapy and hand exercises will be less effective in improving grip ability in patients with rheumatoid arthritis affecting the hands, when compared to patients receiving moist heat therapy and hand exercises.

CHAPTER 5

Discussion

The aim of this study was to compare the effects of paraffin wax therapy and moist heat therapy in the management of patients presenting with stage 2 hand rheumatoid arthritis. The study sought to evaluate the effect of the interventions on pain, joint range of movement and grip ability.

5.1 Sample

Data was collected at a provincial regional/district health care facility in Chatsworth. Chatsworth is a historically Indian township, situated 12 kilometres south-west of Durban (Subramoney, 1994). It has a population of 196,580 (4,600.87 per km^2) and an area of 42.73 square kilometres. According to 2011 census, people of Indian or Asian descent made up 60.03% of the population of Chatsworth. Black Africans made up 38.15% of the population. This can account for Indians making up 79% of the sample and the absence of Caucasian and Coloured subjects from the study. This sample lacked diversity due to the location of the research setting. The use of purposive sampling precluded obtaining a larger general sample which could have enabled comparisons between different race groups.

The sample consisted mainly of females (75%). This is consistent with the epidemiology of RA which has a female to male ratio of 2 to 4: 1 (Khurana and Berney, 2005). Most subjects fell within the range of 32 years of age to 44 years (50% in each group). Surveys on the onset of RA in developing countries shows that the mean age of onset of RA in Black South Africans is 36.6 years and 44.2 years in Caucasian South Africans (Mody and Cardiel, 2008). The age range found in the study population is in keeping with this finding. There were no statistics on the prevalence of RA in the South African Indian population for comparison. Ninety-two percent of subjects were right hand dominant as was anticipated, as only 8 to 15% of the general population is left hand dominant (Eric, Koprivcic, Vucinic, Radic, Krivokuca, Leksan and Selthofer, 2011).

5.2 Pain

According to Ahlstrand et al (2012), pain is the symptom of RA that most patients want alleviated. It impacts negatively on functional ability and independence. This study found that both moist heat and paraffin wax therapies improved pain in 83.5% of the subjects in keeping with assertions by Buljina et al (2001) that superficial heating modalities improved pain in the rheumatoid hand. Hotelling's T-square test on the mean of the difference between the pre and posttest pain ratings for both groups confirmed that both modalities were effective in relieving pain.

The majority of subjects (85.7%) in the wax group reported an improvement in pain as opposed to 81.3% in the heat group. Analysis of variance testing on NPRS difference scores between the wax and heat groups showed no statistical significance between the two groups. The hypothesis that paraffin wax is more effective in relieving pain than moist heat therapy can therefore not be supported by this study.

Anecdotal feedback of patients achieving greater pain relief with paraffin wax than moist heat was not supported by this study. This warrants further study into the effects of paraffin wax on pain relief. A more comprehensive tool such as the McGill Pain questionnaire which is a self-report measure of pain, assessing the quality and intensity of pain (Breivik, Borchgrevink, Allen, Rosseland and Romundstad, 2008) can be used to assess pain as this is the major complaint of RA affecting all spheres of the patient's life (Dedeoglu, Gafuroglu, Yilmaz and Bodur, 2013).

Whilst there was no statistical significance, the findings have clinical significance in that both interventions produced a similar reduction in pain. Majority of subjects reported a mild improvement in pain rating (mean difference of 1.7 units in wax group and 1.6 units in the heat group). Even though previous studies by Ayling and Marks (2000) reiterated the immediate improvement in pain symptoms following paraffin wax application, the degree of pain relief was not ascertained hence no comparison can be made with this study.

Two subjects (1.7%) reported an increase in pain following the interventions. An increase in pain and tenderness following heat applications can be attributed to aggravation of acute inflammation or skin sensitivity (Ayling and Marks, 2000).

Stringent application of the inclusion and exclusion criteria ensured that both heating modalities were safely applied to all subjects. Patients with acute inflammation were excluded from the study. The increase in pain post intervention could be attributed to skin sensitivity even though sensation (light touch, pin prick, hot and cold sensation) was tested on all subjects prior to inclusion in the study. A review of literature by the researcher did not yield any adverse effects of moist heat and paraffin wax therapies, if general precautions for heating modalities and contraindications are heeded. No adverse effects occurred during this study.

5.3 Joint range of movement

The thumb MCPJs and IPJs together with the finger MCPJs, PIPJs and DIPJs were measured with a metal short arm goniometer. Thumb opposition was omitted from the analysis as 114 out of 115 subjects had a zero reading for this variable. Hotelling's T-square test on the mean differences of the post minus pretest ROM measurements for the 14 joints on each hand showed an improvement in the overall ROM after the intervention. This suggests that both heat and wax successfully improved joint mobility. This finding may reinforce previous studies by Kumamoto, Ito, Kubota, Yamamoto, Abe and Fujiwara, (2006) who found that heat modalities improved muscle plasticity and tendon extensibility thereby improving ROM.

The active hand exercise programme which was performed after the wax and moist heat applications may have also contributed to the improvement in joint ROM. Wessel (2004) recommended active hand exercises to reduce immediate stiffness and maintain joint mobility as was included in the procedure of this study. A shortcoming of this study is that the specific effect of exercises on the measured parameters was not taken into account. The study focussed specifically on the effect of heat and wax applications and did not factor the role that exercises could have contributed to the improved mobility and pain relief in the final outcome.

A multivariate ANOVA (MANOVA) on the ROM differences suggested that the interventions produced significant changes in ROM in four joints in each hand ($p \leq 0.05$). Overall, wax therapy produced significantly larger ROM differences in 25% of joints whereas moist heat therapy produced a significantly larger difference in 4%

of joints. This result suggests wax was more effective than heat, thus supporting the hypothesis that paraffin wax therapy will be more effective than moist heat therapy in improving joint ROM. The significant differences that were noted between the two groups did not follow any specific pattern. Even though both modalities improved ROM over all, significant differences between heat and wax applications were noted in only four joints in each hand suggesting limited differences in efficacy between the two modalities. Even though limited significant differences were found between the effects of heat and wax, the findings of this study were in keeping with assertions by Ayling and Marks (2000) that paraffin wax reduced hand stiffness in subacute RA.

Significant changes were only noted in one joint (right little finger PIPJ) when analysing the effects that age had on ROM. This suggests that age did not have a major impact on the results obtained following the interventions. Similar conclusions can also be drawn when analysing of the effects of age together with the interventions, on ROM where the only notable finding was a significant mean difference in the right middle finger MCPJ for ages $\geq$ 36 years in the wax group. Hence it can be assumed that age did not have a major influence on the ROM following the wax and heat interventions.

Significant differences between the left and right hand ROM were found in only four joints. Wax therapy produced significant differences between the thumb IPJ and index finger PIPJ in the right and left hands. The isolated nature of the significant difference findings suggests little difference between the hands.

Even though a comparison of heat and wax yielded limited significant differences in ROM, the application of both heat modalities in this study were shown to clinically improve joint ROM. This may be attributed to increased elasticity of periarticular structures and the relief of muscle spasm as stated by Kavuncu and Evcik (2004). Their paper on physiotherapy in rheumatoid arthritis, advocated the use of heat before exercise for maximum benefit. However, they also found that superficial heating modalities had no beneficial effect on disease prognosis or radiological progression. This is also echoed by Hammond (2004) whose critical review of rehabilitation in RA found that heat applications only offer short term relief of symptoms such as joint stiffness.

5.4 Hand Span

Both interventions successfully improved hand span with a mean difference of 3.6 mm in the right hand and 3.4 mm in the left hand. Analysis of variance testing on the effects of the interventions and age on hand span differences showed a significant effect of the interventions on the right hand ($p=0.013$), with wax producing a greater mean difference than heat. Improvement in hand span can be attributed to increased pliability of soft tissues following the superficial heating effect of the wax. Improved extensibility of ligamentous structures may have also contributed to the increase in hand span. No significant differences were found between the left and right hand span values and age had no effect on hand span. The researcher did not find any comparable studies on the effects of heat or wax, specifically on hand span, therefore a direct comparison of data with other studies is not possible.

5.5 Grip Ability

The Grip Ability Test (GAT) is a modification of the Grip Function Test. It consists of an optimal representation of the different grip types and is sensitive to change in RA patients (Dellhag and Bjelle, 1995). The GAT was used as a measure of object manipulation and hand dexterity. Both paraffin wax and moist heat therapies were successful in improving grip ability in this study.

Analysis of variance testing on the differences between pre and posttest scores for each of the three tasks in the grip ability test showed no significant differences between the two groups. The hypothesis that paraffin wax therapy will be more effective in improving grip ability than moist heat therapy cannot be supported by this study. Clinical significance was however established as both modalities successfully improved grip ability post application.

There are no studies evaluating the effects of heating modalities on the grip ability test enabling comparisons with this study. The improved grip ability in this study can be attributed to improved hand dexterity due to the improved pain levels and joint ROM. This study can therefore postulate that superficial heating modalities improve grip ability in the RA hand.

5.6 Summary

This study sought to compare the effectiveness of paraffin wax therapy and moist heat therapy on pain, joint range of movement (including hand span) and grip ability in the rheumatoid hand. Both modalities were found to be effective in helping moderate pain, increase joint range of movement and improve grip ability, thus showing clinical significance, in keeping with studies by Welch et al (2002), Oosterveld and Rasker (1994), and Dellhag, Wollersjo and Bjelle (1992) which have reported the beneficial effect of heating modalities on ROM, pain and hand function in the rheumatoid hand.

Comparison of paraffin wax and moist heat yielded limited significant differences. When compared to moist heat, paraffin wax was found to significantly increase ROM in only 25% of joints and significantly improved the hand span of the right hand only. However, there were no significant differences between paraffin wax and moist heat on pain and grip ability.

Currently, there are no comparison studies available of wax and heat. This study suggests that paraffin wax produces marginally better results in relieving joint stiffness than moist heat therapy however; it is similar to moist heat in its therapeutic effects on pain and grip ability.

CHAPTER 6

Limitations, Recommendations and Conclusion

6.1 Limitations

Purposive sampling was used at a single health care facility making the sample representative of a single region only. The sample was not demographically diverse making it impossible to generalize the findings to a wider population. The subjects were all evaluated and included in the study on the day of referral to physiotherapy. This was often after the subject had already spent approximately five hours at the health care facility. This could have contributed to fatigue and suboptimal performance in the variables that were measured.

6.2 Recommendations for further studies

Recommendation for further studies could be based on methodological shifts and sample selection. This was a small study limited to 115 subjects. A larger study including more districts (urban and rural), health care facilities and the private sector, will generate a more diverse study population allowing results to be generalized.

A structured appointment system avoiding long delays prior to assessment and treatment of subjects would limit fatigue. A rest break incorporated in future studies after the exercise programme prior to the posttest measurements may also help to limit fatigue.

6.3 Conclusion

Therapeutic heat is widely used in RA patients for pain control, relief of muscle spasm and improved mobility (Kavuncu and Evcik, 2004). A commonly used modality, paraffin wax has been used since the early 1900s as an adjunct to conventional medical therapies to help manage the symptoms of RA in the hands and feet (Myrer, Johnson, Mitchell, Measom and Fellingham, 2010 and Harris, and Millard, 1955).

This study established that paraffin wax therapy and moist heat therapy are both effective in relieving pain, increasing joint range of movement and improving grip ability in the rheumatoid hand. When compared to moist heat therapy, paraffin wax was found to significantly improve joint ROM in 25% of joints and significantly improved hand span in the right hand. Whilst no statistical significance was found between the effects of paraffin wax and moist heat on pain and grip ability, these findings suggest clinical significance as both interventions produced a similar improvement in pain rating and grip ability.

The beneficial effects of the physiotherapeutic modalities of paraffin wax and moist heat on arthritic conditions of the hand are often based upon anecdotal evidence which does not stand the test of scientific scrutiny. This research has provided encouraging scientific evidence that such modalities have a positive therapeutic effect on the management of the hand with rheumatoid arthritis.

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Appendix A- Inclusion and Exclusion Criteria

INCLUSION AND EXCLUSION CRITERIA FOR THE STUDY:

A COMAPARTIVE STUDY OF THE EFFECTIVENESS OF PARAFFIN WAX AND MOIST HEAT THERAPIES ON PAIN, JOINT RANGE OF MOVEMENT AND GRIP ABILITY IN THE RHEUMATOID HAND

Inclusion Criteria:

- Confirmed diagnosis of RA (clinical presentation, positive RF, C-reactive protein test)
- Patients in stage II RA (subacute phase: no acute inflammation, moderate pain, tenosynovitis no obvious joint deformities or bony abnormalities)
- Males and females, all races
- Ages 18-50 years
- Ability to read, write and follow instructions

Exclusion Criteria

- Active/acute inflammation
- Stages I, III and IV RA

Stage I- acute pain, joint swelling and inflammation
Stage III – progressive joint deformities with soft tissue and bone involvement
Stage IV – joint instability, dislocation, spontaneous fusion or fibrous ankylosis

- Surgical intervention in the hands or wrists
- Sensory or vascular impairment of the hands and/or wrists
- Open wounds on the hands or wrists
- Inability to read, write and follow instructions

Appendix B – Researcher's Checklist

RESEARCHERS CHECKLIST

SUBJECT NO: __

	YES	NO
AGE (18-50 YEARS)		
CONFIRMED DIAGNOSIS (RF, C-prot, clinical presentation)		
SENSATION INTACT		
ACUTE INFLAMMATION/SWELLING		
BONY/JOINT DEFORMITIES		
VASCULAR IMPAIRMENT		
OPEN WOUNDS		
SURGICAL PROCEDURES TO DIGITS/WRIST		
CAN READ, WRITE AND FOLLOW INSTRUCTIONS		

SUBJECT IS ELIGIBLE FOR STUDY IF:

Answered **YES** to the following:

- Age
- Confirmed diagnosis
- Sensation intact
- Can read, write and follow instructions

And **NO** to the following:

- Acute inflammation/swelling
- Bony/joint deformities
- Vascular impairment
- Open wounds
- Surgical procedures to digits/hands

Appendix C - Patient Information Sheet (English)

Information Sheet

Paraffin wax therapy and moist heat therapy are physiotherapy treatments often used to treat hand complaints in patients affected with rheumatoid arthritis such as you.

Research Title
A comparative study to determine the immediate effects of paraffin wax and moist heat therapies on pain, joint range of movement and hand function in adults with rheumatoid arthritis affecting the hands.

Why participate in this study?
By participating, you will assist the researcher determine which of these two treatments is better in providing pain relief, relieving the stiffness in your hands and improving your strength. Pending the outcome of this study, your treatment regime will be adjusted to include the treatment found most effective in this study. This will result in you getting the most appropriate and effective physiotherapy management for your condition.

What is required of you?
If you meet the inclusion criteria and agree to participate, you will be required to attend a single session of physiotherapy in the physiotherapy department. Please note this session will be within normal working hours.

Procedure:
The session will last approximately two hours and will be structured as follows:

- Initial assessment (approximately 20 minutes):
  - Your level of pain will be rated.
  - The range of movement at the joints in your hands will be measured.
  - Your hand function will be assessed.

Following this initial assessment, you will be assigned to a treatment group. Depending on the group you are allocated to, you will receive one of the following treatments: paraffin wax therapy and hand exercises or moist heat therapy and hand exercises.

- Paraffin wax therapy:
  - Your hands will be immersed in warm molten wax and withdrawn 8 times, allowing it to cool briefly in between immersions.
  - Your hands will then be wrapped in plastic and towels and rested on a table.
  - The wax will remain on your hands for approximately 15-20 minutes and thereafter removed.

- Moist heat therapy
  - Your hands will be rested on a table.
  - A heat pack wrapped in towelling will be placed over your hands.
  - The heat pack will remain in place for 15-20 minutes and thereafter removed.

- Hand exercise programme
  - A hand exercise programme will be demonstrated to you.
  - You will be required to perform the demonstrated exercises under the supervision of a therapist.
  - The exercise programme will be of approximately 15 minutes duration.

After the hand exercise programme your pain, movement and function will be assessed again.

Are there any risks associated with this study?

The risk of sustaining thermal burns with heat therapy exists. However the possibility of this occurring is very low and can be equated to the risk faced by yourself in everyday life. The temperature of the wax and heat packs will be checked twice with a thermometer and kept at a therapeutic level. Furthermore your sense of touch and heat perception will be tested prior to treatment, thus making sure you will be able tolerate the treatments comfortably. You will also be constantly monitored by the therapist during the heat treatments, and any discomfort experienced by you can be reported immediately to the therapist.

Is there any benefit for you?

The treatment found most beneficial in this study will be included in your physiotherapy management regime. It will help relieve your symptoms more effectively and contribute to your better health. You will not receive any monetary benefits.

Assurance of confidentiality

Information collected from you (raw data) will be treated confidentially. The data collection sheet will include your age, race, and hand dominance. No other identifying information will be recorded. Only the researcher and statistician will have access to the data collection sheets. However, with your consent, this data collection sheet can be kept in your physiotherapy outpatient chart and used to monitor your progress; otherwise, these sheets will be kept by the researcher for 60 months and will then be destroyed by burning it. Any information presented or published will be grouped with other subjects, thus you cannot be identified. Your name will not be used in any part of this study.

Voluntary participation and withdrawal

Your participation in this study is completely voluntary. You have the right to withdraw from this study at any time if you so choose. If you choose to withdraw, your physiotherapy treatment outside this study will not be adversely affected.

Thank you considering participating in this study. Should you have any queries, please don't hesitate to contact the investigator.

Investigator: Ms. Thirusha Ramsudh, Physiotherapist, Tel: 031 459 6105
Email: ramsudht@gmail.com

Supervisor: Dr. T. Nadasan, Lecturer, Department of Physiotherapy
University of KwaZulu - Natal, Tel: 031 260 7817

Appendix D - Patient Information Sheet (IsiZulu)

Ishidi Eligukethe Imininingwane

Unyango lokuncibilika kukapharafini kanye nokushisa okuswakeme kuwunyango lukadokotela olujwayele ukusetshenziselwa ukwelashwa kwesandla esiphazamisekile ezigulini ezikhahlanyezwe ngukugula kwe-rheumatoid arthritis njengawe.

Isihloko socwaningo

Ucwaningo lokuqhathanisa oluphenyisisa imiphumela esheshayo yokuncibilika kukapharafini kanye nonyango lokushisa komswakama ebuhlungwini, ukunyakaza kwamalunga kanye nokusetshenziswa kwesandla kubantu abadala abane-rheumatoid arthritis ephazamisa ukusebenza kwezandla.

Kungani ubamba iqhaza kulolu cwaningo?

Ngokubamba iqhaza, uyosiza umcwaningi ukuba ahlonze ukuthi yiluphi unyango phakathi kwalezi zindlela ezimbili ezisetshenzisiwe olungcono ekudambiseni izinhlungu, ukuqeda inkwantshu ezandleni nokubuyisa amandla kuwena. Indlela othatha ngayo unyango iyoguqulwa ukuba ibandakanye unyango olutholakale lungcono kulolu cwaningo kuncike emiphumeleni yalolu cwaningo. Lokhu kuyogcina ngokuthi uthole unyango oludingekile noluyimpumelelo esimweni sokugula okuso.

Yikuphi okudingeke ukuba ukwenze?

Uma uhlangabezana nemigomo yokubamba iqhaza futhi uvuma ukuzibandakanya nocwaningo, uyocelwa ukuba ufike kudokotela isigamu sibe sinye emnyangweni kadokotela. Qikekela ukuthi lokhu kubonana kuyoba semahoreni ajwayelekile okusebenza.

Inqubo okumele ilandelwe:

Isigamu sokubonana nodokotela siyothatha cishe amahora amabili futhi siyohlukaniswa ngale ndlela:

- Ukuhlolwa kokuqala (Kuyothatha cishe imizuzu engama-20):
  - Izinga lobuhlungu obuzwayo liyokalwa.
  - Izinga lokunyakaza emalungeni ezandla liyokalwa.
  - Ukusebenza kwesandla sakho kuzohlolwa

Okulandela lokhu kuvivinywa kokuqala, uyofakwa ngaphansi kweqoqo elithola unyango. Uyothola lokhu kwelashwa okulandelayo kuncike eqoqweni oyofakwa phansi. a) Unyango lokuncibilika kukapharafini kanye nokuvocwavocwa kwesandla b) unyango lokushisa okuswakeme c) ukuvocwavocwa kwesandla kuphela.

- Unyango lokuncibilika kukapharafini:
  - Izandla zakho siyocwiliswa oketshenzini olunamfukayo siphinde sikhishwe izikhathi eziyisishiyagalombili, ukusivumela ukuba siphole phakathi nokucwiliswa
  - Izandla zakho ziyobe sezisongwa ngopulasitiki kanye namathawula sibekwe phezu kwetafula.
  - Uketshezi olunamfukayo luyosalela ezandleni zakho isikhathi esiyimizuzu cishe engama-15 kuya kwengama-20, emva kwalokho luyosuka.
- Unyango lokushisa okuswakeme:
  - Izandla zakho ziyobekwa phezu kwetafula.
  - Isaka eliqukethe ukushisa liyobekwa phezu kwesandla sakho.
  - Isaka eliqukethe ukushisa liyobekwa endaweni eyodwa imizuzu engama-15 kuya kwengama-20 bese lisuswa emva kwalokho.
- Uhlelo lokuvocwavocwa kwesandla:
  - Uhlelo lokuvocwavocwa kwesandla luyokhonjiswa kuwe.
  - Uyocelwa ukuba wenze njengoba uyokhonjiswa ubhekwe ngudokotela.
  - Uhlelo lokuvocavoca luyothatha cishe imizuzu engama-15.

Emva kohlelo lokuvocwavocwa kwesandla, ubuhlungu bakho, ukunyakaza kanye nokusetshenziswa kwesandla kuyovivinywa futhi.

Ngabe bukhona yini ubungozi obuhambisana nalolu cwaningo?

Ubungozi obukhona obokusalela kwezibazi zokusha ezihambisana nonyango lokushisa. Kodwa-ke amathuba okuthi lokhu kwenzeke mancane kakhulu futhi ayolingana nobungozi ohlangabezana nabo empilweni yakho yansuku zonke. Izinga lokushisa nokubanda koketshezi olunamfuzelayo kanye nokushisa kuyobhekelelwa kabili nesikali sokushisa kugcinwe esikalini sokwelashwa. Okwedlula lokho, umuzwa wokuthinta kanye nokushisa kuyohlolwa ngaphambi konyango, ukuqinisekisa ukuthi uyokwazi ukumelana nocwaningo. Uyolandelelwa eduze ngudokotela ngesikhathi kuqhubeka unyango lokushisa, kanti nanoma yikuphi ukungaphatheki kahle oyohlangabezana nakho kungabikwa kudokotela ngokushesha.

Ngabe ikhona yini imihlomulo elindelekile kuwena

Unyango oluyotholakala lunomhlomulo kakhulu kuwena kulolu cwaningo luyobandakanywa embuthweni wonyango ukuze uthole unyango olunempumelelo oluqondene nesimo okuso. Ngeke ibe khona imihlomulo ehambisana nemali.

Isiqinisekiso sobumfihlo

Ulwazi oluqoqwe ocwaningweni olwenziwe kuwe luyophathwa ngobumfihlo. Ishidi lokuqoqwa kolwazi luyobandakanya iminyaka, ubuhlanga kanye nokusebenza kwesandla. Ayikho eminye imininingwane ethinta wena eyoqoshwa phansi. Umcwaningi kuphela nomgcini wemiphumela yezinombolo oyofinyelela emashidini okuqoqwa kolwazi. Kodwa-ke, ngokuvumelana nawe, leli shidi eligcine ulwazi liyogcinwa eshadini likadokotela leziguli eziphumayo, futhi liyosetshenziswa ukubhekelela indlela oqhubeka ngayo; okwedlula lokho lawa mashidi ayogcinwa ngumcwaningi isikhathi esiyizinyanga ezingamashumi ayisithupha-60 bese lucekelwa phansi ngokuthi lushiswe. Nanoma yiluphi ulwazi oluyokwethulwa noma lushicilelwe luyoqoqwa ndawonye namanye amaqoqo abambe iqhaza, ngakho ngeke ukwazi ukuhlonzwa ngalo. Ngeke igama lakho lisetshenziswe kunanoma yiyiphi ingxenye yalolu cwaningo.

Ukubamba iqhaza ngokungaphoqwa kanye nokuhoxa ocwaningweni

Ukubamba kwakho iqhaza kulolu cwaningo akuphoqelekile. Unelungelo lokuhoxa kulolu cwaningo nangananoma yisiphi isikhathi othanda ngaso. Uma ukhetha ukuhoxa, unyango oluthola ngaphandle kwalolu cwaningo ngeke luphazamiseke.

Siyabonga ngokuthi ukhethe ukuba yingxenye yalolu cwaningo. Uma kwenzeka uba nanoma yiziphi izikhalazo, sicela ungenqeni ukuxhumana nomcwaningi

Umcwaningi: UNksz. T Ramsudh,

UDokotela,

Ucingo: 031-459 6105, I-email: ramsudht@gmail.com

Appendix E - INFORMED CONSENT FORM (English)

Informed Consent Form

Dear participant,

Thank you for deciding to participate in this research project.

This project is being undertaken by Ms. Thirusha Ramsudh in part fulfillment for the degree *Masters in Hand Rehabilitation,* in the School of Audiology, Occupational Therapy and Speech-Language Pathology at the University of KwaZulu-Natal, Westville Campus, Durban.

Research Title
A comparative study to investigate the immediate effects of paraffin wax and moist heat therapies on pain, joint range of movement and hand function in adults with rheumatoid arthritis affecting the hands.

Invitation to participate
You are invited to participate in this research study which will investigate the effects of paraffin wax and heat therapies on your hand symptoms. Your participation in this study is voluntary.

Purpose of this study
The purpose of this study is to investigate the effects of paraffin wax therapy and moist heat therapy on pain, movement of the hand and hand function. The results will be compared to determine which treatment is most beneficial to patients with rheumatoid arthritis affecting the hands.

Explanation of procedures
If you consent to this study, you will be asked to come to the physiotherapy department for a single session that will last approximately 2 hours.
Firstly, you will be assessed by a therapist who will record your level of pain, the movement of your joints and the function of your hands. This will take approximately 20 minutes. Following your assessment, you will be assigned to a treatment group. Depending on which group you are assigned to, you will then receive one of the following physiotherapy treatments:
a) paraffin wax therapy and hand exercises, or
b) moist heat therapy and hand exercises.
The wax and heat treatments will last approximately 15 – 20 minutes each. The hand exercise programme will last approximately 20 minutes. Your level of pain, joint movement and hand function will be reassessed. Refreshments will be available prior to the reassessment.

Potential risks and discomfort
The risk of sustaining thermal burns with heat therapy exists. However the possibility of this occurring is very low and can be equated to the risk faced by you in everyday life. The temperature of the wax and heat packs will be checked twice with a thermometer and kept at a therapeutic level. Furthermore your sense of touch and

heat perception will be tested prior to treatment, thus making sure you will be able tolerate the treatments comfortably. You will also be constantly monitored by the therapist during the heat treatments, and any discomfort experienced by you can be reported immediately to the therapist.

Potential benefit to you

The outcome of the study will be of benefit to you as a patient receiving physiotherapy treatment for rheumatoid arthritis affecting the hands. The treatment found most beneficial in this study will be included in your treatment regime so that you receive the most effective treatment for your condition. There will no monetary benefits to you.

Potential benefit to society

The study findings can help guide therapists in choosing the most beneficial treatment modalities for their patients, thus providing a more cost effective and efficient treatment for patients with rheumatoid arthritis affecting the hands.

Assurance of confidentiality

Information collected from you (raw data) will be treated confidentially. The data collection sheet will include your age, race, and hand dominance. No other identifying information will be recorded. Only the researcher and statistician will have access to the data collection sheets. However, with your consent, this data collection sheet can be kept in your physiotherapy outpatient chart and used to monitor your progress; otherwise, these sheets will be kept by the researcher for 60 months and will then be destroyed by burning it. Any information presented or published will be grouped with other subjects, thus you cannot be identified. Your name will not be used in any part of this study.

Voluntary participation and withdrawal

Your participation in this study is completely voluntary. You have the right to withdraw from this study at any time if you so choose. If you choose to withdraw, your physiotherapy treatment outside this study will not be adversely affected.

Your signature certifies that you have read and understood the content of this consent form. It signifies that you freely volunteer to participate in this study.
It also signifies that you consent to:

- Your level of pain being recorded,
- Your joint movement being measured,
- Your hand function being tested,
- Participation in the treatment procedures described above.

Do you consent to your data collection sheet being attached to your physiotherapy outpatient file?

Yes ☐ No ☐

If you have any additional questions, please don't hesitate to contact the investigator. You will be given a copy of this consent form to keep for your records.

_____	_____	_____
Name of Subject	Signature of Subject	Date

_____	_____	_____
Name of Witness	Signature of Witness	Date

_____	_____
Signature of Investigator	Date

Investigator: Ms. T. Ramsudh, Physiotherapist, Tel: 031 459 6105
Email: ramsudht@gmail.com

Supervisor: Dr. T. Nadasan, Lecturer, Department of Physiotherapy
University of KwaZulu - Natal, Tel: 031 260 7817

Appendix F - INFORMED CONSENT FORM (isiZulu)

Ifomu Elifungelwe Lokuzibophezela

Kobambe iqhaza,

Ngiyabonga ngesinqumo sakho sokubamba iqhaza kulomsebenzi wocwaningo

Lomsebenzi uqhutshwa nguNksz. Thirusha Ramsudh ukugcwalisa iziqu zeMasters in Hand Rehabilitation, ngaphansi kweSikole seZifundo Zocwaningo LwezeSayensi Yokuzwa, uNyango Lwabasebenzi kanye Nolimi Lokukhuluma (School of Audiology, Occupational Therapy and Speech Language); eNyuvesi yaKwaZulu-Natali, oPhikweni LwaseWestville.

Isihloko Socwaningo

Lolu wucwaningo lokuqhathanisa olucubungula imithelela esheshe ibonakale ekwelashweni okuhambisana nokuncibilika kukapharafini kanye nokushisa okunomswakama, ebuhlungwini, ekunyakazeni kwamalunga omzimba kanye nokusetshenziswa kwesandla kubantu abadala abane-rheumatoid arthritis ephazamisa ukusebenza kwezandla.

Isimemo sokubamba iqhaza

Uyamenywa ukuba ubambe iqhaza kulolu cwaningo oluzocubungula imithelela yokwelashwa okuhambisana nokuncibilika kukapharafini nokushisa ezimpawini ezisezandleni zakho. Ukubamba kwakho iqhaza akuphoqelekile.

Inhloso yalolu cwaningo

Inhloso yalolu cwaningo ukuphenyisisa imithelela yokwelashwa okuhambisana nokuncibilika kukapharafini nonyango oluhambisana nokushisa komswakama ebuhlungwini, ukunyakaza kwezandla kanye nokusetshenziswa kwazo. Imiphumela iyoqhathaniswa ukuhlonza ukuthi yiluphi ucwaningo olunosizo ezigulini ezine-rheumatoid arthritis ephazamisa ukusebenza kwezandla.

Incazelo ngengubo okumele ilandelwe

Uma uvuma ukuba yingxenye yalolu cwaningo, uyocelwa ukuba ufike emnyangweni kadokotela, ubonane naye isigamu esisodwa esiyothatha amahora cishe angamashumi amabili.

Okokuqala uyohlolwa wudokotela oyoqopha izinga lakho lobuhlungu, ukunyakaza kwamalunga akho kanye nokusetshenziswa kwezandla zakho. Lokho kuyothatha cishe imizuzu engama-20. Okulandela ukuvivinywa kwakho, uyofakwa ngaphansi kweqoqo elelashwayo. Uyothola lokhu kwelashwa okulandelayo kuncike ekutheni yiliphi iqoqo ofakwe ngaphansi kwalo:

a) Unyango lokuncibilika kukapharafini kanye nokuvocwavocwa kwesandla,

b) Unyango lokushisa komswakama kanye nokuvocwavocwa kwesandla, noma

c) Ukuvocwavocwa kwesandla kuphela.

Ukuncibilika nonyango lokushisa kuyothatha cishe imizuzu engama-15 kuya ku-20. Uhlelo lokuvocwavocwa kwesandla luyothatha ciche imizuzu engama-20. Izinga lobuhlungu obuzwayo, ukunyakaza kwamalunga kanye nokusetshenziswa kwesandla kuyobe sekuvivinywa futhi.Ukudla okulula kuyobe kukhona ngaphambi kokuba uvivinywe futhi.

Ubungozi obungalindelwa kanye nokungaphatheki kahle

Ubungozi obukhona obokusalela kwezibazi zokusha ezihambisana nonyango lokushisa. Kodwa-ke amathuba okuthi lokhu kwenzeke mancane kakhulu futhi ayolingana nobungozi ohlangabezana nabo empilweni yakho yansuku zonke. Izinga lokushisa nokubanda koketshezi olunamfuzelayo kanye nokushisa kuyobhekelelwa kabili nesikali sokushisa kugcinwe esikalini sokwelashwa. Okwedlula lokho, umuzwa wokuthinta kanye nokushisa kuyohlolwa ngaphambi konyango, ukuqinisekisa ukuthi uyokwazi ukumelana nocwaningo. Uyolandelelwa eduze ngudokotela ngesikhathi kuqhubeka unyango lokushisa, kanti nanoma yikuphi ukungaphatheki kahle oyohlangabezana nakho kungabikwa kudokotela ngokushesha.

Imihlomulo olindeleke ukuba uyithole

Umphumela wocwaningo uyoba wumhlomulo kuwe njengesiguli esithola unyango lwe-rheumatoid arthritis ephazamisa ukusebenza kwezandla. Unyango oluyotholakala lunomhlomulo kakhulu kuwena kulolu cwaningo luyobandakanywa embuthweni wonyango ukuze uthole unyango olunempumelelo oluqondene nesimo okuso. Ngeke ibe khona imihlomulo ehambisana nemali.

Imihlomulo elindeleke emphakathini

Imiphumela yocwaningo iyosiza ukulawula odokotela ukuze bakhethe unyango oluyimpumelelo ezigulini zabo, ngalokho kuyohlinzekwa ngonyango olungabizi noluyimpumelelo ezigulini ezine-rheumatoid arthritis ephazamisa ukusebenza kwezandla.

Isiqinisekiso sobumfihlo

Ulwazi oluqoqwe ocwaningweni olwenziwe kuwe luyophathwa ngobumfihlo. Ishidi lokuqoqwa kolwazi luyobandakanya iminyaka, ubuhlanga kanye nokusebenza kwesandla. Ayikho eminye imininingwane ethinta wena eyoqoshwa phansi. Umcwaningi kuphela nomgcini wemiphumela yezinombolo oyofinyelela emashidini okuqoqwa kolwazi. Kodwa-ke, ngokuvumelana nawe, leli shidi eligcine ulwazi liyogcinwa eshadini likadokotela leziguli eziphumayo, futhi liyosetshenziswa ukubhekelela indlela oqhubeka ngayo; okwedlula lokho lawa mashidi ayogcinwa ngumcwaningi isikhathi esiyizinyanga ezingamashumi ayisithupha-60 bese lucekelwa phansi ngokuthi lushiswe. Nanoma yiluphi ulwazi oluyokwethulwa noma lushicilelwe luyoqoqwa ndawonye namanye amaqoqo abambe iqhaza, ngakho ngeke ukwazi ukuhlonzwa ngalo. Ngeke igama lakho lisetshenziswe kunanoma yiyiphi ingxenye yalolu cwaningo.

Ukubamba iqhaza ngokungaphoqwa kanye nokuhoxa ocwaningweni

Ukubamba kwakho iqhaza kulolu cwaningo akuphoqelekile. Unelungelo lokuhoxa kulolu cwaningo nangananoma yisiphi isikhathi othanda ngaso. Uma ukhetha ukuhoxa, unyango oluthola ngaphandle kwalolu cwaningo ngeke luphazamiseke.

Isiginesha yakho iqinisekisa ukuthi uqonde kahle okuqukethwe yileli fomu lesibophezelo. Iqinisekisa ukuthi ubamba iqhaza ngokungaphoqelekile kulolu cwaningo. Iphinde futhi iqinisekise ukuthi uyavumelana nokuthi:

- Izinga lakho lobuhlungu liqoshwe,
- Ukunyakaza kwamalungu kuyakalwa,
- Ukusebenza kwesandla sakho kuyohlolwa,
- Izinqubo zokubamba iqhaza ezichazwe ngenhla.

Uyavumelana nokuthi ishidi eliqukethe ulwazi oluqoqwe kuwena luhambisane nefayela likadokotela eliqukethe imininingwane yeziguli eziphumayo?

Yebo ☐ Cha ☐

Uma unemibuzo eyengeziwe, ungenqeni ukuxhumana nomcwaningi. Uyonikezwa ikhophi yaleli fomu lokuzibophezela ukuze kugcinwe amarekhodi akho.

_____	_____	_____
Igama lobambe iqhaza	Isiginesha yobambe iqhaza	Usuku
_____	_____	_____
Igama lofakazayo	Isiginesha yofakazayo	Usuku
_____	_____	
Isiginesha yomcwaningi	Usuku	

Umcwaningi: UNksz. T Ramsudh, UDokotela, Ucingo: 031-459 6105

I-email: ramsudht@gmail.com

Umeluleki: Dkt. T. Nadasan, UMfundisi, eMnyangweni Wezonyango, eNyuvesi yakwaZulu-Natali, Ucingo: 031-260 7817

Appendix G – Starting Positions and Goniometer Alignment						
Joint Movement	Starting Position	Stabilization	Goniometer Axis	Stationary Arm	Movable Arm	End Position
Wrist flexion and extension	Patient is sitting with shoulder adducted and neutrally rotated, elbow flexed to 90^0, and forearm resting on a table in neutral with the wrist in neutral	Therapist stabilizes the forearm	Level of the radial styloid process	Parallel to the longitudinal axis of the radius	Parallel to the longitudinal axis of the second metacarpal	Flexion: wrist is moved in a volar direction to its limit Extension: wrist is moved in a dorsal direction to its limit
Wrist ulnar (UD) and radial (RD)deviation	Patient is sitting with shoulder adducted and neutrally rotated, elbow flexed to 90^0, and forearm resting on a table in a pronated position, wrist in neutral and fingers relaxed	Therapist stabilizes the forearm	Dorsal aspect of wrist over the capitate bone	Along midline of the forearm	Parallel to longitudinal axis of the shaft of the third metacarpal	UD: wrist is adducted to ulnar side to limit of motion RD: wrist is abducted to radial side to limit of motion
Finger metacarpophalangeal joint (MCPJ)flexion	Patient is sitting with shoulder adducted and neutrally rotated, elbow flexed to 90^0, and forearm resting on a table in neutral with the wrist slightly extended	Therapist stabilizes the metacarpal	Flexion: dorsal aspect of the MCPJ	Parallel to longitudinal axis of shaft of the metacarpal	Parallel to longitudinal axis of proximal phalanx	All fingers are moved towards the palm for flexion to the limit of motion

Appendix G – Starting Positions and Goniometer Alignment….. continued						
Joint Movement	Starting Position	Stabilization	Goniometer Axis	Stationary Arm	Movable Arm	End Position
Finger interphalangeal joint (IPJ)flexion (PIPJ and DIPJ)	Patient is sitting with shoulder adducted and neutrally rotated, elbow flexed to 90^0, and forearm resting on a table in neutral with the wrist slightly extended	Therapist stabilizes the proximal phalanx for the PIPJ and the middle phalanx for the DIPJ	Dorsal surface of interphalangeal joint	PIPJ: parallel to longitudinal axis of proximal phalanx DIPJ: parallel to longitudinal axis of middle phalanx	PIPJ: parallel to longitudinal axis of middle phalanx DIPJ: parallel to longitudinal axis of distal phalanx	PIPJ and DIPJ is flexed to the limit of motion
Thumb metacarpophalangeal and interphalangeal flexion	Patient is sitting with shoulder adducted and neutrally rotated, elbow flexed to 90^0, and forearm resting on a table in neutral with wrist in neutral and thumb MCPJ and IPJ in extension	MCPJ: therapist stabilizes the first metacarpal. IPJ: therapist stabilizes the proximal phalanx	Dorsal aspect of MCPJ and IPJ	MCPJ: parallel to longitudinal axis of shaft of thumb metacarpal IPJ: parallel to longitudinal axis of proximal phalanx	MCPJ: parallel to longitudinal axis of proximal phalanx IPJ: parallel to longitudinal axis of distal phalanx	MCPJ and IPJ is flexed to limit of motion

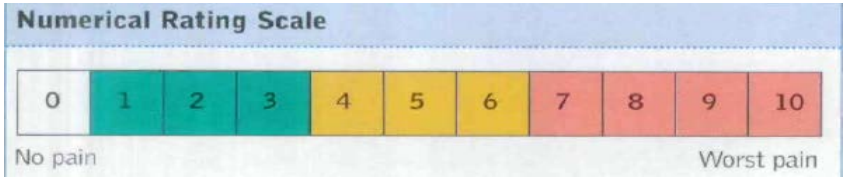
Appendix G – Starting Positions and Goniometer Alignment ….. continued						
Joint Movement	Starting Position	Stabilization	Goniometer Axis	Stationary Arm	Movable Arm	End Position
Thumb carpometacarpal abduction	Patient is sitting with shoulder adducted and neutrally rotated, elbow flexed to 90^0, and forearm resting on a table in neutral with wrist in neutral and thumb in contact with metacarpal and proximal phalanx of the index finger	Therapist stabilizes the second metacarpal	Junction of the bases of the first and second metacarpals	Parallel to longitudinal axis of the second metacarpal	Parallel to longitudinal axis of the first metacarpal	Thumb is abducted to limit of motion in plane perpendicular to palm

Appendix H - DATA COLLECTION SHEET

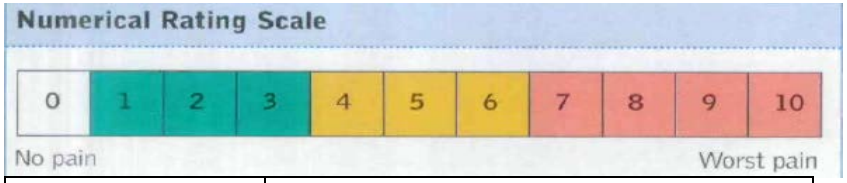
Group: _____ Hospital:_____ Date: _____
Subject Number: _____ Age: _____ Sex: _____
Disease stage: _____ Race: _____
Hand Dominance: _____

ROM		LEFT		RIGHT	
		PRE-TEST	POST-TEST	PRE-TEST	POST-TEST
THUMB	MCPJ				
	IPJ				
	OPP				
IF	MCPJ				
	PIPJ				
	DIPJ				
MF	MCPJ				
	PIPJ				
	DIPJ				
RF	MCPJ				
	PIPJ				
	DIPJ				
LF	MCPJ				
	PIPJ				
	DIPJ				
HAND SPAN (mm)					

Pre Test



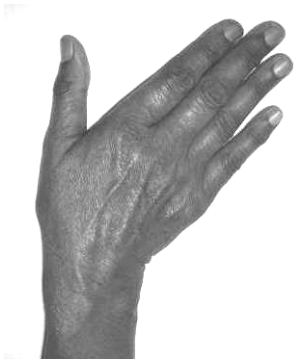
Post Test



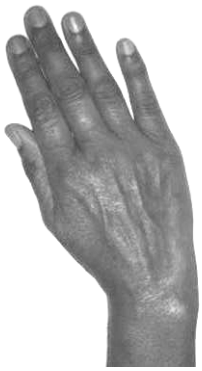
GRIP ABILITY TEST	TIME (IN SECONDS)	
	PRE-TEST	POST-TEST
PUTTING STOCKING ON NON- DOMINANT HAND		
PUTTING A PAPER CLIP ON AN ENVELOPE		
POUR WATER FROM A JUG		

Appendix I - HAND EXERCISE PROGRAMME (English)

Exercise 1: Wrist radial and ulnar deviation

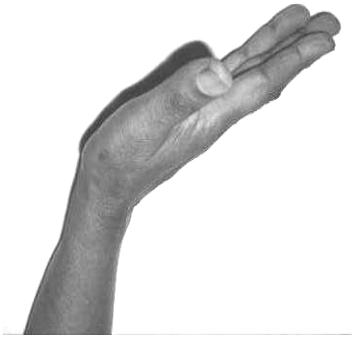


With your fingers straight and hand resting on a flat surface, bend your wrist sideways as in "waving". Keep your forearm still. Repeat 10 times



Exercise 2: Wrist flexion and extension

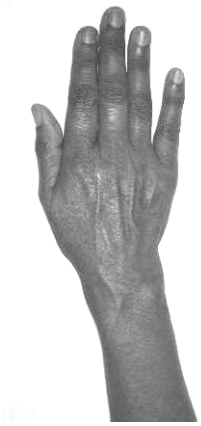
With your fingers straight and the little finger resting on a flat surface, bend your wrist backwards and forwards to the end of range, keeping the forearm still. Repeat 10 times.

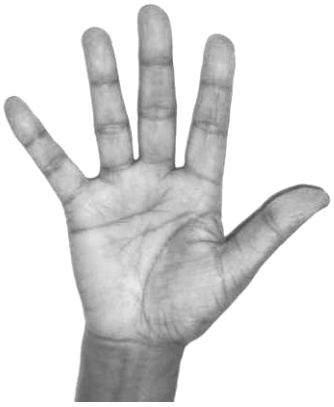


Exercise 3: Pronation and supination

With your elbow resting on a flat surface, turn your forearm so that the palm faces the ceiling, hold for a count of 5. Then turn your forearm so that the palm faces downwards. Hold for 5 seconds. Repeat 10 times.

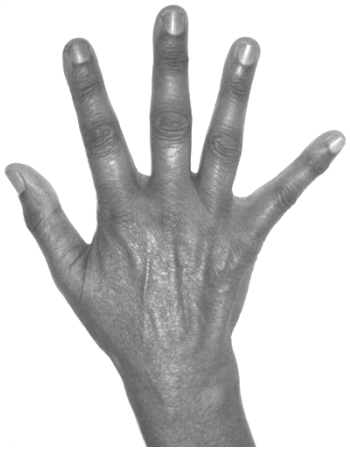
Exercise 4: Composite finger flexion



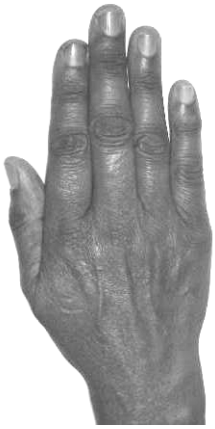


Start with the fingers straight and spread apart, then clench the hand into a fist, making sure each finger joint is bending as much as possible. Hold for 5 seconds. Repeat 5 times.

Exercise 5: Finger abduction and adduction

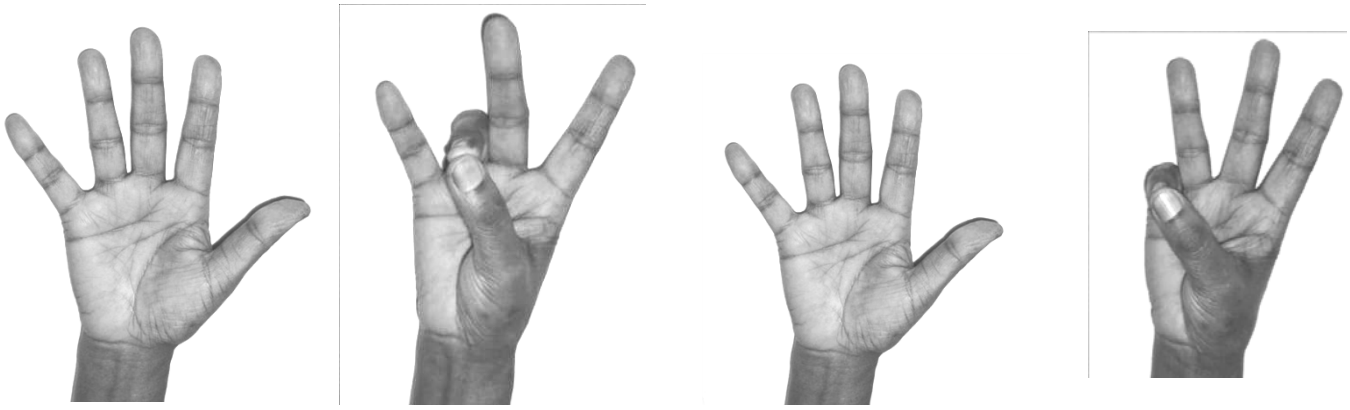


Rest your hand on a flat surface with your palm down. Spread your fingers wide apart and then bring them together again. Repeat 5 times.



Exercise 6: Opposition

Touch the tip of each finger with your thumb, opening the hand wide after touching each finger. Repeat 3 times.



Touch the base of the little finger, repeat 3 times.

<u>Exercise 7</u>: Wrist extension stretch

Press your palms and fingers gently together. Hold for 5 seconds. Repeat 3 times.

Exercise 8: Wrist flexion stretch

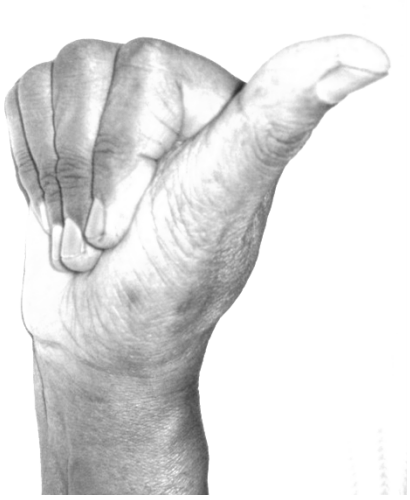
Resting you hands on a flat surface, use one hand to gently bend the other wrist as far as it can go. Hold for 5 seconds. Repeat 3 times.

Exercise 9: Lumbrical movement

Start with your fingers straight and the little finger resting on a flat surface; bend your fingers at the knuckles, keeping the little joints of your fingers straight throughout. Hold for 5 seconds. Repeat 5 times.

Exercise 10: Straight fist

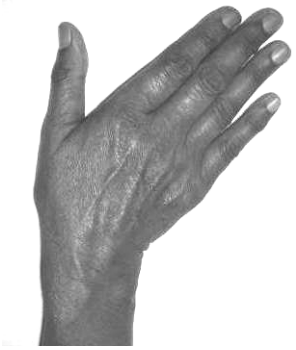
Bend your fingers so that your fingertips touch the palm of your hand. Hold for 5 seconds. Repeat 5 times.



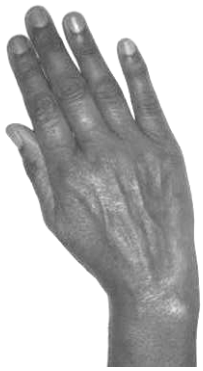
Appendix J - HAND EXERCISE PROGRAMME (IsiZulu)

UHLELO LOKUVOCAVOCA IZANDLA

<u>Ukuzivocavoca kokuqala:</u> Ukuzungezisa izihlakala nokuzithwishila

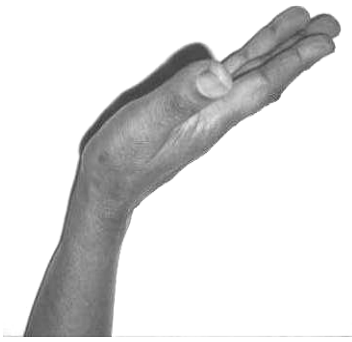


Usebenzisa iminwe yakho uyiqondisile nesandla usibeke endaweni eqondile, gobisa izihlakala zakho siye emaceleni njengoba usuke ubhabhayisa. Gcina ingaphambili lengalo yakho linganyakazi. Phinda lokho izikhathi eziyishumi.



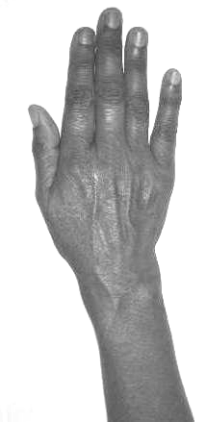
<u>Ukuzivocavoca kwesibili:</u> Ukugobisa nokwelula izihlakala

Uqondise iminwe yakho kanye nomunwe omncane uncike endaweni eqondile, gobisa izihlakala zakho ziye emuva naphambili zifike emaphethelweni, gcina ingaphambili lengalo linganyakazi. Phinda lokho izikhathi eziyishumi.

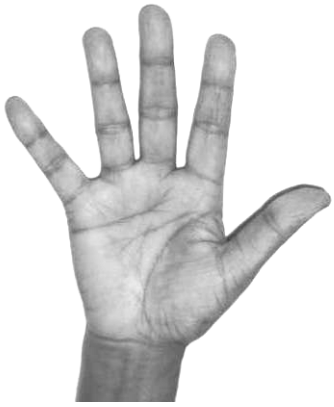


<u>Ukuzivocavoca kwesithathu:</u> i-Pronation ne-supination

Izindololwane zakho zincike endaweni eqondile, phendula ingaphambili lengalo yakho lincike endaweni eqondile, phendula ingaphambili lengalo yakho ukuze intende yakho ibheke phansi. Bamba imizuzwana emihlanu. Phinda lokho izikhathi eziyishumi.

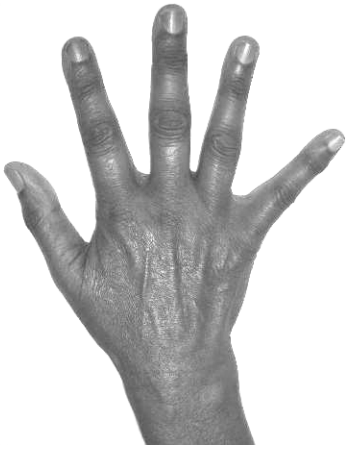


Ukuzivocavoca kwesine: Ukwelula iminwe ngokushintshana

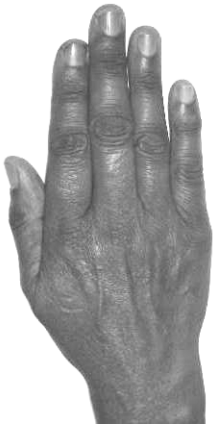


Qala ngokuthi iminwe uyiqondise uyehlukanise, bese ufumba iqupha, uqinisekise ukuthi ilunga lomunwe ngamunye ligobe ngokwanele. Bamba imizuzwana emihlanu: Phinda lokho izikhathi ezinhlanu.

Ukuzivocavoca kwesihlanu: Ukucindezela iminwe



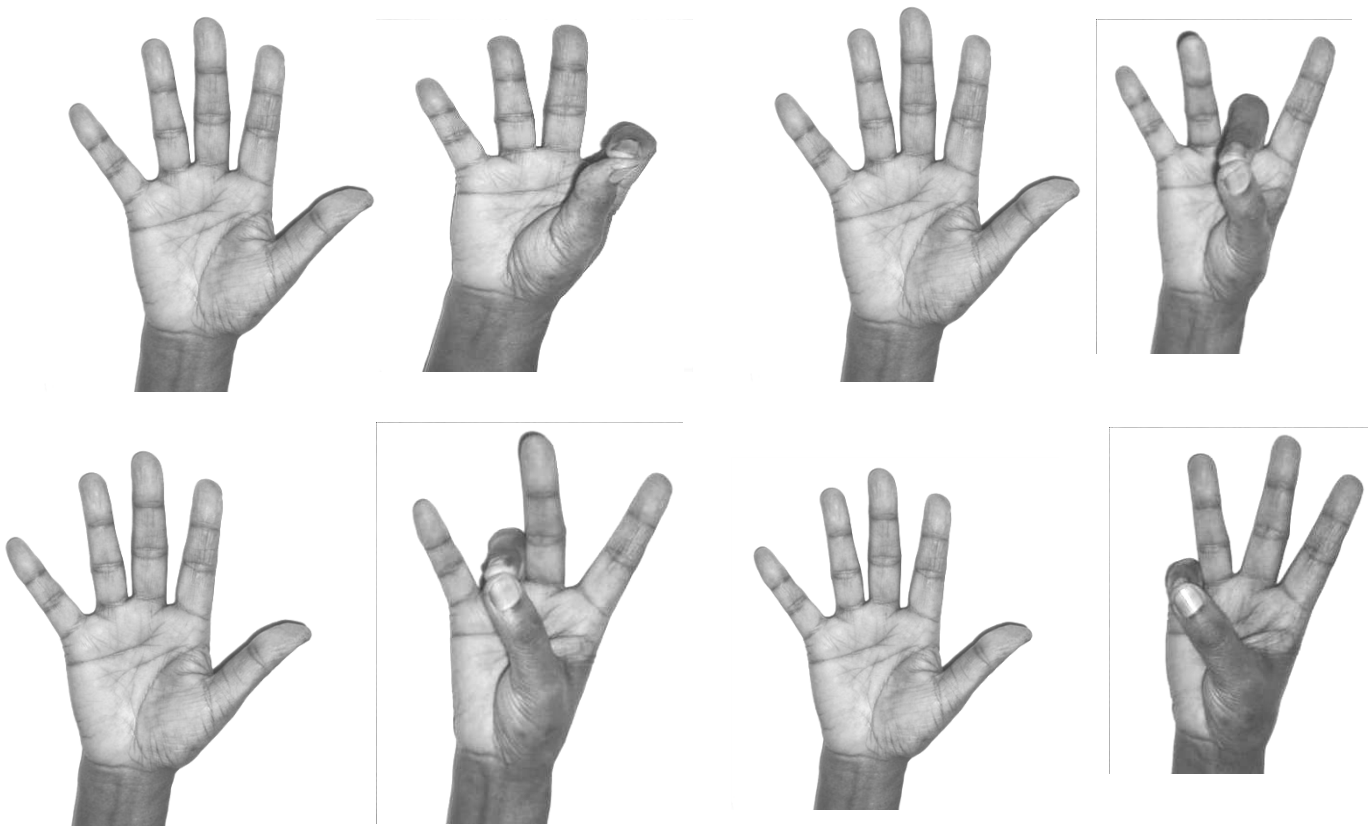
Beka isandla sakho endaweni eqondile intende ibheke phansi. Hlakaza iminwe yakho bese uyihlanganisa futhi. Phinda lokho izikhathi ezinhlanu.



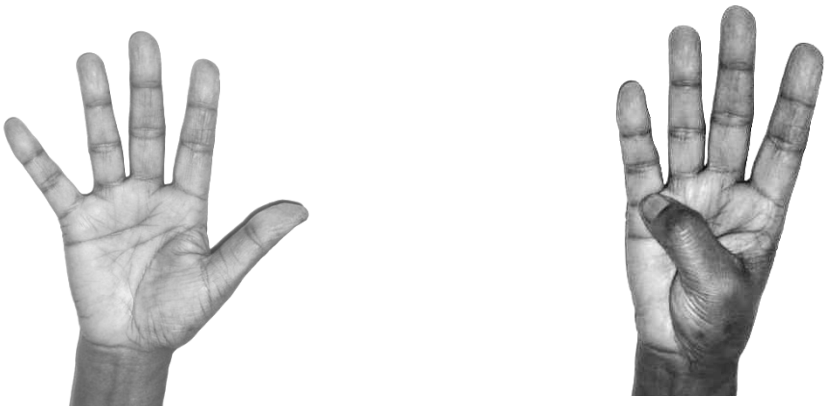
Ukuzivocavoca kwesithupha: Okuphambene

Thinta ingaphezulu ngalinye leminwe ngesithupha, uvule isandla sakho emva kokuthinta umunwe ngamunye. Phinda lokho izikhathi ezinhlanu.

.



Thinta ingaphansi lomunwe omfushane, phinda lokho izikhathi ezintathu



Ukuzivocavoca kwesikhombisa: Ukuthwishila isihlakala ngokwelula

Cindezela izintende zezandla kanye neminwe kancane. Bamba imizuzwana emihlanu. Phinda lokho izikhathi ezintathu.

<u>Ukuzivocavoca kwesishiyagalombili:</u> Ukuthwishila isihlakala ngokwelula

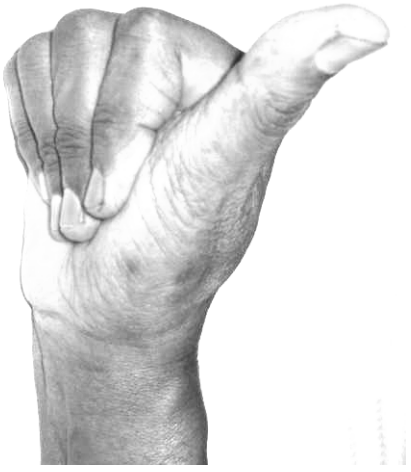
Beka izandla zakho endaweni eqondile, sebenzisa isandla esisodwa ukugobisa kancane esinye sifike ekugcineni. Bamba imizuzwana emihlanu. Phinda lokho izikhathi ezinhlanu.

<u>Ukuzivocavoca kwesishiyagalolunye:</u> Umnyakazo we-Lumbrical

Qala ngokuthi iminwe yakho iqonde ngesikhathi umunwe wakho omfishane ubekwe endaweni eqondile; gobisa iminwe yakho, emaqupheni, ugcine amalunga amancane eminwe yakho eqondile ngaso sonke isikhathi. Bamba imizuzwana emihlanu. Phinda izikhathi ezinhlanu.

<u>Ukuzivocavoca kweshumi</u>: Iqupha eliqondile

Gobisa iminwe yakho ukuze izihloko zayo zithinte izintende zezandla zakho. Bamba imizuzwana emihlanu. Phinda lokho izikhathi ezinhlanu.



Appendix K - LETTER TO HEALTH CARE FACILITY'S CEO REQUESTING PERMISSION TO CONDUCT STUDY

31 Mountain View Drive
Silverglen
4092
1 April 2011

The Hospital Manager

Request to conduct study on hospital premises

I, Thirusha Ramsudh, am registered as a postgraduate student in the Masters in Hand Rehabilitation programme in the Department of Occupational Therapy at the University of KwaZulu-Natal. I hereby request permission to conduct my study, in part fulfillment for the above mentioned degree, at your hospital pending ethical clearance which will be sought from the University of KwaZulu-Natal Ethics Committee.

The purpose of my study is to determine if paraffin wax therapy or moist heat therapy is more beneficial in treating adult patients with rheumatoid arthritis affecting the hands. The results of the study may enhance evidence based clinical practice thus benefitting patients by means of more effective pain relief, better mobility and hand strength. It can also lead to more effective and economic service delivery at your institution.

Following ethical approval from the University of KwaZulu-Natal Ethics Committee and approval from the Department of Health, patients who meet the inclusion criteria and who are willing to participate, will be required to sign an informed consent form after being briefed on the purpose and possible benefits and risks associated with the study. Participants will be required to attend a single treatment session in the Physiotherapy Department that will involve a treatment intervention as well as pre- and post testing. Pending permission, the investigator will use the physiotherapy department premises but will ensure that normal service delivery is not disrupted. The cost of materials and refreshments for the study will be borne by the investigator. I will liaise with the rheumatologists, specialist physicians and physiotherapy manager regarding sampling and the logistics of the study. Kindly refer to the attached research proposal.

Please provide me with a written acknowledgment of this application, indicating if you are willing to allow this study to be conducted on the hospital premises following ethical clearance from the university.

I urgently await your decision on this matter. Thank you for your time and effort.
Yours faithfully

_____ _____

Ms. Thirusha Ramsudh
Physiotherapist
Tel: (031) 4596105

Research Supervisor: Dr. T Nadasan
Department of Physiotherapy
University of KwaZulu-Natal; Tel: (031 2607817

Appendix L – Letter of Permission from health care facility CEO

HEALTH
KwaZulu-Natal

R.K. Khan Hospital
Private Bag X004,
CHATSWORTH, 4030
Tel.: 031 4596001, Fax.: 031 4011247
Email.:reena.ramcharan@.kznhealth.gov.za
www.kznhealth.co.za

ENQUIRIES: DR P.S. SUBBAN

23 JUNE 2010

Ms T. Ramsudh
Physiotherapy Department
R.K. KHAN HOSPITAL

Dear Ms Ramsudh

RE: PERMISSION TO CONDUCT STUDY : EFFECTS OF PARAFFIN WAX AND MOIST HEALTH THERAPIES ON PHYSIOTHERAPY TREATMENT OUTCOMES IN ADULTS WITH RHEUMATOID ARTHRITIS AFFECTING THE HANDS

Permission is granted to conduct the above research at this institution provided:-

- Confidentiality is maintained at all times,
- Your research does not interfere with the smooth running of the hospital
- Proper consent is obtained from patients participating in your study
- Hospital records are not taken out of the hospital
- Research is conducted during normal working hours
- The hospital receives a copy of your research on completion.

Yours faithfully

HOSPITAL CEO

Appendix M – Ethical Clearance

UNIVERSITY OF
KWAZULU-NATAL
INYUVESI
YAKWAZULU-NATALI

RESEARCH OFFICE
Biomedical Research Ethics Administration
Westville Campus, Govan Mbeki Building
Private Bag X 54001
Durban
4000
KwaZulu-Natal, SOUTH AFRICA
Tel: 27 31 2604769 - Fax: 27 31 2604609
Email: BREC@ukzn.ac.za
Website: http://research.ukzn.ac.za/ResearchEthics/BiomedicalResearchEthics.aspx

Received 11th May 2012

19 April 2012

Ms T Ramsudh
School of Audiology, Occupational Therapy and Speech- Language Pathology
Westville Campus
University of KwaZulu-Natal

Dear Ms Ramsudh

PROTOCOL:A comparative study to determine the immediate effects of paraffin wax and moist heat therapies on pain, joint range of movement and muscle strength in adults with rheumatoid arthritis affecting the hands. REF: BE194/11

The study was provisionally approved on 26 January 2012 by a sub-committee of BREC pending appropriate responses to queries raised. Your responses dated 11 April 2012 have been noted by a sub-committee of the Biomedical Research Ethics Committee. The conditions have now been met and the study is given full ethics approval and may begin as from 19 April 2012

This approval is valid for one year from **19 April 2012.** To ensure uninterrupted approval of this study beyond the approval expiry date, an application for recertification must be submitted to BREC on the appropriate BREC form 2-3 months before the expiry date. Any amendments to this study, unless urgently required to ensure safety of participants, must be approved by BREC prior to implementation.

Your acceptance of this approval denotes your compliance with South African National Research Ethics Guidelines (2004), South African National Good Clinical Practice Guidelines (2006) (if applicable) and with UKZN BREC ethics requirements as contained in the UKZN BREC Terms of Reference and Standard Operating Procedures, all available at http://research.ukzn.ac.za/ResearchEthics11415.aspx.
BREC is registered with the South African National Health Research Ethics Council (REC-290408-009). BREC has US Office for Human Research Protections (OHRP) Federal-wide Assurance (FWA 678).

We wish you well with this study. We would appreciate receiving copies of all publications arising out of this study.

Yours sincerely

PROFESSOR D R WASSENAAR
Chair: Biomedical Research Ethics Committee

Appendix N – Letter of Permission from Department of Health

health

Department:
Health
PROVINCE OF KWAZULU-NATAL

Health Research & Knowledge Management
10 – 103 Natalia Building, 330 Langalibalele Street
Private Bag x9051
Pietermaritzburg, 3200
Tel.: 033 – 395 2895
Fax.: 033 – 394 3782
Email.: hrkm@kznhealth.gov.za
www.kznhealth.gov.za

Reference : HRKM 122/11
Enquiries : Mr X. Xaba
Telephone : 033 – 395 2805

Dear Ms T. Ramsudh

Subject: Approval of a Research Proposal

1. The research proposal titled **'A comparative study to determine the immediate effects of paraffin wax and moist heat therapies on pain, joint range of movement and muscle strength in adults with rheumatoid arthritis affecting the hands'** was reviewed by the KwaZulu-Natal Department of Health.

   The proposal is hereby approved for research to be undertaken at RK Khan Hospital for a period of 1 year.

2. You are requested to take note of the following:
   a. Make the necessary arrangement with the identified facility before commencing with your research project.
   b. Provide an interim progress report and final report (electronic and hard copies) when your research is complete.

3. Your final report must be posted to **HEALTH RESEARCH AND KNOWLEDGE MANAGEMENT, 10-102, PRIVATE BAG X9051, PIETERMARITZBURG, 3200** and e-mail an electronic copy to hrkm@kznhealth.gov.za

For any additional information please contact Mr X. Xaba.

Yours Sincerely

Dr E. Lutge
Chairperson: Provincial Health Research Committee
Date: 27/06/2012

Appendix O: Descriptive data for range of movement of the right hand.

Treatment Group		Right thumb MCPJ difference	Right thumb IPJ difference	Right index finger MCPJ difference	Right index finger PIPJ difference	Right index finger DIPJ difference	Right middle finger MCPJ difference	Right middle finger PIPJ difference	Right middle finger DIPJ difference	Right ring finger MCPJ difference	Right ring finger PIPJ difference	Right ring finger DIPJ difference	Right little finger MCPJ difference	Right little finger PIPJ difference	Right little finger DIPJ difference
heat group	N	59	59	59	59	59	59	59	59	59	59	59	59	59	59
	Std. Deviation	6.90695	2.92113	4.17858	4.00358	3.26593	3.78213	3.29710	3.14049	4.59175	5.25226	3.42320	4.94269	3.63839	3.18438
	Median	.0000	.0000	5.0000	5.0000	.0000	5.0000	5.0000	.0000	5.0000	5.0000	.0000	5.0000	5.0000	.0000
	Minimum	-30.00	-5.00	-5.00	-5.00	-5.00	-5.00	-5.00	-5.00	-5.00	-5.00	-15.00	-5.00	-5.00	-5.00
	Maximum	15.00	10.00	20.00	15.00	10.00	15.00	10.00	10.00	15.00	25.00	10.00	20.00	10.00	15.00
	Mean	2.4107	3.6607	4.4643	5.4464	3.1250	4.5536	4.2857	3.3036	5.6250	3.4821	-.0893	5.2679	4.3750	.8036
wax group	N	56	56	56	56	56	56	56	56	56	56	56	56	56	56
	Std. Deviation	5.39285	4.42011	3.65297	4.60008	3.63849	3.60262	3.49397	4.18621	4.16288	3.92192	6.63949	4.61417	3.82129	2.82469
	Median	5.0000	5.0000	5.0000	5.0000	5.0000	5.0000	5.0000	5.0000	5.0000	5.0000	.0000	5.0000	5.0000	.0000
	Minimum	-10.00	-10.00	-5.00	-5.00	-5.00	-10.00	-5.00	-5.00	-5.00	-5.00	-35.00	-5.00	-5.00	-10.00
	Maximum	20.00	20.00	10.00	20.00	15.00	10.00	15.00	15.00	20.00	20.00	20.00	20.00	20.00	10.00
	Mean	1.7826	2.7391	3.9565	4.5652	2.7826	4.1304	3.7826	2.4348	4.9565	4.2609	.6087	4.5217	3.4783	1.3043
Total	N	115	115	115	115	115	115	115	115	115	115	115	115	115	115
	Std. Deviation	6.21936	3.81844	3.94566	4.37122	3.45341	3.70282	3.41509	3.76766	4.41765	4.69432	5.26274	4.82018	3.81444	3.04116
	Median	5.0000	5.0000	5.0000	5.0000	5.0000	5.0000	5.0000	.0000	5.0000	5.0000	.0000	5.0000	5.0000	.0000
	Minimum	-30.00	-10.00	-5.00	-5.00	-5.00	-10.00	-5.00	-5.00	-5.00	-5.00	-35.00	-5.00	-5.00	-10.00
	Mean	1.1864	1.8644	3.4746	3.7288	2.4576	3.7288	3.3051	1.6102	4.3220	5.0000	1.2712	3.8136	2.6271	1.7797

Appendix P: Descriptive data for range of movement of the left hand.

Treatment Group		Left thumb MCPJ difference	Left thumb IPJ difference	left index finger MCPJ difference	Left index finger PIPJ difference	Left index finger DIPJ difference	Left middle finger MCPJ difference	Left middle finger PIPJ difference	Left middle finger DIPJ difference	Left ring finger MCPJ difference	left ring finger PIPJ difference	Left ring finger DIPJ difference	Left little finger MCPJ difference	Left little finger PIPJ difference	Left little finger DIPJ difference
heat group	N	59	59	59	59	59	59	59	59	59	59	59	59	59	59
	Std. Deviation	4.18906	3.37376	3.52829	4.72196	3.56742	3.87939	4.09558	2.75908	3.16135	4.23761	2.33766	3.62027	4.18906	2.80373
	Median	.0000	.0000	5.0000	5.0000	.0000	5.0000	5.0000	.0000	5.0000	5.0000	.0000	5.0000	5.0000	.0000
	Minimum	-10.00	-5.00	-5.00	-5.00	-10.00	-5.00	-5.00	-5.00	.00	-5.00	-5.00	-5.00	-15.00	-5.00
	Maximum	15.00	10.00	10.00	25.00	10.00	15.00	15.00	5.00	10.00	20.00	5.00	10.00	10.00	10.00
	Mean	5.8929	6.6071	3.7500	4.1071	3.1250	3.7500	3.8393	2.7679	3.8393	4.0179	1.6964	4.1964	5.4464	2.7679
wax group	N	56	56	56	56	56	56	56	56	56	56	56	56	56	56
	Std. Deviation	8.42654	4.77752	3.84353	2.87736	5.35660	4.18330	5.04445	5.47055	4.47123	5.34447	3.84670	3.13003	4.29342	5.21533
	Median	5.0000	5.0000	5.0000	5.0000	5.0000	5.0000	5.0000	.0000	5.0000	5.0000	.0000	5.0000	5.0000	.0000
	Minimum	-15.00	.00	-5.00	.00	-15.00	-5.00	-5.00	-15.00	-5.00	-10.00	-5.00	-5.00	-5.00	-5.00
	Maximum	30.00	20.00	10.00	10.00	20.00	10.00	30.00	30.00	15.00	30.00	20.00	15.00	10.00	20.00
	Mean	4.0870	4.3043	3.5652	4.3913	2.4348	4.0435	4.0870	2.0435	3.7826	3.8261	1.4348	3.5217	4.0000	2.3913
Total	N	115	115	115	115	115	115	115	115	115	115	115	115	115	115
	Std. Deviation	6.80501	4.67763	3.67335	3.92628	4.55787	4.02272	4.56832	4.33750	3.83836	4.79082	3.15986	3.43957	4.45248	4.15425
	Median	5.0000	5.0000	5.0000	5.0000	5.0000	5.0000	5.0000	.0000	5.0000	5.0000	.0000	5.0000	5.0000	.0000
	Minimum	-15.00	-5.00	-5.00	-5.00	-15.00	-5.00	-5.00	-15.00	-5.00	-10.00	-5.00	-5.00	-15.00	-5.00
	Mean	2.3729	2.1186	3.3898	4.6610	1.7797	4.3220	4.3220	1.3559	3.7288	3.6441	1.1864	2.8814	2.6271	2.0339