The effect of physiotherapeutic Kinesio taping on selected physical symptoms associated with major depressive disorder

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The effect of physiotherapeutic Kinesio taping on selected physical symptoms associated with major depressive disorder

A research report by

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Declaration by Study Leader

I, Karen Bodenstein, study leader of Karen Erasmus, hereby confirm that the Department of Physiotherapy, University of the Free State, approves the submission of this script. I certify that the script submitted as partial fulfillment of the requirements for the degree **MSc (Physiotherapy)** at the University of the Free State is the student's independent effort and has not previously been submitted, either partially or as a whole, to the assessors. This script has also not previously been submitted for a degree at another university/faculty.

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Declaration by Student

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Karen Erasmus

24 January 2014

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List of Abbreviations

BAS	Body Awareness Scale
BAS-H	Body Awareness Scale - Health
DASH	Disability of Arm, Shoulder and Hand
DSM-5	Diagnostic and Statistical Manual of Mental Disorders – Fifth Edition
EMG	Electromyography
HAM-D	Hamilton Depression Rating Scale
HPCSA	Health Professionals Council of South Africa
KTA	Kinesio® Taping Association
MARM	Manual Assessment of Respiratory Motion
MDD	Major depressive disorder
OSDB	Obstructive sleep disorder breathing
RSA	Respiratory sinus arrhythmia
SF-MPQ	Short Form McGill Pain Questionnaire
VAS	Visual analogue scale

Abstract

Kinesio® taping is a relatively new form of therapeutic taping that has a variety of applications. Physiotherapists can use the tape to treat certain physical symptoms for example, pain, swelling and dysfunctional muscle activation.

Major depressive disorder (MDD) is a mood disorder and physical symptoms most associated with MDD, and tested in this study were muscle tension, pain complaints, restricted breathing, less flexibility and centring of movement. The aim of this study was to investigate the effect of physiotherapeutic Kinesio® taping on selected physical symptoms associated with MDD. A double-blind, randomised controlled design was used, following a quantitative study approach. The study population consisted of 40 patients with MDD admitted to a private and public psychiatric institution in Bloemfontein.

The majority (77.5%) of participants complained of pain during the study period (24 hours) and 58% complained of multiple areas of pain. The sensory and affective components associated with pain and tested by the Short Form McGill Pain Questionnaire (SF-MPQ) showed improvement in combined scores for both the experimental and placebo groups. The results of the Manual Assessment of Respiratory Motion (MARM) displayed improvement in both the placebo and experimental groups for balance of breathing and percentage ribcage motion. The Tinetti Mobility Test which assesses balance and gait showed no distinct results possibly due to the scale not being sensitive enough for the movement disorders tested

Limitations of the study could have influenced the outcomes measured and it should be taken into account that of the 40 participants, 21 received physiotherapy. Other therapies received by participants during the study were not standardised and could not be controlled due to the multitude of stakeholders involved in the care of the patients.

The treatment of physical symptoms associated with MDD with Kinesio® taping had mixed results, but Kinesio® taping could be a valuable adjuvant treatment modality. The importance of physiotherapy as part of the treatment regime for patients suffering from MDD was highlighted.

Key terms: effects, physiotherapeutic, Kinesio® taping, physical symptoms, major depressive disorder, pain, restricted breathing, loss of centring of movements

Chapter 1 Introduction

1.1 Introduction and Background to the Study

Kinesio® taping is a relatively new form of therapeutic taping, using a novel kind of elastic therapeutic tape. The tape and technique was developed by Dr Kenso Kase and differs from classic, non-elastic tape in the sense that Kinesio® tape has a wider treatment approach than just the stabilising and immobilising of joints (Kumbrink, 2012:2). The original concept of Kinesio® taping began in 1973, but the technique is still evolving. The information regarding Kinesio® taping is mostly from books on the subject (Kase, Wallis and Kase, 2003 and Kumbrink, 2012) and is in this stage merely anecdotal as scientific studies on the subject are scarce. Studies on the subject use the methods of Kinesio® taping as set out in the manual written by Kenzo Kase (Kase, Wallis and Kase, 2003:12). This book is currently the reference point on the Kinesio® taping technique. In his book, *Clinical Therapeutic Applications of the Kinesio Taping Method*, Dr Kase, notes that the development of Kinesio® taping has led not only to theoretical usability but also to a practical approach to the taping method (Kase, Wallis and Kase, 2003:12).

The basic functions and effects of Kinesio® taping can be summarised as follows (Kumbrink, 2012:6; Murray, 2000:1):

Improvement of muscle function

Elimination of circulatory impairments

Pain reduction

Support of muscle function

Increased proprioception through increased stimulation of the cutaneous mechanoreceptors

Influencing proprioception and the physiological activity of ligaments and muscles by stimulating cutaneous receptors is older than the Kinesio® taping method; this approach can be traced back to physiotherapy treatments that use manual therapy, rehabilitation and non-elastic taping methods (Kumbrink, 2012:2). Kinesio® taping is used in a variety of treatment settings and for a wide range of conditions (Kumbrink, 2012:6).

Major depressive disorder (MDD) is a mood disorder characterised by a depressed mood. Those suffering from the disorder experience a loss of energy and interest, feelings of guilt, difficulty in concentration, change in appetite and thoughts of death or suicide. Common symptoms of the mood disorder include changes in activity level, cognitive abilities, speech, sleep, sexual activity and biological rhythms. The disorder further almost always causes social and work-related problems (Sadock and Sadock, 2007:527).

Physical symptoms are closely related to MDD and can impede the treatment of the disorder. Physical symptoms associated with the disorder include joint pain, limb pain, back pain, gastrointestinal problems, fatigue, psychomotor activity changes and appetite changes. These symptoms can increase the duration of the MDD episode and cause relapse (Trivedi, 2004:12-13).

Jacobsen, Lassen, Friss, Videbechand Licht (2006:295-296) investigated the physical symptoms most often associated with MDD. These are:

- Muscle tension
- Pain complaints
- Restricted breathing
- Less flexibility and centring of movements
- Negative attitudes towards physical appearance and ability

Physical symptoms associated with MDD are often ignored in the assessment and treatment of the disorder. Remission of MDD without total relief of the physical symptoms might lead to a false or incomplete remission (Trivedi,

2004:13). The link between physical complaints and MDD emphasises the need for physiotherapy as part of the holistic treatment regime for the depressed patient. According to the literature (González-Iglesias, Fernández-De-Las-Peñas, Cleland, Huijbregts and Gutiérrez-Vega, 2009:516) certain physical symptoms for example, pain, swelling and dysfunctional muscle activation can be treated by physiotherapists with the use of Kinesio® taping. These physical symptoms are not always associated with MDD despite the fact that a high percentage of patients with MDD in primary care settings only complain of physical symptoms (Trivedi, 2004:12). Considering the abovementioned effects, it is clear that Kinesio® taping could play a role in the mental health field and especially in the treatment of the MDD-associated physical symptoms (Jacobsen *et al*., 2006:295-296).

There are several benefits of Kinesio® taping intervention in the field of physiotherapy:

1. It will expand the field of physiotherapy into mental health and psychiatry, and contribute to the clinical guidelines of physiotherapy in psychiatry.

The outcome of the study will contribute to evidence-based research into the treatment of mood disorders through physiotherapeutic intervention.

Kinesio® taping is cost effective as 6 to 10 applications are possible per roll and the taping can be worn for several days without re-application (Kinesio South Africa, 2013).

The treatment allows for supportive therapy at home or in the ward – the taping continues to work as long as it remains on the patient (Kumbrink, 2012:3).

1.2 Research Question

The researcher works in a ward for patients with mood disorders at a public psychiatric institution in Bloemfontein. The ward programme includes physiotherapy assessment and intervention only on referral for physical conditions, secondary to pharmacological and psychotherapy interventions. The

physiotherapy provided at this institution includes manual therapy, electrotherapy and exercises. The researcher has worked in this specific ward since April 2010 and observed that patients' physical complaints decreased with physiotherapy interventions. Kinesio® taping is a new and exciting modality in rehabilitation at the moment. The researcher attended a workshop on the taping in September 2010 and found the concept very interesting. The question therefore arose whether Kinesio® taping as new physiotherapeutic intervention method could have a positive effect on selected physical symptoms associated with MDD.

1.3 Aim and objectives the Study

The main aim of the study was to investigate the effect of physiotherapeutic Kinesio® taping on selected physical symptoms associated with MDD.

The specific objectives of the randomised controlled study, within patients between 18 – 65 years, admitted with major depressive disorder to either a public or private psychiatric institution in Bloemfontein was to:

- determine pain complaints before, immediately after and 24 hours after Kinesio® taping application
- determine areas of pain complaints before, immediately after and 24 hours after Kinesio® taping application
- determine breathing restriction before, immediately after and 24 hours after Kinesio® taping application
- determine flexibility and centring of movements before, immediately after and 24 hours after Kinesio® taping application

1.4 Literature Review

Research directly linking Kinesio® taping and MDD-associated physical symptoms could not be found during the literature review. However, the literature search did find a number of articles on the physical symptoms of MDD and the treatment of similar symptoms, not associated with MDD using Kinesio® taping. Although the literature review could not link Kinesio® taping directly with the management of the physical symptoms associated with MDD, evidence exists that Kinesio® taping could treat these physical symptoms in isolation and this will be explained in the following paragraphs.

Four of the five physical symptoms associated with MDD (refer to 1.1) as identified by Jacobsen *et al*. (2006:295-296) were selected to be tested in this study. The fifth symptom, negative attitudes towards physical appearance and ability, falls out of the scope of practice of physiotherapy in mental health. The treatment of these four MDD-associated symptoms with Kinesio® taping is augmented throughout the literature.

Pain can be managed through the use of Kinesio® taping as demonstrated in a case study of a 20 year-old female patient. Application of Kinesio® taping not only improved the range of motion of shoulder abduction and flexion, but on a 10-point visual analogue scale (VAS) pain levels decreased from 10 to 2.7 during movement (García-Muro, Rodriguez-Fernández and Herrero-de-Lucas, 2010:292,294-295).

Kinesio® taping treatment showed that it could improve muscle activity and performance in baseball players during a crossover study with a pre-test/post-test repeated measures design. Measurements were done on strength, electromyography (EMG) or electrical activity in the muscle and scapular motion. The results indicated that taping might have an effect on muscle movement (Hsu, Chen, Lin, Wang and Shih, 2009:2-5,7). Kinesio® taping can further provide stability for task performance. The use of Kinesio® taping improved post-measurement scores of 15 children tested in a

rehabilitation hospital in Chicago. Upper limb function was assessed by the Melbourne Assessment of Unilateral Upper Limb Function and the scores improved over time, with a mean of 60.5 out of 122 before application of the tape and 70.1 out of 122 at the 3 day follow-up (Yasukawa, Patel and Sisung, 2006:105-109).

The use of Kinesio® taping during a randomised controlled study on shoulder impingement contributed to significantly lower scores on the Disability of Arm, Shoulder and Hand (DASH) scale from a median of 57.5 before treatment to a median of 18 after treatment (Kaya, Zinnuroglu and Tugeu, 2010:203-205).

The use of Kinesio® taping as intervention method is, however, controversial. In a study by Zubeyir, Nilufer, Burcu, Onur, Bahar, Saadet, Gülden (2012) the researchers found no significant effect of Kinesio® taping on primary and accessory respiratory muscle strength. Nevertheless it has to be noted that the researchers did not test volumetric changes as applicable in this study (Zubeyir *et al*., 2012:242-244).

This study will examine whether Kinesio® taping can have an effect on selected physical symptoms associated with MDD. Therefore the study will contribute to the current knowledge of Kinesio® taping.

1.5 Significance of the Study

Physiotherapeutic interventions in the treatment of physical symptoms associated with MDD can form an integral part of the treatment regime. The physical symptoms are nonetheless commonly overlooked as being a physical ailment and not part of the psychiatric illness. Insufficient treatment of physical symptoms as part of MDD can lengthen the path of the disease and cause recurrence.

The significance of this study lies in the assessment of a new treatment modality not previously associated with psychiatry. The outcome of the study will also impact on the physiotherapy profession as physiotherapy is not always seen as

part of the treatment regime for MDD. The study will assist the physiotherapist in treating the patient with MDD in a more effective and holistic manner. It will also emphasise the importance of the physiotherapists as part of the multi-professional team in the treatment of affective disorders.

A greater understanding of the treatment of physical symptoms of MDD will enhance service delivery, improve the quality of care given to patients and minimise the burden of the disease. The results of this study can be used for future presentations or publications and contribute to the body of knowledge in physiotherapy in general and specifically in the treatment of mood disorders.

1.6 Definition of Terms

Kinesio® Tex Gold is a specific elastic therapeutic tape designed for Kinesio® taping treatment. It is designed and manufactured by Kinesio in Japan and is the material used in this study.

Kinesio® taping is defined as the application of Kinesio® Tex directly to the skin to achieve the therapeutic effects (Donec, Varžaitytė and Kriščiūnas, 2012:98).

Major depressive disorder is diagnosed when one or more major depressive episodes has occurred. A major depressive episode is characterised by the intensity of sadness that results in "*symptoms of reduced pleasure in activities that used to be pleasurable, weight and sleep disturbance, changes in level of physical activity, fatigue, feelings of worthlessness, reduced ability to concentrate and make decisions, or continuing preoccupation with death or thoughts of suicide. The symptoms must be present most of the day, nearly every day, for a period of at least two weeks"* (World Health Organization/German institute of medical documentation on information, 1994/2006).

Physical symptoms are defined as those physical symptoms most associated with MDD (Jacobsen *et al*., 2006).

1.7 Format of the Research Report

The format of the research report for this study is as follows:

Chapter 1 gives an outline of the study. The background, relevant literature and methodology are briefly explained, and the research question and study objective are stated.

Chapter 2 is an overview of the relevant literature concerned with Kinesio® taping, MDD and the physical symptoms associated with the disease. Pertinent anatomy is mentioned and the treatment with Kinesio® taping discussed in the light of the physical symptoms associated with MDD.

Chapter 3 is an extensive detailed description of the methodology. Topics covered are the study design, sample, pilot study, inclusion and exclusion criteria, and ethical considerations.

Chapter 4 presents the results in the form of graphs and tables.

Chapter 5 discusses the results taking into account the available research.

Chapter 6 draws conclusions and makes recommendations. The value of the study is emphasised and limitations of the study are highlighted.

1.8 Conclusion

This chapter is an overview of the background pertaining to the study as well as the research question that inspired the researcher to formulate the research project. The relevant literature is briefly discussed. In the following chapter a more detailed account of the literature review is given to discuss Kinesio® taping as physiotherapy intervention as well as the specific and selected physical symptoms associated with MDD.

Chapter 2 Literature Review

2.1 Introduction

In this chapter, an overview of the concepts of the study is given. Kinesio® taping and its applications are examined with regards to its supposed effects and applications. Applicable anatomical structures are discussed and the structures and physical symptoms associated with MDD are investigated in depth.

Information for the literature review was obtained through various search engines on the internet (Google and Google Scholar) and the University of the Free State's catalogue (KovsieKat). The following key words were used in the search: "effectiveness", "Kinesio tape", "body awareness therapy", "major depressive disorder", "breathing", "pain" and "physical symptoms". These words were used separately and in different combinations with each other.

2.2 Properties of Kinesio® Tape

Kinesiology tape is an umbrella term used for elastic therapeutic tape. Elastic tape differs from the classic taping method in which non-elastic tape is used. Non-elastic tape prevents movement and stabilises joints, whereas elastic tape follows the muscle or nerve path, allowing freedom of movement and influencing lymphatic drainage (Kumbrink, 2012:2,4).

Kinesio® Tex Gold is a brand name of an elastic therapeutic tape by the name of Kinesio® and it was the chosen brand used in this study. It was developed 25 years ago and has become the "platinum" standard for therapeutic rehabilitative tape (Kinesio South Africa, 2013). The literature on Kinesio® taping focused on the decrease of pain and inflammation as well as joint and muscle re-alignment without compromising mobility (García-Muro, Rodriguez-Fernández and Herrero-de-Lucas, 2010:292). The mechanisms proposed were the constant proprioceptive feedback from the skin applications and the facilitation of proximal

control, space correction, increased lymphatic drainage and pain relief (Kaya, Zinnuroglu and Tugeu, 2010:202).

The original method of Kinesio® taping was developed by Dr Kenzo Kase in 1973 (Kase, Wallis and Kase, 2003:20). It has been used by athletes and clinicians in the sport and medical domains, in the treatment of excessive lymph after mastectomy and surgery (Lipinska, Śliwiński, Kiebzak, Senderek and Kirenko, 2007:256-269; Szczegielniak, Krajczy, Bogacz, Łuniewski and Śliwiński, 2007:299-307; Tsai, Hung, Yang, Huang and Tsauo, 2009:1353-1360) and in the neurological paediatric setting (Yasukawa, Patel and Sisung, 2006:104-108). However, it took centre stage at the 2008 Olympic Games in Beijing when athletes sported the new funky therapeutic tape (Martinez, 2008:1-4).

Kinesio® tape can be used on all body areas and during all the phases of injury and injury prevention (Kinesio® Taping Association [KTA] 2008). The quality and tape properties of different brands of the elastic tape could influence the effect and outcome of the taping (Kumbrink, 2012:3-4).

Acceptable tape qualities are (Kumbrink, 2012:4-5):

1. Cotton fibres woven at right angles to each other. The longitudinal thread must run parallel to the outer edges of the tape.

Elastic fibre woven into the fabric longitudinally must have very specific stretch and endurance limits. Lower elasticity can result in alterations of actions of the tape as well as discomfort during applications.

The acrylic layer allows stretch into a transverse direction by applying it into the tape longitudinally in the form of a sine wave. Refer to Figure 2-1 with regards to the sine wave of a 5 cm strip. The tape itself should only stretch into a longitudinal direction. The forces are distributed horizontally and vertically so that in combination, it allows for the lifting of the skin or underlying tissue. This is one of the principle effects of Kinesio® taping.

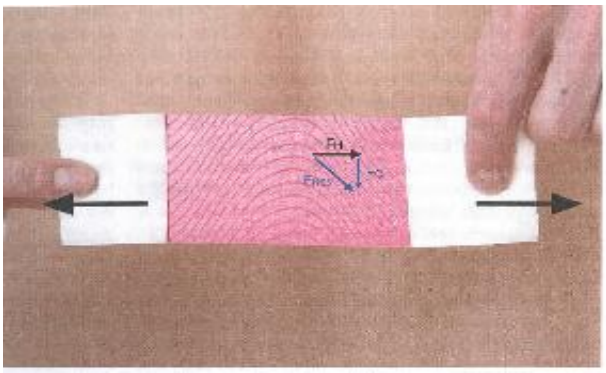


Figure 2-1 The longitudinal sine wave on the tape (Kumbrink, 2012:4)

2.3 The Effects of Kinesio® Taping

Kinesio® taping effects focussed on decreasing pain, correcting mal-alignment, increasing vascular and lymphatic flow as well as the correct stimulation of muscle function. The proposed mechanisms exerted by Kinesio® taping were (González-Iglesias *et al*., 2009:516):

- Increased local blood circulation
- Reduced oedema by decreasing exudative substances
- Facilitation of the muscle
- Sensory stimulation and proprioception to the skin, muscle and fascia structures
- Providing proper afferent input to the central nervous system
- Limiting range of motion of the affected tissue

The value of Kinesio® taping according to the studies considered lay in the immediate improvement of symptoms (González-Iglesias *et al*., 2009:516; Kaya, Zinnuroglu and Tugeu, 2010:205). Randomised clinical pre- and post-test studies showed that Kinesio® taping contributed to immediate improvement and resolution of patients' symptoms, and that Kinesio® tape application could be used as a preventative or intervention method (García-Muro, Rodriguez-Fernández and Herrero-de-Lucas, 2010:295; Hsu *et al*., 2009:7) (refer also

to 2.8). Standing balance in patients with multiple sclerosis was immediately improved after Kinesio® taping application which implied that the improved results were not due to a learning effect of the patients (Cortesi, Cattanceo and Jonsdottir, 2011:370). Donec, Varžaitytė and Kriščiūnas (2012) however, found that maximal grip force was not influenced directly following Kinesio® taping but that the maximal grip force increased from 11.2 kg at 30 minutes after application to 11.8 kg at 1 hour after application.

There are currently no known side effects of Kinesio® taping. However, the following contra-indications should be considered (Kumbrink, 2012:11):

- Open wounds
- Scars which have not healed
- Skin diseases for example neurodermatitis or psoriasis
- Sacral connective tissue massage zone (genital zone) in the first trimester of pregnancy
- Known allergies to acrylic material

2.4 The Application of Kinesio® Tape

Kinesio® tape is applied directly to the skin to achieve the therapeutic effects (Donec, Varžaitytė and Kriščiūnas, 2012:98). Depending on the desired effect required of the Kinesio® taping, the tape is stretched or unstretched. Prior to taping, the tape is cut into “I”, “Y” or fan strips. The base strip is placed without any stretch 2 cm below the area to be treated. Refer to Figure 2-2 for the ways the Kinesio® tape is cut (Rogers, 2009). The corners of the tape should be rounded to prevent premature loosening of the tape. The rounded corners allow the longitudinal forces to be redistributed around the corners (Kumbrink, 2012:9).

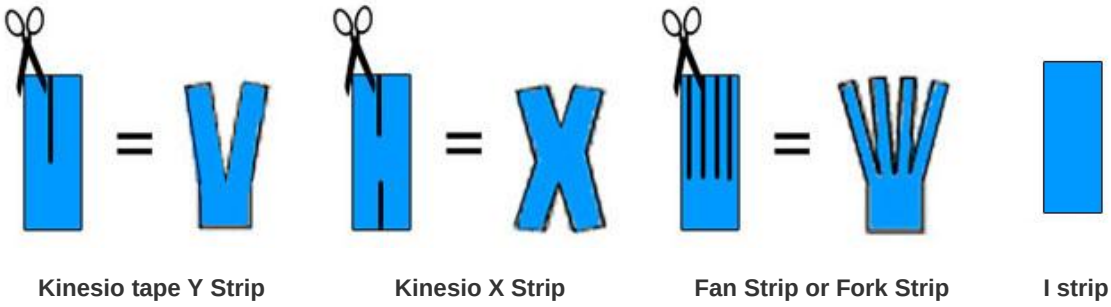


Figure 2-2 Kinesio® tape strips (Rogers, 2009)

The method of application of the tape determined the effect on the conditions treated. Corrective application techniques included (Kase, Wallis and Kase, 2003:21):

- Mechanical correction or recoiling
- Fascia correction or holding
- Space correction or lifting
- Ligament and tendon correction or pressure
- Functional correction or spring
- Lymphatic correction or channelling

The space correction method used in this study uses light to moderate or 25-50% available tension. Kinesio® Tex tape was applied to facilitate more space directly over the treatment area. The technique was aimed at the reduction of pain, inflammation and swelling. The application method lifted the skin decreasing pressure in the area. Reduction of pressure in the treatment area decreased the stimulation of chemical receptors, lessened inflammation and therefore decreased pain. The taping methods also led to increased peripheral circulation and activation of the mechanoreceptors and the gate control theory so that pain perception was decreased (Kase, Wallis and Kase, 2003:29).

Control of pain through the gate theory had been described by Melzack and Wall in 1965 and was cited by Low and Reed (1994:78). Pain perception is regulated

by a gate that can be opened and closed thus increasing or decreasing perceived pain from the peripheral and central nervous system. The pain gate is affected by A-delta (fast) and C-fibres (slow) due to stimulation of the mechanoreceptors in the posterior horn. The morphine effect on the C-fibre system can also be activated by A-delta stimulation and causes stimulation of centres in the midbrain and this can result in serotonin secretion in the posterior horn. The pain gate can be closed via peripheral or inner forces. Inner forces consist of stimulation of large myelinated cutaneous sensory fibres for example, stimulation of the mechanoreceptors (rubbing it better) or via inhibitory control descending from the brain and activated by motivation (Low and Reed 1994:78).

Kinesio® taping is applied directly to the skin and the skin serves as the originator of all the proposed effects. The functions of the skin include: sensory perception; immunity; thermoregulation; and homeostasis of water balance (Amirlak, Shahabi, Campbell, Totonchi, Rowe and Soltanian, 2008). The sensory system of the skin monitors information from the internal and external environment as part of homeostatic feedback control of the body (Kibble and Colby, 2009:49).

Taping could have an effect on the muscle tone as well as muscle control. Skin receptors and proprioceptors are activated by the application of the tape. Tone regulation is reinforced and information with regards to position in space and muscle effort is relayed (Kumbrink, 2012:7). Refer to **Figure 2-3** for the Kinesio® tape application and the underlying structures of the skin (About Kinesio Taping – Concepts & Effects, 2008).

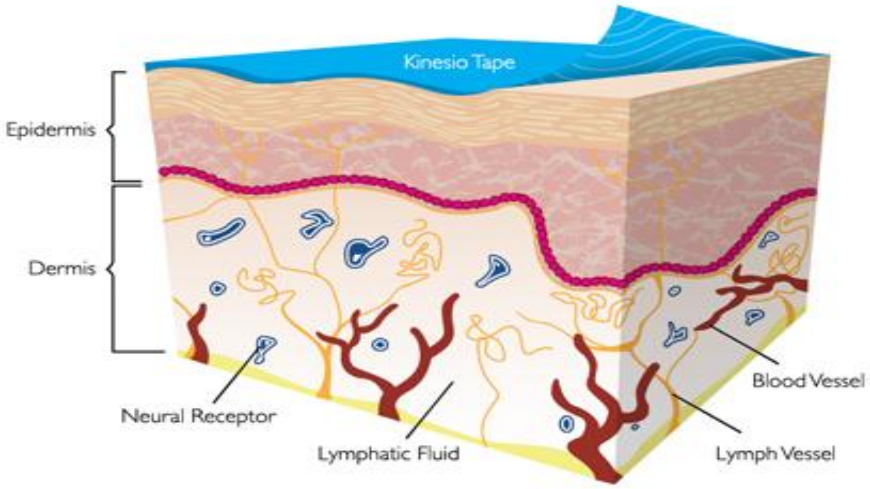


Figure 2-3 Kinesio® application to skin and effect on underlying structures (About Kinesio Taping – Concepts & Effects, 2008)

2.5 Physiotherapeutic Kinesio® Taping

The Health Professionals Council of South Africa (HPCSA) defines the scope of practice for a physiotherapist in the mental health setting as the treatment of physical ailments of psychiatric patients including maintenance or restoration of physical fitness. This includes the use of mechanical aids such as braces, prostheses and other therapeutic and supportive devices, including taping (South African Medical and Dental Council, 1976).

According to Kinesio® Taping South Africa, their Kinesio® taping courses are accredited with the HPCSA and may be attended by chiropractors, physiotherapists, medical doctors, occupational therapists, biokineticists, speech therapists and podiatrists. The course allows the techniques only to be used within the specific scope of practice of the person applying the tape and not outside the specific professional qualification (Kinesio South Africa, 2013).

Physiotherapeutic Kinesio® taping therefore implies the application of Kinesio® Tex utilising the special skill set taught at the course and with the unique approach of a physiotherapist for example, applying the tape to treat the physical symptoms of MDD.

2.6 Major Depressive Disorder

Mood is a persistent, internal feeling that influences a person's behaviour and perception of the world. Mood can be classified as normal (euthymic), increased (euphoric) or depressed (dysphoric). When a patient suffers from a sustained depressed mood, the patient can be diagnosed with a MDD (Sadock and Sadock, 2007:527). The criteria for MDD have been set out in the fifth edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) (American Psychiatric Association, 2013:160-161,344-345).

Major depressive disorder is diagnosed when there is a period of at least 2 weeks during which there is either a depressed mood or the loss of interest or pleasure in nearly all activities. Changes in appetite, weight, sleep and decreased energy are reported. Feelings of worthlessness and guilt, and difficulty in thinking, concentration or making decisions are also noted. Suicide ideation plans or attempts or recurrent thoughts of death may also occur (Sadock and Sadock, 2007:527). The DSM-5 has identified psychomotor retardation or agitation as part of the criterion for MDD. Motor disturbances have to be observable by others and not merely subjective feelings of restlessness or being slowed down and it has to be present every day (American Psychiatric Association, 2013:160-161).

Neuro-Anatomy

The limbic system is the collective name for structures in the brain forming the centre for emotion, behaviour, motivation, long-term memory, motor function and olfaction. It consists of a series of cortical and sub-cortical structures that have connections with the reticular formation and hypothalamus (Baily, 2014).

Depression is associated with dysfunction of the limbic system. Refer to **Figure 2-4** for the main structures of the limbic system (Google Images, 2013b).

The limbic system includes the following structures (Kibble and Colby, 2009:106):

1. The cingulated cortex is linked to the highest centres of cognition in the prefrontal and association areas of the cortex, and is the area where emotion is perceived.

The hippocampus is a curved elevation of grey matter on the medial surface of the temporal lobe and is involved in learning and memory.

The amygdala is situated lateral to the hippocampus and below the basal ganglia. The amygdala is accountable for the perception of strong emotions, for example fear and aggression, and associates emotions with memories.

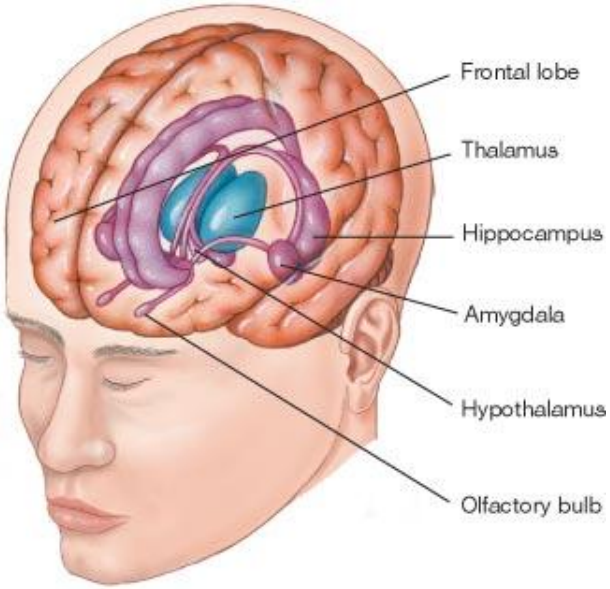


Figure 2-4 Main structures of the limbic system (Google Images, 2013b)

A relationship appears to exist between the three main monoamine neurotransmitters in the brain (that is, norepinephrine, dopamine and serotonin) and specific symptoms of MDD, for example control of movement. Low levels of these neurotransmitters have been linked with MDD (Maletic, Robinson, Oakes, Iyengar, Ball and Russel, 2007:2035).

A neurotransmitter is defined as *"a chemical contained in the synaptic vesicles in nerve endings that is released into the synaptic cleft, where it causes the production of inhibitory or excitatory postsynaptic potentials"* (Fox, 2008:743). Refer to Table 2-1 for neurotransmitters associated with MDD (Kibble and Colby, 2009:48).

Table 2-1 Neurotransmitter system associated with MDD

Chemical	Synthesis	Signal termination	General functions in the nervous system
Norepinephrine	From dopamine in the catecholamine pathway	Re-uptake or breakdown via the enzymes monoamine oxidase and catechol-O-mythyltrans-ferase	Alertness General affect
Serotonin	From the amino acid tryptophan via the enzyme tryptophan hydroxylase	Reuptake	Mood (5-HT reuptake blockers are commonly prescribed as anti-depressants) General arousal
Dopamine	Derived from the amino acid tyrosine via the enzyme tyrosine hydroxylase in the catecholamine pathway	Reuptake	Movement control and general affect

Patients with MDD often complained of physical symptoms and these symptoms decrease in a linear fashion as the MDD decreases (Jacobsen *et al*., 2006:295-296).

The most prominent physical symptoms associated with MDD were (Jacobsen *et al*., 2006:295-296):

- Muscle tension
- Pain complaints

- Restricted breathing
- Negative attitudes towards physical appearance and ability
- Less flexibility and centring of movements

2.7 Current Role of the Physiotherapist in Mental Health

Physiotherapists working in the field of mental health are uniquely placed to provide a broad spectrum of physical approaches to treatment aimed at relieving symptoms, boosting confidence and improving quality of life. Interventions include physical activity, exercise and sport, improvement of balance, postural and movement education, management of chronic or acute pain, manual therapies, acupuncture and complementary therapies (Gray, 2003:xi)

2.8 Selected Physical Symptoms Associated with MDD

Of the five physical symptoms associated with MDD, according to Jacobsen *et al*., (2006:295-296), only four can be treated in the scope of practice of the physiotherapist and with the physical approach of Kinesio® taping. Therefore, the concept of negative attitudes towards physical appearance and ability was omitted from this study. The four selected MDD-associated physical symptoms are augmented throughout the literature, as discussed in the sections below.

2.8.1 Muscle Tension and Associated Pain

Over the last decade several studies have confirmed the relationship between pain and MDD (Bär, Brehm, Boettger, Boettger, Wagner and Sauer, 2005:101-102; Carroll, Cassidy and Cote, 2004:138; Currie and Wang 2004:57-58; Dersh, Gatchel and Polatin, 2001:92-93; Jacobsen *et al*., 2006:296).

Patients diagnosed with MDD have a 50% more likely chance of experiencing chronic neck and low back pain (Carroll, Cassidy and Cote, 2004:137). The reverse is also true: chronic pain is a risk factor for the development of MDD and other psychological disorders (Dersh, Gatchel and Polatin, 2001:92). In a study

conducted in Canada the incidence of MDD was 19.8% in those patients that experienced chronic low back pain (Currie and Wang, 2004:57). In another study in 1996 by Banks and Kerns cited in Bär *et al*. (2005:97) the incidence of MDD in patients with chronic low back pain was found to be between 30 and 54%.

Wideman, Scott, Martel and Sullivan (2012:963) found that depressive symptoms in patients referred for physical therapy for the management of musculoskeletal pain conditions would resolve over the course of treatment, and that this resolution was associated with long term recovery. The level of recovery was greater in patients receiving physical therapy than patients not receiving physical therapy (Wideman *et al*., 2012:963). Furthermore, Jacobsen *et al*. (2006:296) emphasised that pain was often a result of muscle tension. The combination of pain and muscle tension caused restricted movements and changes in posture.

Pain, joint motion and function were successfully treated with Kinesio® taping in a case study of a 20 year-old female patient with acute myofascial shoulder pain. Shoulder mobility was restricted due to pain. A variety of tests to assess the symptoms were preformed including range of motion of abduction, flexion and external rotation as well as the use of a VAS to determine the pain experience. Abduction increased with 125° and flexion with 111° at post-treatment assessment 2 days after the tape was removed. Pain levels decreased from 10 to 2.7 on a 10-point scale during movement. The improvement was hypothesised as being the result of normalisation of muscular function and not merely an analgesic effect. Lower muscle tone, after inhibition of the myofascial trigger points, could account for the decrease in pain. The results of the study might not be widely applicable as the results were only obtained from a single case study. The exact methodology was not mentioned although photos were provided. No mention was made about other therapies received during this time that could have influenced the results (García-Muro, Rodriguez-Fernández and Herrero-de-Lucas, 2010:292,294-295).

Stronger evidence has been obtained for the treatment of muscle pain during a randomised controlled clinical study on 41 patients with whiplash. The

experimental group obtained a greater improvement in pain and cervical range of motion than the control counterparts. In the experimental group, pain decreased from 4.3 to 3.3 at immediate post-treatment on the numeric pain rating scale (NPRS) where 0 was no pain and 10 was maximum pain. The cervical range of motion (in degrees) for the experimental group from baseline to immediate post-treatment were: flexion 55.8 to 60.7, extension 46.7 to 54.9, right lateral flexion 42.3 to 47.2, left lateral flexion 41.8 to 44.5, right rotation 56.1 to 61.1, left rotation 55.7 to 59.9. Although the results showed a statistically significant reduction in neck pain and increase in cervical range of motion the differences between the groups did not, however, exceed the minimum effect for clinically importance as defined by the authors. Again the results could not be generalized due to the small sample size, follow-up being limited to 24 hours and all patients being treated by the same therapist. A placebo taping cancelled out placebo effects and its influence on the results. It seemed that Kinesio-taping was the only intervention during this time, as the participants were instructed not to drink any medication (González-Iglesias *et al*., 2009:516-520).

Muscle activity had been improved with Kinesio® tape applications when scapular kinematics and muscle performance were tested in 17 amateur baseball players with shoulder impingement. The study used a crossover, pre-test/post-test repeated measures design. The study compared the effect of elastic and placebo taping. Measurements were performed on strength, EMG and scapular motion in both groups during a movement of scaption (elevation and lowering of the humerus in the scapular plane). Decreased scapular posterior tilt in the Kinesio® taping group suggested that the tape might assist in correcting affected scapular movement and help the arm to function from a more balanced and stable base. The study design was adequate but the sample size was small and did not support statistical strength. The study tested only the immediate effect of the Kinesio® taping but the skin-based application system, used as measuring instrument in the study could have affected the results (Hsu *et al*., 2009:2-5,7).

Kinesio® taping has been compared to other physical therapy modalities in a randomised controlled study of 55 patients with shoulder impingement (Kaya, Zinnuroglu and Tugeu, 2010:204-205). The DASH scale and a VAS were used to determine baseline disability and pain scores. The DASH and VAS scores decreased significantly in both groups compared to the baseline evaluation but the DASH scores of the Kinesio® taping group were significantly lower at the second week (a score of 18 compared to 31 in the physical therapy group). The first group received the Kinesio® taping intervention with a full physiotherapy program consisting of a home exercise program and electrotherapy. Group two received all the therapies except Kinesio® taping. Therefore the groups were homogeneous in all aspects except the taping intervention.

Data obtained from 30 voluntary subjects participating in a study on the outcome of Kinesio® taping on lumbar range of motion proved that active range of motion of lumbar flexion increased when the subjects were taped with Kinesio® tape (Yoshid and Kahanov, 2007:104-105,108,111). The effects of Kinesio® taping on the musculoskeletal system had been attributed to a reflex mechanism of the nervous system that causes an increase in recruitment of motor units as well as increased bio-electrical activity and muscle strength. The bio-electrical activity reached its peak 10 minutes after application but the effects lasted for 24 to 48 hours after removal of the tape (Slupik, Dwornik, Bialoszewski and Zych, 2007:650).

2.8.2 Restricted Breathing

Breathing disorders frequently manifest simultaneously with MDD. The prevalence of MDD in chronic pulmonary disorders is up to 80% (Kunik, Roundy, Veazey, Souchek, Richardson, Wray and Stanley, 2005:1208). Respiratory sinus arrhythmia (RSA) have been linked to breathing frequency. High levels of RSA have been associated with poor prognosis of MDD 6 months after the onset of the illness as well as individual symptoms of the MDD. Levels of RSA were

not linked to MDD severity (Rottenberg, Wilhelm, Gross and Gotlieb, 2002:266,270).

Overlapping similarities between the presenting symptoms and the neurophysiology of MDD and that of obstructive sleep disorder breathing (OSDB) have been demonstrated. OSDB can contribute to or aggravate the symptoms of those predisposed to MDD and the treatment of OSDB can prevent the presentation of depressive symptoms (Deldin, Phillips and Thomas, 2006:137). Jacobsen *et al*. (2006:296) have explained that restricted breathing and muscle tension are inclined to disrupt the flow of movements, making movement "un-free and disharmonious". This caused adjustments in posture.

Inspiration is an active process that enlarges the thoracic cavity in three dimensions: transverse, anterior-posterior and vertical (Hamilton and Luttgens, 2002:245 and Moore and Dalley, 1999:72). These dimensions were tested during this study.

An increase of the thoracic cavity in the transverse plane is a result of the elevation and eversion of the lateral portion of the ribs. The shape and anterior-posterior attachments of the ribs are responsible for the so-called "bucket-handle effect". A lateral movement of the anterior ends of the ribs accompanies the elevation of the lower ribs. This puts the diaphragm on stretch and expands the lower thorax (Hamilton and Luttgens, 2002:245 and Moore and Dalley, 1999:72).

An increase of the thoracic cavity in the anterior-posterior plane is affected by the elevation of the anterior ends of the obliquely placed ribs and the body of the sternum. Rib movement moves the sternum. The elevation of the anterior ends of the ribs causes the ribs to assume a more horizontal position and results in a straightening of the costal cartilages. The movement of the thorax in the transverse and anterior-posterior plane is related to each other. It is a direct result of the shape of the ribs and of the oblique direction of the axes of motion (Hamilton and Luttgens, 2002:245-246 and Moore and Dalley, 1999:70-72).

An increase in the vertical plane is brought on mainly through the contraction of the diaphragm, but the elevation of the upper two ribs also contributes. During inspiration, the thoracic spine extends to the end range of motion and thereby contributes to the vertical diameter (Hamilton and Luttgens, 2002:246).

Muscles of respiration are divided into muscles of the thorax and muscles of the spine and shoulder girdle. Muscles of the thorax include those associated with rib movement and have a primary function of respiration. Muscles of the spine and shoulder girdle have a secondary function contributing to respiration (Hamilton and Luttgens 2002:246).

Muscles of the thorax and ribs are (Hamilton and Luttgens, 2002:246 and Moore and Dalley, 1999:80-84): the diaphragm; m. intercostales (externi and interni); m. levatores costarum; m. serratus posterior interior; m. serratus posterior superior; and m. transversus thoracis.

Muscles of the spine with a secondary respiratory function include m. abdominals; m. erector spinae; the extensors of the cervical and thoracic spine; m. pectoralis major and minor; m. quadratus lumborum; m. scalenes; m. sternocleidomastoid; and m. trapezius (Hamilton and Luttgens, 2002:246).

M. erector spinae, one of the deep muscles of the back (Snell, 2000: 828-829), stabilises the spine and pelvis against the pull of the abdominal muscles. This results in extension of the spine allowing the abdominal muscles to compress (Hamilton and Luttgens, 2002:250).

Muscles of the back and especially the m.erector spinae are of the utmost importance. The Kinesio® taping is applied directly over the skin area of the muscle and the muscle has a direct function of proximal control as well as volumetric changes of the thorax during breathing. Refer to Figure 2-5 for the m. erector spinae (Google Images 2013a).

Back support greatly influences breathing in the seated position. The abdominal contribution to tidal volume is greater with back support than without back support. This corresponds with lower displacement of the ribcage (in terms of

perimeter, cross-sectional area and volume changes). This is explained by the effect of tonic contraction of abdominal muscles for postural maintenance and trunk stabilisation. If back support is removed, abdominal compliance is reduced and the motion of the abdominal muscles increases. Abdominal muscles as well as the diaphragm are involved with maintaining posture in the erect position (Romei, Lo Mauro, D'Angelo, Turconi, Bresolin, Pedotti and Aliverti, 2010:189-190).

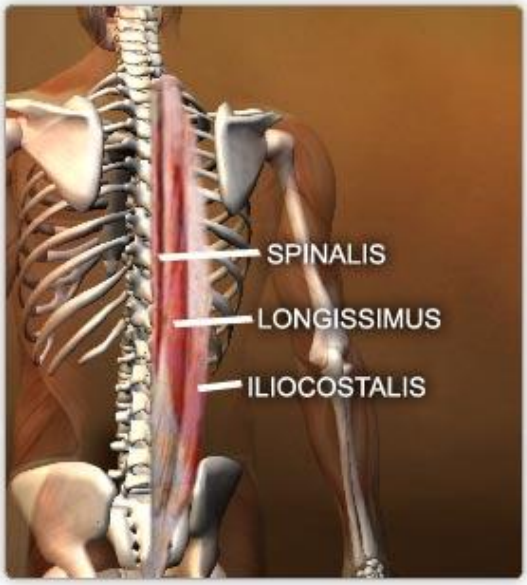


Figure 2-5 M. erector spinae (Google Images, 2013a)

Zubeyir *et al*. (2012) investigated the effect of elastic taping on primary and accessory respiratory muscle strength. The researcher compared the inspiratory muscle strength of 47 subjects. The researchers did not use Kinesio® taping, but a different brand of elastic taped called Pinotape®. The participants were divided into two groups: diaphragmatic kinesiology taping and accessory respiratory muscle kinesiology taping. The researchers found no significant effect on muscle strength of primary or secondary respiratory muscles in healthy subjects. They did, however, not test the volumetric measurements (Zubeyir *et al*., 2012:242-244).

Kinesio® taping can enhance motor skills, aid stability and improve posture. Kinesio® Tex can also be used to facilitate movement patterns, align posture and

improve function (Kinesio South Africa, 2013) and therefore Kinesio® taping could have an effect on selected physical symptoms associated with MDD.

2.8.3 Decrease in Flexibility and Centring of Movements

Major depressive disorder has an influence on gait and posture secondary to the motor retardation that predisposes the patients with MDD to falling. Patients that suffer from MDD have a lower motor performance than non-depressed patients and their postural abilities in standing are severely limited compared to their non-depressed equals (Turcu, Toubin, Mourey, D'Athis, Manckoundia and Pfitzenmeyer, 2004:304,306-307). The more severe the MDD episode, the more impaired the function with regards to motor ability and executive function (Long, 2011).

Decreased flexibility and centring of movements, according to Jacobsen *et al*. (2006:296), in patients with MDD are represented clinically as a lack of rotation in the trunk, a lack of swinging of the arms during gait, reduced coordination of the arms and a decreased ability to initiate movements from the movement centre (proximal control).

Back extensors posteriorly and abdominal muscles anteriorly are important to facilitate trunk and therefore proximal control. Back extensors that surround the vertebral column provide a flexible support for the trunk (Jaraczewska and Long, 2006:33). The postural tone of the back muscles is important for maintenance of normal curvature of the vertebral column as the muscles extend from the sacrum to the skull (Snell, 2000:828). The muscles provide adjustable tension on the spine allowing the spine to deviate in any direction while maintaining adequate support. A stable thorax is needed for the abdominal muscles to function optimally. Excessive kyphotic posture, muscle weakness or muscle imbalance causes a compression of the ribcage, reducing the volume of the lungs (Jaraczewska and Long, 2006:33).

Kinesio® taping can be used to improve purposeful movement and provide the needed stability and alignment (proximal control) to perform a task (Yasukawa,

Patel and Sisung, 2006:104). The effect of Kinesio® Tex tape to enhance stability has been demonstrated during a study at a rehabilitation institute in Chicago. Fifteen children with diverse neurological damage, admitted as in-patients, were tested in a pilot study to determine the effects of Kinesio® taping on upper limb function. The children were pre-tested with the Melbourne Assessment of Unilateral Upper Limb Function, taped with Kinesio® taping and re-tested. The results reflected improved post-measurement scores that were statistically significant and that improved over time with a standard deviation of 23.3 at the follow-up measurement after 3 days. This study had a very small sample size of 15 participants and the patients were not uniform with either diagnosis or taping applied, but they presented with the same causes and functional impairments. The assessment tool was standardized and ideal for testing upper limb function. No control was used in this study and the participants received multiple therapies during this time. Although improvement was seen further research is needed to determine the direct impact the taping intervention had on the impairments (Yasukawa, Patel and Sisung, 2006:105-109).

This has also been confirmed by a case study at the same institute. A 12-year-old boy's right arm function was evaluated with the Melbourne Assessment of Unilateral Upper Limb Function while he was seated in his wheelchair with the lateral trunk support removed. During testing he displayed dystonic movement and overshooting when trying to grasp objects in front of him. He scored 57 out of the possible 122 (47%) on the scale. The Kinesio® tape was applied bilaterally to the erector spinae muscle from L5 to T2 as well as the shoulder and hand to attain the correct alignment and assist with stability and a functional upright position. Immediately after Kinesio® taping, post-measurement of the upper limb function improved and he scored 61 out of 122 (50%). Three days after wearing the Kinesio® Tex he still scored 50% on the Melbourne Assessment (Yasukawa, Patel and Sisung, 2006:107-108).

Kinesio® taping has been used in neurological conditions, for example in the treatment of subluxation following a stroke. It has an effect on the sensorimotor system as well as on proprioception (Jaraczewska and Long, 2006:32). The Berg Balance Scale was used to assess the effect of Kinesio® taping on the static balance in subjects with multiple sclerosis. The balance of the subjects improved only in an anterior posterior direction. The reason for this could be that the taping was applied in such a manner that it primarily worked on the flexion-extension movement of the ankle joint. Subjects with poorer quality initial assessments had better outcome from tape application. Kinesio® taping had no adverse effects but results were specific and axis dependent (Cortesi, Cattanceo and Jonsdottir, 2011:366,368-369).

Bicici, Karatas and Baltaci (2012) have tested functional ability including dynamic balance, in basketball players with chronic inversion ankle sprains. Kinesio® Tex did not limit function as in the case of white rigid athletic tape (Bicici, Karatas and Baltaci, 2012:164). Kinesio® tape could be used to promote postural alignment and stability by supporting weak muscles, relaxing overstretched muscles and reducing pain to promote functional activity (Jaraczewska and Long, 2006:37). Kinesio® tape applied directly and without any tension could also stimulate mechanoreceptors and therefore also proprioception (Kase, Wallis and Kase, 2003:36).

The modification of balance and postural control is explained by two theories. Firstly, it is advocated that due to the mechanical properties of Kinesio® taping a reflex reaction is exerted on the nervous system. It causes overlapping of muscle fibres and results in increased muscle activation (sensorimotor effect). Secondly, the application of tape directly to the skin stimulates the feed forward mechanism in the body allowing for an increase in proprioception and joint control (Slupik *et al*., 2007:650-651).

2.9 Conclusion

The association between physical complaints and MDD emphasises the need for physiotherapy as part of the holistic treatment regime for the depressed patient. Furthermore Kinesio® taping can facilitate muscles, control joint instability, assist postural alignment as well as relax overused muscles (Kaya, Zinnuroglu and Tugeu, 2010:204-205).

Muscle tension and pain, restricted breathing and decreased centring of movement were successfully treated with Kinesio® taping in the literature as discussed in this chapter. These symptoms correspond with the physical symptoms associated with MDD. Therefore Kinesio® taping could have an influence on selected MDD-associated physical symptoms.

Chapter 3 Methodology

3.1 Introduction

This chapter discusses all the elements of the methodology of this study. After a thorough literature review, the physical symptoms associated with MDD to be evaluated were selected (refer to 2.8). The aim of the study was refined and specified. The desired study population, which allowed for data gathering, was selected. The study intervention was by means of a Kinesio® Tex taping. Data were collected through standardised questionnaires via closed interviews and observation. A graphic representation of the study process is depicted in 3.3.

3.2 Aim and objectives the study

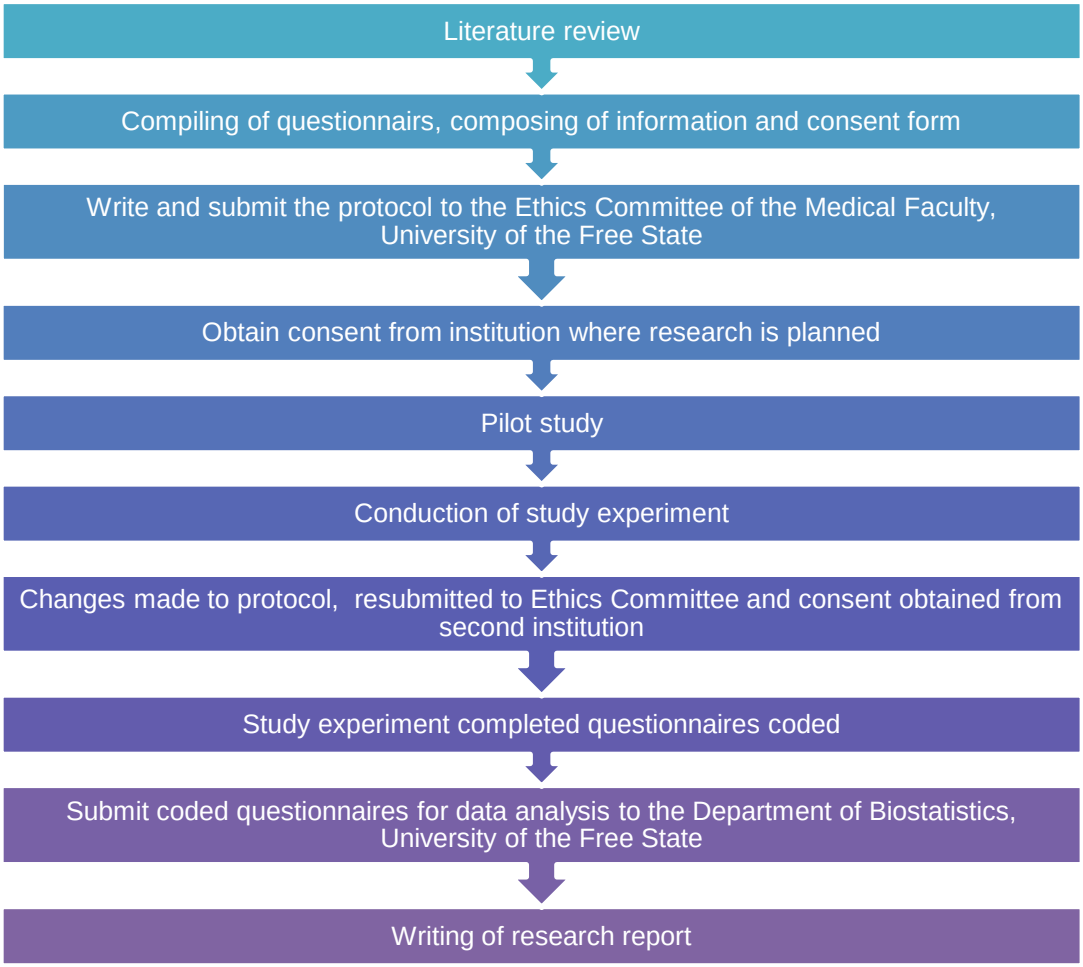
The main aim of the study was to investigate the effect of physiotherapeutic Kinesio® taping on selected physical symptoms associated with MDD.

The specific objectives of the randomised controlled study, within patients between 18 – 65 years, admitted with major depressive disorder to either a public or private psychiatric institution in Bloemfontein, was to:

- determine pain complaints before, immediately after and 24 hours after Kinesio® taping application as measured by the Short Form McGill Pain Questionnaire .
- determine pain areas before, immediately after and 24 hours after Kinesio® taping application as measured by the Short Form McGill Pain Questionnaire.
- determine breathing restricting before, immediately after and 24 hours after Kinesio® taping application as measured by the Manual Assessment of Respiratory Motion.

- determine flexibility and centring of movements before, immediately after and 24 hours after Kinesio® taping application as measured by the Tinetti Mobility Test

3.3 Orientation with Regards to the Study Process



3.4 Research Design

Research can take a qualitative or quantitative approach. A quantitative research approach is used to answer a question that can be measured. The research process consists of testing a hypothesis by means of a standardised data collection method. A quantitative research approach collects numerical data and uses statistical analysis to draw conclusions from the data. Quantitative

research or an experimental approach confirms or rejects the hypothesis (Leedy and Ormrod, 2005:94-95).

A qualitative research approach strives to explore and interpret certain research aspects. The approach is concerned with themes and categories and the analysis is subjective. The purpose of the study is to describe and understand the phenomena from the participants' point of view (Leedy and Ormrod, 2005:94-96).

According to Baily (1997:43-46) an experimental study design has the following properties:

- Manipulation or intervention. The researchers manipulate one or more measurable variables.
- Control. Control is defined as the elimination of interfering influences that are not part of the study design.
- Randomisation. The process reduces systematic bias by ensuring that the study participants are representative of the group (random selection) from the population and ensuring that the placebo control and experimental group participants are similar (random assignment to the groups).

In a randomised controlled study the participants are allocated to either an intervention or control group. The control group receives a placebo treatment which means that the treatment has no known effects but looks similar to the intervention treatment (Morroni and Myer, 2007:89).

A study is blinded when the participants and researchers do not know to which group (experimental or placebo) the study participants are allocated to. In single-blinded studies only the participants are blinded and thus unaware of the group to which they belong. In double-blinded studies, both the participants and researchers are blinded. In triple-blinded studies the participants, researchers and data analysts are blinded (Morroni and Myer, 2007:90).

With regards to the abovementioned characteristics, this study followed a quantitative research approach: numerical data were collected by means of a standardised procedure (standardised questionnaires) and statistical analysis was used to draw conclusions from the data. This was a double-blind, randomised controlled study: the participants were assigned to either an experimental or control group, and both the researcher administering the evaluation and the participants were unaware of group assignment throughout the study. Keeping the taping area covered with a single layer of clothing ensured further blindness of the said researcher. Refer to Figure 3-1 for the design of the study (Morroni and Myer, 2007:90).

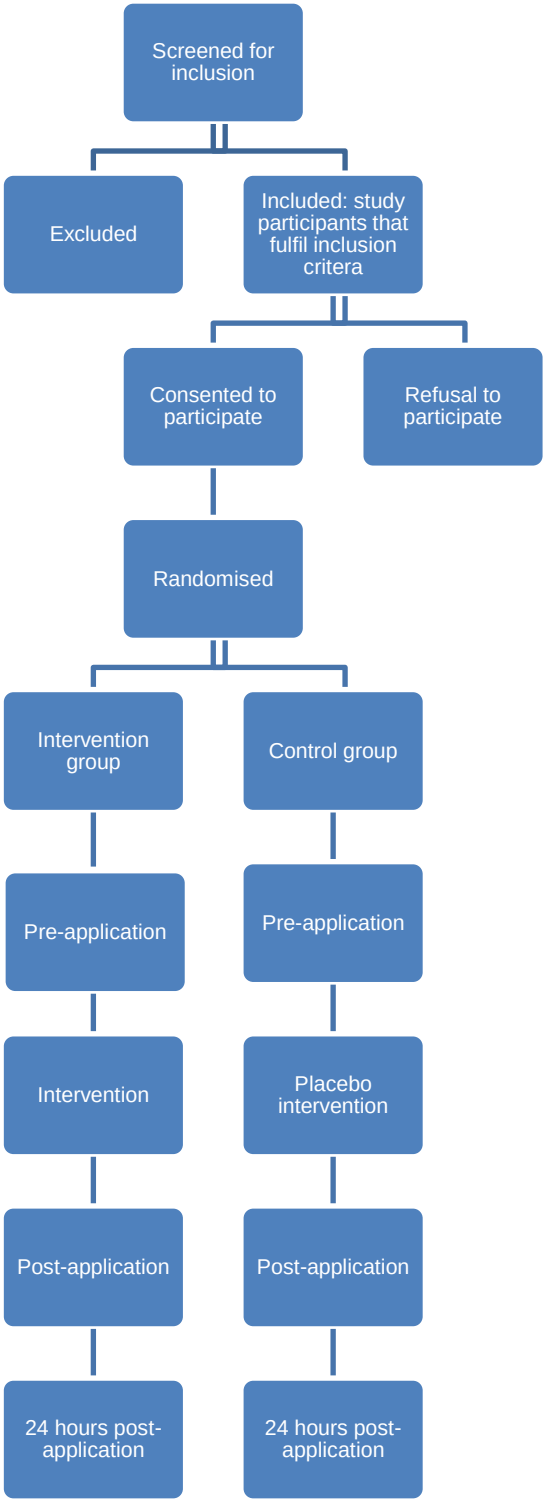


Figure 3-1 Flowchart of study process

3.5 Sample and/or Study Participants

Study participants were patients (male and female) with a DSM-5 criterion diagnosis of MDD admitted to a public psychiatric institution in the affective ward from January 2012 to December 2013. Sample size was determined by taking into account that for small populations with less than a 100 elements the whole population should be sampled (Leedy and Ormrod, 2005:207). The number of patients admitted to the public psychiatric institution in the Free State from January 2010 to December 2010, according to the affective ward admissions register, was 93. Of this 93, only 45 potentially met the proposed inclusion criteria. Of these, 38 females were enrolled. Therefore it was likely to assume that if the trend continued a sample size of 40 would be plausible.

To accommodate the inadequate sample size obtained from this institution from January 2012 to February 2013, three private psychiatric institutions in Bloemfontein were contacted to be sampled from February 2013 to December 2013. Of the three private institutions only one institution gave permission for research to be conducted.

The sample was chosen on the availability of appropriate patients admitted to the ward and integrated in the ward programme. Admission to the ward allows for the sample to be identical with regards to meal times, sleeping times, distance from physiotherapy department as well as other interventions part of the hospital regime. Admission to the ward also ensures minimum fall out of patients from the study.

At the public psychiatric institution the following interventions were received daily by participants: Occupational therapy and pharmacological intervention (medication). Physiotherapy and psychotherapy were on referral basis only. At the private psychiatric institution all participants in the study received daily occupational therapy, psychotherapy, physiotherapy and pharmacological intervention (medication). The therapies received at the two institutions differed and could not be kept the same. The researcher worked at the public psychiatric

institution and could control the physiotherapy received by the participants. The reason physiotherapy could not be controlled at the private psychiatric institution was the fact that the service is provided by private physiotherapists and they could not be expected to discontinue services temporarily on account of the study . This physiotherapy were compensated for by using only patients referred from one psychiatrist to one physiotherapy practice where the treatment regime was kept consistent and included manual therapy, massage, electrotherapy modalities and dry needling for pain as well as a daily exercise program. The physiotherapy at the public psychiatric institution included manual therapy, massage and electrotherapy modalities for pain management.

The Department of Biostatistics at the University of the Free State assisted the researcher with the sampling method. The process was administered by the researcher herself. Convenience sampling was used with random assignment of participants to either an experimental or control group (Polit and Beck, 2006:259). Random assignment to either an experimental or control group was achieved by using a randomisation list provided by the Department of Biostatistics, University of the Free State. Each institution sampled had a separate randomisation list to randomise the participants into either an experimental or control group. Participants that consented were placed chronologically and successively on the list.

3.5.1 Eligibility Criteria

3.5.1.1 Inclusion Criteria

Study participants were eligible for inclusion in this study if they met following criteria:

- Male or female
- Patients admitted in Bloemfontein to a ward for affective disorders in a public psychiatric institution from January 2012 to December 2013 or to a private psychiatric institution from February 2013 to December 2013

- Diagnosis of MDD
- Between the ages of 18 and 65 years (inclusive)
- Speak and understand English and Afrikaans
- Signed informed consent

3.5.1.2 Exclusion Criteria

Patients presenting any of the following were not included in the study:

- Psychosis
- Any primary Axis I diagnosis other than MDD
- Severe suicidality as determined by ward criteria
- Drug addiction
- Brain injury or mental retardation
- Pregnancy
- Medical diagnosis preventing completion of the assessment tool or use of the intervention method.
- Contra-indications for the use of Kinesio® tape. The contra-indications are (Kinesio® Taping Association (KTA) 2008:56):
    - malignancy
    - cellulitis or skin infection
    - open wounds
    - deep vein thrombosis
    - skin irritation after application of a Kinesio® tape test strip

The diagnoses of patients admitted to the institutions were made by the psychiatry registrar under supervision of a qualified psychiatrist or admitting psychiatrist. The inclusion and exclusion criteria were applied by the researcher herself.

3.6 Study Interventions

3.6.1 Kinesio® Tape Application

As muscle tension, pain complaints, restricted breathing, and less flexibility and centring of movements are the physical symptoms most associated with MDD (Jacobsen *et al*., 2006:295) these areas were targeted by one general Kinesio® tape application.

Kinesio® tape was applied from the distal to proximal attachment of the m. erector spinae from L5 to T2 to facilitate a functional upright position of the trunk, promote proximal stability and decrease pain and stiffness due to inflammation (Yasukawa, Patel and Sisung, 2006:108). A bilateral Y-strip application was used. The patient was placed in a neutral spine position – in standing. The base application was applied in the sacro-iliac joint region; a minimum of 5 cm below the area to be taped. During application the patient was asked to move into lumber flexion with rotation to the opposite side to be taped. The Kinesio® tape was applied without any tension. The left tail of the Y-strip was laid down first. The participant was then asked to move into lumber flexion and rotation to the other side and the right tail of the Y-strip was applied (Kase, Wallis and Kase, 2003:83). Refer to Figure 3-2 for the Kinesio® taping intervention (black coloured tape used for photographic purposes only).

Figure 3-2 Kinesio® taping according to standardised treatment guidelines (Van Vuuren, 2010a)

3.6.2 Placebo Application

The placebo taping consisted of four Kinesio® tape I-strips. The dimensions of each strip were 5 cm by 2 cm. The patient was placed in a neutral spine position. The base application consisted of two I-strips and was applied bilaterally in the sacro-iliac joint region of both sides. During application the patient was asked to move into lumber flexion with rotation to the right side. One I-strip was placed on the spina of the left scapula. The participant was then instructed to move into lumbar flexion and rotation to the left side and the right I-strip was applied to the spina of the right scapula. This taping method on the bony areas prevented any interference of the space correction effects of the tape on pain, breathing and proprioception and no effects were expected (refer to Figure 3-3, black coloured tape used for photographic purposes only).

Figure 3-3 Placebo application – Kinesio® taping not in current guidelines (Van Vuuren, 2010b)

3.7 Measurement

3.7.1 Assessments

Major Depressive Disorder: Physical Symptoms

Physical symptoms most associated with MDD were previously classified by Jacobsen *et al*. (2006:295-296) by means of the Body Awareness Scale (BAS) (Roxendal, 1985:16-22). As described by Ryding, Rudebeck and Roxendal (2000:176-182), the BAS and Body Awareness Scale – Health (BAS-H) are the only scales currently available to measure all of the physical symptoms simultaneously. Unfortunately these standardised scales applicable to psychiatry are only available in Swedish and still in the process of being translated (Gyllensten 2011: Personal communication). Therefore to evaluate the selected physical symptoms of MDD the symptoms were assessed separately using standardised, valid scales for that specific symptom as used universally in physiotherapy.

The symptoms tested are:

- Muscle tension
- Pain complaints
- Restricted breathing
- Decreased flexibility and centring of movements

All questionnaires were completed and filled out by the research assistant (Appendices A, B and E). No participants completed any questionnaires. All the questionnaires were verbally translated by the research assistant into Afrikaans if the study participant requested it. The terms used by the research assistant when translating from English to Afrikaans during the interviews were agreed upon beforehand by both the research assistant and researcher. The terms used were kept consistent throughout the study.

Hamilton Depression Rating Scale

The severity of the current major depressive episode was determined by a score from the HAM-D (refer to Appendix B for the summary of the total score). Determining the severity of the current MDD episode was important for two reasons: Firstly, an increase in the severity of a MDD episode can predispose the patient to a psychotic episode. Psychosis was part of the exclusion criteria for the study (Long, 2011). Secondly, severity of MDD is an indication of the functional impact of the disorder and the extent of the symptoms. The efficacy of treatment can vary due to symptom severity and therefore the severity of MDD could influence the results of the outcomes measured (Fourier, Robert, Derubeis, Hollon, Dimidjian, Amsterdam, Shelton and Fawcett 2010:6).The severity of MDD episode was tested to give a reference point on interpreting the results.

The scale was developed by Max Hamilton from the University of Leeds and has endured as the gold standard in clinical practice and research. The complete scale is included in Appendix F (Carroll, 2005:2395-2396; Hamilton, 1960:56-62).

The HAM-D takes 15 to 20 minutes to complete and score. Eight items are scored on a 5-point scale and nine items are scored from 0 to 2. A mild depression is characterised by a score ranging from 8 to 13, whilst a score ranging from 14 to 18 is indicative of moderate depression. Severe depression can be derived from a score that falls within the range of 19 to 22. A score greater than 23 indicates very severe depression. A score of 7 and below indicates the absence of depression or a euthymic mood (Hamilton, 1960:56-52). Mild MDD is characterized by two or three symptoms but the person can continue with most activities. During moderate MDD four to five of the tell-tale signs are present and the individual has a problem continuing with activities of daily living. During severe MDD several characterizing symptoms are present, more physical symptoms could be present and severe MDD is linked to psychotic symptoms and psychomotor retardation (Long, 2011).

Short Form McGill Pain Questionnaire

Muscle tension and pain complaints were assessed using the Short Form McGill Pain Questionnaire (SF-MPQ) administered through a structured interview. The complete scale provides five scores: sensory perception of pain, affective perception of pain, overall scores for the McGill Pain Questionnaire domains, pain intensity through the visual analogue scale as well as the Present Pain Intensity. It was developed by Dr Ronald Melzack in 1980 as the McGill Pain Questionnaire but was too long to use effectively in clinical studies (Melzack, 2005:202). The scale was only used if the participant answers affirmatively to the question whether he/she has pain. The participant was then asked to fill in a body chart with regards to pain complaints (refer to Appendix E). Only the sensory and affective domains of the questionnaire were assessed during this study (refer to Appendix A).

The SF-MPQ contains 11 sensory and 4 affective dimensions of pain with a maximum score of 45. The dimensions are assessed by means of an ordinal scale from 0 (no pain) to 3 (severe pain). There is currently no specific cut-off value when interpreting the results (Hawker, Mian, Kendzerska and French,

2011:S244), but a minimum clinical important change was found to be a difference in pre- and post-measurement of greater than 5 for an improvement in symptoms (Strand, Ljunggren, Bogen, Ask and Johnsen, 2008:924).

Manual Assessment of Respiratory Motion

The Manual Assessment of Respiratory Motion (MARM), a manual assessment technique to evaluate and quantify breathing patterns was used to measure restricted breathing (Courtney, Van Dixhoorn and Cohen, 2008:93-94). Refer to Appendix B. The MARM is a graphic representation of the examiner's manual estimations. The MARM procedure used in this study was the following (Courtney, Van Dixhoorn and Cohen, 2008:93-94):

"Sit behind the subject and place both your hands on the lower lateral rib cage so that your whole hand rests firmly and comfortably and does not restrict breathing motion. Your thumbs should be approximately parallel to the spine, pointing vertically and your hand comfortably open with fingers spread so your hand comfortably open with fingers that the little finger approaches a horizontal orientation. Note that the 4th and 5th fingers reach below the lower ribs and can feel abdominal expansion. You will make and assessment of the extent of overall vertical motion your hand feels relative to the overall lateral motion. Also decide if the motion is predominantly upper rib cage, lower rib cage/abdomen or relatively balanced. Use this information to determine relative distance from the horizontal line of the upper and lower lines of the MARM diagram. The upper line will be further from the horizontal and closer to the top if there is more vertical and upper rib cage motion. The lower line will be further from the horizontal and closer to the bottom if there is more lateral and lower rib cage/abdomen motion. Finally get a sense of the overall magnitude and freedom of rib cage motion. Place lines further apart to represent greater overall motion and closer for less motion."

As this is a palpation test performed by the research assistant, the test was performed over a single layer of clothing without compromising on the integrity of

the test. The research assistant was unaware of the randomisation of the study participants this allowed the study to maintain double blind throughout.

Variables are calculated by measuring the angles between the lines (Courtney, Van Dixhoorn and Cohen 2008:93).

The MARM measurement variables (Courtney, Van Dixhoorn and Cohen 2008:94):

2. Volume is the angle formed between the upper and lower line.

Balance represents the difference between the upper area and lower area.

Freedom of movement or ribcage movement is the area above the horizontal line, divided by the total area between the upper and lower line, multiplied by 100.

Normal values of functional breathing determine average ribcage movement to be around 50 and balance of breathing to be 0. Deviation from the norm can be interpreted as dysfunctional breathing patterns (Courtney, Van Dixhoorn and Cohen 2008:97).

Tinetti Mobility Test

Loss of flexibility and centring of movement was evaluated with the Tinetti Mobility Test (refer to Appendix B). The scale has been developed to evaluate balance and gait in the adult population (Kegelmeyer, Kloos, Thomas and Kostyk, 2007:1370). The Tinetti Mobility Test is a functional performance test. The participants were asked to perform certain functions on command of the examiner for example standing up from a chair, walking over 3 meters of tiled flooring and turning. The examiner would observe these actions and then score them on a scale from 0 to 2. Zero represents the most impairment and 2 the highest function of the performed activity. Individual scores for gait and balance are combined to form and overall score out of 28. Scoring below 19 predisposes a patient for falling and is an indication of a high degree of disturbance in gait.

Scores between 19 and 24 indicates a moderate degree of disturbance (Kegelmeyer *et al*., 2007:1371,1374).

3.7.2 Reliability and Validity

The HAM-D has an acceptable sensitivity and specificity to determine MDD as an observer rating scale (Strik, Honig, Lousberg and Denollet, 2001:425). The HAM-D has a high internal consistency with a Cronbach's alpha of 0.83 (Rush, Trivedi, Ibrahim, Carmody, Arnow, Klein, Markowits, Ninan, Kornstein, Manber, Thase, Kocsis and Keller, 2003:575).

The SF-MPQ validity and reliability was tested on numerous occasions and its usefulness proven by translation of the scale into several languages (Melzack, 2005:202). The internal consistency as determined by Cronbach's alpha was 0.95 for the sensory, 0.88 for affective, 0.89 for the average and 0.96 for total pain components (Grafton, Foster and Wright, 2005:77).

The MARM scale is able to distinguish between different breathing patterns and posture. The MARM has good agreement between examiners and is a valid and reliable research tool, but future studies in a clinical setting are needed to confirm the validity and reliability as no internal consistency coefficient is available at present (Courtney, Van Dixhoorn and Cohen, 2008:98-99; Courtney, Cohen and Reece, 2009:91).

The Tinetti Mobility Test was tested in 2007 and the study concluded that the inter-rater and intra-rater reliability, construct validity and criterion validity was high. The intra-class correlation coefficient (0.87) was greater than 0.80 for all raters (Kegelmeyer *et al*., 2007:1373).

3.8 Pilot Study

After approval was obtained from the Ethics Committee of the Faculty of Health Sciences, University of the Free State, a pilot study was conducted to evaluate the study procedure and to ensure that all persons involved in the study were

aware of their role during the research project. The pilot study also tested the user-friendliness of the data forms.

The pilot study was conducted during January and February 2012 on three patients who met the study eligibility criteria and were admitted to the public psychiatric institution in Bloemfontein. The placebo taping was incorporated in the pilot study by adding a further four patients during March and April 2012. All techniques and procedures were tested and the researcher and research assistant were confident about the execution of the study. Small format changes were made to the questionnaires to ensure easy usage of the questionnaires. Coding blocks were checked and changed accordingly. All changes were communicated to the Ethical Committee (refer to Appendix G). The pilot study was completed in April 2012. The data of the pilot study were not included in the main study.

3.9 Data Collection

3.9.1 Data Collection at the Public Psychiatric Institution

The researcher contacted the nursing matron of the ward telephonically regarding admissions that potentially met the eligibility criteria for the study. All admitted patients were assessed and diagnosed by their attending psychiatrist who documented the diagnosis in the patient file. The researcher screened the patient file to determine eligibility of patients for the study. The researcher determined the language preference of the potential participant and informed consent was obtained in either Afrikaans or English. The research participant then immediately received a test strip of Kinesio® taping on the right anterior forearm to determine the skin reaction prior to full use (Kase, Wallis and Kase, 2003:12).

The HAM-D was administered by an intern psychologist or ward psychologist within 48 hours of obtaining consent. After completion of training to administer the HAM-D in November 2012, the researcher obtained permission from the Ethics Committee of the Faculty of Health Sciences, University of the Free State,

to administer the scale (refer to Appendix G for amendment 4). This helped to control the logistics of the study. The HAM-D was scored immediately after consent was obtained. The total score from the HAM-D is summarised in Appendix B. The HAM-D was not repeated during the study as it was only an indication of the severity of the major depressive episode during testing.

3.9.2 Data collection setting

Evaluations were performed in the following settings: A well-lit, private area with enough space to perform the Tinetti Mobility Test (a minimum of 3 metres tiled floor is needed for the gait evaluation). A chair without armrests was used and the temperature was regulated by means of an air conditioner to ensure a comfortable environment. Lighting was sufficient to ensure effective observation. The sequence and contents of the evaluations were executed without variations. The research personnel were kept constant. Evaluations were done during the same time every day for each participant over the 24-hours of the study. During the 10-minute resting period before tape application, the Kinesio® tape test strip was removed and the skin examined for any adverse reactions. The pre-, post- and 24 hours post-application assessments included all three scales as discussed in 3.7.1.

3.9.3 Data Collection at the Private Psychiatric Institution

The researcher was telephonically contacted on Mondays and Tuesdays regarding admissions that potentially met the eligibility criteria for the study. . All admitted patients were assessed and diagnosed by their attending psychiatrist who documented the diagnosis in the patient file. The researcher screened the patient file to determine eligibility of patients for the study. A suitable time to visit the institution, which complied with the ward programme, was scheduled. During this scheduled time, the researcher visited the institution and obtained informed consent from participants in either Afrikaans of English (according to their language preference). The research participants then also immediately received a test strip with Kinesio® taping on the right anterior forearm to determine the

skin reaction prior to full use (Kase, Wallis and Kase, 2003:12). The same procedure (refer to 3.9.1) was followed for scoring of the HAM-D.

The researcher met the study participants at the institution. The participants rested for 10 minutes before tape application. During this time the Kinesio® tape test strip was removed and the skin was examined for any adverse reactions.

3.9.4 Data Collection Procedures for All Institutions

Participants were randomly assigned to either an experimental or control group according to a randomization list for each institution and instructed not to remove the test strip until pre-application. The randomization list was provided by the Department Biostatistics, University of the Free State. Stratified randomisation was used. The stratification was done per institution to ensure equal distribution between institutions. The researcher applied the randomisation list to participants that were eligible for inclusion in the study and that had consented to participate in the research study. All pre-application was completed within the first 48 hours after the HAM-D had been administered.

The participants were pre-tested with all three scales before the intervention to determine a baseline measurement. The assessment was done by the research assistant, a physiotherapist trained in the assessment tools. The research assistant remained blinded to the assignment of the participants throughout the study. The research assistant performing the assessments was unaware of the group the participant was randomised into as the taped area was covered with a single layer of clothing throughout the assessments during the study. The data were captured on data forms (refer to Appendices A, B and E). The experimental group received an intervention with Kinesio® Tex Gold tape in line with standardised accepted treatment guidelines. The control group received a placebo application with Kinesio® tape, which is not in the current treatment guidelines and of which the effects are not yet known.

Skin preparation took 5 minutes. The skin had to be free of oils and lotions and was cleaned with an alcohol swab prior to application of the tape. Excess body

hair in the treatment area could limit adhesion of the tape and was shaved beforehand (Kase, Wallis and Kase, 2003:13). The taping method took approximately 5 minutes and was performed by the researcher. The researcher was trained in the application method of Kinesio® tape. The participants then rested an additional 2 minutes to minimise any carry over from the strapping method before post-application assessments.

The assessment with all three scales was repeated by the research assistant to obtain a post-application measurement. The participants were instructed not to remove the tape and the assessments of both groups were repeated 24 hours after the first assessment to determine the sustained effect of the taping method (Kase, Wallis and Kase, 2003:16).

All assessments were completed at the same time of the day and scheduled to accommodate the ward programme. The routine treatment protocol, while admitted to the institution, continued for both groups during this time.

3.10 Ethical Issues

The following ethical issues as set out by Leedy and Ormrod (2005:101) were taken into consideration during the execution of this research study.

3.10.1 Protection from Harm

Participants in the study were not exposed to physical or psychological harm. Risk associated with study participation should not be more than normal risk of day-to-day living. Kinesio® tape is a well-tolerated, latex free tape that is safe for paediatric and geriatric populations (Kinesio Taping Association [KTA], 2008:23). No side effects have been noticed in subjects that participated in previous Kinesio® taping studies; not during the treatment or follow-up periods (Kaya, Zinnuroglu and Tugeu, 2010:205). There was no foreseeable discomfort for the participant. Participants received a test strip of Kinesio® taping on the right anterior forearm prior to the intervention. The strip was removed and the skin inspected for any adverse effects before the participants were allowed to

continue with the study. The participant's skin was also examined after the intervention for any irritation or irregular effects.

3.10.2 Informed Consent

The informed consent document (Appendix C) contained the most important information with regards to the study purpose and procedure. This allowed the study participants to give informed consent for participation in this study. The required information in the document was determined by the Ethics Committee of the Faculty of Health Sciences, University of the Free State. The rights of the study participants were clearly stated and a contact number was provided for the secretariat of the Ethics Committee.

Study participants that consented to participate in the study were requested to complete and sign an authorisation document attached to Appendix C. The researcher obtained written consent from the board of directors of all the institutions where this research study was conducted (Appendix D). The researcher's contact details were also provided in case of any enquiries.

Participants were informed about the nature of the study, were given a choice whether or not to participate and were able to withdraw from the study at any time. In this study the differences in intervention between the experimental and control groups could not be mentioned as it could influence the results. Participants were informed that they would receive a physiotherapy assessment and intervention with Kinesio® tape (refer to Appendix C). Participants were informed about a possible skin irritation due to the taping and that the skin would be inspected after the application of a Kinesio® tape test strip and evaluated for any adverse effects.

3.10.3 Right to Privacy

All participants and results were handled as strictly confidential.

3.10.4 Professional Honesty with Colleagues

Results were reported honestly and in a complete fashion. Only completed data sets were used. Data were not fabricated. Plagiarism and document theft was avoided at all times – acknowledgement of material belonging to others is mandatory. Honesty, integrity and respect for the science and the participants are essential. Strict scientific methods were used during the study. The proposal was approved by the Ethics Committee of the Faculty of Health Sciences, University of the Free State. All amendment to the study were approved by the the Ethics Committee of the Faculty of Health Sciences, University of the Free State and included, small formatting changes to the questionnaires, approval for the researcher to perform the HAM-D evaluation and inclusion a new research area (Refer to Appendix G).

Permission for the study to be performed was obtained from the institutions where the study was planned. In this research study approval was granted by one public and one private mental health institution in Bloemfontein. (Refer to Appendix D).

The treating physician and the physiotherapist treating the participants were informed of the study and consent was obtained from them. Relevant feedback was given during the execution of the study. Feedback will be given on request to the participant after the completion of the study. Written feedback to the physicians, physiotherapist and institutions concerned with the research project will be given after compiling the research report.

If the study proves to have a beneficial effect on selected physical symptoms associated with MDD, the method will be incorporated in the routine physiotherapy regime at the public psychiatric institution in Bloemfontein.

3.11 Coding of Questionnaires

The coding of the questionnaires was the responsibility of the researcher. The coding was monitored by an objective third party schooled in coding of questionnaires. In the questionnaires, a numerical value was assigned to the different options of questions. For example yes = “1” and no = “2”. If “yes” was marked during the structured interview or observation the value of the answer was transferred to the coding block.

Coding of open ended questions, for example the body chart, was accomplished by assigning a number to areas noted on the chart by the different participants in chronological order. The first area noted was “upper thoracic” and the number 1 was assigned to it. The coding list with regards to different areas is added in Appendix H.

3.12 Data Analysis

Statistical analyses of the data were performed by the Department of Biostatistics, University of the Free State. The experimental and control group consisted of randomised participants from both institutions and were analysed as such. Results were summarised by frequencies and percentages (categorical variables) and means and standard deviations or percentiles (numerical variables). Changes from pre-test to post-test were summarised similarly and the groups compared using 95% confidence intervals for differences in means, medians or percentages. Categorical variables were compared using chi-squared or Fisher exact test (in the case of small numbers) and numerical variables using t-test (normally distributed variables) and Mann-Whitney test (skew distribution). Changes within groups were analysed using paired t-tests (normally distributed variables) or signed rank tests (skew distributions) (Joubert 2011 and 2014: Personal communication).

3.13 Measurement and Methodological Errors

The following areas of measurement and methodological errors were identified and counter actions to prevent the errors are mentioned.

The sample selection method was biased as not all persons in the population had a chance of being selected (Leedy and Ormrod, 2005:209). Only patients admitted to psychiatric institutions were selected. This was limited by sampling both patients from a public psychiatric institution as well as a private psychiatric institution. If a patient declined participation in the study, the following patient was considered. The eligibility criteria were diligently applied by the researcher (refer to 3.5.1). Participants were allocated to treatment using a randomisation list supplied by the Department of Biostatistics, University of the Free State. Randomisation was performed separately for the two institutions involved to ensure identical groups with regards to facility, medication and ward programme.

Physiotherapy intervention could not be controlled at the private mental health institution, but all patients were referred for physiotherapy to the same practice as part of the daily programme. All referred patients had contact with a physiotherapist prior to the assessment and received the same treatment regime.

All other interventions (occupational therapy, psychotherapy and pharmacology) were part of the treatment regime at the institutions and were recorded by the researcher. The outcomes measured could have been influenced by the therapies as differences might have been detected if separate institutions were compared to each other. The experimental and placebo groups however were completely balanced with regards to institution and treatments received at these institutions. This had to be taken into account when interpreting the results.

Severity of the current MDD episode can influence efficacy of the intervention tested and therefore a baseline score for MDD was assessed before measurements began to use as reference point on interpreting the results. The researcher administered the HAM-D from March 2013 as she received training in

administering the scale during November 2012. Previously the HAM-D was administered by a psychologist or intern psychologist.

The assessment of the participants was carried out by a physiotherapist trained in the assessment procedures. The physiotherapist was unaware of the group the patient was assigned to, thus ensuring blindness and preventing bias. Standardised instructions according to the procedure of the scales were given during the assessment as encouragement as diverse instructions can influence the results of the test. A qualified and certified Kinesio® tape therapist applied the Kinesio® tape according to standardised guidelines. Environmental variables were minimised by assessing and re-testing a participant at the same time of the day and in the same surroundings.

Reliability was enhanced by the same therapist performing the pre- and post-application measurements. Observer expectancy was minimised by keeping the study blinded. The Hawthorne effect was minimised by the use of a placebo control group.

Kinesio® Tex tape is available in red, blue, black and beige. The red tape is a darker colour on the light spectrum, thus absorbing more light and can increase temperature under the Kinesio® tape application. The blue tape is lighter and thus decreases temperature under the Kinesio® tape application. This plays a role in colour therapy, but there is no difference in the manufacturing of the tape except the change in the dye colour required for the different colours. The Kinesio® Tex brand of Kinesio® tape and the neutral beige colour was used in this study to prevent colour or brand influencing the results (Kase, Wallis and Kase, 2003:17).

Skin preparation was done before the application of Kinesio® tape as any restriction of the adhesive ability of the tape to adhere to the skin could influence the effectiveness of the application and length of the tape (Kase, Wallis and Kase, 2003:12).

3.14 Conclusion

This chapter describes the research methodology and procedure for data collection in detail. Measurement and methodological errors that can impede the validity and reliability of the study is taken into consideration and methods are suggested to minimise such errors. Ethical considerations with regards to the study procedure are also explained. The results of this study are presented in Chapter 4.

Chapter 4 Results

4.1 Introduction

In this chapter the results of the study are presented in the form of graphs and tables. The analysed data are presented in accordance with the research objectives.

4.2 Disposition of Study Participants

The study was conducted between January 2012 and December 2013 in Bloemfontein.

Of the 40 participants included this study, 22 (55%) participants were recruited from a private psychiatric institution and 18 (45%) participants from a public psychiatric institution.

The participants were randomised into two groups of 20 participants each. In each group eleven participants were recruited from a private psychiatric institution and nine participants were recruited from a public psychiatric institution. The experimental group received Kinesio® taping as described in the literature (refer to 3.6.1). The placebo group received a placebo taping (refer to 3.6.2).

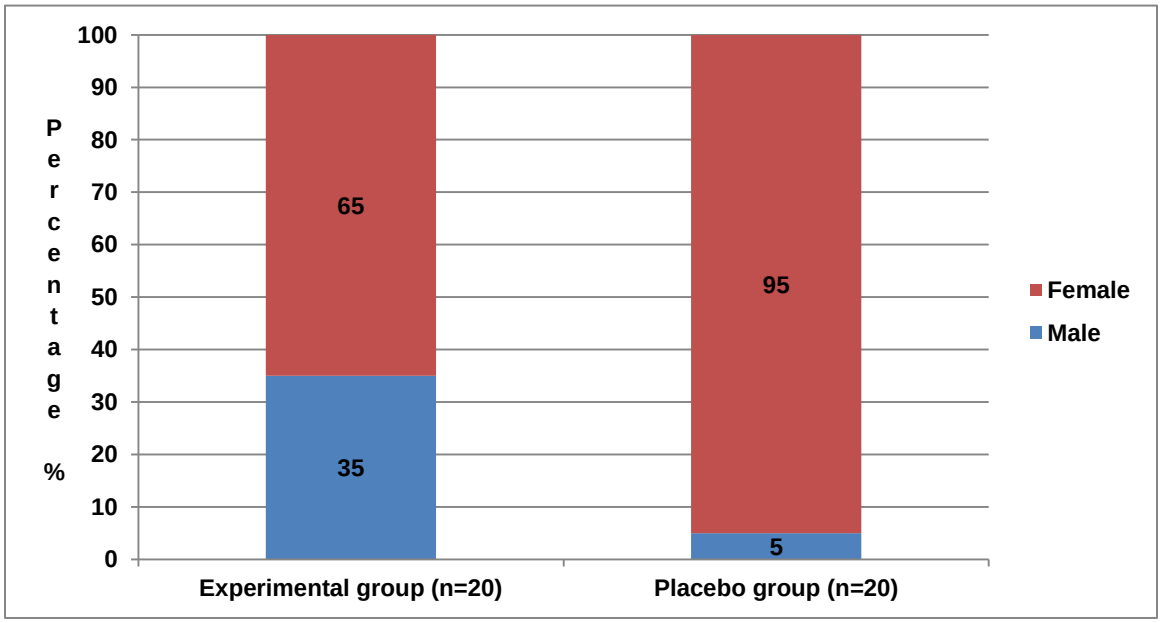
All enrolled study participants completed the 24-hour study period.

4.3 Results of the Questionnaires

Appendices A and E were concerned with the gathering of demographic information including gender and age, and the manifestation of the participant's pain. Appendix B collected baseline scores on the HAM-D, MARM and the Tinetti Mobility Test.

4.3.1 Demographic Information

The majority (80%) of the participants were female. In the experimental group, 35% of participants were male and in the placebo group 5% were male (refer to Graph 4-1).



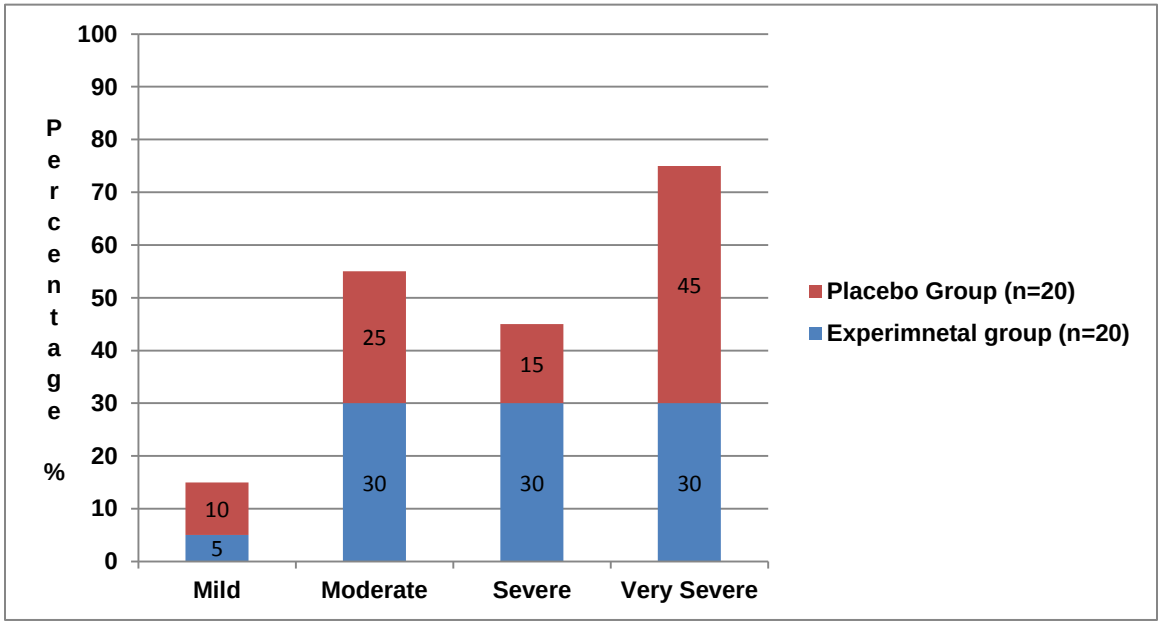
Graph 4-1 Gender distribution across groups

The median age of participants in the experimental group was 37.5 years and in the placebo group it was 34 years (refer to Table 4-1).

Table 4-1 Age distribution across the groups

	Experimental Group (n=20)	Placebo Group (n=20)
Median	37.5	34.0
Lower quartile (25%)	25.5	28.0
Upper quartile (75%)	41.0	49.0
Minimum age	19.0	19.0
Maximum age	52.0	64.0

More than half (60%) of the participants had severe or very severe MDD (refer to Graph 4-2). A classification of very severe MDD was identified in 30% of the participants from the experimental group and 45% of the placebo group.



Graph 4-2 Classification of MDD severity

All of the participants received one or more therapies excluding the intervention during the 24-hour study period. Refer to Table 4-2 for a layout of the different therapy combinations that were received. More than half (55%) of the

participants received all available therapies: occupational therapy, psychotherapy, pharmacology and physiotherapy.

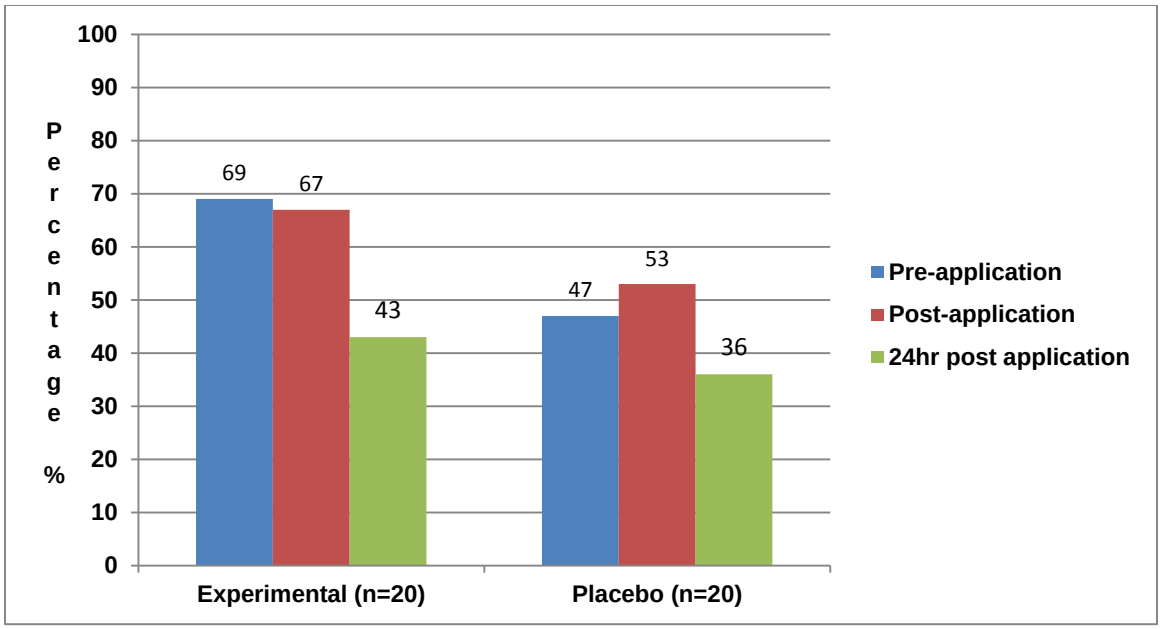
Table 4-2 Therapies received during study period

Therapy combination	Number and percentage of experimental participants (n=20)	Number and percentage of placebo participants (n=20)
All available therapies: • Occupational therapy • Psychotherapy • Pharmacology • Physiotherapy	11 (55%)	11 (55%)
• Occupational therapy • Psychotherapy • Pharmacology	9 (45%)	6 (30%)
• Occupational therapy and pharmacology	0 (0%)	2 (10%)
• Psychotherapy • Pharmacology • Physiotherapy	0 (0%)	1 (5%)

More than half (57.5%) of the participants received physiotherapy during the course of the study.

4.3.2 Pain Symptoms

Most (77.5%) of the participants experienced pain. Respectively, 80% of the participants in the experimental group and 75% of participants in the placebo group experienced pain during the pre-application phase. In the experimental group 69% of the participants with pain reported more than one area of pain during pre-application, compared to the placebo group where 47% of the participants reported more than one area of pain (refer to Graph 4-3).



Graph 4-3 Participants complaining of multiple sites of pain

Participants reported pain in different areas (refer to Table 4-3). The groups complained mostly of cervical pain during the study period – totalling 36.7% of the pain complaints. The exception was the placebo group; at 24 hours post-application they mostly complained of lower back pain which accounted for 30% of the pain complaint score.

4.3.3 Pain areas

Table 4-3 Pain complaint areas

Area of pain complaint		Number and percentage of experimental participants (n=20)	Number and percentage of placebo participants (n=20)
Cervical	Pre-application	10 (50%)	7 (35%)
	Post-application	8 (40%)	7 (35%)
	24 hours post-application	9 (45%)	3 (15%)
Middle trapezius	Pre-application	7 (35%)	1 (5%)

Area of pain complaint		Number and percentage of experimental participants (n=20)	Number and percentage of placebo participants (n=20)
	Post-application	7 (35%)	2 (10%)
	24 hours post-application	6 (30%)	3 (15%)
Thoracic	Pre-application	8 (40%)	6 (30%)
	Post-application	7 (35%)	6 (30%)
	24 hours post-application	4 (20%)	2 (10%)
Lumbar and Sacroiliac joint	Pre-application	3 (15%)	5 (25%)
	Post-application	4 (20%)	5 (25%)
	24 hours post-application	3 (15%)	6 (30%)
Headache	Pre-application	7 (35%)	5 (25%)
	Post-application	4 (20%)	3 (15%)
	24 hours post-application	3 (15%)	4 (20%)
Lower extremity	Pre-application	0	0
	Post-application	1 (5%)	2 (10%)
	24 hours post-application	1 (5%)	2 (10%)
Upper extremity	Pre-application	0	1 (5%)
	Post-application	0	1 (5%)
	24 hours post-application	1 (5%)	0
Other (Abdominal)	Pre-application	0	1 (5%)
	Post-application	0	1 (5%)
	24 hours post-application	0	0

Utilising the SF-MPQ a numerical value was obtained to quantify the participants' pain experience.

Table 4-4 Pre-application pain scores

Components of SF-MPQ	Experimental Group (n=20)			Placebo Group (n=20)		
	Median	Lower Quartile	Upper Quartile	Median	Lower Quartile	Upper Quartile
Sensory	11.5	3.0	15.0	10.5	2.0	15.5
Affective	7.5	2.5	8.5	7.5	1.0	12.0
Combined components	19.0	6.5	23.5	21.5	3.0	25.5

The assessment tool evaluated sensory and affective components of pain. The experimental and placebo groups were closely matched with regards to pre-application scores (refer to Table 4-4).

The pain scores decreased in a similar pattern for the experimental and placebo groups at post- and 24 hours post-application (refer to Table 4-5 and Table 4-6).

Table 4-5 Post-application pain scores

Components of SF-MPQ	Experimental Group (n=20)			Placebo Group (n=20)		
	Median	Lower Quartile	Upper Quartile	Median	Lower Quartile	Upper Quartile
Sensory	9.5	2.0	14.5	8.0	0.5	13.5
Affective	5.5	0.5	8.5	4.0	0	11.5
Combined components	15.0	2.5	23.0	12.0	0.5	24.0

There is a change from pre- to post-application within the groups with a p-value of 0.08 for the combined components of both the experimental and placebo groups.

Table 4-6 24 hours post-application pain scores

Components of SF-MPQ	Experimental Group (n=20)			Placebo Group (n=20)		
	Median	Lower Quartile	Upper Quartile	Median	Lower Quartile	Upper Quartile
Sensory	4.0	0	8.0	4.5	0	8.0
Affective	2.0	0	5.5	1.5	0	6.5
Combined components	5.5	0	14.5	7.0	0	16.0

From pre- to 24 hours post-application, the groups showed significant changes within the groups with a p-value of <0.01 for the combined components. The difference between the two groups for change over time was not significant with p-values of 0.85 and 0.75 for the experimental and placebo groups, respectively.

Table 4-7 Differences between pre-, post-, and 24 hours post-application of the combined components of SF-MPQ

	Experimental Group (n=20)			Placebo Group (n=20)		
	Median	Lower Quartile	Upper Quartile	Median	Lower Quartile	Upper Quartile
Pre- vs. post-application	0	-3.5	0	0	-0.5	0
Pre- vs. 24 hours post-application	-5.5	-19.0	0	-8.0	-15.5	-1.5

Table 4-8 Percentage of participants experiencing pain

Time point	Experimental Group (n=20)	Placebo Group (n=20)
Pre-application	80%	75%
Post-application	75%	75%
24 hours post-application	70%	70%

In the experimental group, 30% of the participants showed improvement in the sensory component of pain between pre- and post-application compared to 25% in the placebo group, with a p-value of 0.87 (refer to Table 4-9). Only 15% of the participants in the experimental group showed a clinical significant change at post-application compared to 20% of the placebo group (refer to Table 4-10).

Half (50%) of the participants in the experimental group showed a clinical significant change of the combined components of the SF-MPQ at the 24 hours post-application compared to 70% of the placebo group (refer to Table 4-10).

Table 4-9 Percentage improvement of SF-MPQ

Components of SF-MPQ	Post-application		24 hours post-application	
	Experimental (n=20)	Placebo (n=20)	Experimental (n=20)	Placebo (n=20)
Sensory	30	25	60	75
Affective	10	15	55	75
Combined components	30	25	65	75

Table 4-10 Percentage clinical significant improvement of SF-MPQ

Components of SF-MPQ	Post-application		24 hours post-application	
	Experimental (n=20)	Placebo (n=20)	Experimental (n=20)	Placebo (n=20)
Sensory	10	20	45	55
Affective	5	15	55	25
Combined components	15	20	50	70

There were no statistically significant differences between the combined components of pre- and post-application scores with p-values of 0.85 and 0.75 for pre- to post-application and from post- to 24 hours post-application, respectively.

4.3.4 Manual Assessment of Respiratory Motion

The MARM is a visual representation to quantify dysfunctional breathing. Two variables are presented: percentage ribcage movement and balance of breathing (refer to Chapter 3.7.1). The maximum balance score obtained by the participants was 101 and the minimum 0. The maximum percentage of ribcage motion achieved by the participants was 61.2% and the minimum was 25%. The experimental and the placebo group displayed slight improvement of balance of breathing at immediate post-application with a slight decrease in scores at 24 hours post-application (refer to Table 4-11).

Table 4-11 The balance of breathing score of the MARM

Time point	Experimental Group (n=20)			Placebo Group (n=20)		
	Median	Lower Quartile	Upper Quartile	Median	Lower Quartile	Upper Quartile
Pre-application	13.5	9.5	18.0	10.0	4.5	24
Post-application	6.5	4.0	10.0	7.5	4.0	12.5
24 hours post-application	8.5	3.5	14.0	10.0	6.0	18.0

Within the experimental group the changes were significant for all phases of testing with p-values of <0.01 from pre- to post-application and 0.01 from pre-application to 24 hours post-application. In the placebo group the changes from pre- to post-application were significant (p-value of 0.01) but the changes from pre-application to 24 hours post-application were not statistically significant (p-value of 0.95).

There was no significant change over time between the two groups with p-values of 0.38 from pre- to post-application and 0.20 from pre- to 24 hours post-application.

The percentage of ribcage movement improved slightly for both groups at immediate post-application. The improvement was maintained at 24 hours post-application (refer to Table 4-12).

Table 4-12 The percentage of ribcage movement score of the MARM

Time point	Experimental Group (n=20)			Placebo Group (n=20)		
	Median	Lower Quartile	Upper Quartile	Median	Lower Quartile	Upper Quartile
Pre-application	39.35	34.74	44.24	42.97	33.33	49.05
Post-application	45.66	41.92	47.44	45.49	39.94	50.51
24 hours post-application	46.38	42.75	49.70	44.68	38.89	51.38

There was no difference in percentage of ribcage movement between the experimental and placebo groups. The p-value for pre- to post-application was 0.57 and 0.53 for pre-application to 24 hours post-application.

4.3.5 The Tinetti Mobility Test

Throughout the study period, 90% of the study participants scored above 25 on the Tinetti Mobility Test: Balance and Gait (refer to Table 4-13). A score of above 25 indicates no dysfunction with regards to balance and gait disturbances (refer to 3.7).

Table 4-13 Tinetti Mobility Test: Balance and gait scores

Tinetti score	Pre-application %		Post-application %		24 hours post-application %	
	Experimental (n=20)	Placebo (n=20)	Experimental (n=20)	Placebo (n=20)	Experimental (n=20)	Placebo (n=20)
< 19	0	5	0	5	0	5
19 - 24	10	5	5	0	0	0
25+	90	90	95	95	100	95

4.4 Summary of Study Results

The following is a summary of the main results of this study:

- A convenience sampling method was used to recruit the 40 study participants. The participants were randomly assigned to either an experimental group (n=20) or a placebo group (n=20).
- Just more than half (55%) of the participants were recruited from a private psychiatric institution and 45% of the participants were recruited from a public psychiatric institution.
- Most (80%) of the participants were female. The median age of participants in the experimental group was 37.5 years and in the placebo group it was 34 years.
- The severity of the current MDD episode of participants ranged between normal and very severe, with 60% of participants experiencing a severe or very severe episode.
- Slightly more than half (55%) of the participants received all available therapies: occupational therapy, physiotherapy, psychotherapy and a pharmacological intervention. This corresponded with the 55% of participants recruited from the private psychiatric institution where all the therapies were part of the treatment regime.

- The majority (77.5%) of participants complained of pain during the study period and 58% complained of multiple areas of pain.
- Participants complained mostly of cervical pain (36.7%) except for the placebo group at 24 hours post-application who complained generally of lower back pain.
- The sensory and affective components associated with pain and tested by the SF-MPQ showed improvement in combined scores for both the experimental and placebo groups. The affective domain tested the emotional component of pain and the results indicated a clinically significant effect on this domain.
- The results of MARM displayed improvement in both the placebo and experimental groups for balance of breathing and percentage ribcage motion.
- The Tinetti Mobility Test showed no distinct results due to the scale not being sensitive enough for the movement disorders tested.

4.5 Conclusion

The results from the questionnaires, used as data collection method, are presented in this chapter. In Chapter 5 the results are discussed in detail and compared to the available literature.

Chapter 5 Discussion

5.1 Introduction

The aim of this study was to determine whether Kinesio® taping had an effect on selected physical symptoms associated with MDD. This was a randomised controlled study and followed and experimental study design.

In this chapter the results of this study are discussed. Possible explanations for the results are given and the results are related to literature and similar studies.

5.2 Discussion of Results

5.2.1 Demographic Information

Just more than half (55%) of the participants were recruited from a private psychiatric institution and 45% of the participants were recruited from a public psychiatric institution. Although the ratio was very closely matched, a possible reason for a higher recruitment from the private institution was that complex medication-resistant cases were admitted to the public psychiatric institution which resulted in a high number of participants at this institution not meeting the study eligibility criteria. Patients diagnosed with a mood disorder have a higher risk for additional Axis I disorders, such as alcohol abuse or dependence, panic disorder, obsessive compulsive disorder and social anxiety disorder (Sadock and Sadock, 2007:529). An additional Axis I diagnosis was part of the exclusion criteria for participation in this study.

The majority (80%) of the participants were female. This result corresponds with that of Sadock and Sadock (2007:529), who stated that regardless of country or culture, a general tendency exists of an almost two-fold greater prevalence of MDD in woman than in men. The reasons hypothesised were the hormonal differences between men and women, effects of childbirth, conflicting psycho-social stressors between the genders and behavioural models of learned

helplessness in woman. Another opinion on the gender difference was that it seems that women were more likely to seek treatment and therefore more women will be sampled from a psychiatric treatment institution (Scheibe, Preuschof, Cristi and Bagby, 2003:231).

The unequal ratio between male and female participants admitted to the institutions for MDD did; however, not influence the treatment, course of the illness, age of onset, number of episodes or duration of current episode (Scheibe *et al*., 2003:231). The gender of the participants therefore had no noteworthy effect on the results of this study.

The median age of participants in the experimental group was 37.5 years and for participants in the placebo group it was 34 years. The ages were matched with those available in literature which stated that the mean age of onset for MDD was 40 years, with 50% of all patients having their first episode between 20 and 50 years of age (Sadock and Sadock, 2007:529).

With regards to the classification of MDD, 60% of participants were diagnosed with having a severe or very severe episode of MDD, 35% of participants had mild or moderate classifications of the current episode and 5% of participants' classification of MDD was seen as normal. The efficacy of treatment in MDD can fluctuate according to the MDD severity. The outcomes between experimental and control can be minimal and clinically insignificant if the participants scores below 25 on the HAMD during a clinical trial (Fourier, Robert, Derubeis, Hollon, Dimidjian, Amsterdam, Shelton and Fawcett 2010:6).

The difference in severity of the MDD scores could have been affected by the length of stay in the hospital. The most appropriate time for the researcher to recruit the participants was on a Tuesday evening, thus, some of the participants might already have been admitted during the previous week. The effects of longer hospitalisation as well as psychotherapy, physiotherapy and occupational therapy could be more noticeable and have some bearing on the severity of the current episode of MDD as tested by the researcher.

All the participants received one or more therapies, excluding the study intervention, during the 24-hour study period, with 55% of participants receiving all available therapies. This corresponded with the percentage of participants recruited from the private psychiatric institution as all therapies formed part of the treatment protocol at this institution. The researcher was working at the public psychiatric institution at the time of the study and could control the physiotherapy intervention there during the study period. At the public psychiatric institution, occupational therapy and pharmacology were routinely part of the treatment protocol whereas psychotherapy and physiotherapy were based on referral, thus, accounting for the differences in therapies received. The experimental and placebo groups were completely balanced with regards to institution (in each group 11 participants were recruited from a private psychiatric institution and 9 participants were recruited from a public psychiatric institution) and treatments received at these institutions.

5.2.2 Pain Symptoms

Most (77.5%) of the participants experienced pain during the study period. This correlated with literature, as seen in a review by Bair, Robinson, Katon and Kroenke (2003:2434), where the prevalence of pain symptoms in patients with MDD ranged from 15% to 100% with a mean of 65%. Most of these studies were uncontrolled and conducted in psychiatric settings but according to the authors the prevalence rates of pain symptoms were independent of the setting (Bair *et al*., 2003:2434).

5.2.3 Pain Areas

Patients diagnosed with MDD have a 50% chance of experiencing chronic neck and lower back pain (Carroll, Cassidy and Cote, 2004:137). This was confirmed by the results of this study as neck pain was the pain complaint area with the highest overall prevalence of 36.7%. Lower back pain had an overall prevalence of 21.6%, ranking third on the overall pain prevalence list. The results of this study differed slightly from a study conducted by George, Coronado, Beneciuk,

Valencia, Werneke and Hart (2011:368). They concluded that the prevalence of cervical and lower back pain would be exactly the same for patients suffering from severe MDD. George *et al*. (2011:361-369) did, however, not take into account variations between regions.

Their anatomical regions were combined into four groups: cervical, lumbar, upper extremity and lower extremity. The current study took all pain complaints into consideration and the following anatomical regions were identified: cervical, thoracic and lumbar area, shoulder area, upper extremity, lower extremity and other (abdominal). This difference in grouping of anatomical regions could account for the variations in data.

The relationship between pain and MDD was confirmed by a number of studies. Carroll, Cassidy and Cote (2004:138) found that MDD was a strong precursor for a troublesome episode of neck or back pain. Currie and Wang (2004:57) found that 19.8% of the Canadian population that complained of lower back pain had depression. This study confirmed a link between lower back pain (21.6%) and neck pain (36.7%) and MDD with a co-morbidity of greater than 20%.

At 24 hours post-application, lower back pain in the placebo group accounted for 30% of the pain area complaints compared to 15% in the experimental group. The percentage pain complaints for lower back pain in the placebo group had increased with 5%. All the other pain complaint areas had decreased from post-application to 24 hours post-application. This could possibly have been due to the fact that the placebo group received a placebo taping and not the full taping over the lumber area, causing an increase in the percentage of lower back pain complaints. The fact that the experimental group did not show this increase in lower back pain at 24 hours post-application might be due to the role that Kinesio® taping played in pain prevention (Kumbrink, 2012:6).

The Kinesio® taping method consisted of taping over and around a muscle to effect changes in pain, muscle contraction and lymph drainage (Kinesio South Africa, 2013). The results of this study showed that neck pain scored

consistently higher as a prominent pain area. This result could be attributed to the fact that only one general taping was applied over the erector spinae muscle in the lumbar and thoracic area. As no taping was applied over the cervical or shoulder area this could explain why the neck pain symptoms did not decrease.

5.2.4 Post-Application Results

While interpreting the results of the questionnaires, the results of post-application of all the evaluation tools showed little improvement from the baseline scores. This correlated with the study by Slupik *et al*. (2007:650-651) who found that Kinesio® taping did not have an immediate effect on muscle activation, as previously believed, but that the effects of the taping reached its full potential only 24 hours after the application of the tape.

Secondly, the effect of a placebo response could not be ignored in this study. The placebo effect/response was an improvement resulting from a number of non-specific factors, for example, patients' and clinicians' beliefs, expectations, past experiences and the clinical setting during a study, and was not just a psychological response to treatment. Previously the placebo effect had been seen as the improvement that could be measured in subjects in the control group, but the placebo effect may or may not have been generated by a placebo treatment (Finniss, Kaptchuk, Miller and Benedeti, 2010:686-687).

In the psychiatric setting, the response to a placebo treatment and therefore the influence of the placebo effect increased from 20% in the 1980s to the present rate of 45% and 48% in studies performed on MDD (Pretorius, Van der Merwe and Westmore, 2010:70). Patients with MDD involved in randomised controlled studies have been displaying an increased receptiveness to these non-specific factors. The reason for this is not yet clearly understood but the placebo effect caused improvement in symptoms of the placebo control group and could influence the conclusions drawn from these studies. Currently, it is difficult to distinguish between the outcomes of the experimental and placebo treatment when researching in the field of MDD (Pretorius, Van der Merwe and Westmore,

2010:70). This corresponded with the results of this study where the experimental and placebo groups had both improved on post-application.

5.2.5 Results of the Pain Score

The SF-MPQ recorded improvement in pain symptoms throughout the study period. The experimental and placebo group showed the same ratio of improvement and the results were not statistically significant (p-values of experimental group were 0.85 and for the placebo group 0.75). The value to determine whether the results were statistically significant was determined by the Department of Biostatistics, University of the Free State, and was defined as a change between groups not due to chance (Leedy and Ormrod, 2005:271). A clinical significant change is seen as the scale's responsiveness to change and has been found for the Norwegian SF-MPQ to be a mean improvement of 5 or more on the 45-item scale (Strand *et al*., 2008:924; Hawker *et al*., 2011: S243-S244).

The combined SF-MPQ score was determined by adding the sensory and affective domains of the scale. The sensory and affective domain improved at post-application and 24 hours post-application for both the experimental and placebo groups (refer to Table 4-5 to Table 4-7). A clinical significant change in the SF-MPQ was observed in both groups and throughout the study.

The results of this study regarding changes in pain symptoms correlated with the results of Kaya, Zinnuroglu and Tugeu (2010:205) who had found no difference in pain symptoms or improvement of disability in shoulder impingement when a physiotherapy intervention group and Kinesio® taping group were compared. In contrast with this, in a study by González-Iglesias *et al*. (2009:517-519), the patients had statistically significant improvements in pain and range of motion, immediately and after 24 hours, but the improvements were small and not clinically meaningful. The 51 patients had been randomised into a experimental and control group to test the short term effects of cervical Kinesio® taping on

cervical pain and range of motion after a whiplash injury (González-Iglesias *et al*., 2009:515-521).

The results of this study with regards to improvement in pain symptoms could further be explained by considering the effects of hospitalisation, medication, other therapies and the fact that pain symptoms decrease with a decrease in MDD symptoms (Wideman *et al*., 2012).

In participants complaining of multiple sites of pain, the sites of pain only decreased in the experimental group from 69% (pre-test) to 43% at 24 hours post-application compared to the placebo group where pain was reported to decrease from 47% (pre-test) to 36% at 24 hours post-application. The reason for this could be that only one standard taping was used in the experimental group (over the lumbar and thoracic area) while most complaints were cervical and over the middle fibres of m. trapezius (refer to Table 4-3).

Another reason for the multiple sites of pain could be the biological link between pain and depression. Limbic structures, involved with emotions, have a role in interpreting peripheral stimuli. Under normal conditions the limbic system has a controlling effect and can decrease the intensity of painful signals. In MDD, there is a shortage of neurotransmitters, especially serotonin and norepinephrine. This shortage of neurotransmitters can cause the limbic system to lose the ability to decrease the signal strength. More pain is experienced and multiple sites are involved (Bair *et al*., 2003:2441).

5.2.6 Results of the restricted breathing score

The MARM scores for both the experimental and placebo groups improved. The changes over time for the experimental and placebo group were not statistically significant with p-values of 0.38 (experimental) and 0.20 (placebo) from pre-application to 24 hours post-application. The results of this study were confirmed by the outcomes of Zubeyir *et al*. (2012:243-244) who had found that Kinesio® taping has no significant effect on maximum primary and accessory respiratory muscle strength when the taping was applied over the primary and

accessory respiratory muscles of healthy individuals. The study did; however, not evaluate the effect of Kinesio® taping on spirometric or volumetric measurements (Zubeyir *et al*., 2012: 244). In this study it was found that Kinesio® taping did not have a significant effect on volumetric changes with regards to balance and percentage ribcage motion between the experimental and placebo group (refer to Table 4-11).

The experimental and the placebo group displayed slight improvement of balance of breathing at post-application (refer to Table 4-11) and could be attributed to the stimulation of the motor units by the taping. The taping resulted in an increase in muscle tone (Slupik *et al*., 2007:650) of the erector spinae muscles resulting in a more erect posture and therefore more ribcage motion and increase balance of breathing.

At 24 hours post-application, both groups had a slight decline in scores for balance of breathing. The decrease in scores after 24 hours corresponded with the results published by Szczegielniak, Krajczy, Bogacz, Łuniewski and Śliwiński (2007:337-341). The effect of Kinesio® taping on lung volume was investigated by Szczegielniak *et al*. in 2007 who had found an increase in spirometric values 24 hours after application. The value of the parameters, however, slightly decreased the following day and no reason was given for this factor.

Another possible reason for the decrease in balance of breathing scores at 24 hours post-application could be that the effectiveness of the tape might have a shorter timeframe than previously anticipated (Slupik *et al*., 2007:651), although it was proposed that the Kinesio® Tex tape could be worn for 3 to 5 days before the elastic polymer diminishes and the tape stops working (Kase, Wallis and Kase, 2003:12).

The slight decline in percentage ribcage motion scores at 24 hours post-application of the participants in the placebo group (refer to Table 4-11) could be accounted for by the lack of taping over the ribcage with the placebo taping and thus no continuous activation of the muscles in that area.

5.2.7 Results of the loss of flexibility and centring of movement score

The Tinetti Mobility Test scores for balance and gait were consistently above 25 for 90% of the participants overall and for 95% of both groups in the post-application phase. This translated in only one of the study participants being pre-disposed to fall and thus no disturbances in balance or gait were observed. Therefore no loss of flexibility or centring of movement was documented.

This did not compare with literature which found that more than 30% of patients diagnosed with MDD had motor disturbances (Caligiuri and Ellwanger, 2000:91). A possible explanation for the difference in the results of this study could be that the Tinetti Mobility Test was not sensitive enough to pick up slight changes. Caligiuri and Ellwanger (200:85-89) have emphasised that instrument sensitivity was essential to pick up abnormalities in motor performance. In their study there had been significant differences between the observed score and using a platform instrument which is sensitive for motor function. Only 22% of patients presented with motor disturbances, as diagnosed by means of observation, compared to 60% diagnosed by means of instrumental measurements (Caligiuri and Ellwanger, 2000:89).

Although the sensitivity of the test used in this study was not optimal, the results compared with literature where the functional performance of basketball players was tested (Bicici, Karatas and Baltaci, 2012:162-163). The athletes had been taped with athletic tape and Kinesio® taping. Results showed no difference between the two tapings or in the performance of the placebo group when doing a balance test (hopping and single limb stance). Bicici, Karatas and Baltaci (2012) had found that Kinesio® taping did not cause any decrease in performance on any of the functional tests. The taping however was not applied in a similar manner (ankle taping) as in this study but the proposed mechanism of Kinesio® taping remains the same regardless of the area taped. This was confirmed by the current study as no decrease in performance was noted during the assessment of the Tinetti Mobility Test. Bicici, Karatas and Baltaci (2012)

had also found that dynamic balance did not change with either tapings whilst the static balance scores were significantly better in the Kinesio® Tex group.

This study used the Tinetti Mobility Test as a functional test which tested dynamic balance and functional activities, for example, gait. It was proposed that Kinesio® taping can influence proprioception and therefore balance by activating the mechanoreceptors (Kumbrink 2012:7). It therefore seemed that the Tinetti Mobility Test was not sensitive enough to pick up the difference between the taping and placebo application.

5.3 Conclusion

In this chapter the results of this study are discussed in detail relating to the available research on the subject. The results are interpreted with regard to the clinical profile of the patients and the mechanisms of Kinesio® taping. The limitations of the study and recommendations for future studies are discussed in

Chapter 6.

Chapter 6 Conclusion and Recommendations

6.1 Introduction

In this final chapter of the dissertation conclusions are drawn from the results found in this study regarding the physiotherapeutic effects of Kinesio® taping on selected physical symptoms associated with MDD. The limitations of this study are identified and recommendations for future research made. Finally the value of the study is emphasised.

6.2 Conclusions

Kinesio® taping is used in a variety of clinical and therapeutic settings as well as in many different kinds of sports, for example, soccer, rugby, gymnastics, skiing, handball, volleyball and biathlon. Furthermore, it is used as after-care in orthopaedics, neurology, gynaecology, surgery, oncology, geriatrics and paediatrics. The concept of Kinesio® taping is also being introduced into hospitals and rehabilitation centres (Kumbrink, 2012:6). The use of Kinesio® taping in psychiatry and especially in the treatment of the physical symptoms associated with MDD has not yet been researched and the parameters of use are still not clearly defined. The taping methods and current applications are, however, expanding daily into new areas.

Participants diagnosed with MDD were enrolled from both public (55%) and private (45%) psychiatric institutions, where they received a variety of therapies to treat the disorder (refer to 4.2).

The development and progression of the disorder in the participants in this study were in line with the available literature, with more females (80%) being enrolled (refer to Graph 4-1) and participants mostly being above 30 years of age (refer to Table 4-1).

Pain is one of the main physical complaints of MDD and in this study 77.5% of participants experienced pain. The severity and number of pain areas increase during an episode of MDD (refer to 2.8.1 and 5.2.2). The severity of the current MDD episode also correlated with physical symptoms experienced by the participants. In this study, 60% of participants experienced a severe episode of MDD and 58% reported multiple areas of pain.

Physiotherapists are especially well equipped to treat the physical complaints associated with MDD and a variety of treatment modalities are available. Kinesio® taping can be utilised in the psychiatric setting for some of the MDD-associated physical symptoms. It should; however, be used for the appropriate condition and the therapist should have proper training to maximise the outcome of this specialised treatment technique (Kumbrink, 2012:6) (refer to).

Participants in this study complained of multiple pain areas which, in the experimental group decreased from 69% (pre-test) to 43% (24 hours post-application) compared to the placebo group where pain deceased from 47% (pre-test) to 36% (24 hours post-application). Therefore it seems that Kinesio® taping can only influence underlying tissue and that the taping has to be applied over or around the affected area to ensure effectiveness (refer to 5.2.2).

In this study, Kinesio® taping did not seem to have an immediate effect on muscle activation, as previously believed, as greater results were achieved only 24 hours after the intervention (refer to Table 4-11 and Table 4-12 and 5.2.7).

Motor disturbances, a decrease in flexibility and centring of movement is not a forthright physical symptom in MDD as previously believed and was not easily observed. The Tinetti Mobility Test could not distinguish any difference between the two groups during the study period (refer to 4.3.5 and 5.2.8). From the results of this study it seems that Kinesio® taping could be used as adjuvant treatment modality to complement physiotherapy modalities currently used in this field of practice when treating pain, restricted breathing, decrease in flexibility and loss of centring of movement in patients diagnosed with MDD.

6.3 Limitations of this Study

1. The admission date of the participants was not taken into account, and the time lapse between admission and the first evaluation by the researcher could have influenced the results. This can also account for lower MDD scores at baseline.
2. The sample size was small and participants were only recruited from two psychiatric institutions in the Free State.
3. The sample was obtained only from one referring practice at the private institution which might not be representative of the bigger population admitted at the private hospitals.
4. Recruitment bias could have factored in due to the convenience sampling method used. This might have had an effect on the placebo response.5. It was not possible for the sample to be blind with regards to depression (Jacobsen *et al*., 2006:296), due to the severity of the disease and the fact that patients diagnosed with MDD formed part of the inclusion criteria.
5. The Tinetti Mobility Test was not sensitive enough to evaluate the decrease in flexibility and centring of movements.
6. Of the 40 participants, 21 received physiotherapy. This could have influenced the outcomes measured after 24 hours. The physiotherapy could have had a positive effect on the outcomes measured accounting for a greater improvement of the groups due to supersession of Kinesio® Taping and other physiotherapy modalities. This has to be taken into consideration when interpreting the results.
7. Other therapies received by participants during the study were not standarised and could not be controlled due to the multitude of stakeholders involved in the care of the patients. It is a limitation that the public and private hospitals could not be analysed separately (with regards to therapies received) and compared.

6.4 Recommendations

1. Patients admitted to psychiatric intuitions should be referred to physiotherapy for screening and evaluation as 77.5% of participants in this study complained of pain. MDD can only fully go into remission if all the symptoms (including physical symptoms) are adequately addressed (refer to 2.8).
2. This study could be repeated with a changed area of taping. The taping could be applied over the area of pain complaints and this could determine the effect of Kinesio® taping on pain management in patients with MDD. The use of a more sensitive balance and gait scale could help draw more accurate conclusions on the loss of flexibility and centring of movement experienced by patients diagnosed with MDD.
3. Follow-up studies are needed to determine the effective response time and most appropriate taping method for Kinesio® taping in the psychiatric setting.
4. Repeating the current study employing the BAS-H (Ryding, Rudebeck and Roxendal, 2000) once it is translated into English could be of value to compare the results with that of previous studies with the BAS-H (refer to 3.7.1).
5. Research should be undertaken comparing results between groups where all other therapies received by the participants are kept constant with only Kinesio® taping as variable as well as comparing a group where no physiotherapy is received with a group where Kinesio® taping is part of a physiotherapy intervention.
6. Further research is needed to determine which physiotherapy interventions will be most effective in treating the selected physical symptoms associated with MDD.

6.5 Value of the Study

This study gathered valuable information on selected MDD-associated physical symptoms and the effect of Kinesio® taping on these symptoms. A new avenue for research was identified in this study as Kinesio® taping is a relatively new treatment technique not previously associated with psychiatry and specifically with MDD. The holistic treatment of MDD will ease the burden of the disease by a decrease in the length of hospital stay and recurrent admissions. This study also emphasises that physiotherapy is an essential part of the treatment regime for patients suffering from MDD as the physical symptoms of MDD are often ignored.

However, Kinesio® taping has to be applied according to the most effective taping method for the symptoms at hand and given enough time to possibly have the desired effect. It also seems that the taping should not be used in insolation. Treatment modalities are seldom used in isolation and Kinesio® taping could be of value as auxiliary treatment modality applied by physiotherapists as part of the multi-professional team approach necessary to manage MDD effectively. Physiotherapists can contribute their extensive knowledge on physical symptoms, such as pain, to treat these patients and ensure quality care and effective holistic management of patients suffering from MDD.

6.6 Final Summary

The aim of the study was to determine the effectiveness of physiotherapeutic Kinesio® taping on selected physical symptoms associated with MDD. The treatment of these physical symptoms with Kinesio® taping had mixed results, but Kinesio® taping could be a valuable adjuvant treatment modality. The importance of physiotherapy as part of the treatment regime for patients suffering from MDD was highlighted and the importance of future research in this field of practise emphasised.

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Chapter 8 Personal Communications

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Appendices

Appendix A

- **Demographic information**
- **Pain**
- **Therapies received**
- **SF-MPQ**

Appendix A

				For Official Use	
Number					1-2
Date		2013 M M D D			3-10
Gender	Male		1		11
	Female		2		
Age					12-13
Pre-Testing			1		14
Post Testing	Immediate		2		
Post Testing	After 24 Hours		3		
Does the paticipant experience any pain?					
	Yes		1		
	No		2		15
Body chart completed					
	Yes		1		16
	No		2		
Has the participant received any other therapy during the 24hr trail period?					
Occupational Therapy			1		17
Psychotherapy			2		
Other (Spesify)			3		

Short Form McGill Pain Questionnaire

Please mark with and (X) the words that are applicable to your pain. Each descriptor is ranked on an intensity scale from none to severe. None indicates that the word is not applicable to your pain. Severe is the worst possible score.

	NONE	MILD	MODERANTE	SEVERE	
THROBBING					18
SHOOTING					19
STABBING					20
SHARP					21
CRAMPING					22
GNAWING					23
HOT-BURNING					24
ACHING					25
HEAVY					26
TENDER					27
SPLITTING					28
TIRING-EXHAUSTING					29
SICKENING					30
FEARFUL					31
PUNISHING-CRUEL					32

Appendix B

- **Summary of total HAM-D Score**
- **MARM**
- **Tinetti Mobility Test**

Appendix B

For Official Use

Number ☐☐ ☐☐ 1-2

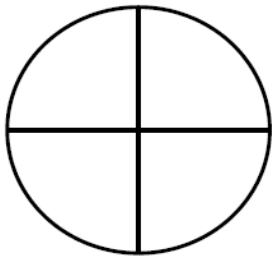
Date 2013 M M D D ☐☐☐☐☐☐☐☐ 3-10

Hamilton Depression Score ☐☐ ☐☐ 11-12

Pre-Testing		☐	1
Post Testing	Immediate	☐	2
Post Testing	After 24 Hours	☐	3

☐ 13

Manual Assessment of Respiratory Motion



Variables Calculated From MARM Graphic Notation

Variable

Area of Breathing

Angle formed between upper and lower line (Angle AB) ☐☐☐ ☐☐☐ 14-16

Balance

Diffrence between angle made by horizontal axis (C) and upper line (B) and horisontal and lower line (AC-CB)

AC			17-19
CB			20-22
AC-CB			23-25

Percent rib cage motion

Area above horizontal /total area between upper line and lower line x 100

AB			26-27
AC/AB x 100			28-30

Balance Test

Subject is seated in hard, armless chair. The following maneuvers are tested.

1. Sitting Balance

Leans or slides in chair	0		31
Steady, safe	1		

2. Arises

Unable without help	0		32
Able, uses arms to help	1		
Able, without using arms to help	2		

3. Attempt to arise

Unable without help	0	33
Able, requires less than 1 attempt	1	
Able to rise with 1 attempt	2	

4. Immediate standing balance (first 5 seconds)

Unsteady: swaggers, moves feet, trunk away	0	34
Steady but uses walker or other support	1	
Steady without using any support	2	

5. Standing Balance

Unsteady	0	35
Steady but wide stance (heels more tan 10.16 cm apart and uses assistive device or any other support	1	
Narrow stance without support	2	

6. Nudged(Subjects feet as close together as possible, examiner pushes lightly on subject's sternum 3 times)

Begins to fall	0	36
Staggers, grabs, catches self	1	
Steady	2	

7. Eyes closed (Subject with feet as close together as possible)

Unsteady	0	37
Steady	1	

8. Turning 360°					
	Discontinuous steps	☐	0	☐	38
	Continuous steps	☐	1		
	Unsteady (Graps, staggers)	☐	0		
	Steady	☐	1	☐	39
9. Sitting down					
	Unsafe - misjudged distance, falls into chair	☐	0	☐	40
	Uses arms or not a smooth motion	☐	1		
	Safe, smooth motion	☐	2		
Gait Test:	**Subject stands with examiner, walks down hallway or across room, first at "usual pace", then back at "rapid but safe pace" using usual walking aid**				
10. Initiation of gait					
	Any hesitancy or multiple attempt to start	☐	0	☐	41
	No hesitancy	☐	1		
11. Step length and height					
	Right swing foot does not pass left stance foot with step	☐	0	☐	42
	Passes left stance foot	☐	1		
	Left swing foot does not pass right stance foot with step	☐	0	☐	43
	Passes right stance foot	☐	1		
	Right foot does not clear floor completely with step	☐	0	☐	44
	Right foot completely clears floor	☐	1		
	Left foot does not completely clear floor with step	☐	0	☐	45
	Left foot completely clears floor	☐	1		
12. Step symmetry					
	Right and left step lengths are not equal (estimate)	☐	0	☐	46
	Right and left steps appear equal	☐	1		

13. Step continuity					
	Stopping or discontinuity between steps	☐	0	☐	47
	Steps appear continuous	☐	1		
14. Path	(Estimated in relation to floor tiles, 30.48 cm diameter, observe excursion of 1 foot over about 3 meters of the course)				
	Marked deviation	☐	0	☐	48
	Mild to moderate deviation or uses walking aid	☐	1		
	Straight without walking aid	☐	2		
15. Trunk					
	Marked sway or uses walking aid	☐	0	☐	49
	No sway but flexion of knees or back or spread arms	☐	1		
	No sway, no flexion, no use of arms, and no use of walking aid	☐	2		
16. Walking stance					
	Heels apart	☐	0	☐	50
	Heels almost touching while walking	☐	1		
Balance score		____	/16	☐☐	51-52
Gait Score		____	/12	☐☐	53-54
Combined Balance and Gait		____	/28	☐☐	55-56

Appendix C

- **Information document for study participants and authorisation form (English and Afrikaans)**

Information document for study and informed consent

The effect of physiotherapeutic Kinesio taping on selected physical symptoms associated with Major Depressive Disorder

Dear Patient

I am a physiotherapist currently busy with research at the University of the Free State as part of my master's degree in Physiotherapy. My field of interest is Mental Health. The aim is to conduct a clinical trial to determine the effects of physiotherapeutic Kinesio taping on selected physical symptoms associated with major depressive disorder. You are being asked to participate in the study.

Previous studies conducted on major depressive disorder determined that pain complaints, muscle tension, restricted breathing, loss of control and coordination of movement are the physical symptoms most associated with the disorder. From literature I have determined that physiotherapy intervention for major depressive disorder has beneficial effects. This study aims to determine the effect of physiotherapeutic Kinesio taping on the above mentioned symptoms.

This is an experimental study and you will be asked to participate in four assessments: a once off mood assessment, assessments before and after the treatment, as well as a third assessment a day after you received the Kinesio taping. The assessment will take 25 minutes at a time. Physiotherapy intervention will either be Kinesio taping according to current described treatment guidelines or Kinesio tape application not described in the treatment guidelines and of which the results are not yet known

There is no risk to participation in the study and no cost will be incurred to you as result of participation in the study. No remuneration will be given to you for participation in the study. Kinesio tape is an elastic therapeutic tape that is latex free. The adhesive used will not leave any residue on removal. This allows for multiple taping techniques without any skin irritation. To minimize any chance of an adverse reaction on your skin to the tape, you will receive a test strip prior to full use of the tape.

Excessive body hair can influence the adhesive ability of the tape and decrease the effectiveness of the treatment. If you have excessive body hair, the researcher may shave the area before the taping intervention can continue.

As participant, you will not be discriminated against due to involvement or withdrawal from the study. Your involvement is voluntary and if you wish to withdraw you may do so at any time. The identity of all participants will be protected and confidentiality will be ensured as participants' data form will receive a number.

Feedback with regards to the result of the assessment will be given on request after the study has been completed. Feedback will be given to your treating doctor and multi-professional team on a regular basis.

You will be asked not to remove the tape between assessment and not discuss your treatment or assessment with other patients in the ward.

The results of the study will help clarify the role of the physiotherapist in the inter-disciplinary team concerned with the treatment of major depressive disorder. It is my belief that the study will assist the physiotherapist in evaluating and treating the patient with major depressive disorder in a more effective and holistic way. This will enhance service delivery, enhance the quality of care you receive and minimize the burden of the disease. The results can be used for future presentation at congresses or publications.

The study was approved by the Ethics committee of the Faculty of Health Sciences, University of the Free State. The number is 150/2011. You may contact the Secretariat of the Ethics Committee at the telephone number 051-405 2812 if you have any questions pertaining to the rights of the participant. Contact the researcher for any inquiries.

If you are willing to participate in the study please fill in the authorization section below. The section must be completed in person and signed and dated to comply with the requirement of the Ethics committee.

For more information on the study, please contact me:
Karen Erasmus (Researcher) at the Free State Psychiatric Complex.
Phone number 051-407 9263
Fax number: 051-436 1672

Authorization

I have read the information document and understand the nature of the study. I understand that my participation is voluntary and that I can withdraw any participation at any time. I understand that I have not waived my human rights and that I can contact the researcher at any time for more information.

I agree to participate in an assessment and intervention on the effect of physiotherapy intervention on the physical symptoms associated with major depressive disorder.

If I have any questions on the study I can contact the Ethics Committee of the Faculty of Health Sciences at the University of the Free State.

All information will be handled with strict confidence, but information may be used for future presentations or publication.

_____	_____	_____
Participants name	Participant signature	Date
Karen Erasmus (Van Vuuren)		_____
Researcher name		Date

Inligtingsdokument vir die studie en toestemmingsbrief

Die effek van fisioterapeutiese Kinesio-pleister aanwending op geselekteerde fisiese simptome geassosieer met major depressiewe versteuring

Geagte Pasiënt

Ek is 'n fisioterapeut wat tans besig is met navorsing aan die Universiteit van die Vrystaat as deel van my meestersgraad in Fisioterapie. My belangstellingsveld is geestesgesondheid. Die doel van hierdie studie is om 'n kliniese proef uit te voer om die effekte van fisioterapeutiese Kinesio-pleister aanwending op geselekteerde fisiese simptome geassosieer met major depressiewe versteuring te bepaal. U word gevra om aan die studie deel te neem.

Vorige studies het bevind dat die fisiese simptome geassosieer met major depressiewe versteuring pyn, spierspanning, beperkte asemhaling en die verlies van beheer en koördinasie van beweging is. Vanuit die literatuur het ek bevind dat fisioterapie behandeling vir pasiënte met major depressiewe versteurings voordelige effekte inhou. Die doelwit van hierdie studie is om die effek van die Kinesio-pleister aanwending op die genoemde simptome te ondersoek.

Hierdie is 'n eksperimentele studie en u word versoek om deel te neem aan vier volledige evaluerings en 'n behandeling: 'n eenmaling gemoedstoestand evaluering asook evaluerings voor en na fisioterapie behandeling, asook 24 uur nadat die pleister aangewend is. 'n Evaluering duur ongeveer 25 minute. Die fisioterapie behandeling sal bestaan uit die aanwending van Kinesio-pleister (aanwending) volgens standaard behandelingsriglyne of volgens 'n aanwending wat nie in die behandelingsriglyne beskryf is nie en waarvan die effekte nog nie bekend is nie.

Daar is geen risiko verbonde aan u deelname aan hierdie studie nie. U sal geen vergoeding ontvang vir u deelname aan die studie nie asook geen onkostes aangaan nie. Kinesio-pleister bevat geen latex nie en sal dus geen allergiese velreaksies tot gevolg hê nie. Die gom aan die pleister wat gebruik word laat geen oorblywende residu op die vel agter na verwydering van die pleister nie en veelvuldige aanwendings sal dus nie die vel irriteer nie. Die kanse op 'n ongewenste velreaksie as gevolg van die aanwending van die pleister word verder beperk deur die aanwending van 'n toetsstrook voor die eerste volledige behandeling met die pleister.

Oormatige liggaamshare kan die plakvermoë van die pleister beïnvloed en dus ook die effektiwiteit van die behandeling. As u baie liggaamshare het, sal die navorser eers die area skeer voor die behandeling kan voortgaan.

Deelname aan die studie is vrywillig en u kan ter enige tyd aan die studie onttrek. As deelnemer aan die studie sal daar geen diskriminasie teenoor u wees as gevolg van u deelname aan of onttrekking

van die studie nie. Die identiteit van alle deelnemers sal beskerm word en konfidensialiteit gewaarborg word deur alle data vorms van 'n nommer en nie u naam te verskaf nie.

Terugvoer oor die resultate van die evaluerings sal slegs op versoek van die deelnemers aan hulle verskaf kan word na afloop van die studie. Terugvoer sal op 'n gereelde basis aan u dokter en interdissiplinêre span gegee word.

U word gevra om nie die Kinesio-pleister aanwending tussen behandelings te verwyder nie en om nie u behandeling met ander pasiënte in die saal te bespreek nie.

Die resultate van hierdie studie sal help om die rol te bepaal van die fisioterapeut wat, as deel van die interdissiplinêre span, pasiënte met major depressiewe versteurings behandel. Die studie sal ook bydra tot meer effektiewe fisioterapeutiese evaluering en behandeling van hierdie pasiënte. Dit sal lei to beter dienslewering en kwaliteit van behandeling asook die impak van die siekte verminder. Die resultate van die studie kan in die toekoms voorgedra word by kongresse of gepubliseer word.

Die studie is goedgekeur deur die Etiekkomitee van die Fakulteit Gesondheidswetenskappe aan die Universiteit van die Vrystaat. Die nommer is 150/2011. Skakel gerus die Sekretariaat van die Etiekkomitee indien u enige navrae het oor die regte van die deelnemers. U kan ook die navorser skakel vir enige verdere navrae.

As u bereid is om deel te neem aan die studie, voltooi assbelief die toestemmingsbrief hieronder. Die afdeling moet persoonlik duer u voltooi en onderteken word om die voorskrifte van die Etiekkomitee na te kom,.

Vir meer inligting oor die studie, kontak my gerus

Karen Erasmus (Navorser) by die Vrystaatse Psigiatriese Kompleks
Telefoon nommer: 051-407 9263
Fax nommer: 051-436 1672
Epos: erasmusk@fshealth.gov.za

Toestemmingsbrief

Ek het die inligtingsdokument gelees en verstaan die doel van die studie. Ek verstaan dat m
deelname vrywillig is, en dat ek te eniger tyd kan onttrek van die studie. Ek verstaan dat ek nie m
menseregte prysgee nie en dat ek die navorser enige tyd kan kontak vir meer inligting.

Ek stem in om deel te neem aan die evaluering en behandeling om die effek te bepaal van '
fisioterapeutiese Kinesio-pleister aanwending op die fisiese simptome geassosieer met majo
depressiewe versteuring.

As ek enige klagtes of navrae het met betrekking tot die studie kan ek die Etiekkomitee van di
Fakulteit van Gesondheidswetenskappe by die Universiteit van die Vrystaat kontak.

Alle inligting sal streng vertoulik hanteer word, maar resultate mag in die toekoms vir pulikasies o
kongresaanbiedinge gebruik word.

_____	_____	_____
Deelnemer se naam	Handtekening	Datum

Karen Erasmus (Van Vuuren)
Navorser se naam

_____
Datum

Appendix D

- **Letter to request approval for research from public psychiatric institution**
- **Permission letter from public psychiatric institution**
- **Letter to request approval for research from private psychiatric institution**
- **Permission letter from private psychiatric institution**

Head of Clinical Services
Free State Psychiatric Complex
Bloemfontein
9301

Dear Dr. Masitha

RE: Request for approval to do research at your institution

I am currently involved in a research project to obtain my Master's degree in Physiotherapy from the University of the Free State.

The title of the proposed study is: "The effect of physiotherapeutic Kinesio taping on selected physical symptoms associated with major depressive disorder". The aim is to conduct a clinical trial on patients admitted in Mafube Affective ward at the Free State Psychiatric Complex.

Previous studies conducted on patients with major depressive disorder determined that the physical symptoms associated with Major depressive disorder are pain complaints, muscle tension, restricted breathing, motor retardation, loss of control and coordination of movement. From literature I have determined that physiotherapy intervention for major depressive disorder has beneficial effects. This study aims to determine whether physiotherapeutic Kinesio taping has a superior effect to a placebo taping intervention on pain restricted breathing and decreased proximal stability associated with Major depressive disorder.

This is an experimental study and the patients will be asked to participate in an assessment before and after a taping session, as well as a third assessment 24 hours after taping to determine the sustained effect of the taping. The assessment will take about 25 minutes at a time. Physiotherapy intervention will either be Kinesio taping according to current described treatment guidelines or a modified Kinesio taping technique. Routine physiotherapy intervention will continue for both groups after the assessment

has been completed. The intervention is not harmful in any way. The assessment tools used in this study are valid and reliable measuring instruments used in physiotherapy to evaluate pain, balance and breathing patterns.

No role players at your institution will be compromised in any way. The participants will not be discriminated against due to participation in or withdrawal from the study and no cost will be incurred to them. The participants can withdraw at any time. The identity of all participants will be protected and confidentiality will be ensured. Patients will be informed about the nature of the study and asked to sign a consent form.

The results can be used for future presentation at congresses or publications.

The study was approved by the Ethics committee of the Faculty of Health Sciences, Ecufs, at the University of the Free State. The Ecufs number is 150/2011. You may contact the Secretariat of the Ethics Committee at the telephone number 051-405 2812 if you have any questions pertaining to the rights of the participant.

Please convey your approval in writing on an institutional letter head as soon as possible, as I will need this approval to comply with approval granted by the Ethics committee, Faculty of Health Sciences.

I hereby request your consent for patients admitted to Mafube Affective Ward at your institution to take part in my study.

Please contact me if you have any inquiries and I am willing to provide you with the research proposal in electronic format.

Thank you for considering my request.

Karen Erasmus
Researcher

free state psychiatric complex

Department of Health
Free State Psychiatric Complex
FREE STATE PROVINCE

17 January 2012

To: Ms Karen Erasmus

Approval to Conduct Research at Free State Psychiatric Complex

Your application to conduct the study entitled **"The effect of physiotherapeutic Kinesio taping on selected physical symptoms associated with Major Depressive Disorder"** was approved at the Free State Psychiatric Complex Clinical Ethics and Research Committee meeting held on 06 December 2011.

With kind regards

DR B MASITHA
CMO & CLINICAL SERVICE MANAGER

Head of Clinical Services
Bloemcare Clinic
11 AG Visser street
Langenhovenpark
Bloemfontein
9301

Dear Doctor/Madam/Sir

RE: Request for approval to do research at your institution

I am currently involved in a research project to obtain my Master's degree in Physiotherapy from the University of the Free State.

The title of the proposed study is: "The effect of physiotherapeutic Kinesio taping on selected physical symptoms associated with major depressive disorder". The aim is to conduct a clinical trial on patients admitted in Care Cure Bloemfontein.

Previous studies conducted on patients with major depressive disorder determined that the physical symptoms associated with Major depressive disorder are pain complaints, muscle tension, restricted breathing, motor retardation, loss of control and coordination of movement. From literature I have determined that physiotherapy intervention for major depressive disorder has beneficial effects. This study aims to determine whether physiotherapeutic Kinesio taping has a superior effect to a placebo taping intervention on pain restricted breathing and decreased proximal stability associated with Major depressive disorder.

This is an experimental study and the patients will be asked to participate in an assessment before and after a taping session, as well as a third assessment 24 hours after taping to determine the sustained effect of the taping. The assessment will take about 25 minutes at a time. Physiotherapy intervention will either be Kinesio taping according to current described

treatment guidelines or a modified Kinesio taping technique. The intervention is not harmful in any way. The assessment tools used in this study are valid and reliable measuring instruments used in physiotherapy to evaluate pain, balance and breathing patterns.

No role players at your institution will be compromised in any way. The participants will not be discriminated against due to participation in or withdrawal from the study and no cost will be incurred to them. The participants can withdraw at any time. The identity of all participants will be protected and confidentiality will be ensured. Patients will be informed about the nature of the study and asked to sign a consent form.

The results can be used for future presentation at congresses or publications.

The study was approved by the Ethics committee of the Faculty of Health Sciences, Ecufs, at the University of the Free State. The Ecufs number is 150/2011. You may contact the Secretariat of the Ethics Committee at the telephone number 051-405 2812 if you have any questions pertaining to the rights of the participant.

Please convey your approval in writing on an institutional letter head as soon as possible, as I will need this approval to comply with approval granted by the Ethics committee, Faculty of Health Sciences.

I hereby request your consent for patients admitted at your institution to take part in my study.

Please contact me if you have any inquiries and I am willing to provide you with the research proposal in electronic format.

Thank you for considering my request.

Karen Erasmus (Van Vuuren)
Researcher

BLOEMCARE
BLOEMCARE (PTY) LTD REG.NO. 1999/003629/07

AG Visserstraat 11 AG Visser Street
Langenhovenpark
Bloemfontein
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Langenhovenpark 9330
(051) 446 3242
446 2650
FAX (051) 446 4469

22 February 2013

The Ethics Community of
Faculty of Health Sciences (Ecufs)
University of the Free State
BLOEMFONTEIN
9301

To Whom It May Concern:

Re: REQUEST FOR APPROVAL TO DO RESEARCH AT BLOEMCARE – KAREN VAN VUUREN

The above matter refers.

We were approached by Karen Van Vuuren to conduct the research for her proposed study "The effect of physiotherapeutic Kinesio taping on selected physical symptoms associated with major depressive disorder" at our institution.

This letters serves to confirm that we have given Karen Van Vuuren permission to conduct her research at our hospital, as per her specific request.

I trust that you will find the above to be in order.

Yours sincerely

M E BOTHA
HOSPITAL MANAGER

Appendix E

- **Body chart**

Appendix E - Body chart

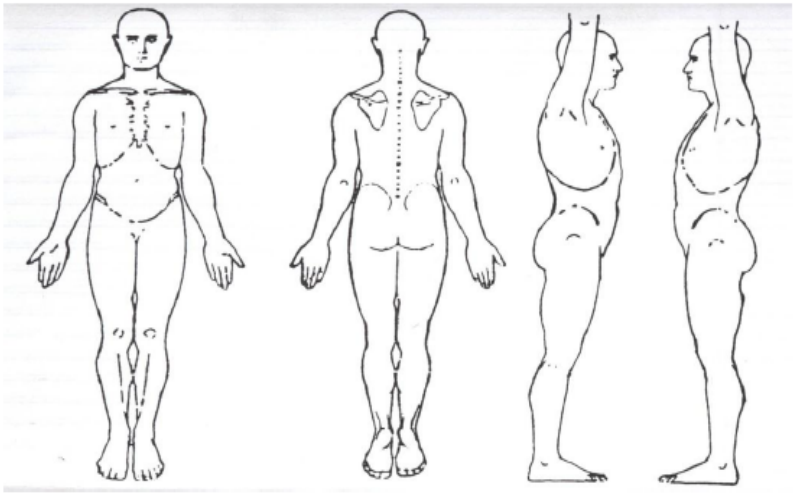
Number

Date 2013 M M D D

Pre-Testing 1

Post Testing Immediate 2

Post Testing After 24 Hours 3



Official Use

1-2

3-10

11

12-13

Appendix F

- **HAM-D**

Patient Name:_____ Date:_____

Hamilton Rating Scale for Depression (17-items)

Instructions: For each item select the "cue" which best characterizes the patient during the past week.

1. **Depressed Mood**
(sadness, hopeless, helpless, worthless)
0 Absent
1 These feeling states indicated only on questioning
2 These feeling states spontaneously reported verbally
3 Communicates feeling states nonverbally, i.e., through facial expression, posture, voice and tendency to weep
4 Patient reports VIRTUALLY ONLY these feeling states in his spontaneous verbal and nonverbal communication

2. **Feelings of Guilt**
0 Absent
1 Self-reproach, feels he has let people down
2 Ideas of guilt or rumination over past errors or sinful deeds
3 Present illness is a punishment. Delusions of guilt
4 Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations

3. **Suicide**
0 Absent
1 Feels life is not worth living
2 Wishes he were dead or any thoughts of possible death to self
3 Suicide ideas or gesture
4 Attempts at suicide (any serious attempt rates 4)

4. **Insomnia - Early**
0 No difficulty falling asleep
1 Complains of occasional difficulty falling asleep i.e., more than ½ hour
2 Complains of nightly difficulty falling asleep

5. **Insomnia - Middle**
0 No difficulty
1 Patient complains of being restless and disturbed during the night
2 Waking during the night – any getting out of bed rates 2 (except for purposes of voiding)

6. **Insomnia - Late**
0 No difficulty
1 Waking in early hours of the morning but goes back to sleep
2 Unable to fall asleep again if gets out of bed

7. **Work and Activities**
0 No difficulty
1 Thoughts and feelings of incapacity, fatigue or weakness related to activities; work or hobbies
2 Loss of interest in activity; hobbies or work – either directly reported by patient, or indirect in listlessness, indecision and vacillation (feels he has to push self to work or activities)
3 Decrease in actual time spent in activities or decrease in productivity. In hospital, rate 3 if patient does not spend at least three hours a day in activities (hospital job or hobbies) exclusive of ward chores.
4 Stopped working because of present illness. In hospital, rate 4 if patient engages in no activities except ward chores, or if patient fails to perform ward chores unassisted.

8. **Retardation**
(slowness of thought and speech; impaired ability to concentrate; decreased motor activity)
0 Normal speech and thought
1 Slight retardation at interview
2 Obvious retardation at interview
3 Interview difficult
4 Complete stupor

9. **Agitation**
0 None
1 "Playing with" hand, hair, etc.
2 Hand-wringing, nail-biting, biting of lips

10. **Anxiety - Psychic**
0 No difficulty
1 Subjective tension and irritability
2 Worrying about minor matters
3 Apprehensive attitude apparent in face or speech
4 Fears expressed without questioning

11. **Anxiety - Somatic**
0 Absent
1 Mild
2 Moderate
3 Severe
4 Incapacitating
Physiological concomitants of anxiety such as:
Gastrointestinal - dry mouth, wind, indigestion, diarrhea, cramps, belching
Cardiovascular – palpitations, headaches
Respiratory - hyperventilation, sighing
Urinary frequency
Sweating

12. **Somatic Symptoms - Gastrointestinal**
0 None
1 Loss of appetite but eating without staff encouragement. Heavy feelings in abdomen.
2 Difficulty eating without staff urging. Requests or requires laxatives or medications for bowels or medication for G.I. symptoms.

13. **Somatic Symptoms - General**
0 None
1 Heaviness in limbs, back or head, backaches, headache, muscle aches, loss of energy and fatigability
2 Any clear-cut symptom rates 2

14. **Genital Symptoms**
0 Absent
1 Mild
2 Severe
0 Not ascertained
Symptoms such as: loss of libido, menstrual disturbances

15. **Hypochondriasis**
0 Not present
1 Self-absorption (bodily)
2 Preoccupation with health
3 Frequent complaints, requests for help, etc.
4 Hypochondriacal delusions

16. **Loss of Weight**
A. When Rating by History:
0 No weight loss
1 Probable weight loss associated with present illness
2 Definite (according to patient) weight loss

B. On Weekly Ratings by Ward Psychiatrist, When Actual Changes are Measured:
0 Less than 1 lb. weight loss in week
1 Greater than 1 lb. weight loss in week
2 Greater than 2 lb. weight loss in week

17. **Insight**
0 Acknowledges being depressed and ill
1 Acknowledges illness but attributes cause to bad food, climate, overwork, virus, need for rest, etc.
2 Denies being ill at all

Total Score:_____

Appendix G

- **Approval from Ethical Committee of the Faculty of Health Science, University of the Free State**
- **Amendments to protocol approved by Ethical Committee of the Faculty of Health Science, University of the Free State**

UNIVERSITY OF THE FREE STATE
UNIVERSITEIT VAN DIE VRYSTAAT
YUNIVESITHI YA FREISTATA

UFS
UV

Research Division
Internal Post Box G40
☎(051) 4052812
Fax (051) 4444359

E-mail address: StraussHS@ufs.ac.za

Ms H Strauss

2012-01-26

REC Reference nr 230408-011
IRB nr 00006240

MS K ERASMUS
73 ALBRECHT STREET
DAN PIENAAR
BLOEMFONTEIN
9301

Dear Ms Erasmus

ECUFS NR 150/2011
MS K ERASMUS **DEPT OF PHYSIOTHERAPY**
PROJECT TITLE: THE EFFECT OF PHYSIOTHERAPEUTIC KINESIO TAPING ON SELECTED PHYSICAL SYMPTOMS ASSOCIATED WITH MAJOR DEPRESSIVE DISORDER.

- You are hereby kindly informed that the Ethics Committee approved the above project at the meeting held on 24 January 2012 after: a) the researcher confirmed that she attended a Research Methodology Course; b) the Afrikaans version of the Information Leaflet and Informed Consent document have been language edited; c) the permission letter from the hospital management/institution was submitted.
- The Ethics Committee took cognisance with approval of the study period that was changed to 2 January 2012 until February 2012.
- 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.
- 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 ECUFS reference number in correspondence to the Ethics Committee secretariat.

Yours faithfully

.....

CHAIR: ETHICS COMMITTEE

Cc Ms K Bodenstein

UNIVERSITY OF THE FREE STATE
UNIVERSITEIT VAN DIE VRYSTAAT
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Fax (051) 4444359

Ms H Strauss

E-mail address: StraussHS@ufs.ac.za

2012-05-29

REC Reference nr 230408-011
IRB nr 00006240

MS K ERASMUS
73 ALBRECHT STREET
DAN PIENAAR
BLOEMFONTEIN
9301

Dear Ms Erasmus

ECUFS NR 150/2011
PROJECT TITLE: THE EFFECT OF PHYSIOTHERAPEUTIC KINESIO TAPING ON SELECTED PHYSICAL SYMPTOMS ASSOCIATED WITH MAJOR DEPRESSIVE DISORDER.

- You are hereby kindly informed that the Ethics Committee approved the following at the meeting held on 22 May 2012:
  - ***Amendments nr 1 and 2 to the project***
- 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.
- 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 ECUFS reference number in correspondence to the Ethics Committee secretariat.

Yours faithfully

.....
PROF WH KRUGER
CHAIR: ETHICS COMMITTEE

Cc Ms K Bodenstein

UNIVERSITY OF THE FREE STATE
UNIVERSITEIT VAN DIE VRYSTAAT
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Ms H Strauss

E-mail address: StraussHS@ufs.ac.za

2012-11-28

REC Reference nr 230408-011
IRB nr 00006240

MS K ERASMUS
DEPT OF PHYSIOTHERAPY
FACULTY OF HEALTH SCIENCES
UFS

Dear Ms Erasmus

ECUFS NR 150/2011
PROJECT TITLE: THE EFFECT OF PHYSIOTHERAPEUTIC KINESIO TAPING ON SELECTED PHYSICAL SYMPTOMS ASSOCIATED WITH MAJOR DEPRESSIVE DISORDER.

- You are hereby kindly informed that the Ethics Committee approved the following at the meeting held on 27 November 2012:
  - ***Changes to the inclusion criteria***
  - ***Request for extension of study period to the 31st December 2013***
- 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.
- 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 ECUFS reference number in correspondence to the Ethics Committee secretariat.

Yours faithfully

.....

DR SM LE GRANGE
ACTING CHAIR: ETHICS COMMITTEE

UNIVERSITY OF THE FREE STATE
UNIVERSITEIT VAN DIE VRYSTAAT
YUNIVESITHI YA FREISTATA
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E-mail address: StraussHS@ufs.ac.za

Ms H Strauss/hv

2013-03-08

REC Reference nr 230408-011
IRB nr 00006240

MS K ERASMUS
DEPARTMENT OF PHYSIOTHERAPY
FACULTY OF HEALTH SCIENCES
UFS

Dear Ms Erasmus

ECUFS NR 150/2011
MS K ERASMUS **DEPT OF PHYSIOTHERAPY**
PROJECT TITLE: THE EFFECT OF PHYSIOTHERAPEUTIC KINESIO TAPING ON SELECTED PHYSICAL SYMPTOMS ASSOCIATED WITH MAJOR DEPRESSIVE DISORDER.

- You are hereby kindly informed that the Ethics Committee approved the following at the meeting held on 5 March 2013:
  - ***Amendment 4: Changes to the Methodology***
- 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.
- 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

.....
PROF WH KRUGER
CHAIR: ETHICS COMMITTEE

Cc **Ms K Bodenstein**

UNIVERSITY OF THE FREE STATE
UNIVERSITEIT VAN DIE VRYSTAAT
YUNIVESITHI YA FREISTATA
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Ms H Strauss/hv

2013-03-19

REC Reference nr 230408-011
IRB nr 00006240

MS K ERASMUS
DEPT OF PHYSIOTHERAPY
FACULTY OF HEALTH SCIENCES
UFS

Dear Ms Erasmus

ECUFS NR 150/2011
MS K ERASMUS **DEPT OF PHYSIOTHERAPY**
PROJECT TITLE: THE EFFECT OF PHYSIOTHERAPEUTIC KINESIO TAPING ON SELECTED PHYSICAL SYMPTOMS ASSOCIATED WITH MAJOR DEPRESSIVE DISORDER.

- You are hereby kindly informed that the Ethics Committee took cognisance with approval of the permission letter dated 22 February 2013 received from ME Botha, Hospital Manager, Bloemcare Hospital. It will be included in the Agenda for the meeting on 9 April 2013.
- 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.
- 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

.....
PROF WH KRUGER
CHAIR: ETHICS COMMITTEE

UNIVERSITY OF THE FREE STATE
UNIVERSITEIT VAN DIE VRYSTAAT
YUNIVESITHI YA FREISTATA
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Research Division
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E-mail address: StraussHS@ufs.ac.za

Ms H Strauss/hv

2013-04-10

REC Reference nr 230408-011
IRB nr 00006240

MS K ERASMUS
DEPT OF PHYSIOTHERAPY
FACULTY OF HEALTH SCIENCES
CR DE WET BUILDING
UFS

Dear Ms Erasmus

ECUFS NR 150/2011
MS K ERASMUS **DEPT OF PHYSIOTHERAPY**
PROJECT TITLE: THE EFFECT OF PHYSIOTHERAPEUTIC KINESIO TAPING ON SELECTED PHYSICAL SYMPTOMS ASSOCIATED WITH MAJOR DEPRESSIVE DISORDER.

- You are hereby kindly informed that at the meeting held on 9 April 2013 the study was approved after all conditions were met when the following was received:
  - *Permission letter dated 22 February 2013 from ME Botha, Hospital Manager, Bloemcare Hospital*
- 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.
- 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

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PROF WH KRUGER
CHAIR: ETHICS COMMITTEE

Appendix H

- **Coding list**

Coding list

Bodychart

Coding nr	**Pain area**
1	Upper thoracic
2	Cervical, shoulders, headache
3	Uppper cervical
4	Lower cervical
5	Cervical
6	Shoulders
7	Headache
8	Shoulders and headache
9	Headache, cervical, chest pain multiple sites
10	Headache, cervical, chest pain one site
11	unilateral leg pain
12	Cervical and upper thoracic
13	Headache, cervical and unilateral arm pain
14	Headache, cervical and bi-lateral arm pain
15	Headache, unilateral cervical, thoracic, lumbar and arm pain
16	Cervical, upper thoracic and shoulders
17	Lower cervical and shoulders
18	No Pain areas affected - no pain
19	Unilateral Sacro-iliaac joint (SIJ) pain
20	Thoracic and unlateral ankle pain
21	Unilateral ankle pain
22	Headache, shoulder and lower back pain
23	Lower thoracic
24	Lower back (lumbar)
25	Cervical, thoracic, lower back and unilateral abdominal pain
26	Unilateral cervical (upper and lower) and shoulder pain
27	Cervical, thoracic and lower back pain
28	Thoracic and lower back pain
29	Cervical and thoracic pain
30	Cervical and unilateral upper thoracic
31	Cervical and shoulder area (middel m. trapezius)
32	Unilateral thoracic (upper and lower)
33	Headache and unilateral thoracic pain
34	Headache and cervical pain
35	Lower back and sacral pain
36	Headache, cervical, thoracic and shoulders (middel m. trapezius)
37	Shoulder (middel m.trapezius) lower thoracic and lower back
38	Cervical, thoracic, lower back and shoulder area
39	Unilateral Lower back and lower limb
40	Bilateral lower limb pain

Other therapies

Coding nr	Therapy combination
1	Occupational therapy
2	Psychotherapy
3	Pharmacology (medication)
4	Physiotherapy
5	All of the above
6	all execpt physiotherapy
7	Psychotherapy and Pharmacology (medication)
8	Occupational therapy and pharmacology (medication)
9	Psychotherapy, Pharmacology and Physiotherapy

Summary

Kinesio® taping is a relatively new form of therapeutic taping that has a variety of applications. Physiotherapists can use the tape to treat certain physical symptoms for example, pain, swelling and dysfunctional muscle activation.

Major depressive disorder (MDD) is a mood disorder which also causes physical symptoms. The physical symptoms most associated with MDD are muscle tension, pain complaints, restricted breathing, less flexibility and centring of movements, and negative attitudes towards physical appearance and ability. These physical symptoms are, however, often ignored in the assessment and treatment of the disorder. Without total relief of the physical symptoms associated with MDD, remission of the condition could be false or incomplete. The association between physical complaints and MDD emphasises the need for physiotherapy as part of the holistic treatment regime for the depressed patient. The aim of this study was to investigate the effect of physiotherapeutic Kinesio® taping on selected physical symptoms associated with MDD.

A double-blind, randomised controlled design was used, following a quantitative study approach. Study participants (40) were male and female patients with a diagnosis of MDD admitted to a public and a private psychiatric institution, respectively, in the Free State. Evaluation of the selected physical symptoms was conducted before, immediately after and 24 hours after the application of the Kinesio® taping. One researcher performed the evaluations and another researcher applied the taping and completed a baseline mood questionnaire with the study participants.

Just more than half (55%) of the participants were recruited from a private psychiatric institution and 45% of the participants were recruited from a public psychiatric institution. Most (80%) of the participants were female. The median age of the participants in the experimental group was 37.5 years and in the placebo group it was 34 years.

The severity of the current MDD episode of participants ranged between normal and very severe, with 60% of participants experiencing a severe or very severe episode. Slightly more than half (55%) of the participants received all available therapies: occupational therapy, physiotherapy, psychotherapy and a pharmacological intervention. This corresponds with the 55% of participants recruited from the private psychiatric institution where all the therapies are part of the daily treatment regime. Pain was assessed using the Short Form McGill Pain Questionnaire (SF-MPQ) by means of a structured interview. Restriction in breathing was evaluated by a palpation test (Manual Assessment of Respiratory Motion) and loss of flexibility and centring of movement was an observation test of functional activities (Tinetti Mobility Test).

The majority (77.5%) of participants complained of pain during the study period and 58% complained of multiple areas of pain. Participants complained mostly of cervical pain (36.7%), except for the placebo group who at 24 hours post-application reported lower back pain (30%).

The sensory and affective components associated with pain and tested by the SF-MPQ showed improvement in combined scores for both the experimental and placebo groups. The affective domain tests the emotional component of pain and the results indicate a clinically significant effect on this domain. The results of the Manual Assessment of Respiratory Motion (MARM) displayed improvement in both the placebo and experimental groups for balance of breathing and percentage ribcage motion. The Tinetti Mobility Test which assesses balance and gait showed no distinct results possibly due to the scale not being sensitive enough for the movement disorders tested.

Limitations of the study could have influenced the outcomes measured and it should be taken into account that of the 40 participants, 21 received physiotherapy and the other therapies received by participants during the study was not standarised and could not be controlled due to the multitude of stakeholders involved in the care of the patients. The treatment of physical symptoms associated with MDD with Kinesio® taping had mixed results, but

Kinesio® taping could be a valuable adjuvant treatment modality. The importance of physiotherapy as part of the treatment regime for patients suffering from MDD was highlighted and the importance of future research in this field of practise emphasised.

Key terms: effects, physiotherapeutic, Kinesio® taping, physical symptoms, major depressive disorder, pain, restricted breathing, loss of centring of movements

Opsomming

Kinesio® pleisters is a relatiewe nuwe vorm van terapeutiese verbinding en het ‘n groot verskeidenheid toepassings. Fisioterapeute kan die pleisters gebruik om sekere fisiese simptome byvoorbeeld pyn, swelling en spier aktiverings disfunksie te behandel.

Major depressiewe versteuring (MDV) is ‘n gemoedversteuring wat ook tot fisiese simptome lei. Die fisiese simptome wat meestal met die versteuring geassosieer word is spierspanning, klagtes van pyn, asemhalingsinkorting, verminderde soepelheid, verlies aan sentrering van beweging, asook ‘n negatiewe houding jeens fisiese voorkoms en vermoeëns. Hierdie fisiese simptome word dikwels geïgnoreer tydens die evaluering en behandeling van die versteuring. Sonder die aangehele verligting van die geassosieerde fisiese simptome van MDV kan remissie vals of onvolledig wees. Die assosiasie tussen fisiese klagtes en MDV beklemtoon die behoefte aan fisioterapie as deel van die holistiese behandelingsregime vir die depressiewe pasiëntDie doel van hierdie navorsingstudie was om die effek van fisioterapeutiese Kinesio® pleister aanwending op geselekteerde fisiese simptome geassosieer met MDV te ondersoek.

Hierdie was ‘n dubbel-blinde, ewekansige gekontroleerde proefneming en ‘n kwantitatiewe studiemetode is gevolg. Studiedeelnemers was manlike en vroulike pasiënte wat met MDV gediagnoseer en opgeneem is in onderskeidelik ‘n staats en ‘n privaat psigiatriese instansie in die Vrystaat. Evaluering van die fisiese simptome is uitgevoer voor, onmiddelik na en 24 uur na die aanwending van die Kinesio® pleisters. Een navorser het die evaluasies behartig en ‘n ander navorser het die pleisters aangewend en die basislyn gemoedsvraelys met die deelnemers gedoenNet meer as die helfte (55%) van die deelnemers is vanaf die privaat psigiatriese instansie gewerf en 45% van die deelnemers vanaf die publieke instansie. Die meeste (80%) van die deelnemers van was vroulik. Die

mediane ouderdom van die deelnemers in die eksperimentele groep was 37.5 jaar en in die plasebo groep 34 jaar.

Die graad van die huidige MDV episode van die deelnemers het gewissel tussen normaal en baie ernstig, met 60% van die deelnemers wat ‘n erge of baie erge episode beleef het. Net meer as die helfte (55%) van die deelnemers het alle beskikbare behandeling ontvang: arbeidsterapie, fisioterapie, psigoterapie en farmakologie. Hierdie resultate stem ooreen met 55% van die deelnemers wat afkomstig was van die privaat psigiatriese instansie waar al die terapieë deel was van die daaglikse behandeling. Pyn is gevalueer met behulp van die “Short Form McGill Pain Questionnaire (SF-MPQ)” deur n gestruktureerde onderhoud Beperking in asemhaling is ‘n palperings toets (‘”Manual Assessment of Respiratory Motion”) en verlies van soepelheid en sentrering van beweging is ‘n observasie toets van funksionele aktiwitiete (“Tinetti Mobility Test”).

Die meerderheid (77.5%) van die deelnemers het pyn klagtes gehad gedurende die studie periode en 58% het gekla van pyn in meer as een area. Deelnemers het meestal (36.7%) nekpyn rapporteer, behalwe vir die plasebo groep wat teen 24 uur na aanwending hoofsaaklik (30%) van lae rugpyn gekla het.

Die sensoriese en affektiewe komponente geassosieer met pyn en gemeet deur die “Short Form McGill Pain Questionnaire” het verbetering in die gekombineerde punte vir beide die eksperimentele en plasebo groepe getoon. Die resultate van die affektiewe afdeling, wat die emosionele komponent van pyn meet, was klinies beduidend. Die resultate van die “Manual Assessment of Respiratory Motion” toon verbetering in beide die eksperimentele en plasebo groepe vir balans van asemhaling sowel as die persentasie borskas beweging. Die “Tinetti Mobility Test” wat balans en looppatroon evalueer het geen duidelike resultate gehad nie as gevolg van die skaal wat moontlik nie sensitief genoeg was om bewegingsversteurings wat getoets is waar te neem nie.

Tekortkominge kon die uitkomste van die studie beïnvloed het. Dit moet in ag geneem word dat van die 40 deelnemers, 21 fisioterapie ontvang. het en dat die ander terapieë wat deur die deelnemers ontvang is nie gestandariseerd was of

beheer kon word nie as gevolg van die hoeveelheid belanghebbendes betrokke by die behandeling van die pasiënte.

Die behandeling van die geselekteerde fisiese simptome geassosieer met MDV met Kinesio® pleisters het gemengde resultate gelewer, maar die behandelingstegniek kan ‘n baie waardevolle aanvullende behandelingsmodaliteit wees. Die belangrikheid van fisioterapie as deel van die behangelingsregime vir pasiënte wat aan MDV ly is bevestig en uitgelig en die noodsaaklikheid van toekomstige navorsing in die veld is beklemtoon.