EFFICACY OF HOMOEOPATHIC ARNICA MONTANA
ON MUSCLE FATIGUE

A Dissertation submitted to the faculty of Health Services,
Technikon Natal in partial fulfilment of the requirements for the
Master’s Degree in Technology: Homoeopathy

by
Andrew Peter Cross
November 1996

I, Andrew Peter Cross, do hereby declare that this dissertation
represents my own work.

Approved for final submission
Dr A. Gerber BSc BSc(Hons) MSc, PhD
Supervisor
DEDICATION

This dissertation is dedicated to my family in appreciation of their love and support.
ACKNOWLEDGEMENTS

I would personally like to thank the following people for their assistance in this study.

Dr A. Gerber - for his guidance as Supervisor.

Dan Grobler - for his insight, ideas and monitoring of the exercise testing.

Mr Worku - for his advice as statistician.

The volunteers - for their responsible and dedicated participation.

Dr Keryn White - for her patience, support and assistance with the typing.
ABSTRACT

Exercise-induced fatigue reduces exercise performance ability, causes discomfort and increases the risk of injury. Homoeopathic *Arnica montana* 30CH, according to the Law of Similars, is well indicated in an attempt to hasten reparation, reduce the risks of injury and improve the quality of muscle contraction (Blackie 1986:252).

Thirty healthy and active male volunteers were required to perform an exercise test on three consecutive days. In the study, two groups of 15 participants, Control and Treatment, received, in double-blind style, either homoeopathic *Arnica montana* 30CH or placebo as their trial medication. This was administered 5 minutes after the first exercise test, and then again immediately prior to and 5 minutes after performing the second and third exercise tests. The exercise, executed on an AKRON Isokinetic Dynamometer under the supervision of a biokinetist, consisted of maximal reciprocal contractions of the knee extensors and flexors, with the readings being recorded on computer using AKRON Test Software. From this the Maximum Torque and Fatigue Index for each participant was calculated. Each participant was required to complete a PARTICIPANT PERCEPTION FORM after the first exercise test, before and after the second and third exercise tests, and again twenty-four hours after the third exercise test.

Mann-Whitney U tests, descriptive statistics and graphs were used to analyse and comment on the data. There was no significant difference (p<0.05) found between the two groups with regard to either the Maximum Torque or Fatigue Index. The exercise test protocol, isolated and fatigued the quadriceps muscle, producing in it symptoms of muscle fatigue in both the Control and Treatment groups. From participant perception, the sensation of stiffness experienced and its severity increased in the Control group over the three days,
and decreased in the Treatment group. Evidence that a larger percentage of the Treatment group took part in regular exercise compared to the Control group places a limitation on the intervention solely providing the benefits noticed.

The intervention of homoeopathic *Arnica montana*, while showing no significant difference between the Control and Treatment groups with regard to the Maximum Torque and Fatigue Index, showed beneficial improvement and use with regard to the sensation of stiffness experienced and its severity.

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LIST OF ABBREVIATIONS

myosin adenosine triphosphatase - myosin ATPase
adenosine triphosphate - ATP
adenosine diphosphate - ADP
phosphate - P
calcium ions - Ca^{2+}
hydrogen ions - H^+
sarcoplasmic reticulum adenosine triphosphatase - SR-ATPase
sodium ions - Na^+
potassium ions - K^+
Watts per second - W.s
degees per second - deg.s
Fatigue Index - F.I.
Maximum Torque - M.T.
CHAPTER ONE  INTRODUCTION

In today's exceedingly sport orientated society, sporting activities play a major role in providing health, leisure and professional opportunities to many people. Post-exercise stiffness and its repercussions including injury, is a very real effect of fatigue from muscular performance (McIntyre et al. 1995). These resultant factors cause discomfort, reduce performance ability and decrease enjoyment people achieve through sport (Jones et al. 1994).

During short duration, high intensity exercise, fatigue is the end result of muscular contraction in the absence of oxygen. This triggers the predominance of anaerobic glycolysis for energy production, which has lactate as its end product (Abeles et al. 1992:597.) Concurrently there is a rise in hydrogen ions and a consequent drop in pH within the muscle cells (Bangsbo 1994). This reduces power output and induces fatigue through inhibitory effects on various functions within the muscle cell (Hawley and Hopkins 1995). Areas suggested to experience these effects include the excitation-contraction coupling, the affinity for calcium to bind to the troponin, the re-uptake of calcium by the sarcoplasmic reticulum, and inhibition of the propagation of the action potential (Bangsbo 1994). Noakes (1992:85) suggests that a limiting factor (fatigue point) in the performance of high intensity activity is the ability of the person to tolerate high concentrations of hydrogen ions (acidity).

Isokinetic dynamometers have been found to accurately assess muscular performance and induce fatigue for diagnostic, therapeutic or training purposes (Baltzopoulos et al. 1988; Perrin 1993:6-8.) There also exists a correlation between the fibre characteristics of the muscle and the torque generation at high isokinetic speed (Abernethy et al. 1995).
Muscle soreness after intense exercise is a common experience (McIntyre et al. 1995). This discomfort is often described as stiffness, aching or tenderness (Apell et al. 1992). Myelinated Group III neurons carrying sharp, localised pain and Group IV neurons which convey dull, diffuse pain are found throughout muscle, particularly in regions of connective tissue (Ebbeling and Clarkson 1989). McIntyre et al. (1995) suggests that stiffness is due to connective tissue damage, including tissue oedema, which causes increased mechanical sensitivity of the muscle receptors giving rise to discomfort. Gibala et al. (1995) reported that the high tensions generated during concentric resistance exercise are sufficient to cause tissue disruption, which Noakes (1992:91) refers to as micro-trauma.

The intervention is a homoeopathically prepared medicine whose choice was based on the principle 'Similia similibus curentuur' (like cures like) called the Law of Similiars. The symptoms presented by Arnica montana when administered in crude dosage to healthy people closely matches or is 'similar' to those symptoms presented by subjects who have exercised at high intensities to fatigue. (Boericke 1990:78.)

The aim of the treatment intervention is firstly to promote regulatory processes in muscle as observed by Lindinger et al. (1995) to help maintain the function of active muscles by delaying the onset of fatigue during exercise and restore homoeostasis during recovery. Secondly, to attempt to assist the micro-trauma and associated post-exercise stiffness noted by Noakes (1992) as a result of exercise to fatigue. The above-mentioned aims and sites of action makes the selection of Arnica montana as a homoeopathic intervention evident as a means to increase the limiting factor of muscular performance and reduce the time needed to recover as well as the risk of possible injury.
CHAPTER TWO       REVIEW OF THE RELATED LITERATURE

2.1. MUSCLE STRUCTURE AND FUNCTION

2.1.1. Structural Overview

There are three types of muscle found in the body. These are: cardiac, skeletal and smooth muscle (Vander et al. 1990:283). This study focuses on skeletal muscle which is attached to the skeleton and contracts to produce locomotion. Each skeletal muscle is made up of individual muscle fibres which are either fast-twitch or slow-twitch. The enveloping connective tissue contains nerves and about five capillaries providing nerve and blood supply to the muscle. (Wilmore and Costill 1994:32.) Each muscle fibre consists of a number of cylindrical myofibrils also lying parallel to each other. These myofibrils are divided into shorter sections called sarcomeres, each of which contain even smaller cylindrical structures lying parallel to each other called myofilaments. (Vander et al. 1990:285.) Myofilaments are made up of two parts, a thick filament consisting of myosin molecules and a thin filament consisting of actin, troponin and tropomyosin molecules (Guyton 1991:26). The myofibrils are suspended inside the muscle fibre in a matrix called sarcoplasm. This sarcoplasm contains numerous mitochondria that lie between and parallel to the myofibrils. (Noakes 1992:21.) Enzymes found within the sarcoplasm provide a metabolic pathway for the production of energy independant of oxygen (Wilmore and Costill 1994:103). Also within the sarcoplasm is an extensive endoplasmic reticulum called the sarcoplasmic reticulum which stores calcium ions (Ca^2+) necessary for muscle contraction (Vander et al. 1990:293).
2.1.2 Types of Muscle fibres

Type I, slow-twitch and type II, fast twitch fibres are the two main types of muscle fibre present in muscles (Noakes 1992:25). Type I fibres are red due to the high content of myoglobin, a protein which transfers the oxygen carried in the blood to the mitochondria and stores oxygen in the muscles. They also contain a high concentration of mitochondria and are generally adapted for endurance exercise. (Bloomfield et al., 1992:83.) Type II fibres are white due to a low amount of myoglobin and they have a lower concentration of mitochondria (Tortora and Grabowski 1992:252). Muscles that consist predominantly of these type II (fast-twitch) fibres are capable of contracting and relaxing faster than type I fibres because they have a higher concentration of myosin adenosine triphosphatase (myosin ATPase). This myosin ATPase activity may have various degrees of contractile speeds in the fast and slow-twitch fibres. (Noakes 1992:25.) To this end, fast-twitch fibres are divided into three types; FTa, FTb and FtC (Wilmore and Costill 1994:34).

FTa - have a high mitochondria content and are similar to slow-twitch fibres.

FTb - a ‘true’ fast-twitch fibre contains a low amount of mitochondria.

FTc - are primitive fibres being able to develop into either FTa or slow-twitch fibres.

2.1.3 Muscle Contraction

In the sliding filament theory of muscle contraction, the proteins of the thin filaments are pulled into the thick filaments (Vander et al. 1990:288-9). Myosin molecules consist of a myosin head and body. These make up the thick filaments. The myosin heads globular protein masses point towards and are attracted strongly towards the actin proteins of the thin filaments, specifically the actin binding site. (Tortora and Grabowski 1992:254.) While a muscle is at rest, this attraction is obstructed by the tropomysin molecules of the thin filaments. The tropomysin
molecules are stimulated to move out of the way by Ca\(^{2+}\), which is released through the transverse tubules. An action potential of the muscle cell surface membrane continues along the cell until it reaches deep inside the muscle cell to the transverse tubules and Ca\(^{2+}\) is released from the stores in the sarcoplasmic reticulum. Ca\(^{2+}\) flooding the filaments binds to specific calcium-binding sites called troponin-C on both the actin and tropomysin. The Ca\(^{2+}\) binding results in a twisting of the troponin-C molecule which removes the obstruction posed by the tropomysin molecules, and allows the myosin head to attach to the actin. (Westerblad et al. 1991.) Energy in the form of adenosine triphosphate (ATP) produced by the mitochondria moves to specific ATP-binding sites on the myosin heads, where it is stored as adenosine diphosphate (ADP) and phosphate (P). As the myosin head attaches itself to actin, myosin ATPase releases the ADP and P. This results in the myosin neck bending 45 degrees (rigor complex) from its normal vertical position. (Noakes 1992:23-4.) The bending action causes the thin filaments to be pulled towards the centre of each sarcomere and produces the muscle shortening of muscle contraction (Wilmore and Costill 1994:33-4). To relax the muscle, the rigor complex is broken by fresh ATP being supplied to the ATP-binding site on the myosin head and Ca\(^{2+}\) bound to troponin-C is removed allowing the tropomyosin to obstruct the actin binding site. This cycle is called the cross-bridge cycle (Vander et al. 1990:292). The rate at which myosin ATPase splits and binds ATP on the myosin head (i.e. the rate at which the cross bridge cycle occurs) will determine an athletes speed. The amount of Ca\(^{2+}\) bound to troponin-C will determine the total number of cross-bridged formed which in turn determines the power of the muscle contraction. (Noakes 1992:24-5.)
2.1.4 Types of Muscle Contractions

Muscle contractions can either be concentric or eccentric. Concentric contractions occur when unloaded muscles contract and shorten. Eccentric contractions occur when the force applied to the muscle is greater than the force that the muscle can produce during contraction resulting in the muscle length increasing as it contracts. During these contractions, instead of the myosin heads bending to 45 degrees, they are flexed to angles of up to 90 degrees. (Noakes 1992:27.) Eccentric activations use less oxygen and ATP than similar concentric contractions because no energy is required for the cross-bridge detachment (Kellis and Baltzopoulos 1995).

2.2. SOURCE OF POWER FOR EXERCISE

2.2.1. Metabolic Pathways in Exercise

In exercise metabolism the energy for muscular contraction is produced by three independent systems, the Phosphagen, Anaerobic Glycolytic (oxygen-independent) and Aerobic (oxygen-dependent). The Aerobic system is further separated into two functionally distinct aerobic power systems, the aerobic glycolytic and aerobic lipolytic systems. (Hawley and Hopkins 1995.) The anaerobic resynthesis of ATP occurs via the hydrolysis of high energy phosphagens (i.e. phosphocreatinine, adenine nucleotides) with the total ATP replenished in this way being defined as the alactic capacity. This is followed by the anaerobic catabolism of carbohydrates and the total ATP regenerated via this pathway being termed the lactic capacity. (Green 1995.) The sum of the alactic and lactic capacities yields the anaerobic capacity (Green and Dawson 1993). The relative contributions of the alactic and lactic capacities to anaerobic capacity generated during exhaustive exercise over several minutes approximate 20% and 80% respectively (Bangsbo et al. 1990).
The relative importance of these metabolic capacities to exercise performance will differ according to intensity and duration of the performance (Green and Dawson 1993). The stores of ATP and phosphocreatinine (alactic capacity) within the muscle provide the immediate energy for muscle contraction and last for about seven seconds of maximum exercise (Hirvonen et al. 1987). Goutanos et al. (1993) found that the crossover points for the phosphagen, anaerobic glycolytic and aerobic glycolytic contributions occur at approximately six seconds and one minute in athletes. The anaerobic glycolytic system predominating from six seconds to up to one minute becoming progressively inhibited by the accumulation of metabolic end-products before the crossover point where oxidative metabolism becomes the predominant energy source and dominates energy supply beyond 90-120 seconds (Noakes 1992:86-7).

2.2.2. Anaerobic Metabolism

Muscle ATP can be replenished via two different mechanisms that do not require oxygen. The muscle cells contain stores of creatine phosphate (CP) which can be broken down to creatine and P under the influence of the enzyme creatine phosphokinase. The reaction releases considerable energy permitting very rapid resynthesis of ATP from ADP and P. (Bloomfield et al. 1995:79.) The ATP/creatine phosphate (CP) anaerobic energy pathway is therefore as follows:

i) CP $\xrightarrow{creatin phosphokinase} C + P$

ii) ADP + P $\rightarrow$ ATP

The catabolism of glucose in the absence of oxygen follows the same course of reactions as it would in the presence of oxygen to the formation of pyruvate which occurs in the muscle cytoplasm, outside the mitochondria (Abeles et al. 1992:597). On entering a muscle cell, each
molecule of glucose is converted to glucose-6-phosphate in a process requiring the breakdown of one molecule of ATP. This is then either metabolised directly or converted to glycogen and stored for later use. Glucose-6-phosphate is converted to fructose-6-phosphate under the influence of phosphofructokinase. Fructose-6-phosphate is converted to fructose 1,6 diphosphate requiring another molecule of ATP. Fructose 1,6 diphosphate breaks down into 3-carbon fragments, glyceraldehyde-3-phosphate and dihydroxyacetone, the latter being enzymatically transformed into another molecule of glyceraldehyde 3-phosphate. These two molecules are converted through five successive steps during which one pair of electrons is picked up by NAD+ and two molecules of ATP are formed from ADP and P to form pyruvate. This is then converted to lactate in the absence of oxygen, instead of entering the mitochondria. Up to this point two moles of ATP are formed for each molecule of glucose utilised. (Bloomfield et al. 1995:78.)

2.2.3. Other Substrates in Energy Metabolism

Another carbohydrate substrate used in energy metabolism is fructose. It is phosphorylated in the cell to produce fructose-1-phosphate, which is then cleaved to form glyceraldehyde and 1,3 dihydroxyacetone phosphate. Glyceraldehyde can be converted to glyceraldehyde-3-phosphate, both of which are intermediates in glycolysis. (Brody 1993:169-70.)

The hydrolysis of triglycerides to free-fatty acids and glycerol is catalysed by hormone-sensitive lipase in adipose tissue. Glycerol can be used for gluconeogenesis by being converted to glycerol phosphate by glycerol kinase, which is then then oxidised to dihydroxyacetone phosphate by glycerophosphate dehydrogenase. Dihydroxyacetone phosphate enters the gluconeogenic pathway at the point catalysed by aldolase or is immediately converted to pyruvate for oxidation in the Krebs cycle. (Abeles et al. 1992:528.)
2.2.4. Aerobic Metabolism

In the presence of oxygen the pyruvate formed enters the mitochondria and is converted to acetyl co-enzyme A involving the loss of one electron pair to NAD+ and the formation of one molecule of carbon dioxide (Abeles et al. 1992:572). Acetyl coenzyme A is then oxidised in the Krebs Cycle (Tricarboxylic Acid Cycle). For every glucose molecule 40 molecules of ATP are produced of which two are used in the early stages of the glycolytic cycle resulting in a net yield of 38 molecules of ATP, together with 12 pairs of electrons that are delivered to the electron transport chain which require 6 molecules of oxygen at the end of the chain (Bloomfield et al. 1995:77). Six molecules of carbon dioxide are produced from one molecule of glucose (Brody 1993:189).

2.2.5. Anaerobic Capacity

The maximal amount of ATP resynthesised via anaerobic metabolism during a specific mode of short duration maximal exercise defines the anaerobic capacity, which together with anaerobic power are important to short duration exercise performance characterised by the generation and/or maintenance of very high power outputs (Green and Dawson 1993). It appears that there is a long lasting residual effect of intense exercise that does not influence maximal force development, but affects the ability to sustain a high power output (Bangsbo 1994).

The hydrolysed ATP provides the chemical input required for the cross-bridge cycling, muscle tension development and ultimately muscle power and this is primarily dependant on the anaerobic capacity and muscle efficiency (Green and Dawson 1993). Muscle efficiency being the ratio of work done during one muscle contraction to the total free energy dissipation during contraction, relaxation and recovery of the muscles to their original state (Woledge 1989).
The subsequent translation of muscle power to mechanical, or, external power output is determined by factors which influence biomechanical efficiency during the movement. (Green and Dawson 1993).

2.2.6. Regulation of Energy Transfer and Fatigue

The most important regulatory mechanisms of the energy pathways are based on the relative concentrations of various phosphate compounds (Bloomfield et al. 1995:79). Muscle contraction during intensive exercise involves the hydrolysis of ATP by actomyosin adenosine triphosphatase (actomyosin ATPase), yielding increasing amounts of P, H and ADP as end products (Noakes 1992:86). Adequate tissue ATP levels must be maintained as this substrate supplies the immediate source of energy for force generation by the myosin cross-bridges. It is also required in functioning of the sodium-potassium pump (Na/K pump) which is essential in the maintenance of a normal sarcolemma and t-tubular action potential. In addition, ATP is a substrate of the sarcoplasmic reticulum adenosine triphosphatase (sarcoplasmic reticulum ATPase) and therefore required in the process of Ca\(^{2+}\) reuptake by the sarcoplasmic reticulum. (Fitts and Metzger 1988.) The ADP concentration rises causing an acceleration of glycolysis until it can produce/generate ATP as fast as it is consumed (McGilvery and Goldstein 1983:487). One of the products of anaerobic glycolysis is lactate, which is both produced and used by the muscles (Wilmore and Costill 1994:109). Its rate of production in fast and slow twitch fibres increase as the exercise intensity increases (Ivy and Costill 1986). Lactate enters the bloodstream when co-transported with H\(^+\) out of the muscle cells (Dennis et al. 1992). During maximal and submaximal exercise a higher lactate concentration is present in muscle compared with blood, but the increase in blood is proportional to that in muscle and is therefore a good indicator of muscle activity at higher intensities of exercise (Bangsbo 1994).
The exercise intensity at which blood lactate concentration begins to rise visibly is termed the Lactate Turnpoint (Noakes 1992:89). This is determined visually not mathematically and therefore no abrupt threshold exists although accurate techniques to measure Lactate Turnpoint involve measuring the gradient of the slope of increasing blood lactate concentration (Campbell et al. 1989; Dennis et al. 1992). Concomitantly, with a large production of lactate during intense exercise the acidity within the exercising muscles is elevated (Bangsbo 1994). Decreases in muscle pH from 7.1 to 6.5 - 6.8 are often observed during intense exhaustive exercise having an inhibitory effect on various functions within the muscle cell, reducing power output and inducing fatigue (Bangsbo 1994; Hawley et al. 1995).

The H⁺ could produce fatigue at numerous sites by: a direct inhibition of the actomyosin ATPase and ATP hydrolysis; by inhibiting phosphofructokinase and subsequently the glycolytic rate; by competitive inhibition of Ca²⁺ binding to troponin C and directly affecting the myosin molecule, together reducing cross-bridge activation; and by inhibiting the SR-ATPase and affecting the Ca²⁺ binding properties of the Ca²⁺ binding protein Parvalbumin, reducing the Ca²⁺ re-uptake and subsequent release (Fitts and Metzger 1988). Noakes (1992:89) suggests that a limiting factor (fatigue point) in the performance of high intensity activity is the ability of the person to tolerate high concentrations of hydrogen ions (acidity).

In studies involving perfusion of isolated muscle preparations with solutions of low pH, decrements in maximum isometric tension have been much less that those observed at a similar muscle pH following intensive exercise suggesting that other factors must be at least partially responsible for fatigue in the exercise situation (Meyer et al. 1983). These factors may be localised within the individual muscle cells and include the failure in the coupling between t-tubular depolarization and Ca²⁺ release from the sarcoplasmic reticulum due to an inhibition of the propagation of the action potential as a result of ion disturbances over the sarcolemma.
and a possible block in its propagation into the t-tubules, which would slow the rate of relaxation (Bangsbo 1994). Two obvious mechanisms by which the ion changes in the t-tubules, i.e. accumulation of potassium (K) and/or depletion of sodium (Na), could be responsible for the decline in force in high-frequency fatigue. Firstly, K\(^+\) accumulation will lead to depolarisation and consequently inactivation of Na\(^+\) channels. Secondly, Na\(^+\) depletion will reduce the peak of the action potential (AP) which if sufficiently great will reduce the Ca\(^{2+}\) release from the sarcoplasmic reticulum. Should the t-tubular action potential conduction be adequate, the reduced Ca\(^{2+}\) release through calcium channels could then be explained as the voltage sensors having become less sensitive to voltage changes; or the sarcoplasmic reticulum calcium channels have become less sensitive to stimulus from the voltage sensors. These sarcoplasmic reticulum calcium channels are sensitive to a lowered pH and show a markedly reduced opening probability at pH 6.5. Also, metabolite-induced reduction in sarcoplasmic reticulum Ca\(^{2+}\) pump effectiveness leads to reduced sarcoplasmic reticulum Ca\(^{2+}\) content. (Westerblad et al. 1991.) Bangsbo's (1994) observation that the Ca\(^{2+}\) uptake by the sarcoplasmic reticulum was depressed after intense exhaustive exercise and, that this reduction was inversely related to the relaxation half-time, supports this theory.

High intensity training (sprint) has been found to improve performance and lower blood lactate, also increasing the ability of the muscle fibres to continue exercising despite high levels of acidity (Acevedo and Goldfarb 1989). Sharp et al (1986) suggests the latter possible as a result of the neutralising capacity being increased in trained muscle. To this end, the uptake of K\(^-\) and lactate by red blood cells and non-contracting tissues regulates ion homeostasis within plasma and the interstitial and intracellular compartments of contracting muscle. The regulatory processes help to maintain the function of active muscles by delaying the onset of fatigue during exercise and to restore homeostasis during recovery. (Lindinger et al. 1995.)
2.3. ISOKINETIC DYNAMOMETRY

Isokinetic devices have been used to assess muscular performance for diagnostic, therapeutic or training purposes (Batzopoulos and Brodie 1989; Perrin 1993:6-8). These devices provide assessments that have logical validity, which involve the measurement of torque and power through a range of motion under optimal loading in which the limb is moving at a constant angular velocity (Abernethy et al., 1995). The perceived advantage of isokinetic assessment over the isoinertial protocols is that there is greater control over velocity of motion, technique and extraneous movement therefore improving measurement reliability and objectivity (Baltzopoulos et al., 1988). Torque generation at high isokinetic speeds has been shown to be correlated with the fibre characteristics of muscle (Abernethy et al., 1995). The mean torque of the first five contractions is labelled the Maximum Torque (Patton and Duggan 1987). Baltzopoulos et al. (1988) reported this to be an indicator of anaerobic power. Power decline over time is used in assessing muscular performance and is known as the Fatigue Index (Bangsbo 1994; Baltzopoulos 1988). The Fatigue Index is used as an indicator of anaerobic capacity and employs the maximum torque value in the first five contractions and minimum torque value in the last five contractions in the following calculation:

\[ FI = \frac{\text{Max torque} - \text{Min torque}}{\text{time difference}} \]

and is measured in watts per second (W.s\(^{-1}\)) (Baltzopoulos et al., 1988).

The internal validity of isokinetic dynamometry is threatened by concentric torque values being altered by the presence or absence of pre-contractions or preceding eccentric contractions; the effect of gravity and the level of feedback to study participants (Bobbert and van Ingen Schenow 1990; Hald and Bottjen 1987). Computer systems such as the AKRON are available that provide correction for gravitational and inertial errors and accurate computation of isokinetic parameters (Baltzopoulos and Brodie 1989).
2.4. MUSCLE STIFFNESS

Muscle soreness after intense exercise is a common experience (McIntyre et al. 1995). This discomfort is often described as stiffness, aching or tenderness (Apell et al. 1992). The tenderness in the quadriceps muscle is reported to begin medially, laterally and distally and then become more diffuse throughout the muscle by 24 to 28 hours after exercise (Newham et al. 1983). Myelinated Group III and unmyelinated Group IV neurons found throughout muscle, particularly in regions of connective tissue, transmit the sensation of pain in skeletal muscle. Group IV nerve fibres are twice as common as Group III fibres and convey dull, diffuse pain, while Group III fibres carry sharp, localised pain (Ebbeling and Clarkson 1989). Mc Intyre et al. (1995) suggests that stiffness is due to connective tissue damage, including tissue oedema, which causes increased mechanical sensitivity of the muscle receptors giving rise to discomfort. Gibala et al. (1995) reported that the high tensions generated during concentric resistant exercise are sufficient to cause tissue disruption, which Noakes (1992:85) refers to as micro-trauma. This damage can be identified by changes in creatinine kinase and lactate dehydrogenase and the release of intracellular enzymes which indicate cell damage (Kellis and Baltzopoulos 1995).

2.5. HOMEOOPATHY

The principles of Homoeopathy are based on the work and findings of the German doctor, Samuel Hahnemann, toward the beginning of the last century. The fundamental principle of its operation is best explained by the Latin phrase, "Similia similibus curentur", which translated means, "Let like substances be used to cure like diseases" (Gaier 1991:264 ). From this the selected similimum remedy is a substance which when administered to a healthy person in its natural, crude or toxic dose produces a pattern of signs and symptoms similar to the signs
and symptoms of the disease pattern with which the patient presents (Vithoulkas 1986:71).

Prescribing the similimum for that disease will bring about cure and raise the base level of strength of the whole system (Koehler 1989:18).

The chosen Homoeopathic remedy, Arnica montana produces similar signs and symptoms when administered to healthy persons in its crude form and dosage as those noted by a person experiencing muscle stiffness. Clarke (1991:158) lists the following as symptoms induced by Arnica montana:

- pains as from fatigue
- stiffness in the limbs after exhaustion
- sensation of soreness in legs as from a bruise
- acute drawing in the different parts of lower limbs
- stiffness and weariness of all the limbs.

In Kent (1989:145) the symptom pattern includes:

- a rheumatic lameness
- increased soreness in the muscles

and states further importance for use in injuries, bruises and shocks.

Allen's (1990:212) symptoms of Arnica montana include:

- drawing, cramplike pressure in the muscles of the thigh
- lassitude of the legs

Boericke (1990:78) promotes the use of Arnica montana for soreness after overexertion.

So according to the "like cures like" principle, this remedy would appear to be the similimum remedy for the effects produced from exercise.
CHAPTER THREE MATERIALS AND METHODS

Thirty healthy and active males between the ages of 18 and 25 years volunteered and gave written, informed consent to participate in this study. Each participant signed an INFORMED CONSENT FORM (APPENDIX B). They were required to visit the biokinetist on three consecutive days (24 hours apart) to perform the exercise tests.

In the study 15 participants received, in double-blind style, homeopathic *Arnica montana* 30CH while the other 15 participants received placebo as their trial medication. They were the Treatment and Placebo groups respectively.

Each participant was administered their trial medication 5 minutes after the first test and then again immediately prior to and 5 minutes after performing the second and third exercise tests. Each participant was required to complete a PARTICIPANT PERCEPTION FORM (APPENDIX A) after the first exercise test, before and after the exercise test on the second and third days and again 24 hours after the third day.

The exercise test was executed on an AKRON Isokinetic Dynamometer under the specialist supervision of a biokinetist with the readings being recorded on computer, using AKRON Test Software. The participants were strapped into the AKRON seat securing the waist, thigh and non-dominant leg, they were required to perform three Extension/Flexion repetitions to warm up at 90 degrees per second (deg. s⁻¹) followed by being instructed and familiarized to enforce maximal effort in extension and flexion throughout the range of movement.

The isokinetic test consisted of maximal reciprocal contractions of the knee extensors and flexors for a period of 60 seconds at 180 deg. s⁻¹. The test started in the knee extension position.
All the data were corrected for the effect of gravity. The variables used in the study were Maximum Torque and Fatigue Index. The Maximum Torque was defined as the mean torque of the first five contractions. The Fatigue Index was calculated using the maximum torque in the first five contractions and the minimum torque in the last five contractions where:

\[
F.I. = \frac{\text{maximum torque} - \text{minimum torque}}{\text{time difference}}
\]

and is measured in W.s\(^{-1}\).

The Maximum Torque data (APPENDIX C) and Fatigue Index data (APPENDIX D) was analysed using Mann-Whitney U tests and descriptive statistics. The Participant Perception Form data was represented graphically.
4.1. MAXIMUM TORQUE

4.1.1. Mann-Whitney U Test

Since the sample sizes of each of the two groups were fifteen, non-parametric statistical tests were used to analyse the Maximum Torque data. The tests were done at the $\alpha = 5\%(p<0.05)$ level of significance. The three Mann-Whitney U tests revealed no significant difference between the Placebo and Treatment groups with regards to the Maximum Torque values on each of the three days.

4.1.2. Descriptive Statistics

Using descriptive statistics a comparison of the median readings between the Placebo and Treatment groups with regards to the Maximum Torque were made. The comparison revealed that the median readings were similar on the first and third days and the same on the second day.

Comparison with respect to M.T.

Median readings

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FIGURE 4.1: Maximum Torque - Median Readings
4.2. FATIGUE INDEX

4.2.1. Mann-Whitney U Test

Since the sample sizes of each of the two groups were fifteen, non-parametric statistical tests were used to analyse the Fatigue Index data. The tests were done at the $\alpha = 5\%$ level of significance. The three Mann-Whitney U tests revealed no significant difference between the Placebo and Treatment groups with regards to the Fatigue Index values on each of the three days.

4.2.2. Descriptive Statistics

Using descriptive statistics a comparison of the median readings between the Placebo and Treatment groups with regards to the Fatigue Index was made. The comparison revealed that the median readings were similar on all three days.

Comparison with respect to F.I.

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FIGURE 4.2: Fatigue Index - Median Readings
4.3. PARTICIPANT PERCEPTION

FIGURE 4.3: Sensation of Stiffness Experienced - Before Exercise Test on Second and Third Days

In the Treatment group, six and eight participants experienced a sensation of stiffness on reporting for the exercise tests on the 2nd and 3rd days respectively. The Placebo group had less participants, two and four on the 2nd and 3rd days exercise tests respectively, who experienced stiffness prior to the exercise tests.

FIGURE 4.4: Sensation of Stiffness Experienced - After Exercise Test

*DAY 4 - 24 hours after final exercise test.

The majority of both the Treatment and Placebo groups’ participants experienced a sensation of stiffness immediately after the exercise tests on the three days. Six participants in the Placebo group compared to three in the Treatment group still experienced stiffness 24 hours after the final exercise test.
Immediately after the first exercise test forty percent (40%) of the participants within the Control group, who experienced a sensation of stiffness, rated their discomfort as moderate (3) with the remaining sixty percent (60%) of these participants being shared either side of the moderate rating. The Treatment group participants, who experienced a sensation of stiffness, in comparison had their majority (85%) shared either side of the moderate rating, and alone had participants experience severe discomfort.

Before doing the second exercise test, all of the participants in the Control group who were experiencing a sensation of stiffness rated their discomfort as mild (1), compared to those participants in the Treatment group, who were experiencing a sensation of stiffness, half of whom rated their discomfort as mild (1) and the rest up to a moderate (3) rating.
Immediately after the second exercise test, the majority (93%) of the participants in the Placebo group, who were experiencing a sensation of stiffness, rated their discomfort as moderate (3) or less than moderate (3). The Treatment group participants, who were experiencing a sensation of stiffness, had their majority (79%) rate their discomfort as moderate (3) or worse than moderate (3), and alone had participants experience severe discomfort.

Before doing the third exercise test, half of the participants in the Placebo group and the majority (87.5%) of the participants in the Treatment group, who were experiencing a sensation of stiffness, rated their discomfort as mild (1) while the remainder in the Control group were shared up to a moderate (3) rating.
Immediately after the third exercise test, the majority of the participants in the Placebo (88%) and Treatment (75%) groups who were experiencing a sensation of stiffness, rated their discomfort between 2 and 4 on the scale of severity. The Treatment group within this range showed their rating of the discomfort to be slightly worse compared to those of the Placebo group.

Twenty-four hours after the final exercise test, of the participants in the Placebo group, who were experiencing a sensation of stiffness, half rated their discomfort as mild (1) while the remainder as moderate (3) or worse. In comparison, of the participants in the Treatment group, who were experiencing a sensation of stiffness, two-thirds rated their discomfort as mild (1) with the remaining third expressing a rating of below moderate (2).
Immediately after the first exercise test, the participants in both the Treatment and Placebo groups, who experienced a sensation of stiffness, identified similar areas of the leg involved in discomfort. The quadriceps muscle was the most common muscle group affected.

Before doing the second exercise test, half of the Placebo and two-thirds of the Treatment group participants, who experienced a sensation of stiffness, identified the quadriceps muscle as the site of discomfort. The remaining half of the Placebo group participants were experiencing discomfort in their calf muscles. The quadriceps muscles showed to be the main site of discomfort.
Immediately after the second exercise test, the majority of the Placebo(60%) and Treatment(57.2%) groups' participants, who experienced a sensation of stiffness, identified the quadriceps muscle as the location of their discomfort.

Before doing the third exercise test, the majority of the Placebo(75%) and Treatment(62.5%) groups' participants, who experienced a sensation of stiffness, identified the quadriceps muscle as the location of their discomfort.
Immediately after the third exercise test, the majority of the Placebo (80%) and Treatment (78.5%) groups' participants, who experienced a sensation of stiffness, identified the quadriceps muscle as the location of their discomfort.

Twenty-four hours after the final exercise test, the majority of the Placebo (83.3%) and Treatment (66.67%) groups' participants, who experienced a sensation of stiffness, identified the quadriceps muscle as the location of their discomfort.
Immediately after the first exercise test, a similar majority of the Placebo (66.6%) and Treatment (71.4%) groups' participants, who experienced a sensation of stiffness, described their sensation of stiffness as 'Heavy'.

Before doing the second exercise test, of the participants in the Placebo group, who experienced a sensation of stiffness, half described the sensation as 'Cramping' and the remaining half as 'Heavy'. Half of the Treatment groups' participants, who had experienced a sensation of stiffness, described the sensation as ‘Aching’ with the remaining describing it as ‘Boring’, ‘Sharp’ or ‘Heavy’.
Immediately after the second exercise test, the majority of the Placebo (66.6%) and Treatment (57.1%) groups’ participants who experienced a sensation of stiffness, described the sensation as ‘Heavy’.

Before doing the third exercise test, of the participants in the Placebo group who experienced a sensation of stiffness, half described the sensation as ‘Aching’ with the remaining being shared equally as either ‘Cramping’ or ‘Gnawing’. In comparison, the majority of the participants in the Treatment group, who experienced a sensation of stiffness, described the sensation as ‘Aching’.
Immediately after the third exercise test, the majority of the participants in the Placebo (71.7%) and Treatment (64.2%) groups who experienced a sensation of stiffness, described the sensation as ‘Heavy’.

Twenty-four hours after the final exercise test, of the participants in the Placebo group, who had experienced a sensation of stiffness, half described the sensation as ‘Aching’ with the remaining describing it as either ‘Cramping’ or ‘Heavy’. In comparison, two-thirds of the participants in the Treatment group described the sensation as ‘Aching’ and the remaining third as ‘Boring’.
FIGURE 4.23: Participants who Exercised Twice or more per Week

Of the participants in the Placebo group, who took part in physical exercise twice or more per week, half did ‘Running’ with the remaining half shared between ‘Cycling’ and ‘Gym’. In comparison half of the Treatment group did ‘Running’ with the remaining half doing either ‘Aerobics’, ‘Gym’ or ‘Soccer’.

FIGURE 4.24: Participants who Competed in Sport

The majority of the participants in the Placebo group (57.1%), who competed in sport, competed in ‘Running’ with the remaining competing in either ‘Cycling’ or ‘Tennis’. In comparison, forty percent of the participants in the Treatment group competed in ‘Running’ with the remaining competing in either ‘Soccer’, ‘Tennis’ or ‘Squash’. 
CHAPTER FIVE DISCUSSION

The Maximum Torque values between the Placebo and Treatment groups showed no significant difference \( (p<0.05) \) after performing the Mann-Whitney U test on the data for each of the three days. Using descriptive statistics, median readings of the Maximum Torque values were extracted. These readings showed the Maximum Torque increased progressively in both groups on the second and third days of exercise testing. This could be explained by one of the following reasons. Despite simplicity of the movements, Abernethy et al. (1995) suggests that scores can be enhanced through learning. Another explanation could be that velocity-specific adaptation of motor units within the muscle and velocity-specific adaptation within the nervous system takes place (Sale et al. 1983). As there was no significant difference between the groups, no effects of the treatment intervention were visible.

The maximum torque during isokinetic movements is a measure of muscular force applied in dynamic conditions (Baltzopoulos and Brodie 1989). It is also an indicator of anaerobic power (Baltzopoulos et al. 1988). In this study, Maximum Torque was defined as the mean torque from the first five maximal repetitions (Patton and Duggan 1987). The mean torque calculated from torque values recorded at different angular positions has been criticised as not being a meaningful measurement of muscle function due to the lack of information about the angular position (Baltzopoulos and Brodie 1989). It is possible that significant differences could be observed between the groups if the maximum torque was calculated at a specific angular position.
Magee (1992:164) reports that the knee extensor muscles develop the greatest force around the angle of sixty degrees.

The Fatigue Index values between the Placebo and Treatment groups showed no significant difference (p<0.05), after performing the Mann-Whitney U test on the data for each of the three days. Using descriptive statistics, median readings of the Fatigue Index values were extracted. These readings, graphically depicted, indicates that the Fatigue Index in both groups improved slightly on the second day before returning on the third day to a similar level as those on the first day. As there was no significant difference between the two groups, no effects of the treatment intervention were visible.

Computing a Fatigue Index using an isokinetic dynamometer assesses muscular endurance in dynamic conditions. Patton and Duggan (1987), defined the Fatigue Index as the average torque in the last five contractions expressed as a percentage of average torque in the first five contractions. This did not take into account the time difference between the maximum and minimum power used. In his study, Baltzopoulos et al. (1988) showed that the Fatigue Index (defined as the difference between the highest torque value in the first five contractions and the lowest torque value in the last five contractions divided by the time difference in seconds) of an isokinetic endurance test and the Fatigue Index in the Wingate test correlated significantly. This shows that the Fatigue Index computed from an isokinetic endurance test may be used as a measure of anaerobic capacity. Computation of the Fatigue Index may be affected by the difference in angular position of the maximum torque and by the reduction of the angular velocity as the muscles fatigue (Baltzopoulos and Brodie 1989). It is possible that significant differences between the two groups could be observed if the work performed were to be used as a measure.
of muscle function, as it takes into account the force output throughout the range of motion.

The Participant Perception Form was completed after the first exercise test. Thereafter, Questions 1 - 4 (Related to stiffness) were completed before and after the second and third exercise tests and again twenty-four hours after the final exercise test.

The majority of the Treatment (93%) and Placebo (100%) groups participants experienced a sensation of stiffness after the first and second exercise tests with only the percentage of participants experiencing stiffness in the Placebo group decreasing by 6.67% after the third exercise test. This trend in these results to remain similar, almost the same over three days, indicates that no effect of the treatment intervention was observed with regard to the sensation of stiffness experienced after the exercise tests. This observation does however indicate consistency and test reliability of the exercise test protocol to induce fatigue and produce stiffness.

Before the second exercise test (24 hours after the first exercise test), 40% of the participants in the Treatment group and 16.6% of the participants in the Placebo group experienced a sensation of stiffness. This rose to 53.3% and 26.6% of the Treatment and Placebo groups participants respectively before the third exercise test. This percentage increase in the Treatment group could be seen as a possible aggravation or worsening in the participants in the Treatment group which occurs commonly before an improvement in homoeopathic treatment (Vithoulkas 1986:227-8).

Twenty-four hours after the third exercise test 25% of the participants in the Treatment group compared to 50% of the Placebo group participants experienced a sensation of stiffness. The trend in these results indicates an improvement in the Treatment group compared to a deterioration in the Placebo group with regard to the sensation of stiffness experienced.

Interestingly, the participants in both groups who experienced a sensation of stiffness, described
the discomfort as one predominantly of 'heaviness' immediately after each exercise test changed to one predominantly of 'aching' before each exercise test. The results above agree with McIntyre et al. (1995) which reported that Delayed onset muscle soreness (DOMS) is a sensation of discomfort which is most evident in skeletal muscle, developing in the twenty-four hours following exercise and manifesting as a dull, aching pain with tenderness. Boericke (1990:78) promotes the use of *Arnica montana* for soreness after overexertion, while Kent (1989:145) found it of benefit in increased soreness of the muscles and muscle injuries. The description of the discomfort as being predominantly 'aching' before the exercise tests, together with the repeated aetiology of overexertion indicates that the selection of homoeopathic *Arnica montana* as the treatment intervention was accurate.

Before the second exercise test, all of the participants in the Placebo group, who were experiencing a sensation of stiffness, rated this as mild(1). Compare this to those participants in the Treatment group, half of whom, rated their discomfort as mild(1) and the rest up to a moderate(3) rating. This pattern changed before the third exercise test, where 90% of the Treatment group participants, who experienced a sensation of stiffness, compared to 50% of those participants in the Placebo group, rated the discomfort as mild(1) with the remaining half rating the discomfort up to a moderate(3) rating. Of the participants, who experienced a sensation of stiffness 24 hours after the third exercise test, 50% in the Placebo group again rated the discomfort as mild(1), while the remaining half showed increased severity (moderate and above). At the same stage, of those participants who experienced a sensation of stiffness, two-thirds rated the discomfort as mild(1), while the remaining one-third rated their discomfort as below-moderate(2). The trend in these results indicates that the severity of the discomfort experienced
before taking part in the second and third exercise tests (24 hours apart) and 24 hours after the third exercise test, increased in the Placebo group and decreased in the Treatment group, in those participants who experienced a sensation of stiffness. This indicates that the treatment intervention of homoeopathic *Arnica montana* could have facilitated a reduction in severity of discomfort in the Treatment group.

The information gathered about the area of the leg affected by the exercise test showed the quadriceps muscle to be the area predominantly affected in participants in both the Placebo and Treatment groups. This indicates that the exercise test protocol on the AKRON Isokinetic Dynamometer was consistent in isolating the quadriceps muscle to function.

The amount and type of exercise that the volunteers in each group were involved in at the time of the exercise testing was analysed. It showed that 53% and 80% of the Placebo and Treatment groups respectively took part in exercise twice or more per week. Further, 41.6% of the participants in the Treatment group, who exercised on two or more occasions per week, compared to 87.5% of those in the Placebo group, competed in sporting activities. It is well known that besides age and sex criteria, the level of fitness and type of exercise being undertaken by the participants at the time of exercise testing is of great importance to the performance and the degree and duration of discomfort experienced (Noakes 1992:89-90). Sharp *et al.* (1986) reports that within trained muscle there is an increased neutralising capacity. Having a larger percentage of the Treatment group population exercising regularly could therefore have affected the improvement in the Treatment group participants compared to the Placebo group participants with regard to experiencing a sensation of stiffness and its severity. Future studies could possibly address this by using a population trained to a certain level of fitness in a specific sporting activity.
CHAPTER SIX CONCLUSIONS AND RECOMMENDATIONS

The exercise test protocol, using an isokinetic dynamometer, isolated and fatigued the quadriceps muscle and produced in it symptoms of muscle fatigue in both the Placebo and Treatment groups. The treatment intervention of homoeopathic *Arnica montana* on fatigue made no significant difference (p<0.05) between the Placebo and Treatment groups with regard to the Maximum Torque and the Fatigue Index.

The number of participants in the Placebo group who experienced a sensation of stiffness increased progressively over the three days of exercise testing. In comparison the number of participants in the Treatment group, who experienced a sensation of stiffness, increased by 13.3% before the third exercise test before reducing to 25% 24 hours after the final exercise test, which is less than the percentage of participants in this group who experienced a sensation of stiffness before the second exercise test. The initial worsening before improvement in the Treatment group is common to the principles of homoeopathic practise and therefore leads to a conclusion of improvement in the sensation of stiffness experienced by the participants in this group compared to the Placebo group. The trend in the results of the severity of discomfort experienced before taking part in the second and third exercise tests and 24 hours after the final exercise test, showed to increase in the Placebo group and decrease in the Treatment group, in those participants who experienced a sensation of stiffness.
It is recommended that an accepted, standardised isokinetic dynamometer, corrected for the effects of gravity is used. The Maximum Torque readings should be taken from a specific angular position for the joint and movement involved. Due to the observation that exercise training and level of fitness play an important role in the outcome of results in exercise physiology studies, acceptance criteria with regard to present exercise and training level and participation should be made. Eccentric muscle contraction could be used, and over a longer exercise period to induce even further severity of fatigue and its symptoms.

The population size should be increased to enable more detailed statistical tests to be performed.
REFERENCES


PARTICIPANT PERCEPTION FORM

Name

Thank you for participating in my study.
Please answer the following questions. Taking your time, please answer the questions as accurately and honestly as possible.
The questions apply to your perceptions NOW as you answer them NOT to your perceptions DURING the exercise tests.

INSTRUCTIONS: Answer all of the questions by either circling the number or placing a tick in the space alongside your choice/s.

1. Do you feel any sensation of stiffness in the leg that you exercised in the last test?

YES ______
NO ______

2. If your answer in 1. is YES, please rate the discomfort due to stiffness.

MILD 1 2 3 4 5 SEVERE

3. In which area of your leg can you feel the discomfort?(if any)

1 Thigh (front)
2 Thigh (back)
3 Calf muscles
4 1 and 3
5 2 and 3
6 1,2 and 3
4. If any, which of the following best describes discomfit in your leg?

1. Aching
2. Boring
3. Sharp
4. Burning
5. Cramping
6. Gnawing
7. Heavy

5.1 Do you take part in regular physical exercise involving your legs?

YES ___
NO ___

5.2 If YES, tick the applicable space/s:

- Running
- Cycling
- Aerobics
- Gym
- Rugby
- Soccer
- Tennis
- Other

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5.3 Do you feel discomfit from stiffness after taking part in this/these sporting activity/ies?

YES ___
NO ___
5.4 If YES, How does this discomfit from stiffness compare to the discomfit from stiffness experienced at this point in the testing?

1. Less than this
2. Same/similar to this
3. Worse than this

5.5 If your answer in 5.3 included Running or Cycling, please answer the following questions.

Running: Which of the following most accurately describes the majority of your training?
1. Endurance (long)
2. Sprint (short)
3. Intermediate
4. 1 and 2

Cycling: Which of the following most accurately describes the majority of your training?
1. Endurance (long)
2. Sprint (short)
3. Intermediate
4. 1 and 2

6.1 Do you compete in sporting competitions?

YES
NO

6.2 If YES, Which of the following?

- Running
- Cycling
- Triathlons
- Rugby
- Soccer
- Tennis
- Squash
- Other ________________
TO BE ANSWERED ON DAY 4 ONLY

7.1 On which day did you experience the most discomfit due to stiffness?
1. Day 1
2. Day 2
3. Day 3
4. Day 4 (today)

7.2 How does the discomfit from stiffness you are experiencing now (if any) compare to that you experienced on Day 2?
1. Much worse now
2. Worse now
3. About the same
4. Less now
5. Much less now
6. Uncertain
INFORMED CONSENT FORM  (To be completed in duplicate by patient/subject *)

TITLE OF RESEARCH PROJECT: __________________________________________________________

__________________________________________________________________________________

NAME OF SUPERVISOR: ________________________________________________________________

NAME OF RESEARCH STUDENT: ________________________________________________________

PLEASE MARK YOUR ANSWER WITH AN 'X'

1. HAVE YOU READ THE RESEARCH INFORMATION SHEET? YES/NO

2. HAVE YOU HAD AN OPPORTUNITY TO ASK QUESTIONS REGARDING THIS STUDY? YES/NO

3. HAVE YOU RECEIVED SATISFACTORY ANSWERS TO YOUR QUESTIONS? YES/NO

4. HAVE YOU HAD AN OPPORTUNITY TO DISCUSS THIS STUDY? YES/NO

5. HAVE YOU RECEIVED ENOUGH INFORMATION REGARDING THIS STUDY? YES/NO

6. HAVE YOU SPoken TO ____________________________ YES/NO

7. DO YOU UNDERSTAND THE IMPLICATIONS OF YOUR INVOLVEMENT OF THIS STUDY? YES/NO

8. DO YOU UNDERSTAND THAT YOU ARE FREE TO WITHDRAW FROM THIS STUDY? YES/NO
   a) at any time
   b) without having to give any reason for withdrawing, and
   c) without affecting your future medical care

9. DO YOU AGREE TO VOLUNTARILY PARTICIPATE IN THIS STUDY? YES/NO

PATIENT/SUBJECT* Name ____________________________ (in block letters)

SIGNATURE ________________________________________

WITNESS: Name ________________________________ (in block letters)

SIGNATURE ________________________________________

RESEARCH STUDENT: Name ________________________ (in block letters)

SIGNATURE ________________________________________

* Delete whichever is not applicable
APPENDIX D: Fatigue Index Data

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