THE EFFECTS OF WEIGHT TRAINING ON PAIN RELIEF AND FATIGUE IN PATIENTS WITH FIBROMYALGIA

by

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DECLARATION

I, Gerhard Coetzer (Student No: 1999061854) certify that the script hereby submitted by me for the **M. Sports Medicine** degree at the University of the Free State is my independent effort and had not previously been submitted for a degree at another University or Faculty. I hereby cede copyright of this product in favour of the University of the Free State.

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DEDICATION

I dedicate this dissertation to my family and thank them for all their support.

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Opsomming

Objektiewe: Die doel van die studie was om vas te stel wat die effek van weerstands oefening op pyn verligting en moegheid in pasiente met Fibromyalgia (FM) sal wees.

Metodes: Die studie was ‘n gerandomiseerde kontrole studie op pasiente wat met FM gediagnoseer is. Die groep van FM pasiente was onderworpe aan insluitings en uitsluilings kriteria. Randomisering was op die pasiente toegepas wat aan die insluitings kriteria voldoen het deur die Departement van Biostatistieks by die Universityd van Die Vrystaat. Die eksperimentele groep was onderworpe aan ‘n oefen program, onder supervisie, terwyl die kontrole groep verbale instruksies ontvang het om ‘n oefen program te volg. (Glombiewski et al., 2010).

Die oefen periode was 12 weke. Die pasiente het by hul daaglikse take en fisiese aktiwiteite gebly. Die eksperimentele groep het ‘n weerstands oefen program gevolg. Oefenings intervalle was 3 keer per week. Gedurende die eerste 3 weke het pasiente begin met 8 – 12 repetisies vir elke stel, met gewigte van 40 - 60% van die “one repetition maximum”(1 RM) en aan gehou vir die volgende 4 weke met 10 – 12 repetisies met die gewig van 60 – 70% van 1 RM. Gedurende week 8 – 12 is die hoeveelheid repetisies van 10 vervang met gewig van 60 – 80%van 1 RM. Addisioneel tot die spier versterking oefining het elke sessie ge-eindig met 5 – 10 minute kern spier versterking. Alle oefen sessies het ingesluit opwarming met n trapmuil of oefen fiets en is be-eindig deur strek oefeninge. Steeds het die pasiente hul natuurlike take en fisiese aktiwiteite behou. Die pasiente het 15 minute opgewarm, wat bestaan het uit 15 minute ligte aerobiese werk gevolg deur 30 – 40 minute weerstands oefening gevolg deur 10 – 15 minute afkoelling. Die program het verskil van ‘n Maandag tot ‘n Woensdag tot ‘n Vrydag, waar verskillende spier groepe getyken was deur die oefening.

Resultate: Die anthropometries karaktertrekke in die huidige studie van die oefen en kontrole groep is baie dieselfde. Die “Student T-Test” het die verskille tussen die kontrole groep en die oefen groep se Fibromyalgia Impak Vrae lys (FIQ) oor 12 weke gemeet. ‘n 95% vertrouens interval was gebruik om die verskille tussen die twee groepe te bereken. Die vertrouens interval het gewys dat daar geen statistiese verskille tussen die FM experimenteel (FMT) end FM kontrole groep (MC) was nie. Die volgende veranderlikes, V = FIQ: W4-W1 is waar die FIQ telling van week 4 af getrek was van week 1.Geen statistiese verskil($p<0.05$) was op gemerk tussen die gekontruleerde groep en die oefin groep tussen week 1 en week 4 nie. Die oefen groep se vordering was statisties beter ($p<0.05$) as die kontrole groep in weke 4 – 8. Teen week 8 was die FMT group’s fibromyalgia inpak vrae lys punte median 39 teen die FMC se groep median van 63. Ongelukkig het die oefen groep versleg. statistes opmerkbaar ($p<0.05$) in die FIQ punte vergelyk met die gekontroleede groep van week 8 – 12. Laastens was daar geen statistiese verskil ($p<0.05$) tussen week 1 en week 12 tussen die FM gekontroleerde groep en die oefen groep tot opsigte van verbetering van simtome wat geraporteer nie.

Opmerkings: Dit is steeds onduidelik watter kombinasie, tipe, intensiwitiet en durasie van oefen voorskrif die beste werk in die behandeling van FM. Dit is belangrik om te erken dat in die geval van

‘n kroniese pyn sindroom soos FM, behandeling nie net gefokus moet wees op die onmiddelikke simtoom verligting nie maar ook lang termyn behoue leefstyl gedrag. So lank as wat FM etiologie onduidelik bly, is daar ‘n behoefte om verskillende behandelings modaliteite te ondersoek wat gebruik kan word om die simptome te verlig. Navorsing moet aan gaan met eksperimentele metodes om simtome te verlig op kort termyn en aangaande lang termyn gedrags verandering en funksie te verbeter en kwalityd van lewe vir pasiente met FM.

Objectives: The aim of this study was to determine the effect of weight training on pain relief and fatigue in patients with fibromyalgia (FM).

Methods: This study was a randomized control study on patients diagnosed with FM. The group of FM patients was subjected to inclusion and exclusion criteria. Randomization was done on the patients who have met the inclusion criteria by the Department of Biostatistics at the University of The Free State. The experimental group was subjected to a training programme under supervision while the control group received verbal instructions to follow a training programme and the benefits thereof (Glombiewski et al., 2010), but did not undergo supervised training.

The training period was 12 weeks. The subjects maintained their ordinary daily chores and physical activity. The experimental group started a supervised strength training period. Training was carried out 3 times a week and. During the first 3 weeks patients started with 8 - 12 repetitions for each set, with loads of 40 – 60% of the one repetition maximum (1 RM) and continued during the next 4 weeks with 10 – 12 repetitions with loads of 60 – 70% of 1 RM. Subsequently, during week 8 – 12 the number of repetitions was 10 for each set with loads of 60 – 80% of 1 RM. In addition to the muscle strengthening exercises each session ended with 5 – 10 minutes of core strengthening. All training sessions included warm up and cool down exercises using either a treadmill or bicycle ergometer and muscle stretching. Moreover, the subjects continued their ordinary chores and physical activities. The patients did a 15 minute warm up consisting of 10 minutes light aerobic work followed by 30 – 40 minutes weight training followed by 10 – 15 minutes of cool down. The programme differed from a Monday, to a Wednesday, to a Friday, where different muscle groups were targeted by the weight training.

Results: The anthropometric characteristics in the current study for the exercise and control group are very similar. The Student T-Test was used to test for significant differences between the control and experimental group Fibromyalgia Impact Questionnaire (FIQ) scores over the 12 weeks. A 95% confidence interval was used to determine the difference between the two groups. The confidence interval shows that there is no statistical difference between the FM experimental (FMT) and FM control group (FMC). The following variable, V = FIQ: W4-W1 is where the FIQ score of week 4 were subtracted from week 1. No statistical difference ($p<0.05$) was observed between the control and the exersice group between week 1 and 4. The exercise group's progress was statistically better ($p<0.05$) than control group in week 4 - 8. At week 8 the FMT group's fibromyalgia impact questionnaire score median was 39 compared to the FMC group's median of 63. Unfortunately, the exercise group deteriorated statistically significant ($p<0.05$) in the FIQ scores compared to control group improvement from week 8 – 12. Lastly, there was no statistical difference ($p<0.05$) between week 1 and week 12 between the FM control group and the exersise group regarding improvement of symptoms as reported in the FM impact questionnaire.

Conclusions: It is still unclear what combination of type, intensity and duration of exercise treatment works best in the treatment of FM. It is important to recognize that in the case of a chronic pain

disorder like FM, treatment must be focused not just on immediate symptom relief but also on maintaining long term lifestyle behaviour. As long as FM aetiology remains unclear, there is a need to explore mediating variables that can be used to intervene in order to ameliorate symptoms. Research efforts must continue to explore methods to relieve symptoms short term and support ongoing long term behaviour change to improve functioning and enhance the quality of life for patients with FM.

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LIST OF ABBREVIATIONS AND ACRONYMS

1-RM	One Repetition Maximum
ACSM	American College of Sports Medicine
AIMS	Arthritis Impact Measurement Scales
FM	Fibromyalgia
FMC	Fibromyalgia control group
FMT	Fibromyalgia training group
FDA	Federal Drug Administration
FIQ	Fibromyalgia Impact Questionnaire
RET	Resistance Exercise Therapy
ACR	American College of Rheumatology
HPA	Hypothalamic-Pituitary-Adrenal
FMC	Fibromyalgia Control Group
FMT	Fibromyalgia Training Group

ABSTRACT

Key words: *Fibromyalgia, Resistance training, Pain relief*

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from week 8 – 12. Lastly, there was no statistical difference ($p<0.05$) between week 1 and week 12 between the FM control group and the exersise group regarding improvement of symptoms as reported in the FM impact questionnaire.

Conclusions: It is still unclear what combination of type, intensity and duration of exercise treatment works best in the treatment of FM. It is important to recognize that in the case of a chronic pain disorder like FM, treatment must be focused not just on immediate symptom relief but also on maintaining long term lifestyle behaviour. As long as FM aetiology remains unclear, there is a need to explore mediating variables that can be used to intervene in order to ameliorate symptoms. Research efforts must continue to explore methods to relieve symptoms short term and support ongoing long term behaviour change to improve functioning and enhance the quality of life for patients with FM.

CHAPTER 1

INTRODUCTION AND PROBLEM STATEMENT

1.1 INTRODUCTION

Fibromyalgia (FM) is defined as a condition of chronic wide spread pain; that is pain that is present in all four quadrants of the body. Axial pain, anterior chest wall, cervical spine and lumbar spine pain must be present. Pain must also be present in 11 of the 18 tender points (Wolfe *et al*., 1990).

The prevalence of FM in South Africa is unknown, but in the USA it is the second most common disease seen at the rheumatology clinic (Panton *et al*., 2009). Initial complaints when presenting to a physician are fatigue, sleep disturbance, wide spread pain and morning stiffness. The differential diagnosis of FM includes, polymyalgia-rheumatica, viral infections, early stages of rheumatoid arthritis and systemic lupus erythemathosis, sjörgens syndrome, polyarticular osteo-arthritis, severe vitamin D deficiency, statin therapy, inflammatory myopathies, joint hypermobility syndromes and myotonic dystrophy (Bennett, 2009). Considering such a wide differential diagnosis, FM is possibly under-diagnosed in South Africa.

The symptoms of FM affect all parts of a patient's wellbeing. The physical and mental distress experienced by patients with FM greatly reduces their quality of life and leads to social withdrawal (Storge-Jacobs, 2002). According to Wolfe *et al*., (1990) FM patients are regularly diagnosed with depression and anxiety disorders. Musculo- skeletal pain is of a chronic nature, wide spread, achy, and accompanied by stiffness (Mannerkorpi & Iversen, 2003). Compared to asymptomatic patients, patients with FM display reduced upper and lower extremity physical capacity that makes every day work for example, walking, sitting, and working with arms very hard. Mannerkorpi & Iversen, (2003) also stated that these patients have a decreased aerobic capacity when compared to normal individuals of the same age

group. Aggravation of symptoms are associated with increased activity, anxiety and stress.

Historically, the treatment of FM was pharmacological, but with the recent growth in sports medicine and exercise prescription, an increasing number of studies are published on the benefits on pain relief through exercise (Jones *et al*., 2006). Through the years many different studies have been done to show the effect of exercise on patients with FM. Most studies have included aerobic exercise of some sort which concluded that aerobic studies improve pain, fatigue, morning stiffness, irritable bowel syndrome, tender points score and psychological status (Bircan *et al*., 2008). Aya´n *et al*. (2007) also stated that aerobic fitness generally improves quality of life. Other forms of exercise also show positive results in the management of FM. A six week whole body vibration exercise programme also improved pain and fatigue (Alentorn-Geli *et al*., 2008). A Meta-analysis showed that most forms of exercise have a positive effect on the symptoms of FM (Mannerkorpi & Iverson, 2003).

According to Kingsley (2010) resistance exercise was initially overlooked as a treatment modality for FM, because it was thought that FM was a disease of the skeletal musculature. However, recent evidence has pointed to more central mediation mechanisms responsible for FM. Therefore, resistance exercise may be beneficial for this population. Studies utilizing resistance exercise therapy in women with FM have demonstrated increases in maximal strength as well as decreases in FM severity such as the number of active tender points, the myalgic score and improvements in quality of life (Kingsley, 2010).

Unfortunately only a few studies are available using strength training as a modality (Geel & Robergs, 2002; Valkeinen *et al*., 2006; Figuera *et al*., 2008; Panton *et al*., 2009). Therefore specific parameters for strength training in FM are not clearly set out in the literature. Nevertheless, these studies on resistance training, report improvements in patient's strength, mood, myalgia and function without exacerbations of their symptoms (Mannerkorpi & Iverson, 2003).

Despite reoccurrences of symptoms being reported while exercising, literature seems to suggest that exercise relieve symptoms of FM. However, adequate evidence to inform treatment guidelines for physical activity is still lacking. Also, most research studies from literature used interventions falling short of the frequency (amount of exercise per week) suggested by the American College of Sports Medicine (ACSM) to induce health benefits associated with physical activity (Haskell *et al*., 2007). It is recommended that a person exercises for 150 minutes per week.

1.2 THE AIM OF THE STUDY

The aim of this study is therefore to evaluate the effect of a 12 week resistance training programme on pain and fatigue in patients with FM.

1.3. SYNTHESIS OF THE DISSERTATION

The dissertation is presented in five chapters, supported by additional material in Appendices. This chapter briefly introduces the topic of FM and the role of exercise in the management thereof to motivate the purpose of the study. In Chapter Two, a review of the relevant literature on physiological and clinical aspects of FM is presented, in association with literature on the effects of exercise modalities on the condition. Lacunae in current knowledge are exposed, leading to the aim of the study. In Chapter Three, the methodology of the experiment is presented, including a description of the study population, methods, statistical analysis and ethical aspects. Chapter Four presents the results of the study. The results are discussed according to the available literature, observations and recommendations made and conclusions are drawn. All documentation used in the study are presented as Appendices.

1.4. CONCLUSION

This chapter introduced the motivation and synthesis of the study. A more in-depth literature study is presented in the next chapter, Chapter Two.

CHAPTER 2

LITERATURE REVIEW

THE EFFECTS OF WEIGHT TRAINING ON PAIN RELIEF AND FATIGUE IN PATIENTS WITH FIBROMYALGIA

2.1 INTRODUCTION

About 10% of the general population reports chronic musculo-skeletal pain of generalised origin that cannot be tracked to a specific structural or inflammatory cause (Goldenberg *et al*., 2004). Ngian *et al*., (2011) described fibromyalgia (FM) as a disease characterised by wide spread chronic pain and allodynia. Fibromyalgia has been recognised as a diagnosable disease by the US National Institute of Health and the American College of Rheumatology (Hawkins, 2013). Fibromyalgia is also a central nervous system disorder and is caused by neurobiological abnormalities and causes physiological pain, cognitive impairments, as well as neuropsychological symptoms (Nigian *et al*., 2011). Patients that suffer from FM have lower mechanical and thermal pain thresholds, higher pain ratings for noxious stimulae and altered temporal summation of pain stimulae (Goldenberg *et al*., 2004).

Like most chronic illnesses however, the symptoms of FM extend far beyond the defining criteria. Many patients also report fatigue, disrupted or non-refreshed sleep, mood disturbances, exercise induced symptom flares and multiple other syndromes (e.g., restless legs, irritable bowel and bladder, and chronic headaches) (Clauw & Crofford, 2003; Bennett, 2005). According to Burckhardt *et al*. (1993) and Strombeck *et al*. (2000) the physical and emotional health as well as quality of life of fibromyalgia patients is often seriously impaired.

2.2 CLASSIFICATION

Wolfe *et al*. (2010) stated that “The introduction of the American College of Rheumatology (ACR) fibromyalgia classification criteria 20 years ago began an era of increased recognition of the syndrome. The criteria required tenderness on pressure (tender points) in at least 11 of 18 specified sites and the presence of

widespread pain for diagnosis. Widespread pain was defined as axial pain, left- and right-sided pain, and upper and lower segment pain. Over time, a series of objections to the ACR classification criteria developed, some practical and some philosophical. First, it became increasingly clear that the tender point count was rarely performed in primary care where most fibromyalgia diagnoses occurred, and when performed, was performed incorrectly".

Many physicians do not know how to examine for tender points and some simply refused to do so. Consequently, FM diagnosis in practice has often been a symptom-based diagnosis. Secondly, the importance of symptoms that had not been considered by the ACR Multicenter Criteria Committee became increasingly known and appreciated as key FM features: for example, fatigue, cognitive symptoms, and the extent of somatic symptoms. In addition, a number of FM experts believed that tender points obscured important considerations and erroneously linked the disorder to peripheral muscle abnormality. Finally, some physicians considered that FM was a spectrum disorder and was not well served by dichotomous criteria (Wolfe *et al*., 2010).

According to Clauw *et al*. (2011) FM is classed as a disorder in pain processing due to abnormalities in our pain signals is processed in the central nervous system. Physiological evidence does exist for the processing of pain in patients with FM and has been demonstrated by brain imaging. In addition, a three times higher concentration of substance P has been shown in cerebral spinal fluid in patients with FM. According to Geoffroy *et al*. (2012) individuals with FM got classified into 4 individual groups:

1. Extreme sensitivity to pain but no associated psychiatric conditions.
2. Fibromyalgia and comorbid, pain related depression.
3. Depression with concomitant fibromyalgia syndrome.
4. Fibromyalgia due to somatization (Geoffroy *et al*., 2012).

2.3 SIGNS AND SYMPTOMS OF FIBROMYALGIA

Fibromyalgia is a disorder of unknown etiology characterized by widespread pain, abnormal pain processing, sleep disturbance, fatigue and often psychological distress. People with FM may also have other symptoms; such as,

- Morning stiffness
- Tingling or numbness in hands and feet
- Headaches, including migraines
- Irritable bowel syndrome
- Sleep disturbances
- Cognitive problems with thinking and memory (sometimes called "fibro fog")
- Painful menstrual periods and other pain syndromes (Smith *et al*., 2011).

Fibromyalgia is also identified by chronic pain, in all four quadrants of the body, fatigue and heightened pain response to tactile pressure. Irritable bowel syndrome (Wallace & Hallegua, 2002) as well as sleep disturbances are also common (Stormorken & Brosstad, 1992).

The prevalence of FM in South Africa is unknown, but in the USA it is estimated as 2% of the general population (Chakrabarty & Zoorob, 2007). It is the second most common disease seen at Rheumatology clinics in the USA (Panton *et al*., 2009). Patients who suffer from FM have limited physical ability, increased stress and have a greater need for rest. Most of these patients find it hard to work and the unemployment rate of these patients are between 34% - 77% (Mannerkorpi & Gord, 2012). The cost to the medical insurance provider increases when the diagnosis of FM is made (Palacio *et al*., 2010).

2.4 CAUSES OF FIBROMYALGIA

2.4.1 Genetics

There is increasing evidence that FM is caused by a disorder of the central sensitisation and/or a defective pain inhibitory system (Meyer, 2011). Thus pain control mechanisms are in disarray and which causes pain amplification of pain and hyperalgesia.

The central sensitisation is thought to be brought on by different mechanisms. There is evidence that genetic factors can contribute to the development of FM. Research has demonstrated that FM is potentially associated with polymorphisms in genes in the dopaminergic, catecholaminergic and serotoninergic systems (Cohen *et al*., 2002; Zubieta *et al*., 2003; Buskila *et al*., 2004). There is evidence that FM might be inherited, but the mode of inheritance is unknown (Buskila and Sarzi-Puttini, 2006).

2.4.2 Lifestyle

Stress, physical and emotional, may also be a trigger for FM (Anderberg *et al*., 2000). Certain psychological factors like major depression, is also associated with FM (Goldenberg, 1999). Poor lifestyles for example lack of physical activity, obesity and smoking also puts you in increased risk of developing FM (Sommer *et al*., 2012). Hippocampal abnormalities have been demonstrated by magnetic resonance spectroscopy. Some authors suggest that stressful conditions may alter the function of the HPA axis, causing FM.

2.4.3 Sleep disturbances

Fibromyalgia patients usually report problems with initiating sleep and maintaining sleep. The most notable feature is feeling tired upon wakening. This causes greater daytime impairment (Beltran, 2003). Rizzi and colleagues reported that a cyclic alternating pattern of sleep correlated with FM symptoms. By disrupting stage 4 sleep in young healthy subjects researchers reproduced a significant increase in

muscle tenderness similar to FM. The pain resolved when normal sleeping patterns were resumed (Beltran, 2003).

The circadian pacemaker, located in the hyphothalamus, influences melatonin secretion and activity of the hypothalamic-pituitary-adrenal (HPA) axis. These systems have been shown to be abnormal in individuals with FM. Melatonin, a serotonin derivative, has been used successfully in the treatment of sleep disorders (Reiter *et al*., 2007). In a non-controlled pilot study of FM patients, self-reported sleep scores improved significantly over baseline measures after treatment with melatonin (Citera *et al*., 2000).

2.5 PSYCHOLOGICAL FACTORS OF FIBROMYALGIA

A comprehensive review in the relationship between major depression disorder and FM found substantial similarities in neuroendocrine abnormalities, physical symptoms and psychological characteristics (Pae *et al*., 2008).

2.6 PATHOPHYSIOLOGY OF FIBROMYALGIA

Various studies have suggested that abnormalities in dopamine function and serotonin function are responsible for the symptoms of FM, where dopamine is responsible for the pain symptoms (Holman & Meyers, 2005) and serotonin for the neuropsychological symptoms e.g. decreased concentration and sleep disturbances (Stormorken & Brosstad, 1992).

Neuroendocrine disruption characterised by mild hypcortisolemia, hyperreactivity of pituitary adrenocorticotropin hormone release and glucocorticoid feedback resistance has also been noticed in patients with FM (Bennet, 2002). These changes might be a result of chronic stress. Sympathetic hyperactivity has also been demonstrated in patients with FM (Martinez-Lavin, 2007).

2.7 DIAGNOSIS OF FIBROMYALGIA

According to Bennet, (2009) FM can easily be misdiagnosed as early rheumatoid arthritis. The differential diagnosis of FM includes, Polymyalgia-rheumatica, viral infections, early stages of rheumatoid arthritis and systemic lupus erithromatosis, sjorgens syndrome, polyarticularo osteoarthritis, severe vitamin D deficiency, statin therapy, inflammatory myopathies, joint hypermobility syndromes and myotonic dystrophy (Bennett, 2009). Considering such a wide differential diagnosis, FM is possibly under diagnosed in South Africa.

Fibromyalgia is defined as a condition of chronic widespread pain; that is pain that is present in all four quadrants of the body. Axial pain, anterior chest wall, cervical spine and lumbar spine pain must be present. Pain must also be present in 11 of the 18 tender points (Wolfe *et al*., 1990).

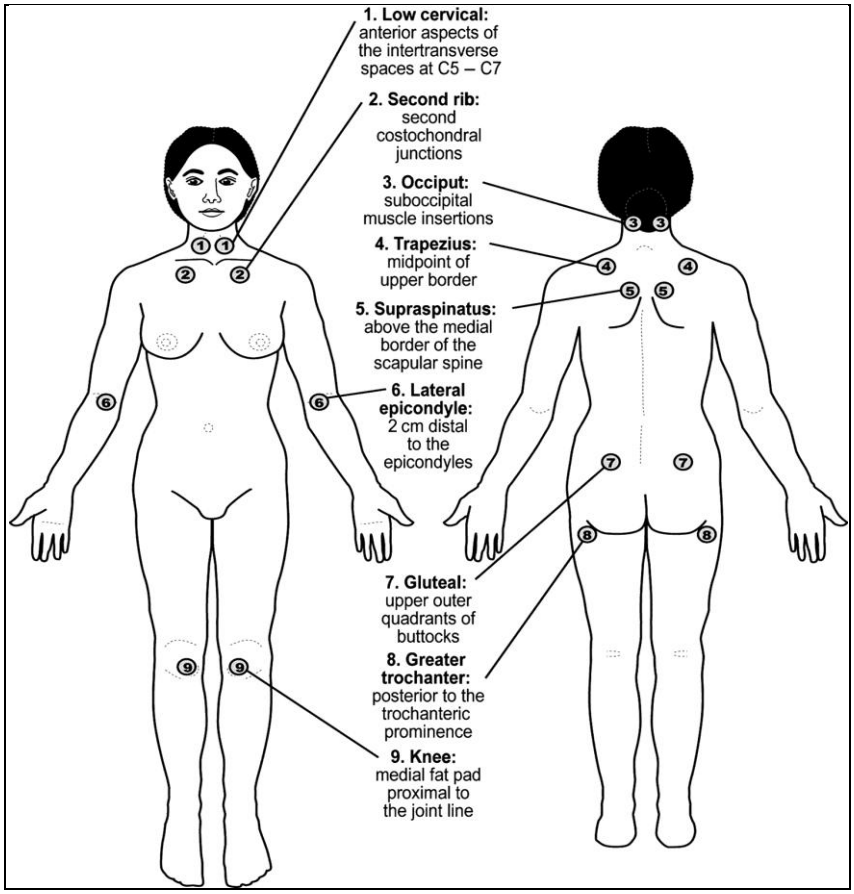

Figure 2.1: The 18 Tender Points for the diagnosis of fibromyalgia (Wolfe *et al*., 1990).

Symptoms of FM affect all parts of wellbeing. The physical and mental distress experienced by patients with FM greatly reduces their quality of life and leads to social withdrawal (Storge-Jacobs, 2002). They are regularly diagnosed with depression and anxiety disorders (Wolfe *et al.*, 1990). Musculo- skeletal pain is of a chronic nature, wide spread, achy, and accompanied by stiffness (Mannerkorpi & Iversen, 2003). Compared to asymptomatic patients, patients with FM display reduced upper and lower extremity physical capacity that makes every day work for example, walking, sitting, and working with arms very hard. They also have decreased aerobic capacity when compared to normal individuals in the same age group (Mannerkorpi & Iversen, 2003). Aggravation of symptoms is associated with increased activity, anxiety and stress.

2.8 MANAGEMENT OF FIBROMYALGIA

Treatment of FM can be divided into 3 different categories, namely psychological therapy, pharmacological and exercise therapy. Historically, the treatment of FM was pharmacological, but with the recent advances in sports medicine and exercise prescription more and more studies were published on the benefits on pain relief through exercise (Jones *et al*., 2006). It is clear that patients with FM experience a similar set of symptoms and show abnormalities in a number of physiological systems. While a growing body of evidence supports the idea of a centrally mediated etiology, there has been little effort to develop a treatment that would address the disorder in a way that would correct multiple system disruption. Pharmacological treatments as well as non-pharmacological treatments such as exercise have been used to ameliorate FM symptoms with varied results (Jones *et al.*, 2006).

At any one time, 10% to 12% of the general population report chronic generalized muscular skeletal pain that cannot be traced to a specific structural or inflammatory cause. Such idiopathic widespread pain most often will fit the classification criteria for FM (Goldenberg, *et al*., 2004). Despite improved recognition and understanding of FM, treatment remains challenging. Some believe that no effective treatment exists (Ehrlich, 2003).

A lack of standardized treatment therefore highlights how little is known about the etiology of FM. (Riedel *et al*., 2002). Currently, treatment for FM mainly relies on pharmacological and cognitive behaviour therapy (Peterson, 2005). Exercise interventions predominantly focus on endurance (aerobic) activity (Meiworm *et al*., 2000; Mannerkorpi *et al*., 2000; Jentoft, *et al*., 2001; Mannerkorpi *et al*., 2002; Jones *et al*., 2002; Beltran, 2003; Aya´n *et al*., 2007; Bircan *et al*., 2008) with only a few studies investigating resistance exercise training (RET) (Häkkinen *et al*., 2001; Rooks *et al*., 2002; Kingsley *et al*., 2005; Figueroa *et al*., 2008, Panton *et al*., 2009; Häuser *et al*., 2010; Kingsley, 2010). Studies that involve resistance exercise vary in duration, sets, repetitions, and intensity, making it difficult to compare data (Jones & Clark, 2002). These studies have shown improvements in maximal strength and endurance (Häkkinen *et al*., 2001; Panton *et al*., 2009), and perceived pain (Figueroa *et al*., 2008; Häkkinen *et al*., 2001) in women with FM but have done so without knowing the physiological mechanisms behind these changes. However, none of these modalities have been able to completely alleviate the symptoms of those that suffer from FM.

2.8.1 Psychological treatment

Cognitive behavioural therapy has shown a small effect in reducing the effects of FM (Glombiewski *et al*., 2010). In a systemic review of 14 studies, cognitive behavioural therapy has been shown to be effective on self-efficacy, but did not improve the symptoms of FM (Bernardy *et al*., 2010). According to Williams (2003) the greatest benefit with cognitive behavioural therapy is when it is used with exercise.

There is also strong evidence that intensive patient education is an effective treatment in FM. Randomised controlled trials compared patient education with weight lifting, untreated controls or with stretching and movement. Patients who received education improved in one or more outcomes including pain, sleep, fatigue, self-efficacy, quality of life and a six minute walk (Goldenberg *et al*., 2004).

2.8.2 Pharmacological treatment of fibromialgia

A summary of the available evidence, the treatment options for FM have been summarised and categorised by Goldenberg *et al*. (2004). Pharmacotherapy for FM has been most successful with central nervous system agents **(Table 2.1**).

Pharmacologically, paracetamol with a weak opioid is the treatment of choice (Goldenberg, 2007). Tramadol is the best for this is because it binds mu-opioid receptors and inhibits the re-uptake of norepinephrine and serotonin (Goldenberg, 2007). Other drugs that also show good efficacy are tricyclic anti-depressants and mixed reuptake inhibitors which are increase the norephinephrine and serotonin levels. There are three drugs approved by the FDA for the treatment of FM, namely pregabalin, duloxetine and milnacipran (Goldenberg, 2007).

TABLE 2.1: **Treatment of Fibromyalgia Syndrome (Goldenberg *et al*., 2004).**

Medications **Strong Evidence for Efficacy** Amitriptyline: often helps sleep and overall well-being; dose, 25-50 mg at bed-time. Cyclobenzaprine: similar response and adverse effects; dose, 10-30mg at bedtime. **Modest Evidence for Efficacy** Tramadol: Long-term efficacy and tolerability unknown; administered with or without acetaminophen; dose, 200-300 mg/d. Serotonin reuptake inhibitors (SSRIs): Fluoxetine (only one carefully evaluated at this time): dose, 20-80 mg; may be used with tricyclic given at bedtime; uncontrolled report of efficacy using sertraline. Dual-reuptake inhibitors (SNRIs): Venlafaxine: 1RCT ineffective but 2case reports found higher dose effective. Milnacipran: effective in single RCT. Duloxetine: effective in single RCT. Pregabalin: second-generation anticonvulsant; effective in single RCT. **Weak Evidence for Efficacy** Growth hormone: modest improvement in subset of patients with FMS with low growth hormone levels at baseline. Hydroxytryptamine (serotonin): methodological problems. Tropisetron: not commercially available. S-adenosyl-methionine: mixed results.
No Evidence for Efficacy Opioids, corticosteroids, nonsteroidal anti-inflammatory drugs, benzodiazepine and nonbenzodiazepene hypnotics, melatonin, calcitonin, thyroid hormone, guaifenesin, dehydroepiandrosterone, magnesium. **Nonmedicinal Therapies**

Strong Evidence for Efficacy (Wait-List or Flexibility Controls But Not Blinded Trials). Cardiovascular exercise: efficacy not maintained if exercise stops. CBT: improvement often sustained for months. Patient education: group format using lectures, written materials, demonstrations; improvement sustained for 3 to 12 months. Multidisciplinary therapy, such as exercise and CBT or education and exercise. **Moderate Evidence for Efficacy** Strength training. Acupuncture. Hypnotherapy. Biofeedback. Balneotherapy.
Weak Evidence for Efficacy Chiropractic, manual, and massage therapy; electrotherapy, ultrasound. **No Evidence for Efficacy** Tender (trigger) point injections, flexibility exercise. CBT indicates cognitive behavioural therapy; RCT, randomized controlled trial; SSRI, selective serotonin reuptake inhibitor; SNRI, serotonin and norepinephrine reuptake inhibitor.

Rossy *et al*. (1999) compiled a meta-analysis of fibromyalgia treatment interventions across four types of outcome measures, that is; physical status, self-report of FM symptoms, psychological status and daily functioning. Antidepressants were shown to improve physical status and self-report of FM symptoms, and muscles relaxants were significantly associated with improved daily functioning, however, treatment with NSAIDs did not show significantly improved outcomes on any measure (Rossy *et al*., 1999).

Although analgesia, norephinephrine and serotonin reuptake inhibitors provide symptomatic relief in some patients Meyer (2011) suggests that Alpha-2-delta ligands (egpregabalin) can be the last resort.

2.8.3 Exercise therapy

There is strong evidence that cardiovascular exercise is effective treatment in FM. The therapeutic benefit of exercise for individuals with FM was first recognized 20 years ago when patients randomized to 20 weeks of high-intensity exercise had greater improvements in fitness, tender point pain thresholds, and global assessment ratings than did patients randomized to flexibility training (McCain, 1986; McCain, *et al*., 1988; Goldenberg *et al*., 2004). The benefits of aerobic exercise (Jentoft *et al*., 2001; Gowans *et al*., 2002; Schachter *et al*., 2003, Aya´n *et al*., 2007) and muscle strengthening (Jones *et al*., 2002) have subsequently been confirmed in FM clinical trials. Pool exercise has also been well-tolerated and especially helpful (Jentoft *et al*., 2001).

2.8.3.1 *Aerobic Exercise*

Through the years many different studies have been done to show the effect of exercise on patients with FM. Most studies have included aerobic exercise of some sort which concluded that aerobic exercise improves pain, fatigue, morning stiffness, irritable bowel syndrome, tender points score and psychological status (Bircan *et al*., 2008). Aerobic fitness generally improves quality of life (Beltran, 2003; Aya´n *et al*., 2007). Jones *et al*. (2002) found that aerobic exercise (Nordic Walking) significantly improved quality of life in patients with FM, but there was no statistical difference in the pain scores. Häuser (2010) concluded that there is no difference between water based aerobic treatment or land based aerobic treatment. The meta-analysis showed improved outcomes in pain, fatigue, depression and quality of life.

Early efforts to determine the effects of exercise on FM symptoms focused on the increasing physical and cardiovascular fitness utilizing stationary cycling. In two studies participants met three times per week over a 20 week period to participate in a randomly assigned group of cycling or flexibility training. For the cardiovascular FM group, improvements were found on post-treatment scores. Cardiovascular exercise participants also showed an improvement in physical wellbeing as well as psychological wellbeing compared to the flexibility group (McCain *et al., 1988;* Beltran, 2003).

Significant increases in cardiovascular fitness and improvement in pain parameters was found in participants in an exercise-only study utilizing walking, jogging, stationary cycling or swimming (Meiworm *et al*., 2000). Subjects trained at home for an average of 25 minutes two to three times a week, based on individualized exercise protocols which increased in aerobic intensity over the 12 week training period. Although the effects of this treatment on psychological status and physical functioning were not measured, the researchers were able to demonstrate that regular, moderate-intensity aerobic exercise can benefit pain and fitness levels in patients with FM.

The benefits of moderately-paced exercise were also demonstrated by Meyer and Lemley (2000). They compared the effects of high and low intensity walking on physical and psychological status as well as physical functioning in patients with FM. Due to poor compliance, statistical analyses were performed on reassigned groups based on actual exercise participation as noted in subjects exercise logs. Significant improvements in cardiovascular fitness were found in both groups, along with a 54% decrease in functional impairments (Beltran, 2003)

2.8.3.2 *Group walking*

In two studies that compared walking to flexibility training and sedentary controls, it was found that when the walking intensity was low, there was no significant difference between the walking group and the sedentary controls. However, when the intensity of the walking was a bit higher there was improvement in the myalgia score of patients with FM, thus suggesting that higher intensity aerobic exercise is necessary for symptomatic relief (Nichols & Glenn, 1994; Martin *et al*., 1996).

2.8.3.3 *Pool exercise*

Various studies provided evidence that low to moderate intensity and/ or water based aerobic exercise performed three to four times per week for 20 – 30 minutes had improved symptoms of FM, by combining aerobic training with resistance

training in water (Meiworm *et al*., 2000; Mannerkorpi *et al*., 2000; Jentoft *et al*., 2001 and Mannerkorpi *et al*., 2002).

In a study utilizing pool exercise and education treatment, Mannerkorpi *et al*. (2000) compared a FM group to a group of FM patients who met once a week for six months to participate in a 35 minute pool exercise class comprising of exercises for endurance, coordination, flexibility and relaxation. The FMC group met for six one-hour sessions designed to introduce coping strategies for FM symptoms and encourage physical activity. Significant differences between groups were found on measures of general health, social functioning and quality of life, demonstrating improvement for treatment participants compared to controls. In addition, treatment participants improved compared to pre-treatment measures of physical functioning, health, vitality, social functioning, and pain severity as well as physical fitness. This study adds to the body of evidence supporting a multidimensional treatment for FM that includes an exercise component (Beltran, 2003).

2.8.3.4 *Pool versus land exercise*

Only one study to date has compared the effects of two types of cardiovascular exercise performed at comparable levels of intensity to determine which more effectively relieved FM symptoms. Both groups showed significant improvements in cardiovascular capacity and daytime fatigue. The pool FMT group also showed improvement in self-reported number of good days, physical impairment, pain, anxiety, and depression. A finding that was mainly unchanged at six month follow up. These results demonstrate that both land and pool-based physical exercise can increase physical capacity in FM patients. In addition, pool exercise may have additional benefits on self-report symptoms of mood, functioning and well-being (Beltran, 2003).

2.8.3.5 *Resistance training*

Resistance exercise was initially overlooked as a treatment modality because it was thought that FM was a disease of the skeletal musculature However, recent

evidence has pointed to more central mediation mechanisms responsible for FM. Therefore, resistance exercise may be beneficial for this population (Kingsley, 2010).

Studies utilizing resistance exercise therapy (RET) in women with FM have demonstrated increases in maximal strength as well as decreases in FM severity such as the number of active tender points , the myalgic score and improvements in quality of life (Kingsley, 2010). An increase in maximal strength in women with FM has been shown. In one of Kingsley earlier studies they demonstrated that women had significant improvement in upper body strength and lower body strength with full body workout consisting of 10 resistance machines utilizing just one set of eight to twelve repetitions being performed twice a week for 12 weeks. In this particular study, participants began training at 40% of their one repetition maximum and finished training at 80% of their predetermined one repetition maximum (1-RM). In addition, a more recent study from their laboratory utilized a similar RET protocol over a period of 16 weeks in which participants began RET at 50% of their 1-RM. Increases in upper body strength and lower body strength were both over 30%. In a study by Häkkinen *et al*. (2001), 21 weeks of RET increased maximal leg extension force similarly in women with FM and HC by 18% and 22% respectively. These studies suggest that RET is not only tolerable, but also efficacious for women with FM (Kingsley *et al*., 2005; Kingsley, 2010).

In an earlier study by Kingsley *et al.* (2005), they assessed 12 weeks of RET on FM severity. They reported no significant changes in the number of active tender points, the myalgic score or the FIQ after RET. Similar results were reported by Häkkinen *et al*. (2001) following 21 weeks of RET. However, a study by Valkeinen *et al*. (2006) did show a reduction in the number of active tender points from 16.5 to 14.6 units after 21 weeks of RET. Rooks *et al.* (2002) found a significant 28% reduction in FIQ score with a combined aerobic and strength program. A more recent study from Kingsley demonstrated that RET twice a week for 16 weeks was sufficient to decrease FM severity. Specifically, they concluded that 16 weeks of RET decreased the number of active tender points, the myalgic score and the FIQ (Kingsley, 2010).

According to Mannerkorpi & Iverson, (2003) patients with FM are 20 – 30% weaker when compared to healthy individuals. Unfortunately only a few studies are available using strength training as a modality. Therefore specific parameters for strength

training in FM are not clearly set out in the literature. These studies on resistance training report improvements in patient's strength, mood, myalgia and function without exacerbations of their symptoms (Mannerkorpi & Iverson, 2003). Although women with FM are reported to be 20 – 30% weaker than healthy individuals, in a study done by Häkkinen *et al*. (2001) showed that patients with FM has the same ability to improve strength and power than healthy individuals.

Despite recurrences of symptoms being reported while exercising, literature seems to suggest that exercise can relieve the symptoms of FM. However, adequate evidence to inform treatment guidelines for physical activity is still lacking. Also, most research studies from literature used interventions falling short of the frequency (amount of exercise per week) suggested by the American College of Sports Medicine (ACSM) to induce health benefits associated with physical activity (Haskell *et al*., 2007). Therefore, this study will aim to evaluate the effect of a 12 week resistance training programme on pain and fatigue in patients with FM.

According to Goldenberg *et al*. (2004) many of the commonly used FM therapies have not been carefully evaluated. Based on these reports, a stepwise FM management guideline can be recommended.

In Table 2.2 a stepwise FM management plan is presented.

TABLE 2.2: Stepwise Fibromyalgia Management (Goldenberg *et al*., 2004).

Step 1
Confirm the diagnosis.
Explain the condition.
Evaluate and treat comorbid illness, such as mood disturbances and primary sleep disturbances.
Step 2
Trial with low-dose tricyclic antidepressant or cyclobenzaprine.
Begin cardiovascular fitness exercise program.
Refer for cognitive behavior therapy or combine that with exercise.
Step 3
Specialty referral (eg, rheumatologist, physiatrist, psychiatrist, pain management).
Trials with selective serotonin reuptake inhibitor, serotonin and norepi-nephrine reuptake inhibitor, or tramadol.
Consider combination medication trial or anticonvulsant.

2.9 CONCLUSION

While it is still unclear what combination of type, intensity and duration of exercise treatment works best in the treatment of fibromyalgia, the most recent research suggests that graded, moderate intensity pool exercise in combination with an exercise component has advantages in terms of compliance and efficacy. It is important to recognize that in the case of a chronic pain disorder like FM, treatment must be focused not just on immediate symptom relief but also on maintaining long term lifestyle behaviour change. Resistance training seems to have promising results, but the safe and effective guidelines for resistance training prescription in FM have not been established. This study aims to address this chasm in our knowledge of FM management.

CHAPTER 3

METHOD OF RESEARCH

3.1 INTRODUCTION

This chapter describes the protocol that was designed to investigate the objective stated in Chapter One. In preparation for this dissertation, literature was collected from the electronic databases PubMed, Science Direct, (Academic Search Elite and Medline), academic journals and text books.

3.2 STUDY DESIGN

This study was a randomized controlled study on patients diagnosed with FM. The group of FM patients was subjected to inclusion and exclusion criteria. Randomization was done on the patients who had met the inclusion criteria by the Department of Biostatistics of the University of The Free State. The experimental group was subjected to a training programme under supervision while the FM group received verbal instructions to follow a training programme and the benefits thereof (Glombiewski *et al.*, 2010), but did not undergo supervised training.

3.3 STUDY PARTICIPANTS

A meeting with the FM patients was arranged in order to obtain full permission for execution of the investigation, as well as to explain the procedures that followed (Appendix 1- 5). The inclusion and exclusion criteria were based on the 1990 American College of Rheumatology classification (Wolfe *et al.*, 1990).

- **INCLUSION CRITERIA**

- Pain lasting longer than 3 months in all 4 quadrants of the body where 11 of the 18 tender points are tender.

- **EXCLUSION CRITERIA**
  - Orthopaedic limitations, cardiovascular limitations, pulmonary limitations, involved in regular exercise already, practical limitations such as transport problems or time constraints.

- **DISQUALIFICATION OF A STUDY PARTICIPANT**
  - If the patient is unable to train for more than 100 minutes per week

3.3.1 Target Population

Twenty one (21) patients with FM were recruited for this study. Before inclusion the patients were examined by the researcher to confirm the diagnosis of FM according to the 1990 American College of Rheumatology classification (Wolfe *et al*., 1990).

3.3.2 Sample Population

After advertising in the local newspaper for volunteers with FM to participate in the study, a total of 32 patients were identified. Of these 32 patients 21 met the inclusion criteria. After inclusion the patients were randomly allocated to the experimental (FMT; n = 11) or control (FMC; n = 10) group.

3.3.3 Exercise Intervention - Experimental Strength Training

The training period was 12 weeks. The subjects maintained their ordinary daily chores and physical activity. The experimental group was exposed to a supervised strength training period. Training was carried out three times a week and each training session included six to eight exercises, such as squat exercises, knee and

trunk extension and flexion exercises, bench press and lateral pull downs. During the first three weeks patients started with eight to twelve repetitions for each set, with loads of 40 – 60% of the one repetition maximum. (1-RM) and continued during the next four weeks with ten to twelve repetitions with loads of 60 – 70% of 1-RM (Hakinnen *et al*., 2001). Subsequently, during week eight to twelve the number of repetitions was ten for each set with loads of 60 – 80% of 1-RM. The protocol for resistance training in this study is similar to the protocol followed in similar studies on FM patients (Kingsley, 2010). In addition to the muscle strengthening exercises each session ended with 5 – 10 minutes of core strengthening, for example sit-ups and planking. All training sessions included warm up and cool down exercises using either a treadmill or cycle ergometer and muscle stretching. Moreover, the subjects continued their ordinary chores and physical activities. Some patients was on anti-depressant medication, but no alterations was made to any patients pharmacological treatment.

The patients did a 15 minute warm up consisting of 10 minutes light aerobic work followed by 30 – 40 minutes isotonic weight training followed by 10 – 15 minutes of cool down. The programme differed from a Monday, to a Wednesday, to a Friday, where different muscle groups were targeted by the isometric weight training in each session. The sessions were administered and monitored by trained fitness and health professionals.

3.4 MEASUREMENT

Pain was measured using the visual analogue scale (Appendix 2). Fatigue was measured using the Fibromyalgia Impact Questionnaire (FIQ) (Burckhardt *et al*., 1993). Test-retest reliability correlations for items on the FIQ ranged from 0.56 to 0.95, demonstrating adequate reliability over six one-week intervals. Construct validity testing of the FIQ yielded correlations ranging from 0.67 to 0.83. Subscales of the Arthritis Impact Measurement Scales (AIMS) were compared to subscales of the FIQ (Burckhardt *et al*., 1993), supporting the construct validity of the FIQ. Fatigue data was collected before the exercise intervention started and then on week 1, 4, 8, 12. All the data was collected by the researcher.

The FIQ was used to measure the outcome of the study, where a patient with a lower score indicated that the symptoms for FM were less severe.

The FIQ questionnaire (Appendidix 1) is scored in the following manner (Burckhardt *et al*., 1993):

1. The first item consists of 11 questions that make up a physical functioning scale. The 11 questions are scored and summed to yield one physical impairment score. Each item is rated on a four point Likert type scale. Raw scores on each item can range from 0 (always) to 3 (never) - thus the highest total possible raw score is 33. Because some patients may not do some of the tasks listed, they are given the option of deleting items from scoring. In order to obtain a valid summed score for questions 1 through 11, the scores for the items that the patient has rated are summed and divided by the number of items rated (e.g. if the patient completed only nine items at a score of 2 for each, the final score would be 9x2/9= 2). An average raw score between 0 and 3 is obtained in this manner.
2. Item 2 is scored inversely - so that a higher number indicates impairment (i.e., 0=7, 1=6, 2=5, 3=4, 4=3, 5=2, 6=1 and 7=0, etc.). Raw scores can range from 0 to 7.
3. Item 3 is scored directly (i.e. 7=7 and 0=0). Raw scores can range from 0 to 7.
4. Items 4 through 10 are scored in 10 increments. Raw scores can range from 0 to 10. If the patient marks the space between two vertical lines on any item, that item is given a score that includes 0.5.
5. Once the initial scoring has been completed, the resulting scores are subjected to a normalization procedure so that all scores are expressed in similar units. The range of normalized scores is 0 to 10 with 0 indicating no impairment and 10 indicating maximum impairment.

3.4.1 Data Collection

After obtaining approval, participants were handed a research folder, consisting of the following:

(1) Cover letter (Appendix 4)

(2) Information sheet (Appendix 5)

(3) Informed consent (Appendix 3)

(4) Fibromyalgia Impact Questionnaire (FIQ) (Appendix 1)

(5) Visual Analogue Pain Scale (Appendix 2)

At the first meeting, all the patients that met the inclusion criteria were informed about the purpose of the study. It was explained to the patients that they will be randomized by the Department of Biostatistics into two groups. All the patients then signed consent and all the participants' names were sent to the Department of Biostatistics for random allocation of patients into the experimental (FMT) and control (FMC) groups. Following a talk on the benefits of exercise for patients with FM, the FMC group was then seen once a month (week 1, 4, 8 and 12) to complete their forms. The FMT group proceeded to go to gym 3 times per week, at 1hour per session as explained in the study design. The forms were filled in before the training session on the Monday of week 1, 4, 8 and 12.

A schematic illustration of the data collection is presented in **Figure 3.1**.

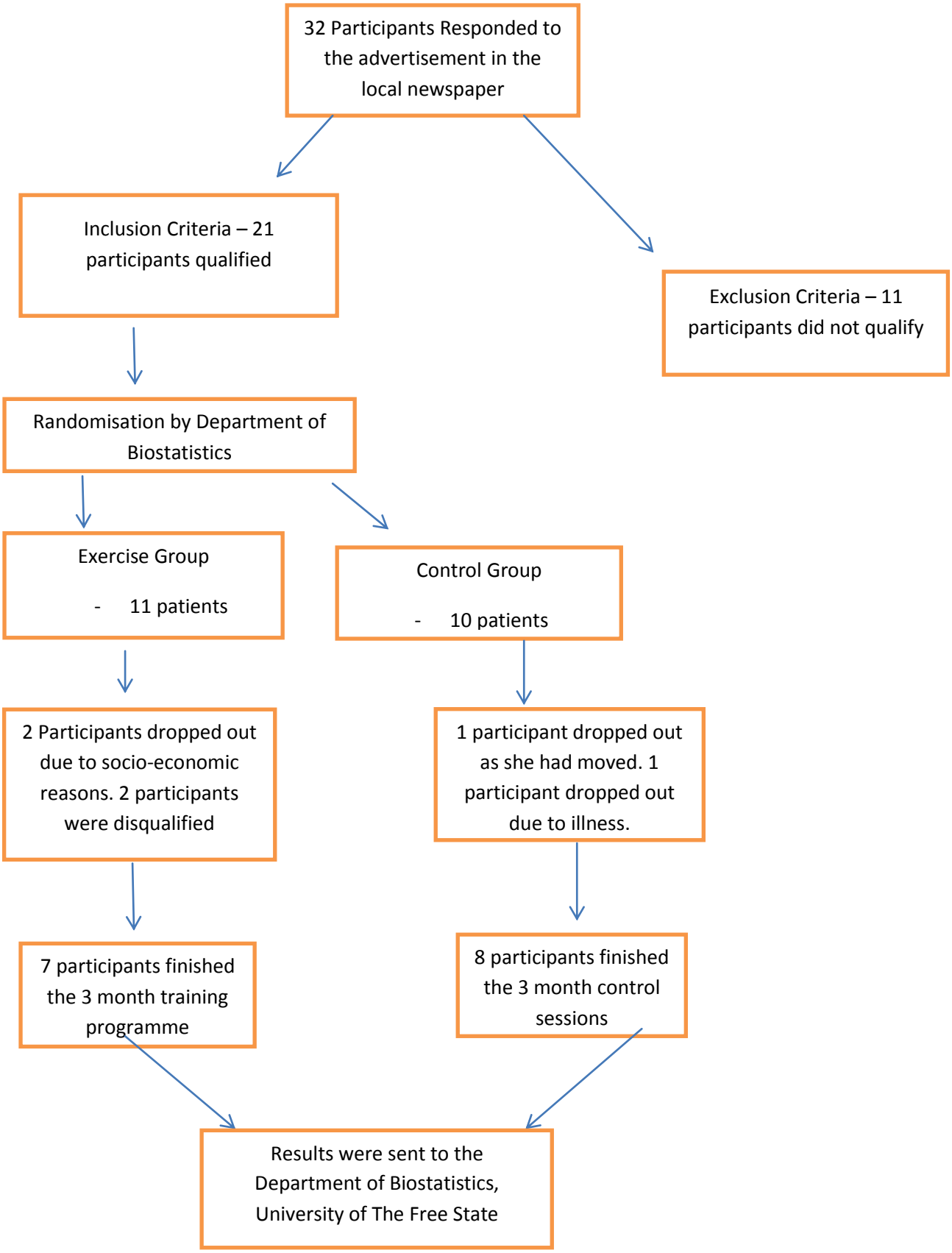

Figure 3.1: Schematic representation of the data collection.

3.5 METHODOLOGICAL AND MEASUREMENT ERRORS

Errors were minimised by the researcher by using the same protocol and methodology using the FIQ questionnaire. Supervision was done by trained personnel.

3.6 PILOT STUDY

A pilot study with one Fibromyalgia patient was conducted three months prior to the intervention regimen. It consisted of testing the ability of the patient to perform strength training with regards to flare-up of pain and fatigue. It was also used to expose any inadequacies in the data sheets, equipment and protocols, and it was found to be effective.

3.7 ANALYSIS OF THE DATA

Data was captured electronically by the Department of Biostatistics of the University of the Free State. Further analysis was then done by a biostatistician using SAS version 9.1.3. Descriptive statistics namely mean, standard deviations, minimum and maximum values were calculated for all variables. The Student T-Test was used to test for significant differences between the control and experimental group. A significance level of $p<0, 05$ was used throughout the study.

3.8 IMPLEMENTATION OF FINDINGS

Results of the study were reported to the participants of the study. The results of the study can serve as a training guideline for patients with FM.

3.9 ETHICS

3.9.1 Ethical Approval

Before the study commenced and the subjects were recruited, the study was approved by the Ethics Committee of the Faculty of Health Sciences, University of the Free State. (ETOVS No199/2011). The informed consent form, approved by the University of The Free State, was handed out and had to be signed by the patients (Appendix 3). If the patients sustained any injury or complications, he/she would be referred to an appropriate specialist. The study was done in English.

To obtain written informed consent the following items were included:

- Purpose of study.
- Duration of study.
- Potential advantages of study.
- Risk for the patient.
- Reversebility of side effects.
- Alternative methods of treatment.
- Patient may withdraw from study at any time.
- Participation is voluntary.
- Information obtained will be treated as confidential.
- Insurance has been taken out to protect participants.
- Name and details of contact persons.
- The results may be published.
- That no cost will be payable by the participant involved in the study.
- Results will be made available at the end of the programme.

3.9.2 Information to participants and informed consent

After obtaining the relevant consent, patients were giving a FM folder with a cover letter, consent form and information sheet. Emphasis was made that the study is completely voluntary and that the patients can withdraw from the study at any stage without explanation. The information sheet ensured that all the patients received the

same information regarding the study, exercise and FM. Patients were made aware that all information was confidential.

3.10 LIMITATIONS OF THE STUDY

Sample size was a major limitation of the study. Recruitment was a challenging process, made difficult by the fear of exercise that many fibromyalgia patients share. The time commitment also posed a challenge. Other limitations include the brief time spent in the psycho-educational component of the treatment program. The attempt at group facilitation of biofeedback for participants in the multi-component treatment group limited the efficacy of that part of the program; an individual or better designed group protocol might show greater treatment effects. The study also was limited by heavy reliance on self-report measures, an issue common in fibromyalgia research. The use of physiological or functional measures is more objective, and could add more important data about physical change over time.

CHAPTER 4

RESULTS

4.1 SAMPLE CHARACTERISTICS

In this randomised control study 21 patients met the inclusion criteria to participate in the study. Seven FM patients (7) completed the exercise therapy and 8 patients from the FMC group. Five (5) FM patients did not complete the study due to various reasons.

TABLE 4.1: Demographic information of exercise- and FMC group

FMT group		FMC group	
Age	**Gender**	**Age**	**Gender**
32	Male	37	Female
44	Female	49	Female
53	Female	50	Female
54	Female	53	Female
59	Female	55	Female
61	Female	58	Female
66	Female	59	Female
		68	Male
X = 52.7		**X= 53.6**	

MEAN = X

Table 4.1 shows the demographic information of the participants in the study. Only one male in both groups met the inclusion criteria for the study. The mean age of the exercise (FMT) group was 52.7 years, which was very similar to the mean age of the control (FMC) group (53.6 years). The minimum and maximum age of the experimental- and FMC group was respectively 32 years for the FMT group and 37 years for the FMC group. The maximum age for the FMT group was 66 years and that of the FMC group was 68 years.

Table 4.2 to Table 4.5 show the results of the FMT group score out of 100 for the FIQ during week 1 to week 12. A score more than 70 is "**severely**" afflicted FM patients. **Table 4.2 to Table 4.5** also indicated how many patients scored more than 70 per week (indicated in grey). **Table 4.6 to Table 4.9** show the results of the FMC group score out of 100 for the FIQ during week 1 to week 12. **Table 4.6 to Table 4.9** also indicated how many patients scored more than 70 per week (Indicated in grey).

4.2 THE RESULTS OF FIBROMYALGIA IMPACT QUESTIONNAIRE (FIQ)-WEEK 1 – 12 (FMT Group)

The FIQ was utilized to determine the impact of FM on a week-to-week basis. The FIQ consists of 20 questions that assess items such as the ability to perform activities of daily living, well-being, and symptoms of FM. The greater the FIQ score, the greater the impact of the disease (Bennett, 2005). Researchers have demonstrated that the average woman with FM scores 50 units, while a more severely impacted woman with FM has scores of 70 units and above (Marques *et al*., 2004). The FIQ has been shown to be both a reliable and valid questionnaire for impact of FM (Burckhardt *et al*., 1993).

TABLE 4.2: The Fibromyalgia Impact Questionnaire (FIQ)- Week 1

The SAS System

FMT group

FIQ score: week 1	Frequency	Percent	Cumulative Frequency	Cumulative Percent
28.21	1	14.29	1	14.29
47.94	1	14.29	2	28.57
51.31	1	14.29	3	42.86
57.56	1	14.29	4	57.14
63.84	1	14.29	5	71.43
69.64	1	14.29	6	85.71
81.11	1	14.29	7	100.00

Minimum: **28.21**
Median: **57.56**
Maximum: **81.11**

As shown in **Table 4.2** on the first day of data collection (week 1) of the FMT group the, afflicted fibromyalgia patients had a median score of 57.56 for the FIQ. The minimum score was only 28.2 and the maximum score on the FIQ was 81.1 out of 100. It is also important to notice that only one patient obtained a score more than 70 per week which indicated “severely” afflicted FM.

TABLE 4.3: The Fibromyalgia Impact Questionnaire (FIQ)- Week 4

The SAS System

FMT group

FIQ score: week 4	Frequency	Percent	Cumulative Frequency	Cumulative Percent
22.31	1	14.29	1	14.29
41.04	1	14.29	2	28.57
44.01	1	14.29	3	42.86
44.29	1	14.29	4	57.14
49.11	1	14.29	5	71.43
69.56	1	14.29	6	85.71
82.21	1	14.29	7	100.00

Minimum: 22.31

Median: 44.29

Maximum : 82.21

Table 4.3 shows that the minimum, median and maximum FIQ scores of the FMT group were 22.3, 44.29 and 82.21 respectively in week 4. Only the maximum score in week 4 was very similar to the score in week 1. Again only one patient obtained a score more than 70.

TABLE 4.4: The Fibromyalgia Impact Questionnaire (FIQ)- Week 8

The SAS System

FMT group

FIQ score: week 8	Frequency	Percent	Cumulative Frequency	Cumulative Percent
12.50	1	14.29	1	14.29
17.00	1	14.29	2	28.57
23.36	1	14.29	3	42.86
39.71	1	14.29	4	57.14
49.88	1	14.29	5	71.43
53.48	1	14.29	6	85.71
81.246	1	14.29	7	100.00

Minimum: 12.50

Median: 39.71

Maximum: 81.24

From **Table 4.4** it can be seen that the fibromyalgia patients in the FMT group in week 8 indicated that they had a median score of 39.71, and they obtained a maximum score of 81.24 which is very similar as found in week 1 and 4, and only a minimum score of 12.50 in week 8. As in week 1 and 4 only 1 patient obtained a score more than 70.

TABLE 4.5: The Fibromyalgia Impact Questionnaire (FIQ)- Week 12

The SAS System

FMT group

FIQ score: week 12	Frequency	Percent	Cumulative Frequency	Cumulative Percent
15.30	1	14.29	1	14.29
20.00	1	14.29	2	28.57
26.96	1	14.29	3	42.86
42.11	1	14.29	4	57.14
57.66	1	14.29	5	71.43
60.82	1	14.29	6	85.71
86.64	1	14.29	7	100.00

Minimum: 15.30
Median: 42.11
Maximum: 86.64

As shown in **Table 4.5** on the last week of data collection (week 12) of the FMT group, the afflicted FM patients had a median score of 42.11 for the FIQ. The minimum and maximum score was slightly higher (minimum - 15.30, maximum- 86.64) than found in week 8. The same tendency was also found in week 12 where only one patient obtained a score more than 70 in the FIQ.

4.3 THE RESULTS OF FIBROMYALGIA IMPACT QUESTIONNAIRE (FIQ)- WEEK 1 – 12 : (FMC group)

TABLE 4.6: The Fibromyalgia Impact Questionnaire (FIQ)- Week 1

The SAS System

FMC group

FIQ score: week	Frequency	Percent	Cumulative Frequency	Cumulative Percent
20.42	1	12.50	1	12.50
37.37	1	12.50	2	25.00
50.00	1	12.50	3	37.50
52.70	1	12.50	4	50.00
64.48	1	12.50	5	62.50
70.03	1	12.50	6	75.00
71.26	1	12.50	7	87.50
86.58	1	12.50	8	100.00

In week 1 there were 3 patients with a score of more than 70.

Minimum: **20.42**
Median: **58.59**
Maximum: **86.58**

Table 4.6 shows that on the first day of data collection (week 1), the FMC group afflicted FM patients had a median score of 58.59 for the FIQ, which is similar as the FMT group with a score of 57.56. The minimum score was only 20.42 and the maximum score on the FIQ was 86.58 out of a 100. It is important to note that 3

patients score more than 70 per week in the FIQ which indicated “severely” afflicted FM patients.

TABLE 4.7: The Fibromyalgia Impact Questionnaire (FIQ)- Week 4

The SAS System

FMC group

FIQ score: week 4	Frequency	Percent	Cumulative Frequency	Cumulative Percent
17.53	1	12.50	1	12.50
42.35	1	12.50	2	25.00
45.30	1	12.50	3	37.50
56.75	1	12.50	4	50.00
57.04	1	12.50	5	62.50
64.34	1	12.50	6	75.00
66.54	1	12.50	7	87.50
76.36	1	12.50	8	100.00

Minimum: 17.53

Median: 56.89

Maximum: 76.36

Table 4.7 shows that the minimum, median and maximum FIQ scores of the FMC group was 17.53, versus 22.3 in the FMT group, 56.89, versus 44.29 of the FMT group and 76.36 versus 82.21for the FMT group respectively in week 4. Interestingly, the maximum scores obtained in week 4 was much lower as in week 1, where only one patient obtained a score more than 70 in week 4.

TABLE 4.8: The Fibromyalgia Impact Questionnaire (FIQ)- Week 8

The SAS System

FMC group

FIQ score: week 8	Frequency	Percent	Cumulative Frequency	Cumulative Percent
40.68	1	12.50	1	12.50
55.04	1	12.50	2	25.00
58.83	1	12.50	3	37.50
63.40	1	12.50	4	50.00
64.40	1	12.50	5	62.50
72.96	1	12.50	6	75.00
75.05	1	12.50	7	87.50
82.57	1	12.50	8	100.00

Minimum: 40.68
Median: 63.90
Maximum: 82.57

From **Table 4.8** it can be seen that the FMC group in week 8 had a median score of 63.90, a maximum score of 82.57 and a minimum score of 40.68. It is interesting to note that as in week 1, 3 patients obtained scores higher than 70 in week 8. It is also interesting to note that the minimum scores were almost double the scores found in week 1 and 4.

TABLE 4.9: The Fibromyalgia Impact Questionnaire (FIQ)- Week 12

The SAS System

FMC group

FIQ score: week 12	Frequency	Percent	Cumulative Frequency	Cumulative Percent
22.74	1	12.50	1	12.50
24.90	1	12.50	2	25.00
50.44	1	12.50	3	37.50
55.32	1	12.50	4	50.00
61.23	1	12.50	5	62.50
67.48	1	12.50	6	75.00
70.89	1	12.50	7	87.50
72.36	1	12.50	8	100.00

Minimum: 22.74
Median: 58.28
Maximum: 72.36

As shown in **Table 4.9** on the last week of data collection (week 12) of the FMC group, the afflicted FM patients had a median score of 58.28 versus the 63.90 found in week 8. The minimum score was much less (minimum 22.7 versus 40.68) as found in week 8. The same tendency is also found in the maximum scores in week 12, where a score of 72.36 was obtained versus 82.57 obtained in week 8. Only 2 FM patients obtained a score more than 70 in the last week, week 12 in the FIQ.

4.4 THE DIFFERENCE IN RESULTS of FIBROMYALGIA IMPACT QUESTIONNAIRE (FIQ)- Week 1 – 12 : (FMT group)

Table 4.10 shows the difference in the results of the FIQ score between week 1 and 4 of the FMT group. The following variable, V = FIQ: W4-W1 is where the FIQ score of week 1 were subtracted from week 4. Negative values show an improvement and positive values deterioration. Values in grey is the minimum, median and maximum values respectively.

TABLE 4.10: The difference in the results of the Fibromyalgia Impact Questionnaire: (FIQ)- Week 4 - 1

The SAS System

FMT group

0V=FIQ: W4 - W1	Frequency	Percent	Cumulative Frequency	Cumulative Percent
-25.62	1	14.29	1	14.29
-14.73	1	14.29	2	28.57
-13.27	1	14.29	3	42.86
-11.55	1	14.29	4	57.14
-10.26	1	14.29	5	71.43
12.57	1	14.29	6	85.71
15.80	1	14.29	7	100.00

Minimum: -25.62

Median: -11.55

Maximum: 15.80

As shown in **Table 4.10**, in week 1 to 4, the afflicted FM patients had an improvement in the results of minimum FIQ scores (-25.62) and the median FIQ scores (-11.55) but the more severe afflicted FM patients deteriorated over the 4 weeks (15.80).

Table 4.11 shows the difference in the results of the FIQ score between week 8 and 4 of the FMT group. The following variable, V = FIQ: W8-W4 is where the FIQ score of week 4 were subtracted from week 8. Negative values show an improvement and positive values deterioration. Values in grey is the minimum, median and maximum values respectively.

TABLE 4.11: The difference in the results of the Fibromyalgia Impact Questionnaire (FIQ)- Week 8 - 4

The SAS System

FMT group

V=FIQ: W8 – W4	Frequency	Percent	Cumulative Frequency	Cumulative Percent
-69.71	1	14.29	1	14.29
-20.92	1	14.29	2	28.57
-5.30	1	14.29	3	42.86
-4.3	1	14.29	4	57.14
0.77	1	14.29	5	71.43
11.68	1	14.29	6	85.71
12.43	1	14.29	7	100.00

Minimum: -69.71

Median: -4.3

Maximum: 12.43

Table 4.11 shows again that week 4-8, as in week 1 – 4, that the patients had an improvement in the results of minimum FIQ scores (-69.71) and the median FIQ scores (-4.3) but the more severely afflicted FM patients deteriorated over the 4 weeks (12.43).

Table 4.12 shows the difference in the results of the FIQ score between week 12 and 8 of the FMT group. The following variable, V = FIQ: W12-W8 is where the FIQ score of week 8 was subtracted from week 12. Negative values show an improvement and positive values deterioration. Values in grey indicate the minimum, median and maximum values respectively.

TABLE 4.12: The difference in the results of the Fibromyalgia Impact Questionnaire (FIQ)- Week 12 - 8

The SAS System

FMT group

V=FIQ: W12 – W8	Frequency	Percent	Cumulative Frequency	Cumulative Percent
2.39	1	14.29	1	14.29
2.80	1	14.29	2	28.57
2.99	1	14.29	3	42.86
3.59	1	14.29	4	57.14
4.18	1	14.29	5	71.43
5.39	1	14.29	6	85.71
10.94	1	14.29	7	100.00

Minimum: 2.39

Median: 3.59

Maximum: 10.94

Interestingly, **Table 4.12** shows no improvement in the results of minimum FIQ scores (2.39) the median FIQ scores (3.59) and the maximum scores (10.94) from week 8-12. The patients in the FMT group had deteriorated in the minimum, median and maximum scores over the last 4 weeks of intervention.

Table 4.13 shows the difference in the results of the FIQ score between week 12 and 1 of the FMT group. The following variable, V = FIQ: W12-W1 is where the FIQ score of week 1 was subtracted from week 12. Negative values show an improvement and positive values deterioration. Values in grey indicate the minimum, median and maximum values respectively.

TABLE 4.13: The difference in the results of the Fibromyalgia Impact Questionnaire (FIQ)- Week 1-12

The SAS System

FMT group

V=FIQ: W12 – W1	Frequency	Percent	Cumulative Frequency	Cumulative Percent
-54.33	1	14.29	1	14.29
-30.60	1	14.29	2	28.57
-27.94	1	14.29	3	42.86
-3.01	1	14.29	4	57.14
5.52	1	14.29	5	71.43
6.35	1	14.29	6	85.71
13.90	1	14.29	7	100.00

Minimum: -54.33

Median: -3.01

Maximum: 13.90

However, as shown in **Table 4.13**, from week 1 to 12, the patients had an improvement in the results of minimum FIQ scores (-54.33) and the median FIQ scores (3.01) but the more severe afflicted fibromyalgia patients had deteriorated over the 12 weeks of intervention, maximum scores (13.90).

4.5 THE DIFFERENCE IN RESULTS OF FIBROMYALGIA IMPACT QUESTIONNAIRE (FIQ)- Week 1 – 12: (FMC group)

Table 4.14 shows the difference in the results of the FIQ score between week 1 and 4 of the FMC group. The following variable, V = FIQ: W4-W1 is where the FIQ score of week 1 was subtracted from week 4. Negative values show an improvement and positive values show deterioration. Values in grey indicate the minimum, median and maximum values respectively.

TABLE 4.14: The difference in the results of the Fibromyalgia Impact Questionnaire (FIQ)- Week 4 - 1

The SAS System

FMC group

V=FIQ: W1 – W4	Frequency	Percent	Cumulative Frequency	Cumulative Percent
-20.03	1	12.50	1	12.50
-13.28	1	12.50	2	25.00
-7.43	1	12.50	3	37.50
-7.40	1	12.50	4	50.00
-2.88	1	12.50	5	62.50
4.98	1	12.50	6	75.00
5.10	1	12.50	7	87.50
14.33	1	12.50	8	100.00

Minimum: -20.03
Median: -5.15
Maximum: 14.33

Table 4.14 also shows, as similarly indicated in **Table 4.10,** that the FMC group as well as the FMT group in week 1 to 4, that the patients showed an improvement in the results of minimum FIQ scores (-20.03 versus FMT group -25.62) and the median FIQ scores (-7.40 versus FMT group -11.55) but the more severely afflicted FM patients in the FMC group had deteriorated over the 4 weeks (14.33 versus FMT group 15.80).

Table 4.15 shows the difference in the results of the FIQ score between week 8 and 4 of the FMC group. The following variable, V = FIQ: W8-W4 is where the FIQ score of week 4 was subtracted from week 8. Negative values show an improvement and positive values show deterioration. Values in grey indicate the minimum, median and maximum values respectively.

TABLE 4.15: The difference in the results of the Fibromyalgia Impact Questionnaire (FIQ)- Week 4 – 8

The SAS System

FMC group

V=FIQ: W8 – W4	Frequency	Percent	Cumulative Frequency	Cumulative Percent
-3.4	1	12.50	1	12.50
-0.93	1	12.50	2	25.00
2.08	1	12.50	3	37.50
12.69	1	12.50	4	50.00
16.03	1	12.50	5	62.50
18.01	1	12.50	6	75.00
19.10	1	12.50	7	87.50
23.149	1	12.50	8	100.00

Minimum: -3.4
Median: 14.36
Maximum: 23.14

Table 4.15 shows only an improvement the minimum scores of the FMC group in week 4-8 (-3.4 versus FMT group -69.71) and the median FIQ scores no

improvement (14.36 versus FMT group -4.3). The more severely afflicted FM patients in the FMC group had also deteriorated over the first 4 weeks (23.14 versus FMT group 12.43).

Table 4.16 shows the difference in the results of the FIQ score between week 12 and 8 of the FMC group. The following variable, V = FIQ: W12-W8 is where the FIQ score of week 8 was subtracted from week 12. Negative values show an improvement and positive values indicate deteriorations. Values in grey is the minimum, median and maximum values respectively.

TABLE 4.16: The difference in the results of the Fibromyalgia Impact Questionnaire (FIQ)- Week 8 – 12

The SAS System

FMC group

V=FIQ: W12 – W8	Frequency	Percent	Cumulative Frequency	Cumulative Percent
-30.13	1	12.50	1	12.50
-19.72	1	12.50	2	25.00
-17.939	1	12.50	3	37.50
-15.09	1	12.50	4	50.00
-12.96	1	12.50	5	62.50
-0.6	1	12.50	6	75.00
2.39	1	12.50	7	87.50
6.48	1	12.50	8	100.00

Minimum: -30.13

Median: -15.09

Maximum: 6.48

Interestingly, **Table 4.16** shows no improvement in the afflicted FMC patients results of minimum FIQ scores (2.39) the median FIQ scores (3.59) and the maximum scores (10.94) from week 8-12. It seems that the afflicted FM patients in the FMC group had deteriorated in the minimum, median and maximum scores over the last 4 weeks of intervention.

Table 4.17 shows the difference in the results of the FIQ score between week 12 and 1 of the FMT group. The following variable, V = FIQ: W12-W1 is where the FIQ score of week 1 was subtracted from week 12. Negative values show an improvement and positive values indicate deteriorations. Values in grey are the minimum, median and maximum values respectively.

TABLE 4.17: The difference in the results of the Fibromyalgia Impact Questionnaire (FIQ)- Week 1 - 12

The SAS System

FMC group

V=FIQ: W12 – W1	Frequency	Percent	Cumulative Frequency	Cumulative Percent
-19.09	1	12.50	1	12.50
-12.46	1	12.50	2	25.00
-9.15	1	12.50	3	37.50
-8.80	1	12.50	4	50.00
0.44	1	12.50	5	62.50
1.10	1	12.50	6	75.00
2.32	1	12.50	7	87.50
18.18	1	12.50	8	100.00

Minimum: -19.09

Median: -4.18

Maximum: 18.18

4.6 A SUMMARY OF THE RESULTS OF FIBROMYALGIA IMPACT QUESTIONNAIRE (FIQ) Week 1 – 12 : (FMT versus FMC group)

The Student T-Test was used to test for significant differences between the control and experimental group FIQ scores over the 12 weeks. A significance level of $p<0,05$ was used throughout the study.

- A 95% confidence interval was used to determine the difference between the two groups. The confidence interval shows that there is no statistical

Difference between the experimental and FMC group. The following variable, V = FIQ: W4-W1 is where the FIQ score of week 4 were subtracted from week 1. Negative values show an improvement and positive values indicate deteriorations.

- **V=FIQ: W4-W1 =** VT [-18.4 ; 10.8] **No statistical difference** was observed between the control and the exersice group between week 1 and 4.

- **V=FIQ: W8-W4 =** VT [-38.9 ; -1.0] **Statistical difference**. Intervention group's progress is statistically better than FMC group. At week 8 the FMT group's fibromyalgia impact questionnaire score median was 39 compared to the FMC group's median of 63.

- **V=FIQ: W12-W8 =** VT [1.8 ; 25.1] **Statistical difference**. Intervention group's deterioration is statistically significant compared to controlled groups improvement from week 8 – 12.

- **V=FIQ: W12-W1 =** VT [-32.9 ; 15.2] **There was no statistical difference** between week 1 and week 12 between the FMC group and the exercise group regarding improvement of symptoms as reported in the fibromyalgia impact questionnaire.

CHAPTER 5

DISCUSSION OF RESULTS

5.1 INTRODUCTION

It has been shown that at any time around the world about 10% of the population suffer with generalized body pains of unknown origin. These symptoms can fit in with FM. Exercise has been used since the 1980s in the treatment of FM (Goldenberg *et al*., 2004). Although exercise was used as a treatment modality for FM, only a limited amount of information is available, and specific guidelines regarding dose and type of exercise are still unclear. For this reason, the researcher initiated this study to determine the influence of resistance training for 150 minutes per week as a treatment modality for FM patients. The dose of 150 minutes of moderate intensity exercise per week is the recommended dose for healthy individuals by the American College of Sports Medicine (Haskell *et al*., 2007). The question arises, is this recommended doses also applicable for FM patients.

5.2. DEMOGRAPHIC INFORMATION AND ANTHROPOMETRIC CHARACTERISTICS

Fifteen patients completed the study. The sample characteristics are presented in **Table 4.1**

As shown in **Table 4.3** the patients in the exercise (FMT) group showed immediate improvement when starting to train. There were no signs of a flare-up of symptoms and their fibromyalgia impact questionnaire score started decreasing immediately. As mentioned in Chapter Three, the patients started with 50% of their one repetition maximum resistance effort (1-RM). No patient reported a flare-up of symptoms and there were no patients that stopped training as a result of pain. Häkkinen *et al*. (2001) also reported no flare-up of symptoms when starting resistance training at 40-60% of 1-RM. No change was made to any of the patients chronic medication.

5.3 DISCUSSION OF THE RESULTS OF FIBROMYALGIA IMPACT QUESTIONNAIRE (FIQ)- Week 1 – 12 : (FMT versus FMC group)

Table 4.2 to 4.5 shows the results of the FIQ scores of the FMT group from week 1 to week 12. The patients reported significant improvements on their FIQ scores from week 4 to week 8. For some unknown reason there was a significant deterioration ($p<0.05$) of all the patients in the FMT group from week 8 to week 12. Possible causes for this deterioration might be incorrect training volume or type of exercise. In a study by Häkkinen *et al*. (2001) his patients reached a plato after 14 weeks. He concluded that a more patient specific program was needed to continue improving results. Recent studies have shown that high intensity interval training, although aerobic, yielded good results (Goldenberg *et al*., 2004). The author speculates that the intensity of the resistance training might have not been high enough to further improve symptoms. Studies have shown that heavy resistance training is safe in patients with FM (Häkkinen *et al*., 2001). **Table 4.5** indicated a 14 point improvement at the end of the 12 weeks. It must be noted, that there was some improvement in the FMT group, although they deteriorated over the last 4 weeks.

Table 4.6 to 4.9 show the results of the FIQ scores of the FMC group. As indicated in Tables 4.2 to Table 4.9 the baseline tests for both groups were similar. From week 1 to week 12 there was no statistical significant difference ($p<0.05$) in the FIQ scores between the FMT and FMC groups.

When comparing the FMT group with the FMC group, **Table 4.13 and Table 4.17** reveal differences between the FIQ scores from week 1 to 12. Firstly, no statistical difference ($p<0.05$) was observed between the FMT and the FMC group between week 1 and 4. Secondly, the FMT group's progress is statistically better ($p<0.05$) than the FMC group. At week 8 the FMT group's FIQ median score was 39 compared to the FMC group's median score of 63. Thirdly, in week 8 to 12, the FMT group's deterioration is statistically significant ($p<0.05$) compared to the FMC group's improvement, and lastly, there was no statistical difference ($p<0.05$) between week 1

to week 12 between the FMC group and the FMT group regarding improvement of symptoms as reported on the FIQ.

In other studies using resistance training, no significant improvement was seen in the amount of tender points, but there was a statistical improvement in pain and fatigue, especially neck and shoulder pain. There was also marked improvement of daily function (Häkkinen *et al*., 2001).

Häkkinen *et al*. (2001) compared healthy individuals with patients with FM over 24 weeks which is twice as long as the current study. They also showed improvement in daily functioning and that resistance treatment can be used as an effective treatment for FM. Häkkinen *et al*. (2001) reported a statistical difference in pain and fatigue after 24 weeks, while in the current study improvement was reported but no statistical difference was recorded in daily functioning.

Jones *et al*. (2006) also reported that resistance training is beneficial in the treatment of FM, but that more structured guidelines are needed for exercise prescription. He did however conclude that all forms of exercise can be used in the treatment of FM. The results of the study also show that resistance exercise can improve measures of fibromyalgia symptoms at a rate that is statistically significant ($p<0.05$) as seen between week 4 and 8, however the FMT group showed a significant deterioration in FM scores in the last week (week 8 – week 12). In this regard it is important to monitor the patient closely as they will reach a plato with no further improvement. It is then advised to adjust the exercise program accordingly. This should be done according to individual assessment, as suggested by Häkkinen *et al*. (2001).

Gowans *et al*. (2001) questioned the functional significance of tender points, and remarked that programs which fail to result in tender point change may nonetheless be effective. We must also remember that a small but statistically significant improvement may have great relevance to a patient who has seen only decline in functioning over a period of years. Measures of doctor's office visits, medication use, or pain behaviours may be a more objective way to determine whether treatment results are more than statistically significant, but do not measure the patient's subjective experience (Beltran, 2003). In the current study, participants in the treatment groups reported "feeling better", and reported that their physicians noticed improvements in their condition.

5.4. CONCLUSION

This study was conducted with a small sample of participants, which created limitations both statistically and in terms of generalizability. In addition to the difficulty in recruiting FM patients into an exercise program, eligibility to take part in the study was determined in part by participants' time schedules and availability, since sessions were facilitated in groups on a time schedule that had to fit into the schedule of a busy fitness facility.

A small but statistically significant improvement may have great relevance to a patient who has seen only decline in functioning over a period of years. From a clinical point of view, this study showed that fibromyalgia patients can experience symptomatic improvement when treated with group exercise and education. Whether the active ingredient in the treatment was improved strength or fitness, education, attention, self-efficacy, or some combination of the above is still unknown. Based on the results of the present study there are many areas for future research.

While it is still unclear what combination of type, intensity and duration of exercise treatment works best in the treatment of fibromyalgia, the most recent research suggests that graded, moderate intensity pool exercise in combination with an exercise component has advantages in terms of compliance and efficacy. It is important to recognize that in the case of a chronic pain disorder like FM, treatment must be focused not just on immediate symptom relief but also on maintaining long term lifestyle behaviour. Exercise self-efficacy, a strong and consistent predictor of future exercise, can be considered for future research examining the effects of exercise on FM (Beltran, 2003).

According to Beltran (2003) FM will also continue to pose treatment challenges due to its chronic and disabling course. As long as its aetiology remains unclear, there is a need to explore mediating variables that can be used to intervene in order to ameliorate symptoms. Research efforts must continue to explore methods to relieve symptoms short term and support ongoing long term behaviour change to improve functioning and enhance the quality of life for patients with FM.

Overall, more research on FM is necessary to expand the existing literature. Large longitudinal studies with ample sample sizes are needed. Current studies in patients with FM are plagued by high drop-out rates resulting in small sample sizes. Large longitudinal studies to evaluate the most appropriate modality, frequency, intensity and volume of training are necessary.

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Appendix 1: FIBROMYALGIA IMPACT QUESTIONNAIRE (FIQ)

Last name: First name: Age : Todays date :
Duration of FM symptoms (years) : Years since diagnosis of FM :

Question 1

Directions: For questions "a" through "k", please check the number that best describes how you did overall for the *past week*. If
you don't normally do something that is asked, place an 'X' in the 'Not Applicable' box.

Were you able to: Always Most Occasionally Never Not Applicable

a. Do shopping? □0 □1 □2 □3 □4
b. Do laundry with a washer and dryer? □0 □1 □2 □3 □4
c. Prepare meals? □0 □1 □2 □3 □4
d. Wash dishes / cooking utensils by hand? □0 □1 □2 □3 □4
e. Vacuum a rug? □0 □1 □2 □3 □4
f. Make beds? □0 □1 □2 □3 □4
g. Walk several blocks? □0 □1 □2 □3 □4
h. Visit friends or relatives? □0 □1 □2 □3 □4
i. Do yard work? □0 □1 □2 □3 □4
j. Drive a car? □0 □1 □2 □3 □4
k. Climb stairs? □0 □1 □2 □3 □4
Sub-total scores *(for internal use only)*
Total score *(for internal use only)*

2. Of the 7 days in the past week, how many days did you feel good? **Score**
□0 □1 □2 □3 □4 □5 □6 □7

3. How many days last week did you miss work, including housework, because of fibromyalgia? **Score**
□0 □1 □2 □3 □4 □5 □6 □7
(Continued)
(Continuation)

Directions: For the remaining items, mark the point on the line that best indicates how you felt overall for the past week.

4. When you worked how much did pain or other symptoms of your fibromyalgia interfere with your ability to do your work, including housework? (for internal use only)

No problem with work ⟷ Great difficulty with work

Score

5. How bad has your pain been?
No pain ⟷ Very severe pain

Score

6. How tired have you been?
No tiredness ⟷ Very tired

Score

7. How have you felt when you get up in the morning?
Awoke well rested ⟷ Awoke very tired

Score

8. How bad has your stiffness been?
No stiffness ⟷ Very stiff

Score

9. How nervous or anxious have you felt?
Not anxious ⟷ Very anxious

Score

10. How depressed or blue have you felt?
Not depressed ⟷ Very depressed

Score

Sub-total

FIQ TOTAL

Appendix 2: Visual Analoc Scale (Vas)

Patient Name: _____ Date: _____

Visual Analog Scale (VAS)*

No Pain  Pain as bad pain as it could possibly be

*A 10-cm baseline is recommended for VAS scales.

Appendix 3: Informed concent

Purpose of the study is to examine the effect of a 12 week weight training of a pain and fatigue in patients with Fibromyalgia.

The duration of the study will be 12 weeks of training with 150 minutes of training per week.

The benefit of the study will potentially be improvement in pain and fatigue.

Risk for you includes injury through exercise as well as flair-up of the symptoms.

The flair-up of the symptoms is fully reversible.

You may withdraw from the study at any time without giving reason.

Participation is voluntary.

The information obtained will be treated as confidential.

The result may be published.

No cost will be payable by the participant.

Results will be made available and the exercise programme.

_____

Dr Gerhardus Coetzer

I _____, ID No _____ hereby give consent to participate in this study

_____ _____

Patient **Dr Coetzer**

Appendix 4: Information sheet

THE EFFECTS OF WEIGHT TRAINING ON PAIN RELIEF AND FATIGUE IN PATIENTS WITH FIBROMYALGIA

Greeting:

I, Dr Gerhard Coetzer, through the UFS, am doing research on Fibromyalgia. Research is just the process to learn the answer to a question. In this study we want to learn the effect of a 12 week weight training exercise programme on pain and fatigue in Fibromyalgia.

Invitation to participate: I am inviting you to participate in a research study by Dr G Coetzer and UFS.

What is involved in the study: You will be asked to complete a 12 week exercise programme, during which we will monitor the effect of exercise on pain and fatigue. You will also be asked to exercise for a minimum of 100 minutes per week, with a maximum of 150 minutes per week. We will monitor pain and fatigue through forms that will be filled in by yourself on week 1, 4, 8, 12.

Risks of being involved in the study: The risks involved in this study are flair-up of symptoms as well as injury from exercising.

Benefits of being in the study: The benefits include reduced pain and an overall increase in energy and well-being.

The subject will be given pertinent information on the study while involved in the project and after the results are available.

Participation is voluntary, and refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled; the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Reimbursement for “out of pocket” expenses: Reimbursement will not be paid, but all gym fees and personal training will be paid by the researcher (Dr G Coetzer). You will be expected to pay for your own travelling costs to and from the gym.

Confidentiality: Efforts will be made to keep personal information confidential. Absolute confidentiality cannot be guaranteed. Personal information may be disclosed if required by law.

Results may be published, but your identity and involvement in the study will not be disclosed in the process.

Contact details of researcher: Dr G Coetzer Intercare Gonubie East London. Cell No 083 294 5337

Contact details of REC Secretariat: Mrs H Strauss. Email: StraussHS@ufs.ac.za

_____ **_____**

Participant **Witness**

_____

Date

Appendix 5: Cover letter

Where the study will be conducted:

- The study will be done at Boost Fitness Gym in Gonubie East London Eastern Cape.

What population will be included in the study:

- Male and Female patients that meet the inclusion criteria between the ages of 30 and 65

What method will be used:

- The participating group will be enrolled in a 3 month training programme and will be monitored during that time.

What treatment will be administered to participants:

- A weight training programme, supervised by a personal trainer.

What control method will be used:

- It will be a randomised control trial where the control group will receive verbal instructions to exercise and the benefit there of.

Risk and adverse effects of participating in the study:

- A flair up of symptoms is possible, as well as possible injury through the exercising self.

Expected outcome of the research:

- Based on the literature study most patients will benefit from a decrease in overall pain and fatigue.

Appendix 6: Ethics Approval letter

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Ms H Strauss/jdpls

2014-01-27

REC Reference nr 230408-011
IRB nr 00006240

DR G COETZER
DIVISION SPORT AND EXERCISE MEDICINE
FACULTY OF HEALTH SCIENCES
UFS

Dear Dr Coetzer

ECUFS NR 199/2011
PROJECT TITLE: THE EFFECTS OF WEIGHT TRAINING ON PAIN RELIEF AND FATIGUE IN PATIENTS WITH FIBROMYALGIA – A META-ANALYSIS AND INTERVENTION.

- You are hereby kindly informed that the Ethics Committee approved the following at the meeting held on 21 January 2014:
    - ***Project title changed to: "The effects of weight training on pain relief and fatigue in patients with Fibromyalgia"***
- Committee guidance documents: Declaration of Helsinki, ICH, GCP and MRC Guidelines on Bio Medical Research. Clinical Trial Guidelines 2000 Department of Health RSA; Ethics in Health Research: Principles Structure and Processes Department of Health RSA 2004; Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa, Second Edition (2006); the Constitution of the Ethics Committee of the Faculty of Health Sciences and the Guidelines of the SA Medicines Control Council as well as Laws and Regulations with regard to the Control of Medicines.
- Any amendment, extension or other modifications to the protocol must be submitted to the Ethics Committee for approval.
- The Committee must be informed of any serious adverse event and/or termination of the study.
- All relevant documents e.g. signed permission letters from the authorities, institutions; changes to the protocol, questionnaires etc. have to be submitted to the Ethics Committee before the study may be conducted (if applicable).
- A progress report should be submitted within one year of approval of long term studies and a final report at completion of both short term and long term studies.

- Kindly refer to the ETOVS/ECUFS reference number in correspondence to the Ethics Committee secretariat.

Yours faithfully

DR SM LE GRANGE
ACTING CHAIR: ETHICS COMMITTEE

Cc Ms S Van Der Merwe