

CROSS-CULTURAL ADAPTATION AND VALIDATION OF THE STarT BACK SCREENING TOOL IN isiZULU

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A research report submitted to the Faculty of Health Sciences, University of the Witwatersrand, Johannesburg in partial fulfilment of the requirements for the degree of Master of Science in Physiotherapy

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DECLARATION

I, Peta-Ann Schmidt, declare that the contents of this research report are my own work, except what is indicated in the acknowledgement sections. This research report is being submitted for a degree of Master Science in Physiotherapy, at the University of the Witwatersrand, Johannesburg, South Africa. This work has not been submitted for any other degree or examination in this or any other university.



03/07/2019

Signature

Date

DEDICATION

In memory of
my mom, Janice (1946-2013)
and my dad, Toekie Schmidt (1939-1997),
who taught me the value of hard work

ABSTRACT

Background: Non-specific low back pain (NSLBP) is one of the most prevalent conditions in the world and identifying patients at risk for developing chronic NSLBP is key to effectively treating these patients. The STarT back screening tool is a validated, prognostic screening tool that identifies subgroups of non-specific low back pain patients and the risk factors associated with each subgroup, which can direct the treatment decision-making process in the primary care of NSLBP. This study's objective was to translate and validate the English version of the STarT back screening tool into isiZulu, making the tool useful and accessible to the isiZulu population of South Africa.

Method: Translation was done in four phases, based on best practice guidelines, which included forward translation, synthesis of forward translation, backward translation and expert review. Validation included expert review for content validity and testing and retesting of the preliminary translated tool on a sample of 30 participants. Statistical analysis included content validity, test-retest reliability, usability and internal consistency.

Results: Minor linguistic differences occurred with the translating process. The expert committee came to agreement around the challenging translation of the terms “more slowly” in question 4, “physically active” in question 5, “terrible” in question 7 and “bothersome” in question 9. A total of 30 patients were recruited, with 77% female and 23% male. Item content validity for relevance was excellent (I-CVI = 1.00), and satisfactory (I-CVI = 0.94) for clarity, simplicity and ambiguity. Scale content validity was acceptable at 0.955. Spearman's CC for test-retest reliability was acceptable at 0.73. Cronbach's Alpha for internal consistency for the total score was 0.68, and the psychosocial scale was also 0.68. Thirty three percent reported the translated tool very easy to understand and 40% reported it very easy to complete.

Conclusion: The isiZulu STarT back screening tool showed excellent validity, acceptable reliability, less than acceptable internal consistency and can therefore be used by an isiZulu population of NSLBP patients.

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LIST OF ABBREVIATIONS

ACTFL	– American Council on Teaching of Foreign Languages
ADL's	– Activities of Daily Living
ASQ	– Absenteeism Screening Questionnaire
AUC	– Area Under the Curve
BDQ	– Back Disability Questionnaire
BT1	– Back Translation 1 from English second language speaker uninformed, non-medically trained, proficient in isiZulu
BT2	– Back Translation 2 from English second language speaker uninformed, non-medically trained, proficient in isiZulu
CB-CFT	– Classification Based Cognitive Function Therapy
CI	– Confidence Interval
CPR	– Clinical Prediction Rule
CPRS	– Chronic Pain Risk Score
EQ-5D	– EuroQol5 Dimension Scale
FABQ	– Fear Avoidance Beliefs Questionnaire
GDP	– Gross Domestic Product
GP	– General Practitioner
HADS	– Hospital Anxiety and Depression Scale
HCPR	– Hancock Clinical Prediction Rule
HIV/AIDS	– Human Immunodeficiency Virus/ Acquired Immunodeficiency Syndrome
HREC	– Human Research Ethics Committee
IASP	– International Association for the Study of Pain
ICC	– Intraclass Coefficient Correlation
I-CVI	– Item Content Validity
LBP	– Low Back Pain
LBPPS	– Low Back Pain Perception Scale
LR	– Likelihood Ratio
MA	– Master of Arts
MDI	– Major Depression Inventory
MSc	– Master of Science
n	– Sample Size
NIH	– National Institutes of Health
NPRS	– Numeric Pain Rating Scale
NSLBP	– Non-Specific Low Back Pain

OMPSQ	– Orebro Musculoskeletal Pain Screening Questionnaire
PCS	– Pain Catastrophizing Scale
PhD	– Doctorate
RCT	– Randomized Controlled Trial
RMDQ	– Roland Morris Disability Questionnaire
RR	– Risk Ratio
STarT	– Subgroups for Targeted Treatment
S-CVI	– Scale Content Validity
TB	– Tuberculosis
TSK-11	– 11-item Tampa Scale of Kinesiophobia
T1	– Forward translation 1 from an informed, medically trained translator
T2	– Forward translation 2 from an uninformed, non-medically trained translator
T12	– Synthesis of T1 and T2
UK	– United Kingdom
UNESCO	– United Nations Educational, Scientific and Cultural Organization
USA	– United States of America
VDPQ	– Vermont Disability Prediction Questionnaire
YLDs	– Years lived with a disability

LIST OF DEFINITIONS

Backward translators	: translated the tool from isiZulu to English
Discrepancies	: ambiguous words or incorrect word choices
Expert	: “a person with a sufficient number of years of training, considerable experience, and working in the field in question, and who has acquired very high-level knowledge and skills” (Siren, 2002).
Expert committee	: healthcare professionals, language professionals and the forward and back translators.
Forward translators	: translated the tool from English to isiZulu.
Informed participant	: “aware of the concepts being examined in the questionnaire being translated” (Beaton, et al, 2000).
Language proficiency	: “able to use the language skilfully, and with accuracy, efficiency, and effectiveness, educated, articulate users of the language” (ACTFL guidelines, 2012).
Reliability	: “the extent to which results are consistent over time and are an accurate representation of the total study population” (Joppe, 2000 in Golafshani, 2003).
Translate	: “the way to express the sense of words or writing in another language” (Soanes, 2006).
Translation	: “a word or written work that is translated into another language” (Soanes, 2006).
Translatio (latin)	: “a carrying across” or “a bringing across” (Translation, 2018).
Uninformed participant	: “neither be aware nor informed of the concepts being quantified” (Beaton, et al, 2000).

- Validity : “determines whether the research instrument truly measures that which it intended to measure” (Joppe, 2000 in Golafshani, 2003).
- Wits Translate : the University of the Witwatersrand Language School’s professional translating and interpreting agency

CHAPTER 1

1. INTRODUCTION AND SCOPE OF THE RESEARCH REPORT

1.1 INTRODUCTION

Non-specific low back pain (NSLBP) is one of the most prevalent conditions in the world (Bruyere et al, 2012), and was the leading cause of disability worldwide in 2015 (GBD, 2015). The prevalence of NSLBP in African populations has been shown to be similar to that of the rest of the world (Louw et al, 2007), with economic costs amounting to 1-2% of annual GDP (Frohlich et al, 2007).

Many patients experience short episodes of acute NSLBP that resolves quickly, but many others go on to develop chronic NSLBP which can persist for up to one year after the initial onset (Hill et al, 2008). Approximately 23% of patients will experience ongoing symptoms, of which 11-12% continue to experience long-term disability (Airaksinen et al, 2006). Chronic NSLBP thus places a significant socioeconomic burden on society (Melloh et al, 2009), making diagnosing patients at risk of developing chronic NSLBP of high importance.

Predicting the development of chronicity in NSLBP through the early identification of risk factors (van Tulder et al, 2006) has been shown to lead to more effective treatment interventions (Melloh et al, 2009). Emphasis on psychosocial factors as risk factors for developing chronic NSLBP has been demonstrated in most of the clinical guidelines on the management of low back pain (Koes et al, 2010), and they can in turn influence the prognosis of these patients (Pilz et al, 2014).

It was noted by Koes et al (2001) that there was no consensus at the time, on how to assess these risk factors, and that there was limited availability of a specific tool in use. Hill et al (2008) developed and validated such a tool - the STarT (Subgroups for Targeted Treatment) back screening tool (Keele University, 2017), a back-pain prognostic screening tool which could be used to identify subgroups of patients and associated risk factors. In a randomized controlled trial Hill et al (2011) then compared a stratified care approach based on this back-pain prognostic screening tool with current best practice. It showed a significant improvement in patient outcomes and substantial economic benefits. The STarT back screening tool can thus be used to stratify or group patients with NSLBP into acute, subacute and chronic or low, medium and high-risk groups.

The STarT back screening tool is a self-administered tool, therefore, understanding the written language of a standardised tool is integral to its usage and interpretation, with language being important to every aspect and interaction of our daily lives (The Importance of Languages, 2017). Understanding language is automatic, but it requires integration of a huge amount of information along with the use of certain cognitive abilities. This organizes the information into a single comprehensive concept (Van Dyke, 2016). Understanding a language, written or spoken, therefore involves the need to integrate new information with what is already known (Van Dyke, 2016), and is thus the means of expression of a culture (The Importance of Language, 2017). Translation gives different cultures the opportunity to access this huge amount of new information available in the English world, and in return allows the English world an understanding of other cultures.

The STarT back screening tool was originally developed and validated in English and has been translated into 35 languages worldwide (Appendix 22). There is to date only one translated version of this tool in any of the other official languages of South Africa (Afrikaans) (The 11 languages of South Africa, 2019 and Keele University, 2017).

Most South Africans, particularly in the African population, are bilingual and often use more than one language at home, with English usually considered a second or third language to most South Africans. Cultural differences in a multicultural South African society are most often revealed in language, and most misunderstandings arise due to the use of different languages (The Importance of languages, 2017). If a person is not able to use the language most familiar to them, they are unlikely able to perform at their best, and their self-confidence will be undermined (The Importance of languages, 2017).

Therefore, understanding the STarT back screening tool in their first language will allow patients with NSLBP to use the tool to the best of their ability, with self-confidence and an increased sense of self. It will also assist practitioners to accurately group the aforementioned patients into low, medium or high-risk groups, which in turn will direct treatment interventions.

1.2 PROBLEM STATEMENT

Many South Africans do not speak English as their first-language, and most have varying degrees of English language competence, so understanding the STarT back screening tool in English is problematic for many isiZulu-speaking patients presenting

with NSLBP, which leads to inaccurate stratification of these patients and ineffective treatment interventions.

1.3 **AIM OF THE STUDY**

To translate and validate the isiZulu STarT back screening tool.

1.4 **OBJECTIVES OF THE STUDY**

1. To translate the STarT back screening tool into isiZulu in a manner acceptable to experts.
2. To validate the translated STarT back screening tool in an isiZulu population of NSLBP patients.

1.5 **SIGNIFICANCE OF THE STUDY**

The use of the STarT back screening tool translated into isiZulu will enable isiZulu speaking South Africans to fully understand and use the tool, and assist practitioners in screening, stratifying and treating isiZulu South Africans with NSLBP more effectively.

1.6 **ORGANISATION OF THE RESEARCH REPORT**

The research report will be organised into seven sections as represented in Figure 1.1.

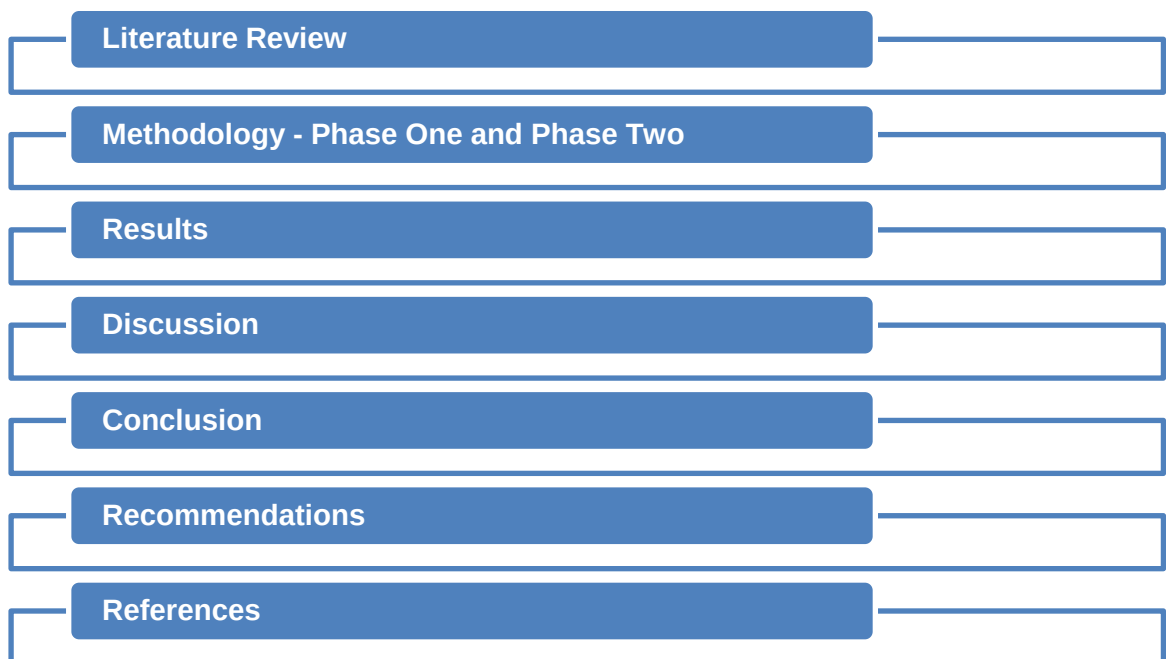


Figure 1.1: Diagrammatic Representation of Research Report

CHAPTER 2

2. LITERATURE REVIEW

This chapter will provide an overview of the literature related to NSLBP (acute and chronic); the early diagnosis of chronic NSLBP; the risk factors associated with the development of chronic NSLBP; how these risk factors influence the prognosis of chronic NSLBP; the stratification of NSLBP into subgroups based on these risk factors; the application of stratification in prognostic screening tools; the development and validation of the original STarT back screening tool; the influence of language in translation; and the translation and validation of the STarT back screening tool into other languages.

Various databases were used in the search for sound literature including EBSCO, Pubmed, Google Scholar, Clinical Key, PEDro and Medline. The key words that were used included non-specific low back pain, chronic NSLBP, acute NSLBP, psychosocial risk factors, prognostic indicators, stratification of NSLBP and the STarT back screening tool. The search period included literature published from 2006 -2019.

2.1 INTRODUCTION

Non-specific low back pain is one of the most prevalent and costly conditions globally (Bruyere et al, 2012). Acute NSLBP usually resolves quickly but can at times persist and become chronic (Hill et al, 2008), which can place an unusually high socioeconomic burden on society. Early diagnosis can decrease this burden and lead to more effective treatment interventions (Melloh et al, 2009).

Clinical guidelines on the management of NSLBP (Oliveira et al, 2018) emphasize the importance of addressing psychosocial factors, which play a significant role as risk factors in the development of chronic NSLBP. These factors in turn influence the prognosis of this condition (Pilz et al, 2014).

Patient-reported standardized outcome measures can be used to assess these risk factors, guide clinicians in evidence-based practice and assess changes over time (Kyte et al, 2015).

Hill et al (2008) developed and validated such an outcome measure – the STarT back screening tool, which can be used to identify subgroups of patients and risk factors

associated with each subgroup. As it is a self-administered questionnaire, understanding the language of the tool is important to its usage and application (The Importance of Languages, 2017), and translation of the tool allows people from other cultures whose first language is not English, the opportunity to use the tool and access the information available in it.

The STarT back screening tool has already been translated into 35 languages worldwide (Appendix 22), but into only one of the 11 official South African languages – Afrikaans. South Africa is a multicultural society with the majority of the African population speaking isiZulu as their home language, with English as their second or third language (The 11 languages of South Africa, 2019). Therefore, understanding the STarT back screening tool in isiZulu will allow patients to more accurately express the influence their condition, and assist clinicians in accurately diagnosing and treating these patients.

2.2 NON-SPECIFIC LOW BACK PAIN

Non-specific low back pain can be defined as “low back pain without a specific known cause or pathology” (Maher et al, 2017), and is categorized into three subgroups based on the duration of pain – acute, subacute and chronic. Common onset of NSLBP occurs between the ages of 30 and 60 years, mainly in females and is the leading cause of years lived with a disability (YLDs) in developed and developing countries (Maher et al, 2017). The number of YLDs due to NSLBP increased by 30%, from 1990 to 2007, and further increased by 18% from 2007 to 2017, causing 162 million YLDs globally in 2017 (Kadel, 2018). NSLBP is further estimated to represent 90-95% of all low back pain cases (Oliviera et al, 2018).

It has furthermore been identified as one of the most expensive conditions that occur globally, with costs varying significantly from country to country (Kadel, 2018). In the United States of America (USA) chronic NSLBP costs about \$365 billion a year (Deyo et al, 2015), with indirect costs due to lost production and household productivity typically higher than direct healthcare costs (Kadel, 2018). Furthermore, people with NSLBP who retire early and are out of the workplace have 87% less wealth than those working full time (Maher et al, 2017). Annual costs for NSLBP in Germany, the Netherlands and Australia are estimated at €17.4 billion, €3.5 billion and AUD \$9.17 billion respectively (Oliviera et al, 2018), whilst there is a significant lack of literature on treatment cost-effectiveness in developing countries.

The occurrence of NSLBP has risen significantly in developing countries compared to developed countries in the last decade (Buchbinder et al, 2013), due to the increase in population size, the number of obese people and industrial growth (Buchbinder et al, 2013). As of 2016, 1.2 billion people live on the continent of Africa (United Nations Population Division, 2017), and a lack of essential resources like access to clean water, sanitation, nutrition and health care have become key factors in the increase in prevalence of disease and disability (Louw et al, 2007), particularly NSLBP. A large number of productive citizens on the African continent are affected by NSLBP (Buchbinder et al, 2013), but due to limited resources, the management of HIV/AIDS, malaria and tuberculosis (TB) are the focus, and not the management of NSLBP (Major-Helsloot et al, 2014).

Health care workers in developing countries have shown an increase in NSLBP (Sikiru et al, 2009), particularly nurses, who reported 70.87% prevalence in two large hospitals in Nigeria and Ethiopia. This is on par with similar studies conducted on nurses in developed countries (Sikiru et al, 2009). A high prevalence (up to 25%) of musculoskeletal pain has also been found in South African factory workers, and up to eight percent of the South African general population have been found to experience neuropathic pain (Frohlich et al, 2007).

Most NSLBP research has occurred mainly in developed countries, where racial, economic and social homogeneity exists (Louw et al, 2007). This is not the case in Africa, where racial, economic and social heterogeneity may influence the reported prevalence of NSLBP, along with other factors like HIV/AIDS, nutrition and working environments (Louw et al, 2007). Published data on pain in South Africa is also limited, even though the pathology is similar to that of developed countries (Frohlich et al 2007). The only systematic review done on the prevalence of NSLBP among African populations (Louw et al, 2007) has shown a minimal difference in the prevalence of NSLBP between developing and developed countries, with lifetime prevalence in African populations ranging between 28% - 74%, whilst developing populations range between 30% -80% (Louw et al, 2007).

The prevalence of NSLBP continues to increase across the globe, in both developing and developed countries alike (Buchbinder et al, 2013), and economic costs of incorrectly diagnosing and treating NSLBP are also increasing (Buchbinder et al, 2013). This places a significant burden on society and remains a challenge for clinicians who are faced with treating this condition.

2.2.1 **Acute Non-Specific Low Back Pain**

Acute NSLBP is one of the most common conditions in primary health care (Outhoff, 2015), with statistics showing at least three out of five adults experiencing acute low back pain in their lifetime (Hasegawa et al, 2014). It can be defined as “persistent low back pain, with pain between the costal margin and the inferior gluteal folds, lasting for less than six weeks” (Moosajee et al, 2015). It is self-limiting in most cases, with patients improving and returning to work in four to six weeks (Hasegawa et al, 2014). Most patients with acute NSLBP have a 90% recovery rate and will stop consulting their primary physician within three months after the initial episode (Koes et al, 2010), however recurrences are common, and two to seven percent will go on to develop chronic NSLBP (Van Tulder et al, 2006 and Melloh et al, 2008).

A number of studies agree that strenuous physical work, a sedentary lifestyle, previous incidence of low back pain, smoking, and obesity are significant risk factors for the development of acute NSLBP (Moosajee et al, 2015, Maher et al, 2017 and Balague et al, 2012), with obesity found to be the most definitive risk for acute NSLBP and an even higher risk of chronic NSLBP development (Shiri et al, 2010).

Treatment of acute NSLBP should take an active approach, with emphasis on education, pain relief, increased levels of physical activity and early return to work, as well as identification of risk factors for chronicity (Van Tulder et al, 2006).

2.2.2 **Chronic Non-Specific Low Back Pain**

The National Institutes of Health (NIH) Research Task Force (Deyo et al, 2015) defined chronic low back pain (LBP) as “back pain that has persisted for at least 3 months and has resulted in pain on at least half the days in the past 6 months”. The International Association for the Study of Pain (IASP, 2019) defines chronic pain as “pain persisting for longer than three months, presenting as the predominant clinical problem”. It is defined as non-specific when it becomes impossible to identify the mechanisms causing the chronic low back pain (Deyo et al, 2015). Chronic NSLBP is therefore defined by European Guidelines as “low back pain persisting for at least 12 weeks, unless otherwise specified, and that is not attributable to a recognisable or known specific pathology” (Airaksinen et al, 2006).

Injury or disease can trigger chronic LBP, but it is perpetuated by factors other than those that caused the pain. It often has psychological, environmental and social problems associated with it, which may play a role in maintaining the pain and result

in increasing disability (Kamper et al, 2014). Evidence shows that chronic LBP can progress beyond just a symptomatic state, including a number of complex changes in the central nervous system (Deyo et al, 2015), thus becoming non-specific. Numerous studies have shown that psychosocial risk factors influence this progression resulting in persistent chronic NSLBP (Koes et al, 2010, Hayden et al, 2010, Ramond-Roquin et al, 2015 and Alhowimel et al, 2018).

2.2.3 Diagnosing Chronic Non-Specific Low Back Pain

Only about four percent of LBP cases have a specific cause, so most LBP cases, $\pm 90\%$, are identified as non-specific (Maher et al, 2017). This makes correctly diagnosing chronic NSLBP an important part of primary care. In an overview of fifteen international clinical practice guidelines regarding the management of NSLBP, Oliveira et al (2018) identified current international recommendations from the Australia, Belgium, Canada, Finland, Malaysia, Mexico, the Netherlands, the Philippines, Spain and the UK for the diagnosis of both acute and chronic NSLBP. Most of these guidelines recommend an initial history taking and physical examination to rule out any signs of serious conditions in both cases and did not recommend the use of routine imagery when making a diagnosis.

Making the diagnosis of acute or chronic NSLBP based solely on the duration of the pain as defined above is also not accurate enough (Balague et al, 2012). There are a number of other factors that need to be taken into account particularly when diagnosing chronic NSLBP, like psychosocial risk factors.

Psychosocial risk factors need to be assessed from the beginning (Chenot et al, 2017) as they play a significant role in the development of chronic NSLBP (Petersen et al, 2017). Eight out of 12 of the international guidelines recommended psychosocial risk factor assessment (Oliviera et al, 2018). Four out of twelve international guidelines, as well as Maher et al (2017) recommended the use of validated prognostic screening tools like the STarT back screening tool and the Orebro Musculoskeletal Pain Screening Questionnaire (OMPSQ) to assess and identify these psychosocial risk factors.

2.3 PSYCHOSOCIAL RISK FACTORS

Evidence shows that psychosocial risk factors are the most common occurring risk factors in the development of chronic NSLBP (Ramond-Roquin et al, 2015), and therefore early identification of these risk factors is essential in preventing chronicity,

determining appropriate treatment interventions and preventing long term disability (Koes et al, 2010).

Psychosocial is defined by the Oxford Dictionary in Blyth et al (2007) as “pertaining to the influence of social factors on an individual’s mind or behaviour, and to the interrelation of behavioural and social factors”. Psychosocial factors are thus the influence of psychological and social factors on a person’s beliefs and behaviour, which are directly related to persistent pain and disability (Van Erp et al, 2017).

Psychosocial risk factors can be divided into two distinct groups (Van Erp et al, 2017) – psychological factors and social factors.

2.3.1 Psychological Factors

The most commonly occurring psychological factors are:

- Stress, distress, anxiety, despondency and depression (Nicholas et al, 2011 and Matsudaira et al, 2015)
- Fear avoidance beliefs (Van Erp et al, 2017 and George et al, 2015)
- Catastrophizing (Alhowimel et al, 2018 and Yoshimoto et al, 2017)
- Passive coping strategies (Ramond et al, 2011 and Nicholas et al, 2011)
- Somatization (Hill et al, 2011b and Yoshimoto et al, 2017)

Authors agree that stress, distress, anxiety, despondency and depression are predictive of time to recovery (Ramond et al, 2011), are associated with increasingly negative outcomes (Nicholas et al, 2011) and are associated with disability in subacute and chronic pain (Heneweer et al, 2007).

Fear-avoidance beliefs are pain-related negative beliefs which can lead to catastrophizing, result in activity avoidance and function restriction (Yoshimoto et al, 2017). Evidence has shown that it is the most common occurring psychosocial risk factor (Van Erp et al, 2017, Nicholas et al, 2011, Alihowimel et al, 2018 and Yoshimoto et al, 2017), and is predictive of increased disability and the development of chronic pain (Ramond et al, 2011).

Catastrophizing is the negative exaggerated perception of pain which leads to maladaptive function (Ogunlana et al, 2015), and can lead to an increased pain experience, an increase in disability (Yoshimoto et al, 2017), and poor outcomes.

Passive coping strategies rely on the assistance of other people to deal with the pain, are characterized by an increased feeling of helplessness (Carroll, 2013), and are also associated with poor outcomes (Nicholas et al, 2011).

Somatization, according to Yoshimoto et al (2017) is the tendency to worry excessively about common somatic symptoms like headaches or dizziness, and in turn affects the pain experience and can be a predictor of other health aspects (Hill et al, 2011b).

2.3.2 Social Factors

Social factors can occur at three levels, according to Blyth et al (2007) - the socioeconomic and legal level, the workplace level and the personal level. The largest body of evidence for social factors that can affect the pain experience occurs at the workplace level (Blyth et al, 2007, Van Erp et al, 2017, Nicholas et al, 2011, Hill et al 2011b, Matsudaira et al, 2015, Yoshimoto et al, 2017 and Yang et al, 2016). Evidence shows that job satisfaction is the most common occurring workplace social factor associated with the development of chronic NSLBP (Matsudaira et al 2015, Yoshimoto et al, 2017 and Hill et al, 2011b). The perception of the workplace as stressful, unsupportive and demanding, along with absenteeism and compensation issues are factors that play a significant role in the development of chronic NSLBP (Ramond et al, 2011 and Nicholas et al, 2011).

2.3.3 Other Factors

There are a number of other risk factors mentioned in the literature that do not fit into the psychological or social factors categories, but still fall under the broad umbrella of psychosocial risk factors, and which play a significant role in the development of chronic NSLBP and long-term disability (Nicholas et al, 2011, Yang et al, 2016, George et al, 2015, Alhowimel et al, 2018 and Hill et al, 2011b)

These risk factors include:

- Older age
- Female
- Poor general health
- Pain intensity
- Higher baseline pain severity
- Extended pain duration
- Pain in multiple sites
- Previous pain episodes

- Greater movement restriction
- Self-efficacy

Evidence has thus established the role of the abovementioned psychosocial factors in influencing pain, long term disability and predicting poor outcomes (Hill et al, 2011b, Nicholas et al, 2011, Alhowimel et al, 2018, Yoshimoto et al, 2017, Yang et al, 2016 and Matsudaira et al, 2015). Therefore, early identification of these risk factors and use of them as predictors or prognostic indicators for poor outcomes will have a significant impact on treatment interventions and long-term recovery.

2.3.4 **Psychosocial Risk Factors as Prognostic Indicators of Chronicity**

Research has shown the connection between the development of chronicity and the presence of psychosocial risk factors (George et al, 2015, Hill et al, 2011b, Wertli et al, 2014), and the benefit of identifying these factors as prognostic indicators (Hayden et al, 2010). Prognostic indicators are defined as “characteristics that help to estimate a patients’ likely outcome irrespective of the chosen management” (Hill et al, 2011b), and therefore are factors that can influence or predict a certain outcome, over time, of a certain condition (Wertli et al, 2014).

The earliest attempt to use prognostic factors to predict outcomes was the use of the “yellow flags” (psychological factors that influence pain-related outcomes) concept (Hayden et al, 2010). This concept was further expanded due to the multi-dimensional nature of prognostic factors to include “blue flags” (workplace and environmental factors) and “black flags” (personal factors). This eventually led to the development of outcome prediction models like the OMPSQ and the STarT back screening tool to guide treatment decisions (Hayden et al, 2010). In a study by Jellema et al (2007), a significant improvement in general practitioner (GP) prediction of high- risk patients with chronic NSLBP was shown when using a prediction model, the OMPSQ and the Low Back Pain Perception Scale (LBPPS). George et al (2015) found the use of psychosocial factors predictive of NSLBP outcomes for pain and disability using the STarT back screening tool.

Current evidence has therefore shown that identifying psychosocial risk factors as prognostic indicators to stratify patients into high, medium or low risk groups through the use of screening tools can improve clinical decision-making and treatment interventions (George et al, 2015, Hayden et al, 2014, , Hill et al, 2011b and Jellema et al, 2007).

2.4 STRATIFICATION OF NSLBP

Stratification of NSLBP involves subgrouping patients based on prognostic risk, causal mechanisms or treatment responsiveness and then matching these subgroups with the most appropriate treatment intervention for their risk profile (Foster et al, 2013). Systematic targeting of treatment occurs to ensure the “right patient gets the right treatment at the right time” (Foster et al, 2013). In contrast, usual management of NSLBP follows a ‘one-size fits all’ approach (Foster et al, 2011) based on clinical intuition instead of on subgrouping.

Stratification as an idea is more than 50 years old (Foster et al, 2013). In 1957, Cronbach stated that “we should design treatment not to fit the average person but to fit groups with particular aptitude patterns, on the assumption that aptitude treatment interactions exist” (Foster et al, 2013). Many clinical fields have been progressing towards “stratified medicine”, with stratification being called the “Holy Grail” of back pain research (Cochrane Back Review Group in Foster et al, 2013). Much research was done on the stratification of back pain, and earlier evidence showed mixed results, with some reviews concluding there was no evidence for stratified care in the clinical setting (Haskins et al, 2012), and others stating that there was not enough evidence of improved outcomes with the stratified approach (Patel et al, 2012). More recent research has broadened focus to include applying stratified care to different size sample populations, as well as assessing resource use, the impact of stratified care on clinical outcomes and the cost of treatment (Foster et al, 2013 and Kent et al, 2010).

Evidence shows that stratifying NSLBP patients into subgroups and basing treatment on this stratification produces better patient outcomes (Benecuik et al, 2015 and Brennan et al, 2006), improvement in physical function, less fear avoidance, less time off work, better use of resources (Foster et al, 2013), and is much more cost effective (Cherkin et al, 2009 and Whitehurst et al, 2012) than when not stratified.

2.4.1 Models of Stratification

Three overlapping models of stratification have been identified by Foster et al (2013) – firstly, the prognostic risk model, which determines patient risk for developing chronic NSLBP and matches appropriate treatment interventions, for example the STarT back screening tool (Hill et al, 2008), which stratifies patients into three risk subgroups – low, medium or high risk. Secondly, the causal mechanisms model, which links treatment to the underlying mechanism or pathology driving the pain, for example the Classification Based Cognitive Function Therapy (CB-CFT) system (Fersum et al,

2009), which stratifies patients across five domains, namely pathoanatomical, neurophysiological, psychosocial, physical and lifestyle. This model links treatment approaches to NSLBP affected specifically by movement and posture. The final model of stratification identified by Foster et al (2013) is the treatment responsiveness model, which links evidence-based treatment to patients who would benefit from that specific treatment, for example the Clinical Prediction Rule (CPR), which identifies a patients' response to manipulation (Rubenstein et al, 2011).

The prognostic risk model appears to be the most clinically beneficial stratification model in that it is able to 'fast-track' appropriate treatment for certain risk groups (medium and high) and guide others (low) away from over investigation and over treatment (Hill et al, 2011). Causal mechanism models are able to address the heterogeneity of LBP, but tend to be unidimensional (Karayannis et al, 2012), and extensive clinician training is needed to effectively implement this approach. The treatment responsiveness model faces the challenge of how to determine which patients will respond to a specific treatment, with only a small portion of patients actually meeting CPR criteria, making implementation of this model challenging (Foster et al, 2013).

2.4.2 Prognostic Screening Tools

The prognostic risk factor model of stratification can be applied through the use of prognostic screening tools (Foster et al, 2013), and international back pain guidelines recommend the use of these screening tools to assist in the management of NSLBP patients, particularly chronic NSLBP (Karran et al, 2017).

A prognostic screening tool describes a self-assessment of predictive factors, which indicate prognosis for musculoskeletal pain (Karran et al, 2017). In a systematic review to investigate the accuracy of various such screening tools, Karran et al, (2017) determined that both the Orebro Musculoskeletal Pain Screening Questionnaire (OMPSQ) and the STarT back screening tool showed acceptable scores for discriminating disability outcomes (pooled Area Under the Curve (AUC) = 0.83 and 0.74 respectively), but showed poor or 'non-informative' results for discriminating pain outcomes (pooled AUC = 0.69 and 0.59 respectively). All the other screening tools identified: the Vermont Disability Prediction Questionnaire (VDPQ), the Back Disability Questionnaire (BDQ), the Absenteeism Screening Questionnaire (ASQ), the Chronic Pain Risk Score (CPRS) and the Hancock Clinical Prediction Rule (HCPR) showed an inability to predict more than one clinical outcome, with limited studies available to

support their prognostic ability. Therefore, the OMPSQ and the STarT back screening tool showed the best evidence as prognostic screening tools.

The OMPSQ compares most closely with the STarT back screening tool in that it identifies patients at risk of developing chronic pain through identifying psychosocial risk factors (Johnson, 2009), and it does this in terms of work-related musculoskeletal pain and function.

The STarT back screening tool was developed to assist in primary care or first contact clinician decision making (Foster et al, 2013). It is simple (a nine-item self-report) and inclusive and matches subgroups of patients to stratified care pathways (Hill et al, 2008), which has a significant clinical benefit.

2.5 THE STarT BACK SCREENING TOOL

The STarT back screening tool (Figure 2.1) was developed as a prognostic screening tool to identify modifiable prognostic risk factors in a primary care setting, subgrouping patients into various risk groups for targeted treatment (Hill et al, 2008). The development and validation process were both extensive (Hill et al, 2008) and numerous post-development studies were done to test the tool's clinical effectiveness, cost-effectiveness and applicability in various clinical settings (Beneciuk et al, 2013, Fritz et al, 2011, Hill et al, 2011, and Kongsted et al, 2011), which will be discussed below.

Patient name: _____ Date: _____

Thinking about the **last 2 weeks** tick your response to the following questions:

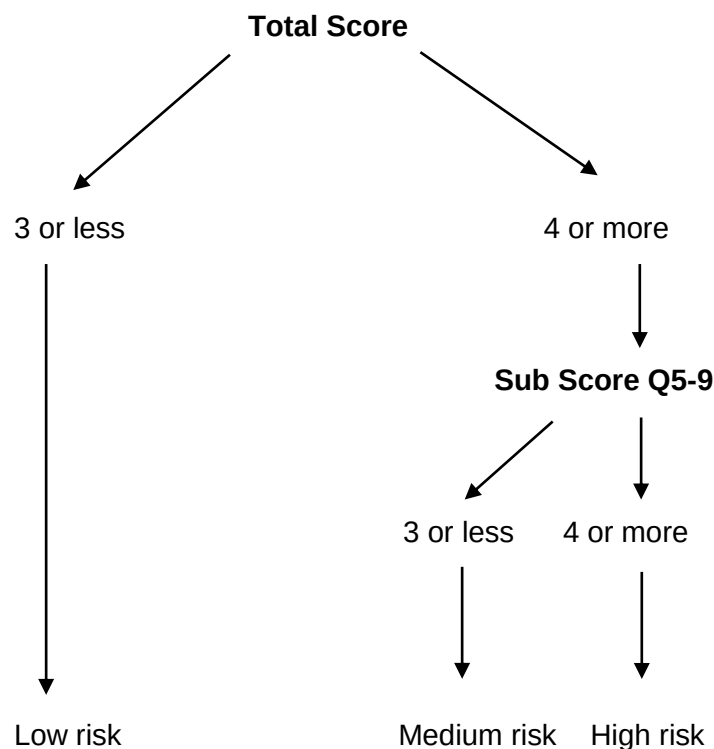
	Disagree	Agree
1. My back pain has spread down my leg(s) at some time in the last 2 weeks	☐	☐
2. I have had pain in the shoulder or neck at some time in the last 2 weeks	☐	☐
3. I have only walked short distances because of my back pain	☐	☐
4. In the last 2 weeks, I have dressed more slowly than usual because of back pain	☐	☐
5. It's not really safe for a person with a condition like mine to be physically active	☐	☐
6. Worrying thoughts have been going through my mind a lot of the time	☐	☐
7. I feel that my back pain is terrible and it's never going to get any better	☐	☐
8. In general I have not enjoyed all the things I used to enjoy	☐	☐
9. Overall, how bothersome has your back pain been in the last 2 weeks ?		
Not at all Slightly Moderately Very much Extremely		
☐ ☐ ☐ ☐ ☐		

0 0 0 1 1

Total score (all 9): _____ Sub Score (Q5-9): _____

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Figure 2.1: The Keele STarT Back Screening Tool



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Figure 2.2: The STarT Back Tool Scoring System

2.5.1 Objectives of the STarT Back Screening Tool

The objectives of the STarT back screening tool (Figure 2.1) are firstly to, identify patients who have possible "treatment-modifiable" prognostic factors, and secondly, to validate cut off scores for subgrouping patients into one of three risk groups (low risk, medium risk, and high risk) (Hill et al, 2008). The low risk subgroup (who score less than three for the total score) (Figure 2.2) are patients with minimal negative identifiable prognostic factors who can be treated with analgesia, advice and education in a primary care setting. The medium risk subgroup (who score more than four for the total score, and three or more for the psychosocial subscale -the sum of questions five, six, seven, eight and nine) (Figure 2.2) consists of patients with higher levels of negative identifiable prognostic factors, where physiotherapy is the treatment of

choice, and the high-risk subgroup (who score more than four for the total score, and four or more for the psychosocial subscale - the sum of questions five, six, seven, eight and nine) (Figure 2.2) are patients with a poorer prognosis and very high levels of negative identifiable prognostic factors, where combining cognitive and physical treatment approaches are necessary (Hill et al, 2008). The tool (Figure 2.1) therefore identifies patients at risk of developing chronic NSLBP, and patient management can thus be stratified according to prognostic risk factors, depending on the score obtained.

2.5.2 Development and Validation of the STarT Back Screening Tool

The development and validation of the STarT back screening tool was done by Hill et al (2008) in four steps:

1. Prognostic indicators were identified, that could be addressed through treatment, by performing a secondary analysis of a randomized control trial and a prospective cohort study as well as a literature review for prognostic indicators for back pain. A list of identified indicators was then reviewed by a clinical advisory panel, which excluded non-modifiable or inappropriate indicators. The panel grouped items as either physical, which consisted of referred leg pain, comorbid pain and disability or psychosocial, which consisted of bothersomeness, catastrophizing, fear, anxiety and depression. This grouping helped to link specific items with the appropriate subgroup and identify items specific to a psychosocial subscale, like catastrophizing, anxiety, fear, depression and bothersomeness.

A small sample of primary care back pain patients (n=12) then assessed patient acceptability of the tool (Hill et al, 2008).

2. Psychometric testing of the screening tool for test-retest reliability, internal consistency and discriminant validity was done in a new group of NSLBP patients, known as the development sample (Hill et al, 2008). A sample of 200 patients were identified and tested.

Overall tool scores best discriminated referred leg pain and disability (AUC = 0.73 and 0.94 respectively), and psychosocial subscale scores best discriminated catastrophizing, fear and depression. Cronbach's alpha for internal consistency for overall scores and the psychosocial subscale scores were 0.79 and 0.74 respectively, with poor internal consistency defined as less than 0.70. No item redundancy was noted. Substantial reliability was demonstrated with test-retest

reliability kappa scores of 0.73 (95% confidence interval (CI) 0.57-0.84) for overall scores and 0.69 (95% CI 0.51-0.81) for psychosocial subscale scores. No floor or ceiling effects were present (Hill et al, 2008).

3. Scoring rules were developed to allocate patients to three subgroups by using the development sample data (Hill et al, 2008)
4. An independent external sample (n=500) was used to investigate the external validity of the subgroups and the predictive validity of the screening tool of primary care back pain patients who were part of an ongoing prospective cohort study (Hill et al, 2008). Forty-seven percent of this sample fell into the low risk subgroup, 38% into the medium risk subgroup and 15% into the high-risk subgroup.

External validity between the external sample and the development sample did not differ markedly, with scores for disability, bothersomeness and fear in the external sample recorded as 0.90 (95% CI 0.88-0.93), 0.89 (95% CI 0.86-0.91) and 0.79 (95% CI 0.75-0.83) respectively, and in the development sample as 0.92 (95% CI 0.88-0.97), 0.92 (0.88-0.97) and 0.81 (95% CI 0.74-0.89).

Age and sex had a small influence on predictive abilities of the screening tool, and older persons and men showed higher positive likelihood ratios (LR's) and lower negative LR's, which demonstrates better outcome discrimination in these patients. At six months follow up, 17% of the low risk subgroup demonstrated poor disability outcomes, with the medium and high-risk subgroups demonstrating 53% and 78% poor disability outcomes respectively, thus showing a stronger predictive ability for extended NSLBP episode duration on disability outcomes in the medium and high-risk subgroups versus the low risk subgroup (Hill et al, 2008).

A finalized list of nine screening questions, emphasizing eight indicators were included in the final version of the tool, namely depression, anxiety, fear, catastrophizing, disability, comorbid pain, referred leg pain and bothersomeness. Two disability items ("In the last two weeks, I have dressed more slowly than usual because of my back pain" and "in the last two weeks, I have only walked short distances because of my back pain") from the Roland Morris Disability Questionnaire (RMDQ) were added, which allowed for more sensitivity (Hill et al, 2008).

Overall scores are determined by adding up the positive responses (the number of agree boxes checked for questions one to nine), and the psychosocial subscale score is determined by the sum of the scores for depression, anxiety, catastrophizing, fear and bothersomeness questions (questions five, six, seven, eight and nine) (Hill et al, 2008). The low risk subgroup is identified by overall scores of 0-3; the high-risk subgroup is identified by an overall score of four or more, and a psychosocial subscale score (questions five, six, seven, eight and nine) of four or more, and the medium risk subgroup by an overall score of four or more and a psychosocial subscale score of three or less (Hill et al, 2008) (Figure 2.2).

The development of the STarT back screening tool by Hill et al (2008) was strengthened by using four large data sets which included three primary care sets of one randomized controlled trial (RCT) and two cohorts, and another cohort which evaluated external validity, increasing the generalizability of the tool.

By using a 'reference standard' instrument, the OMPSQ, concurrent validity was further tested by Hill et al (2010b), to compare the clinical characteristics of the subgroups identified in each tool. Excellent correlation between the STarT back screening tool and the OMPSQ was noted, with Spearman's correlation coefficients for the STarT back tool at 0.82 and the OMPSQ at 0.769. The same proportion of patients were allocated to the low risk subgroup in both tools (40%), with more allocated to the medium risk subgroup in the STarT back tool (35%) versus 22% in the OMPSQ. Less patients were allocated to the high-risk subgroup in the STarT back tool (25%) versus 38% in the OMPSQ. Similar discrimination occurred for disability, time off work, fear, comorbid pain and catastrophizing. The OMPSQ showed better discrimination for pain intensity (AUC 0.891 OMPSQ: AUC 0.825 STarT back) whilst the STarT back tool showed better discrimination for bothersomeness and referred leg pain (AUC 0.848, 0.769 OMPSQ: AUC 0.924, 0.841 STarT back) (Hill et al, 2010b). Therefore, similar abilities to differentiate and similar subgroup characteristics between the OMPSQ and the STarT back tool were found, but Hill et al (2010b) reported that the STarT back tool was less time consuming for patients to complete and for clinicians to score.

2.5.3 Clinical Testing of the STarT Back Screening Tool

The STarT back screening tool has been further tested in various clinical settings. Clinical effectiveness and cost-effectiveness of the stratified approach in the STarT back screening tool was compared to non-stratified current best practice (Hill et al, 2011), and the results showed a significant improvement in treatment satisfaction,

disability, global improvement ratings, quality of life, days off work, pain intensity and physical and emotional functions in favour of the STarT back screening tool. This confirmed improved clinical outcomes and decreased healthcare costs through the use of a stratified care approach. Existing opinion (Deyo et al, 2009) that unnecessary treatment was received by a number of low-risk patients, and that more in-depth treatment for medium-risk and high-risk patients was not being offered was also confirmed. “Psychologically informed physiotherapy” (Hill et al, 2011) made a significant difference in the high-risk patient group.

The use of the STarT back screening tool was also tested in a physical therapy and chiropractic setting (Fritz et al, 2011 and Kongsted et al, 2011). The physical therapy setting (Fritz et al, 2011) demonstrated that the high-risk subgroup reported the highest pain intensity and disability scores, whilst the low-risk subgroup reported the lowest pain intensity and disability scores, with more patients allocated to the medium risk subgroup (48%) than in the original STarT back study (35-38%). This difference could be as a result of the fact that the medium risk subgroup of patients usually has the most modifiable physical prognostic factors and are more likely to be referred to physical therapy than those in the low and high-risk subgroups. The chiropractic setting (Kongsted et al, 2011) demonstrated a good relationship between all the STarT back risk subgroups and established psychological prognostic risk factors (fear-avoidance, depression and catastrophization) measured by the Fear Avoidance Beliefs Questionnaire (FABQ) and the Major Depression Inventory (MDI), showing a positive likelihood ratio (LR) of 7.6 (95% CI 4.9-11.7) for the FABQ, and 3.8 (95% CI 2.3-6.3) for the MDI.

The STarT back screening tool has shown good results when being tested in a clinical setting. It remains a systematic, consistent way to allocate patients to risk subgroups along with matching patients to stratified care pathways (Hill et al, 2010). Thus, for the STarT back screening tool to be effective in assisting clinical decision-making, it needs to be completely understandable by the patient population it is being used upon.

2.6 THE IMPORTANCE OF LANGUAGE

Language is defined as spoken or written human communication (Soanes, 2006), but it is much more than a “structural grammatical system” (Scarino, 2010), it is an interaction between social beings across cultures (Scarino, 2010). Through language we experience the world. It allows us to connect with and learn from others (Del Carpio et al, 2015), and shapes the way we interact with the world.

Language comprehension is one of the most complex but automatic tasks that a human being performs on a daily basis (Van Dyke, 2016). There are 6912 languages still spoken in the world, many of which are spoken in a number of dialects (The Importance of Languages, 2017). All these languages carry cultural values and traditions, shaping people's identities and influencing interpersonal relationships. They are the source of a vast amount of information about the origin, social status, gender and ethnicity of a people, and are the vehicles for social and cultural learning (Esseily et al, 2016). Culture is defined by language, through the people who speak it (Del Carpio et al, 2015), with culture being defined by Sirbu (2015) as "the lifestyle of a community, the way its members behave, their beliefs, their values and the way they communicate".

"Every act of language, be it written or spoken, is a statement about the position of its author within the social structure in a given culture" (Sirbu, 2015). Each language is the means of expression and reflection of the cultural heritage of people (The Importance of Languages, 2017), and is the keeper of the memories of a culture. It maintains a link between a culture's past and present and protects its uniqueness (The Importance of Languages, 2017).

Article five of the United Nations Educational, Scientific and Cultural Organization's (UNESCO's) Universal Declaration on Cultural Diversity (in The Importance of Languages, 2017) states that everyone should be able to communicate in their own mother tongue, thus making translation of languages vital to the fabric of a functioning society.

2.6.1 The South African Context

South Africa is a diverse nation of approximately 56.52 million people (Stats SA, 2017), with a diverse language and cultural heritage (The 11 languages of South Africa, 2019). Approximately 51% of the population are female, 30% of the population are younger than 15 years and 8% are 60 years or older (Stats SA, 2017). Life expectancy for males is approximately 61 years and for females 67 years, with infant mortality rate estimated at 33 per 1000 live births (Stats SA, 2017).

South Africa is a multilingual society with 11 official languages (The 11 languages of South Africa, 2019) -isiZulu, isiXhosa, Afrikaans, Sepedi, Setswana, English,

Tshivenda, Sesotho, isiNdebele, Xitsonga and Siswati. Most South Africans speak at least two or more of these official languages (Stats SA, 2017), and are able to switch between more than one language in a single conversation (The 11 languages of South Africa, 2019). isiZulu is the most widely spoken of all the languages in South Africa, with almost 25% of the population speaking it as their home language (The 11 languages of South Africa, 2019).

South Africa remains a unique, culturally diverse country, with unique, culturally diverse languages, and being able to communicate, that is to understand and be understood, is vital to all aspects of life.

2.7 TRANSLATION/CULTURAL ADAPTATION

Translation seeks an equivalent for the original meaning which must preserve the original context (Translation, 2018). Its ultimate purpose is thus to demonstrate the “original tone and intent” of a text whilst taking cultural differences between the source and target languages into account (Translation, 2018).

The process of translation includes analysis, wherein the text in the source language is analysed for grammar and meaning, transfer, wherein the analysed text is transferred into the target language and restructuring, wherein the transferred text is restructured to make it more understandable (Essays, UK, 2013). A text is taken through this process to “reproduce particularities of the original text and its musicality” (Essays, UK, 2013).

Translation is not just translating each word into a similar word in another language and then rearranging the words to fit that specific languages’ word order. Some words have different meanings in different contexts and each language has certain idioms that do not make sense when translated word for word. Furthermore, words that describe certain cultural practices or ideas do not always translate precisely into another language (Del Carpio et al, 2015).

Translation is therefore a means of communication which transfers cultural characteristics and cultural context from one language to another, focussing on how the target audience will understand the text.

2.7.1 Translation/Cultural Adaptation of the STarT Back Screening Tool into other Languages

The STarT back screening tool has been translated into 35 languages worldwide (Appendix 22), with most of the translations following Beaton et al's (2000) guidelines for translation and cultural adaptation. Minor linguistic and cultural differences were experienced in most of the published translations.

The Finnish (Piironen et al, 2016), and the Dutch (Bier et al, 2017) versions of question one ("My back pain has spread down my leg(s) at some time in the last 2 weeks") posed a challenge to their translators. The Finnish version translated "spread down my leg(s)" as "radiated" and "leg" as "lower extremity", (Piironen et al, 2016), and the Dutch translators translated "my leg(s)" to mean "to one or both legs" (Bier et al, 2017), which were both found to be more relevant and easier to understand than the original version.

Question five ("It's not really safe for a person with a condition like mine to be physically active") posed a challenge in most of the translated studies. The Spanish (Gusi et al, 2011), German (Aebischer et al, 2015) and Swedish (Betten et al, 2015) studies noted patient uncertainty in understanding the meaning of "physically active", as different interpretations of the term exists. The Finnish (Piironen et al, 2016) and Italian study (Maggiani et al, 2019) noted that patients confused the term "physically active" with "exercise", and they decided to keep their translations as close to the original English term "physically active" as possible instead of "exercise".

Translating question six ("Worrying thoughts have been going through my mind a lot of the time") was also found to be challenging for most of the translated studies. The Danish study (Morso et al, 2011) translated it as "I have been worried a lot of the time". The Brazilian Portuguese study (Pilz et al, 2014) translated it as "worrying thoughts have been going through my mind a lot of the time due to the pain in my back", and there was no equivalent in French (Bruyere et al, 2012), so it was translated to mean "I have often been concerned about the pain in my back".

The Finnish translation (Piironen et al, 2016) was the only study that found translating the word "terrible" in question seven ("I feel that my back pain is terrible and it's never going to get any better") challenging and translated it to "very difficult". The Danish translation (Morso et al, 2011) was the only study that found uncertainty with the response options of "agree/disagree" and changed them to "yes/no".

Question nine (“Overall, how bothersome has your back pain been in the last 2 weeks?”) with the term “bothersome”, was a challenging term to translate for two of the translated studies. The Finnish version (Piironen et al, 2016) translated it as “disruptive” and the Danish version (Morso et al, 2011) translated it as “overall, how much of an irritation...”, whilst the Swedish version (Betten et al, 2015) experienced challenges with the Likert answering scale in this question. They had found that the words that could be used were grammatically incorrect or changed the intended meaning of the statement. It was thus decided by their expert committee to use the grammatically incorrect words as they were the easiest to understand: the word “slightly” was thus back translated to mean “somewhat”, and a translation for “very much” was used that attempted to keep the grading between the alternatives as close as possible to the original English version.

Cultural differences were noted as the most difficult challenges when translating some English words into Chinese (Mandarin) (Luan et al, 2014), particularly when using the term “low back pain” which confused Chinese patients who normally refer to pain in the lumbosacral region as “lumbago”. It was decided that the translated term for “low back pain”, instead of “lumbago”, was to be used as it is more widely accepted around the world (Luan et al, 2014).

The Portuguese (Raimundo et al, 2017) and Spanish (Gusi et al, 2011) were the only two studies that did not follow a standardized translation and cross-cultural adaptation process (Beaton et al, 2000). Both studies tested their forward translations on a patient population before back translation and the expert committee review occurred, as in all the other studies, relying heavily on patient interpretation of the forward translation before the full translation process was completed.

The expert committee in most of the studies played a significant role in clearing up minor cultural and linguistic differences that occurred during the translation and cross-cultural adaptation process (Beaton et al, 2000). All of the abovementioned translation studies, along with the original English version (Hill et al, 2008) tested the pre-final version of their translated tools on a small sample population, ranging from two to forty patients, for usability, which prepared the way for a more in-depth validation process.

The STarT back screening tool has only been translated into one of the official languages of South Africa - Afrikaans (Keele University, 2017) which is spoken by only

14% of South Africans (The 11 languages of South Africa, 2019), with no evidence on the translation and validation process yet been published.

2.8 VALIDITY AND RELIABILITY

Measurement tools capture the value of certain abstract concepts (Bolarinwa, 2015), and need to measure what they intend to measure, so establishing their validity and reliability is essential.

Two measures of validity occur - external and internal validity (Roberts et al, 2006). External validity determines how accurately the tool is able to describe the sample population and be applied in other situations (Bolarinwa, 2015), whereas internal validity determines the accuracy of the tool to quantify that which it should measure (Bolarinwa, 2015). Face validity, content validity, construct validity and criterion validity are all measures of internal validity.

Reliability refers to how accurately the results of a tool can be reproduced (Bolarinwa, 2015). It consists of the degree to which a tool stays the same over time, and how similar tools are in a particular time frame (Golafshani, 2003).

Validity and reliability thus both contribute to the validation process of the STarT back screening tool and have been determined in a number of ways in the various translations of the tool, namely face validity, content validity, construct validity, criterion-related validity, test-retest reliability and internal consistency.

2.8.1 Validity and Reliability of the STarT Back Screening Tool in Other Languages

The validation of the STarT back screening tool in other languages followed two methods. Firstly, through an expert committee who tested the theoretical constructs in the questionnaire by testing face validity and content validity (Bolarinwa, 2015). Secondly, through the testing of the questionnaire in a sample population by testing criterion-related validity, which included predictive and concurrent validity, and by testing construct validity, which included convergent and discriminant validity (Bolarinwa, 2015).

Face validity, which determines if the questionnaire measures the concepts just on the face of it (Bolarinwa, 2015), was tested in the Chinese-Mandarin (Luan et al, 2014) and the Portuguese (Raimundo et al, 2017) studies, and both showed acceptable face

validity with no ambiguity. Content validity, which determines if the questionnaire fully measures the theoretical constructs it should (Bolarinwa, 2015), was only tested by the Dutch study, which found good content validity (Bier et al, 2017).

The testing of face validity and content validity in a translation study is an important part of the validation process (Bolarinwa, 2015), as they determine whether the translated questionnaire is really measuring the theoretical constructs that were developed in the original questionnaire (Hill et al, 2008). The literature shows only three translation studies – the Chinese-Mandarin (Luan et al, 2014), Portuguese (Raimundo et al, 2017) and Dutch (Bier et al, 2017) testing either face validity or content validity. Validity is therefore the measure of what a questionnaire intends to measure (Bolarinwa, 2015), and there are numerous variations of validity testing available, as described by the various translation studies. Bolarinwa (2015) is of the opinion that any variation of validity tests can be done on a questionnaire, as long as they test whether they are measuring what they should be measuring, and they clearly describe the reference population. The majority of the abovementioned translation studies have tested at least one aspect of validity, which is enough to declare them valid (Bolarinwa, 2015).

The Dutch study (Bier et al, 2017) was also the only study that tested predictive validity, testing the ability of the questionnaire to predict outcomes (Bolarinwa, 2015). A relative risk ratio (RR) of 1.8 (95% CI 1.0-3.1) for the medium risk group was shown, compared with the low risk group for persisting disability, for persisting pain 1.6 RR (95% CI 0.9-3.0) and for perceived recovery 1.0 RR (95% CI 0.7-1.3). A risk ratio of 1.8 indicates that a patient with medium risk had 1.8 times higher chance for developing persisting disability than the low risk group. The risk ratios for the high-risk group was 2.7 (95% CI 1.4-4.9) for persisting disability, 3.4 RR (95% CI 2.3-6.8) for persisting pain and 0.6 RR (95% CI 0.3-1.2) for perceived recovery compared to the low risk group. During the development of the original English STarT back screening tool, predictive ability for disability was tested at six months only, as the tool was mainly developed as a primary care back pain screening tool and not as a long- term back pain predictive tool. Thus, no other translated studies tested predictive validity.

Concurrent validity compares the questionnaire against an existing standard measure (Bolarinwa, 2015). The Swedish (Betten et al, 2015) translation of the STarT back screening tool was compared to the OMPSQ and showed a large correlation between the total scores and psychosocial scores of both tools, with all patients allocated to the

high-risk STarT back group, also being allocated to the high-risk group in the OMPSQ (Betten et al, 2015). The Japanese (Matsudaira et al, 2016) translation was compared to the Numeric Pain Rating Scale (NPRS), the RMDQ, the FABQ, the Pain Catastrophizing Scale (PCS), the Hospital Anxiety and Depression Scale (HADS), the 11-item Tampa Scale of Kinesiophobia (TSK-11) and the EuroQol 5 Dimension Scale (EQ-5D), with results showing moderate to strong correlation of both the total score and psychosocial scores with the other questionnaires. The German (Aebischer et al, 2015), French (Bruyere et al, 2012) and Persian (Abedi et al, 2015) studies showed similar correlations between their STarT back translation and the RMDQ, the TSK-11, the PCS and the HADS questionnaires with regards to both total and psychosocial scores.

The Persian (Abedi et al, 2015), Dutch (Bier et al, 2017), Finnish (Piironen et al, 2016) and French (Bruyere et al, 2014) studies tested the construct validity of their studies - how meaningful the questionnaire is when it is used in practice (Bolarinwa, 2015). The Persian study used Pearson's correlation coefficient (above 0.40) and the French study used Spearman's correlation coefficient (0.74) to show excellent correlation with the RMDQ. The Dutch study, using Pearson's correlation coefficient, showed moderate to high correlation with the NPRS for question nine ($r = 0.6$), with the RMDQ for questions three and four ($r = 0.5$) and with the PCS for question eight ($r = 0.5$). The Finnish study found moderate correlation with the OMPSQ, using Spearman's correlation coefficient (0.31-0.45).

A number of the validation studies also examined discriminative validity, testing the difference in concepts within the same questionnaire (Bolarinwa, 2015) using Area Under the Curve (AUC) calculations. The Danish (Morso et al, 2012) study showed similar AUC results to the original English study, but lower AUC results for the three psychosocial sub-score items of anxiety, catastrophization and depression, and the German (Aebischer et al, 2015) study showed strong discriminative ability with AUC's similar to the original English study. The Chinese study (Luan et al, 2014) showed similar discriminative validity for questions three to six, and lower discriminative validity for questions seven and eight. The Persian (Abedi et al, 2015) study showed a similar discriminative validity to the Dutch version, but lower than the original English version.

Validity is therefore the measure of what a questionnaire intends to measure (Bolarinwa, 2015) and there are numerous variations of validity testing available, as described by the various translation studies. According to Bolarinwa (2015) the

preferred methodology for determining the validity of a tool is to either use a panel of experts or through a field test, and he is of the opinion that any variation of these validity tests can be done on a questionnaire, as long as they test whether they are measuring what they should be measuring, and they clearly describe the reference population. The majority of the abovementioned translation studies have tested at least one aspect of validity, which is enough to declare them valid (Bolarinwa, 2015).

Reliability of the STarT back screening tool in other languages was examined through test-retest reliability, testing the stability of the translation over time (Bolarinwa, 2015), and through internal consistency, testing whether the questions measure the same thing (Bolarinwa, 2015).

The Brazilian Portuguese (Pilz et al, 2014), the Portuguese (Raimundo et al, 2017), the Chinese-Mandarin (Luan et al, 2014), the Persian (Abedi et al, 2015), the Finnish (Piironen et al, 2016), the French (Bruyere et al, 2014), the German (Karstens et al, 2015) and the Norwegian (Robinson et al, 2017) studies all showed good test-retest reliability, ranging from 0.7 to 0.8, which correlated with the original English tool.

Internal consistency was tested in the Brazilian Portuguese (Pilz et al, 2014), the Portuguese (Raimundo et al, 2017), Finnish (Piironen et al, 2016), French (Bruyere et al, 2014), Persian (Abedi et al, 2015) and the Japanese (Matsudaira et al, 2016) studies, all showing good internal consistency (0.70-0.75), which was again similar to the original English tool.

Reliability tests the ability of a questionnaire to produce consistent responses over time, which is important when using a questionnaire as an objective form of measurement. A lack of reliability affects the validity of a questionnaire (Bolarinwa, 2015). Only two translation studies did not test reliability – the Swedish (Betten et al, 2015) and Danish (Morso et al, 2011) studies, which could possibly affect the validity of their translations.

The validation process thus differed in many of the translated versions of the STarT back screening tool but most correlated well with the original English study. Overall, most of the translated versions of the STarT back screening tool measured what they intended to measure and produced results that were representative of the study populations and that could be accurately reproduced.

2.9 CONCLUSION

The increasing prevalence and cost of NSLBP highlights the need for effective diagnosis and management, particularly regarding the psychosocial component. Psychosocial prognostic risk factors play a huge role in the long-term course of NSLBP, and the use of a standardized validated prognostic back screening tool to stratify patients based on these risk factors can assist clinicians in determining appropriate treatment interventions.

Prognostic back screening tools need to be fully understood in all languages, so that the meaning of the tool can be transferred into a different culture and context. Translation enables this transfer of culture and context from one language to another. Although thirty-five translations (Appendix 22) of the STarT back screening tool have been done, and many of these translations have been validated and proved reliable, allowing the use of the tool in a wide range of cultures and contexts, there is still a lack of validation in the South African context. This is particularly evident in the lack of an isiZulu translation, which is the most widely spoken language in South Africa.

CHAPTER 3

3. METHODOLOGY

This chapter describes in detail the study design, participant sample and the methodology used in this study. It is described in two phases – the translation phase and the validation phase (Figure 3.1.)

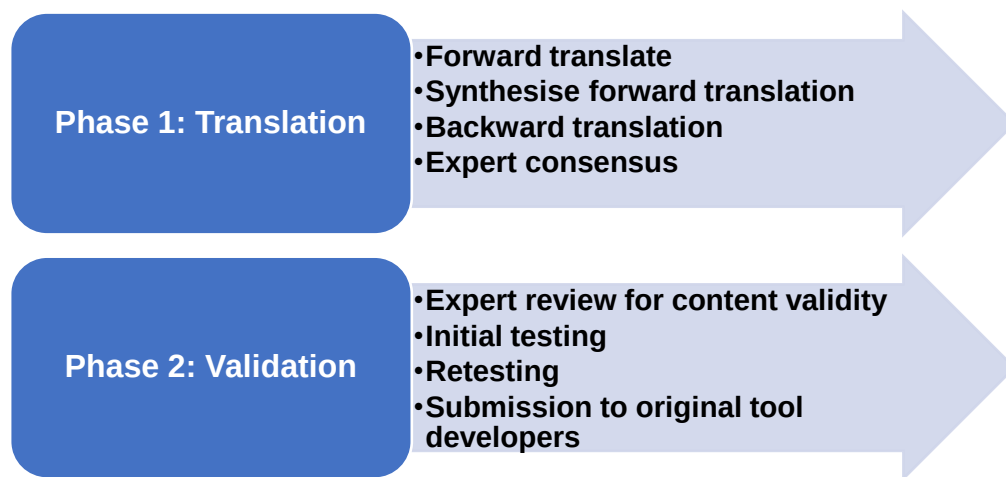


Figure 3.1: Diagrammatic Representation of the Study Methodology

The methodology in this study follows the same procedure outline in Beaton et al (2000), who described the steps to follow when translating and validating a tool into a different language.

3.1 TYPE OF STUDY

1. Translation study which included forward translation, translation synthesis, back translation and expert committee review.
2. Validity study which included content validity, test-retest reliability, usability and internal consistency.

3.2 PHASE ONE: TRANSLATION

The aim of this phase of the study was to translate the original STarT back screening tool into isiZulu.

3.2.1 Participants

3.2.1.1 Source of participants

The participants in this phase of the study included two forward translators (they translated the tool from English to isiZulu), two backward translators (they translated the tool from isiZulu to English) and an expert committee (healthcare professionals, language professionals and the forward and back translators).

To forward translate the STarT back screening tool into isiZulu, an isiZulu first language speaking, medically trained person, and an isiZulu first language speaking university-educated, non-medically trained person from Witbank/eMalahleni were recruited (Beaton, et al, 2000).

To back translate the STarT back screening tool into English, two second language English speaking individuals, proficient in isiZulu, but non-medically trained, from Wits Translate, were recruited (Beaton et al, 2000).

To review the translation for consensus, an expert committee of health professionals, language professionals and the forward and back translators from Wits Translate and Witbank/eMalahleni respectively, were recruited (Beaton, et al, 2000). The experts in this study comprised of three physiotherapists (two MSc graduates and one PhD graduate), one language professional (MA graduate), and both forward and back translators, all with at least five years' experience in their respective fields.

3.2.1.2 Sample selection

Purposive sampling was used in this phase, based on the guidelines established by Beaton et al (2000), for the process of cross-cultural adaptation of self-report measures.

3.2.1.2.1 Inclusion criteria

For forward translation:

- A medically trained isiZulu first language speaker - an informed participant ("aware of the concepts being examined in the questionnaire being translated") (Beaton, et al, 2000) and,
- A university educated, non- medically trained isiZulu first language speaker – an uninformed participant ("neither be aware nor informed of the concepts being quantified") (Beaton, et al, 2000).

For back translation:

- Two second language English speaking individuals, proficient in isiZulu, non-medically trained.

For expert review:

- One healthcare professional proficient in isiZulu and English.
- Two healthcare professionals proficient in English, with translation experience.
- One language professional proficient in isiZulu and English.
- Aforementioned forward and back translators.

3.2.2 Instrumentation and Outcome Measures

The original English STarT back screening tool was used for translation (Appendix 3). Four large data sets were used to demonstrate the original tool's reliability and validity. Secondary analyse of one prospective cohort study (n=739) and one RCT (n=402) were used to identify prognostic indicators in primary care and then develop the tool. Two hundred patients were then recruited for psychometric testing of the tool, and a final fourth independent external cohort (n=500) was recruited to evaluate the external validity of the tool. All cohorts were LBP patients recruited from different general practices in the UK. Good reliability and validity of the tool was established. Test-retest reliability kappa scores for the overall tool scores were 0.73 (95% CI 0.57 – 0.84) and for the psychosocial subscale 0.69 (95% CI 0.51 – 0.81), showing substantial reliability of the tool. External validity was demonstrated by AUC scores (95% CIs) for disability as 0.90 (0.88 – 0.93), for bothersomeness 0.89 (0.86 – 0.91) and for fear 0.79 (0.75 – 0.83) in the fourth independent external cohort (n=500) (Hill et al, 2008).

3.2.3 Procedure

3.2.3.1 Main study

Two translators, an informed, medically trained and an uninformed, non-medically trained translator, from Witbank/eMalahleni were recruited from a local private hospital and a local community project respectively (Appendix 7 and 8), to forward translate the English version of the STarT back screening tool (Appendix 3) into isiZulu. Translation 1 (T1) (Appendix 14) and translation 2 (T2) (Appendix 15) (Beaton et al, 2000) were developed (Figure 3.2).

T1 and T2 were compared, and discrepancies (ambiguous words or incorrect word choices) were discussed between the researcher and the translators, until a consensus on a common translation was reached (Beaton et al, 2000). Synthesis of these two translated screening tools (T1 and T2) were done, and a new screening tool (T12) (Appendix 16) was produced (Beaton et al, 2000) (Figure 3.2).

Two new blinded English second language uninformed, non-medically trained individuals (Appendix 9 and 10), proficient in isiZulu back translated the T12 screening tool into English (Beaton et al, 2000), producing translations BT1 (Appendix 17) and BT2 (Appendix 18) (Figure 3.2).

The expert committee reviewed all the screening tools (T1, T2, BT1 and BT2), discussed discrepancies, and consolidated all the screening tools to develop the preliminary translated isiZulu STarT back screening tool (Appendix 19) (Beaton et al, 2000) (Figure 3.2).

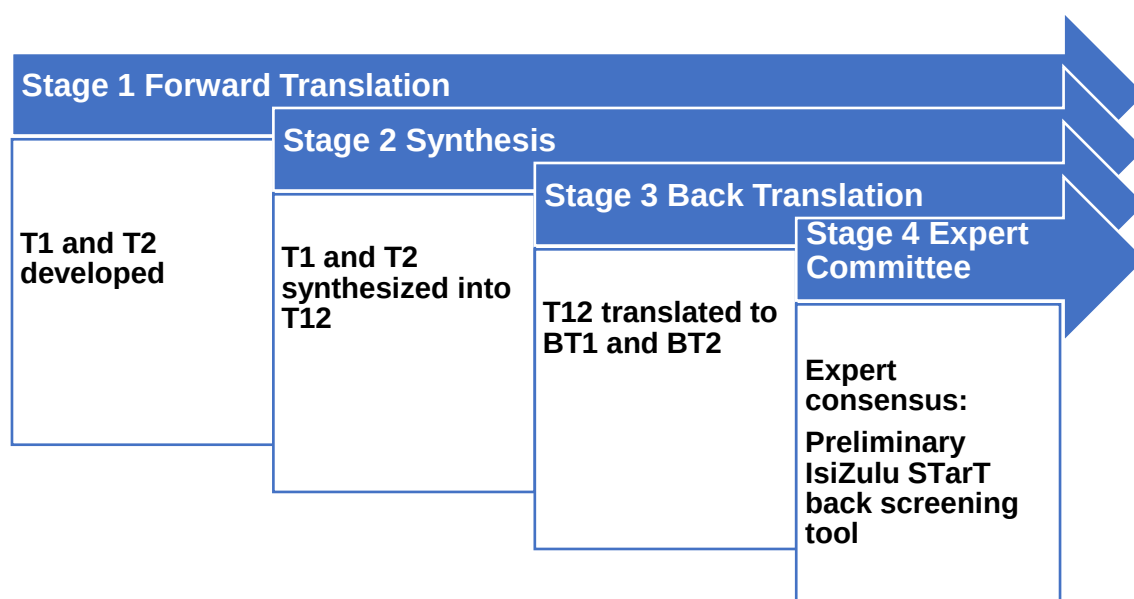


Figure 3.2: Diagrammatic Representation of Phase One: Translation

3.3 PHASE TWO: VALIDATION

The aim of this phase of the study was to validate the preliminary translated isiZulu STarT back screening tool. The tool was validated by testing item (I-CVI) and scale (S-CVI) content validity, as well as through test-retest reliability, usability and internal consistency (Figure 3.3).

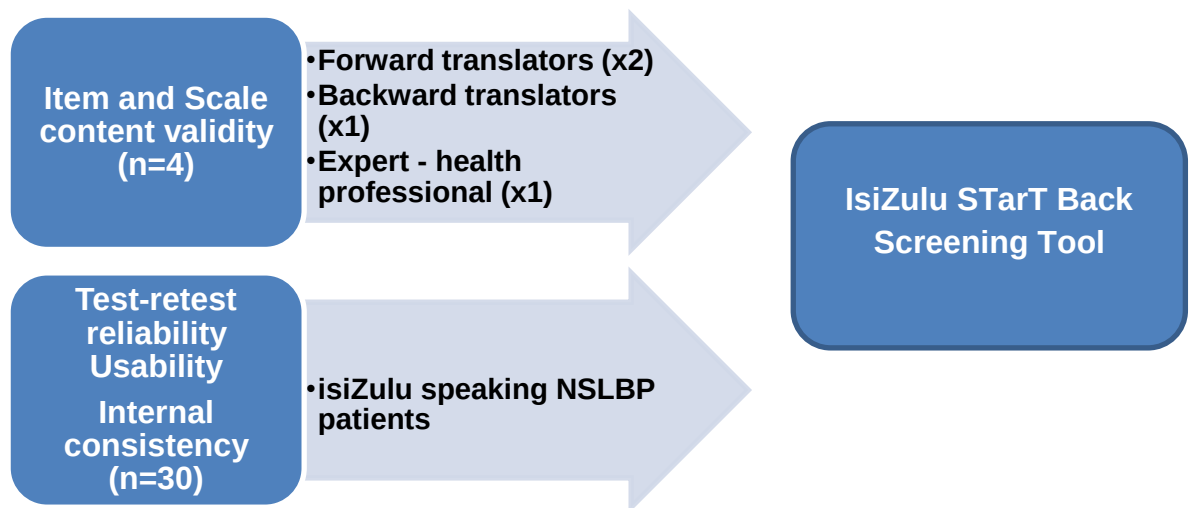


Figure 3.3: Diagrammatic Representation of Phase Two: Validation

3.3.1 Participants

3.3.1.1 Source of participants

The forward translators, one backward translator and one healthcare professional from the expert committee, proficient in isiZulu and English were recruited (Beaton et al, 2000), to test item (I-CVI) and scale (S-CVI) content validity.

To test the test-retest reliability, internal consistency and usability, isiZulu speaking South African's presenting with acute and chronic NSLBP were recruited from Erasmus Physiotherapists (Appendix 1), Witbank General Hospital, Siphosensimbi CHC and Lynnville Polyclinic (Mpumalanga Department of Health) in Witbank/ eMalahleni (Appendix 2) (Beaton, et al, 2000).

3.3.1.2 Sample selection and sampling technique

This phase of the study used a sample of convenience.

3.3.1.2.1 Inclusion criteria

For item and scale content validity:

- One medically trained isiZulu first language speaker, informed participant (forward translator).
- One university educated, non- medically trained isiZulu first language speaker, uninformed participant (forward translator).
- One English second language speaker, proficient in isiZulu, non-medically trained (backward translator).
- One healthcare professional proficient in isiZulu and English.

For test-retest reliability, internal consistency and usability:

isiZulu South African males and females aged 18 years and older with acute or chronic non-specific low back pain, with or without associated leg pain, willing to participate in this study, and able to return two weeks later for re-testing, were included.

3.3.1.2.2 Exclusion criteria

For item and scale content validity:

Non-university educated, non-Zulu speaking and reading persons.

For test-retest reliability, internal consistency and usability:

Patients with potentially serious pathology (cauda equina, cognitive, neurologic or rheumatologic disease, fracture of the spine, and malignancy), current specific diagnoses like disc herniation or spondylolisthesis, spinal surgery in the last six months, pregnancy, and those who do not read or speak isiZulu, were identified through a subjective interview.

3.3.1.2.3 Sample size calculation

Polit et al (2006) and Yaghmaie (2003) recommended a panel of four experts, to determine item and scale content validity, as the minimum number of participants required.

The formula for the calculation of the sample size was $N = [16p(1-p)]/w^2$ where p is the expected intraclass correlation coefficient (ICC) of 0.9 and w is the width of the 95% CI. The expected ICC and the maximum width of 95% confidence interval (CI) was based on translation and validation studies done in Xhosa, Afrikaans and English populations (Morris et al, 2012). Therefore, based on an ICC of 0.9 and a maximum width of 0.23, the minimum total sample size was calculated to be 27 subjects.

3.3.2 **Instrumentation and Outcome Measures**

A self-developed demographic questionnaire was used to obtain information regarding gender, age, educational level, employment status, occupation and previous back pain history (Appendix 5a and 5b).

The preliminary translated isiZulu STarT back screening tool was used for validation (Appendix 19)

A self-developed post-retest evaluation questionnaire (Appendix 6) was used to determine if there were any factors affecting test-retest reliability, and to determine the usability of the translated questionnaire.

3.3.3 Procedure

3.3.3.1 Main study

The preliminary translated isiZulu STarT back screening tool (Appendix 19) was reviewed for I-CVI by the four intended experts (section 3.3.1.2.1.) They were asked to use a four-point ordinal scale to rate each question/item based on relevance, clarity, simplicity and ambiguity. (Appendix 20) (Yaghmaie, 2003) which included the following:

- 1 = not relevant (not clear/not simple/doubtful)
- 2= question needs some revision
- 3= relevant (clear/simple/no doubt, but needs minor revision)
- 4= very relevant (clear/simple/meaning is clear)

Scale content validity was subsequently calculated based on these results, by adding the I-CVI for each aspect (relevance, clarity, simplicity and ambiguity) and dividing this by the total number of aspects to get the average (I-CVI for relevance + I-CVI for clarity + I-CVI for simplicity + I-CVI for ambiguity/4).

The preliminary translated isiZulu STarT back screening tool (Appendix 19) was then tested on the intended patient population (Beaton et al, 2000), and again two weeks later (Hill et al 2008) a re-test of the preliminary translated isiZulu version on the same intended patient population was performed (Beaton et al, 2000). Transport costs for each participant were reimbursed by the researcher. The post-retest questionnaire was also administered at this point (Appendix 6), within which each patient reported on the ease of comprehension of the translated tool, the ease of completing the tool, the time needed to complete the tool (5 minutes, 10 minutes, 15 minutes and 20 minutes), and any suggestions to improve the clarity of the tool (Beaton et al, 2000).

The participants were sent reminders via SMS to attend follow-up visits at the same place where they were recruited (Erasmus Physiotherapists, Witbank General Hospital, Siphosensimbi CHC and Lynnville Polyclinic (Mpumalanga Department of Health) in Witbank/ eMalahleni). There was no control for confounding factors during the two weeks until follow up.

After all the testing and re-testing was completed, the pre-final version of the translated isiZulu STarT back screening tool was submitted to the original developers of the tool (Beaton et al, 2000) (Appendix 19). This allowed the original developers the opportunity to test the translated tool to determine if all the stages of development recommended by Beaton et al (2000) were followed. Once the original developers of the STarT back screening tool were satisfied with the translation and validation process, the translated isiZulu tool was made available on their website: <https://startback.hfac.keele.ac.uk/training/resources/start-back-translations/>

3.4 ETHICAL CONSIDERATIONS

Approval from the Health Research Ethics Committee (HREC) of the University of the Witwatersrand was obtained (Appendix 21). Permission to translate and validate the STarT Back screening tool into isiZulu was obtained from the original authors at the Keele University in North Staffordshire, England (Appendix 11). An informed consent form was read and signed by all eligible subjects prior to participating in the study (Appendix 12a, 12b, 13a and 13b). Confidentiality of data and subject information was maintained. A unique study identification number/code was allocated to each subject on recruitment, to ensure anonymity. The participant personal information was stored separately, in a locked cupboard, and the researcher was the only one who had access to this information. Participants in phase two of this study were reimbursed for transport costs.

3.5 DATA ANALYSIS

Data was collected, collated and entered into an Excel spreadsheet. Descriptive statistics analysed the data regarding socio-demographic information and previous history of low back pain. Information about dropouts and missing data was also recorded.

Content validity was determined by calculating item rating or I-CVI and scale level rating or S-CVI and measured the representativeness and comprehensiveness of the items in a scale (Yaghmaie, 2003), as well as the degree to which the instrument measures a specific construct (Bolarinwa, 2015).

I-CVI was calculated as the number of experts giving a rating of three or four divided by the total number of experts, for each question/item. I-CVI should be 1.00 when there are five or less experts (Polit et al, 2006). This was done to ensure that the translated version of the STarT back screening tool was understood in the local context

and language, and that the questions/items measured what they intended to measure (Polit et al, 2006).

Scale content validity is the proportion of the total number of items that are content valid, or the proportion of items that received a score of three or four by the experts (Polit et al, 2006). Scale content validity was calculated by adding the I-CVI for each aspect (relevance, clarity, simplicity and ambiguity) and dividing by the total number of aspects to get the average (I-CVI for relevance + I-CVI for clarity + I-CVI for simplicity + I-CVI for ambiguity/4) (Polit et al, 2006). Scale content validity is thus the average number of items rated as three or four across the questions/items for relevance, clarity, simplicity and ambiguity (Polit et al, 2006). Scale content validity of 0.80 or higher is considered acceptable (Polit et al, 2006).

Test-retest reliability was measured using Spearman's correlation coefficient, with coefficients higher than 0.8 showing good to excellent reliability and 0.6 to 0.8 showing good reliability, while less than 0.6 shows poor reliability.

Internal consistency index of reliability or homogeneity is the degree to which the questions or items in the tool measure the same thing (Bolarinwa, 2015), and the higher the internal consistency index of reliability value, the more reliable the measure. The internal consistency index of reliability of this tool was evaluated by calculating Cronbach's alpha coefficients for the total score (questions 1 - 9) and for the psychosocial subscale (questions 5, 6, 7, 8 and 9). An alpha index equal to or more than 0.90 is considered excellent (Bolarinwa, 2015); equal to or more than 0.80 is considered good; equal to or more than 0.70 is considered acceptable; equal to or more than 0.60 is considered questionable, whilst less than 0.60 shows poor internal consistency.

Usability is the extent to which a tool is able to be used by participants within its specific context (Glover et al, 2007). A self-administered post-retest questionnaire was given to each participant after the second round of testing was completed, to evaluate their utility, efficiency, learnability and satisfaction (Nielsen, 2012) with the tool. Descriptive statistics was used to analyse the data.

Table 3.1: Data Analysis

Objective	Type of Data	Statistical Test	Method/Mean
To describe the study population	Descriptive (continuous data)	Frequency distributions	Demographic questionnaire
To translate the STarT back screening tool into isiZulu	Content validity (the degree to which the instrument measures a construct) (categorical data)	I-CVI S-CVI	Preliminary translated questions in tool rated by four experts on a 4-point ordinal scale
To validate the preliminary translated STarT back screening tool in an isiZulu speaking population of non-specific back pain patients	Test-retest reliability (reliability of test over time) (categorical data)	Spearman's correlation coefficient	Tested and retested preliminary translated tool in the sample population
	Internal consistency index of reliability (extent to which questions measure the same thing) (categorical data)	Cronbach's Alpha coefficients	Calculated for questions 1-9 of preliminary translated tool
	Usability (degree to which a tool is able to be used by participants in its specific context) (continuous data)	Frequency distributions	Self-administered post-retest questionnaire after second round of testing of preliminary translated tool

3.6 CONCLUSION

Ethical clearance was obtained from the HREC of the University of the Witwatersrand along with permission from the original developers to translate and validate the STarT back screening tool in isiZulu. This study was done in two phases.

Phase one was the translation phase, where the original STarT back screening tool was forward translated into isiZulu, synthesized into one translation and then back translated into English. Thereafter an expert committee reviewed all the translated tools (forward and back) and formulated the preliminary translated isiZulu STarT back screening tool.

Phase two was the validation phase. The preliminary translated isiZulu STarT back screening tool was reviewed for I-CVI and S-CVI content validity by four experts and then tested on the intended isiZulu population. It was retested two weeks later. A

post-retest questionnaire was also administered at this time. The pre-final version of the translated isiZulu tool was then submitted to the original developers of the STarT back screening tool.

Spearman's correlation coefficient determined the test-retest reliability of the tool. Cronbach's Alpha was calculated to determine the internal consistency of the tool, and usability of the tool was determined through a self-developed questionnaire and analysed using descriptive statistics.

CHAPTER 4

4. RESULTS

The aim of this study was to translate the STarT back screening tool into isiZulu and validate the translated version in an isiZulu population of NSLBP patients. This chapter will present the results of the study.

4.1 PHASE ONE: TRANSLATION

Minor linguistic differences emerged during the forward and back translation phases which were addressed in consultation with the expert committee.

For questions one and two “sometime” was translated to mean “other time” in isiZulu, as there is no word that means exactly the same thing as “sometime” in isiZulu. In question three the word “wami” was added to the preliminary translated tool by the expert committee to confirm the translation said ‘my’ back pain and not ‘the’ back pain. The expert committee also adjusted the tense of the sentence to mimic that of the original, changing “ngihamba” to “ngihambe”, adjusting it to mean walked (past tense) and not walk (present tense).

The words “more slowly” in question four were translated to mean “long time” in isiZulu, as no isiZulu word for slowly exists. In question five the words “physically active” were initially translated as “avocavoce” which means *mostly exercise* with a bit of other activity. The expert committee agreed that the meaning of “physically active” relates to being physically active during activities of daily living (ADL’s) and not specific exercises. The word “avocavoce” was thus changed to “anyakazise” to mean *general activity*, which better aligns with the original text.

The translators agreed that the term “worrying thoughts” in question six could be translated in a number of different ways, either to mean worry or stressful. It was decided that “engikhatazayo” which means *bothering me* was the closest translation, as worry and stressful are understood as the same concept in isiZulu. The phrase “a lot of the time” in question six was initially translated to mean *all the time* – “ngasosonke isikhathi”, but the expert committee agreed to the translation of “izikhathi eziningi” which means *many times* and better resembles the original text. The forward and back translators found the word “terrible” in question seven difficult to translate, as no

specific word exists in isiZulu. The expert committee agreed to “ngizwa sengathi” which means *I feel like* and better covers the original meaning of the word.

Difficulty was found in translating “in general” and “enjoy” in question eight, as no direct translated words exist in isiZulu. The expert committee revised the full sentence to convey the meaning of these two terms – “Angizange ngizithokozele izinto engivame ukuzijabulisa ngazo njengenjwayelo” which translates as *I did not enjoy the things I usually enjoy*.

The word “bothersome” in question nine is not a word often used in Africa, and does not exist in isiZulu, so the expert committee agreed to the most common translation “kukuhlophe kangakanani” to be used, which means *to bother or trouble*.

All the above changes were made, and the preliminary final translation (Appendix 19) was resubmitted to the expert committee for editing. No further changes were required, and this preliminary final translation (Appendix 19) was used in the validation process.

4.2 PHASE TWO: VALIDATION

4.2.1 Demographic characteristics

A summary of the demographic characteristics of the sample population is given in Table 4.1. A total of 37 patients were recruited to participate in the study, with seven patients not returning for the second round of testing. Two questionnaires were declared invalid due to missing data (with one or more questions/items unanswered).

Table 4.1: Demographic Characteristics (n=30)

Variable	Category	Frequency (n)	%
Gender	Male	7	23%
	Female	23	76%
Age	21-29yrs	4	13%
	30-39yrs	2	6%
	40-49yrs	8	26%
	50-59yrs	12	40%
	60 – older	4	13%
Level of	Primary school	10	33%

Variable	Category	Frequency (n)	%
Education	High school	16	53%
	University	4	13%
Occupation	Sedentary	3	10%
	Non-sedentary	9	30%
	Unemployed	18	60%
Hours worked	40 hours per week	7	23%
	Less than 40 hours per week	4	13%
	Retired	3	10%
Previous history of back pain	None	15	50%
	Falls	5	16%
	Physical violence	1	3%
	MVA's	2	6%
	Back and neck injury	2	6%
Risk groups Test one	Low risk	6	20%
	Medium risk	6	20%
	High risk	18	60%
Test two	Low risk	6	20%
	Medium risk	4	13%
	High risk	20	60%

The majority of the participants (76%) were females; with a large number (40%) in the 50-59yr old age category. Fifty-three percent had high school level of education. The majority of the participants (60%) were unemployed; 30% of the employed had non-sedentary work, while 23% of the employed participants worked for 40 hours per week. The majority of the participants (50%) had no previous history of back pain.

4.2.2 Content Validity

Content validity is the measure of what a questionnaire intends to measure (Yaghmaie, 2003), and is divided into two components, item content validity (I-CVI) and scale content validity (S-CVI), which were both measured in this study.

4.2.2.1 Item content validity (I-CVI)

Item content validity for relevance was excellent (mean I-CVI= 1.00), as an I-CVI of 1.00 is required when there are five or fewer experts (Polit et al, 2006).

Table 4.2: Item Content Validity for Relevance (n=4)

Question	Expert 1	Expert 2	Expert 3	Expert 4	Number of experts in agreement	Item CVI
1	4	4	4	4	4	1.00
2	4	4	4	4	4	1.00
3	4	4	4	4	4	1.00
4	4	4	4	4	4	1.00
5	4	3	4	4	4	1.00
6	4	3	4	4	4	1.00
7	4	4	4	4	4	1.00
8	4	4	4	4	4	1.00
9	4	4	4	4	4	1.00
						Mean I-CVI= 1.00

Item content validity for clarity was satisfactory (mean I-CVI = 0.94).

Table 4.3: Item Content Validity for Clarity (n=4)

Question	Expert 1	Expert 2	Expert 3	Expert 4	Number of experts in agreement	Item CVI
1	4	4	3	4	4	1.00
2	4	4	4	4	4	1.00
3	4	4	4	4	4	1.00
4	4	4	4	4	4	1.00
5	3	-	4	4	3	0.75
6	4	-	4	4	3	0.75
7	3	4	4	4	4	1.00
8	4	4	4	4	4	1.00
9	3	4	4	4	4	1.00
						Mean I-CVI= 0.94

Item content validity for simplicity was satisfactory (mean I-CVI = 0.94).

Table 4.4: Item Content Validity for Simplicity (n=4)

Question	Expert 1	Expert 2	Expert 3	Expert 4	Number of experts in agreement	Item CVI
1	4	4	4	4	4	1.00
2	4	4	4	4	4	1.00
3	4	4	4	4	4	1.00
4	4	4	4	4	4	1.00
5	3	-	4	4	3	0.75
6	4	-	4	4	3	0.75
7	3	4	4	4	4	1.00
8	4	4	4	4	4	1.00
9	3	4	4	4	4	1.00
						Mean I-CVI= 0.94

Item content validity for ambiguity was satisfactory (mean I-CVI = 0.94).

Table 4.5: Item Content Validity for Ambiguity (n=4)

Question	Expert 1	Expert 2	Expert 3	Expert 4	Number of experts in agreement	Item CVI
1	4	4	4	4	4	1.00
2	4	4	4	4	4	1.00
3	4	4	4	4	4	1.00
4	4	4	4	4	4	1.00
5	3	-	4	4	3	0.75
6	4	-	4	4	3	0.75
7	4	4	4	4	4	1.00
8	4	4	4	4	4	1.00
9	4	4	3	4	4	1.00
						Mean I-CVI= 0.94

4.2.2.2 Scale content validity (S-CVI)

Scale content validity was calculated by adding the I-CVI for each category (relevance, clarity, simplicity and ambiguity) and dividing by the total number of categories to get the average (Appendix 23).

The S-CVI for the final translated isiZulu STarT back screening tool is 0.955, which agrees with Polit et al's (2006) recommendation of a S-CVI being considered acceptable when 0.80 or higher.

4.2.3 Test-Retest Reliability

Test-retest reliability determines the reliability or stability of a test over a period of time (Bolarinwa, 2015), and is measured using Spearman's correlation coefficient. Coefficients higher than 0.8 showing good to excellent reliability, 0.7 to 0.8 showing acceptable reliability and 0.6 to 0.7 showing questionable reliability (Test-retest reliability, 2018).

A total of 30 reliability, test-retests were done in this study, and Spearman's correlation coefficient for reliability between test one and test two was 0.73, which demonstrates acceptable test-retest reliability.

Table 4.6: Test-Retest Reliability

Sample size (n)	Spearman's correlation coefficient (rho)	Significance level (p)	95% confidence interval
30	0.73	0.0001	0.381-0.820

4.2.4 Internal Consistency

Internal consistency is the degree to which the questions or items in the tool measure the same construct (Bolarinwa, 2015). The internal consistency was evaluated by calculating Cronbach's alpha coefficients for questions 1 – 9. An alpha index of more than 0.70 is considered acceptable internal consistency (Bolarinwa, 2015).

Cronbach's alpha was calculated for the total score (questions 1 to 9) of the isiZulu STarT back screening tool as 0.68, and for the psychosocial subscale (questions 5, 6, 7, 8 and 9) as 0.68.

Thus, the total score (questions 1 to 9) showed less than acceptable internal consistency (0.68), and the psychosocial subscale (questions 5, 6, 7, 8, and 9) also showed less than acceptable internal consistency (0.68).

4.2.5 Usability

Usability is the degree to which a tool is able to be used with ease by participants within its specific context (Glover et al, 2007). A self-administered post-retest questionnaire (Appendix 6) was given to each participant after the second round of testing was completed, to evaluate the usability of the tool.

Ease of understanding questions 1-9 of the translated tool ranged from 33% rating it very easy to three percent rating it very difficult (Figure 4.1). Ease of completion of questions 1-9 of the translated tool ranged from very easy (40%) to moderately difficult (10%) (Figure 4.2). Time to complete the questionnaire was calculated, with 23% completing it in five minutes, 43% completing it in 10 minutes, 13% completing it in 15 minutes and 20% completing it in 20 minutes (Figure 4.3). The post-retest questionnaire also asked for suggestions on any changes that could be made to the translated tool or the testing process. Twenty-seven percent requested assistance with explaining the individual questions (Table 4.7).

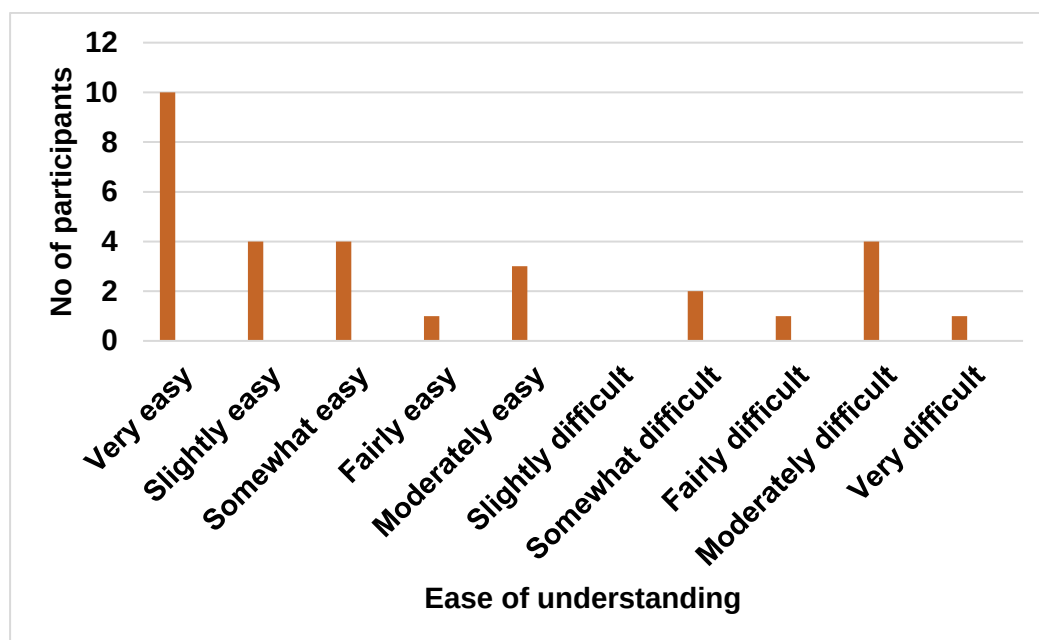


Figure 4.1: Ease of Understanding Translated Tool (n=30)

The majority of the sample population (72%) found the translated tool easy to understand, with only a quarter (25%) finding it difficult to understand.

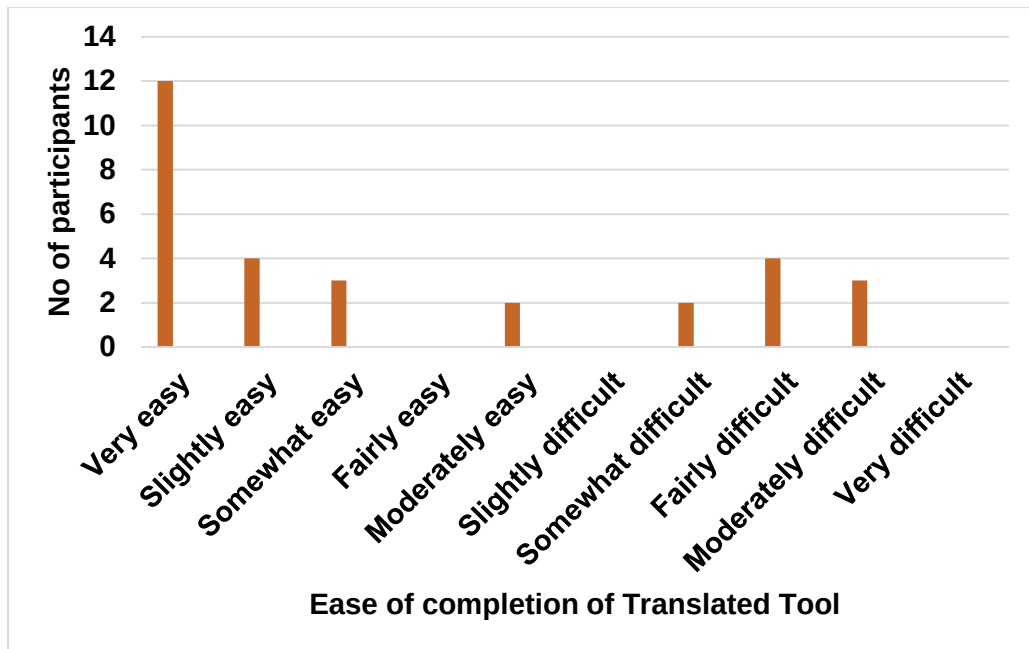


Figure 4.2: Ease of Completion of Translated Tool (n=30)

The majority of the sample population (69%) found the translated tool easy to complete, with a little more than a quarter (29%) of the sample population finding it difficult to complete.

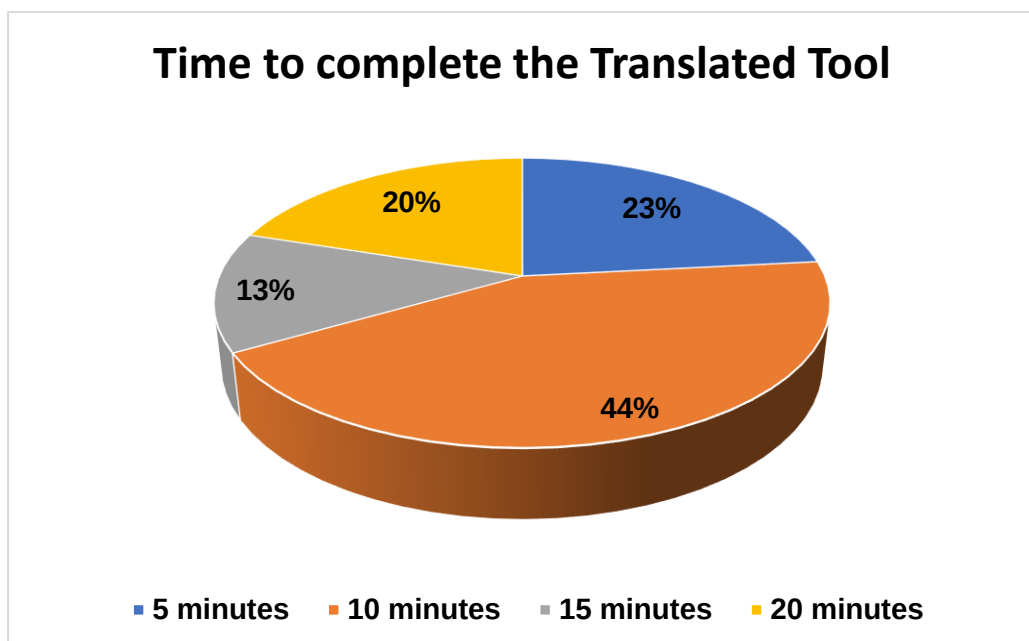


Figure 4.3: Time to Complete the Translated Tool (n=30)

The majority of the sample population (44%) took 10 minutes to complete the tool, with a quarter of the sample population taking 5 minutes (23%) and 20 minutes (20%) respectively.

Table 4.7: Participants' Suggestions (n=30)

Variable	Category	Frequency (n)	Percentage (%)
Suggestions	None	19	63%
	Include more questions about lifting, bending and standing	1	3%
	Prefer tool in English	1	3%
	Need assistance with explanation of questions	8	27%
	Title of tool needs to be translated	1	3%

Sixty-three percent were satisfied with the translated tool.

4.2.5.1 Additional information obtained from the participants

Forty percent of the study sample reported a change in their back pain within the two-week period between tests, and 60% reported no change in their back pain (Table 4.8). Thirty percent reported additional injuries to their back within the two-week period, with 70% reporting no additional injuries (Table 4.8).

Table 4.8: Changes to Back Pain and Additional Injuries (n=30)

Variable	Category	Frequency (n)	Percentage (%)
Changes to back pain in the past two weeks	Yes	12	40%
	No	18	60%
Additional injuries to the back in the past two weeks	Yes	9	30%
	No	21	70%

The majority of the sample population reported no changes (60%) and no additional injuries (70%) to their back pain in the two weeks between test one and test two.

4.3 CONCLUSION

The minor linguistic differences that occurred during the translation phases were addressed and adjusted by the expert committee to produce the preliminary isiZulu translated tool which was used in the validation process.

Item content validity of the translated tool showed good validity, and S-CVI was acceptable at 0.955. Acceptable test-retest reliability (0.73) and less than acceptable (0.68) internal consistency for the total score (questions 1 to 9) and the psychosocial subscale (0.68) was obtained.

The tool was easy to understand (72% finding it easy to understand) and complete (69% finding it easy to complete), with the majority completing the tool in 10 minutes. The most significant suggestion from the study population was the need to have assistance when completing the questionnaire, however the majority showed complete satisfaction with the tool as a whole.

CHAPTER 5

5. DISCUSSION

The aim of this study was to translate the STarT back screening tool into isiZulu and then to validate the translated version in an isiZulu population of NSLBP patients, by testing the content validity, test-retest reliability, internal consistency and the usability of the translated version.

The study results show that the isiZulu STarT back screening tool is linguistically accurate and acceptable and is a valid and reliable prognostic back screening tool for use in an isiZulu NSLBP population.

5.1. PHASE ONE: TRANSLATION

Standardised outcome measures provide baseline information that can be used to objectively evaluate treatment outcomes, guide clinicians in evidence-based practice and assess changes over time (Kyte et al, 2015). In order to be used effectively these standardised outcome measures should be available in the language of the population being treated. Although the original STarT back screening tool has been translated into 35 other languages (Appendix 22), no translation/ cross-cultural adaptation in isiZulu was available. The original English questionnaire administered to an isiZulu population proved difficult to obtain reliable information due to the language nuances, therefore the need for a valid and reliable cross-cultural adaptation process. The translation procedure applied in this study followed the guidelines set out by Beaton et al (2000), which were also applied in the Finnish (Piironen et al, 2016), Dutch (Bier et al, 2017), Italian (Maggiani et al, 2019), Persian (Abedi et al, 2015), Chinese (Luan et al, 2014), Swedish (Betten et al, 2015), Brazilian Portuguese (Pilz et al, 2014), German (Aebischer et al, 2015), Danish (Morso et al, 2012) and French (Bruyere et al, 2012) translation studies.

The problems experienced with translation in general are finding the equivalent words without altering the meaning of the original sentence. This was evident in many of the translated studies (Aebischer et al, 2015, Betten et al, 2015, Bier et al, 2017, Bruyere et al, 2012, Gusi et al, 2011, Maggiani et al, 2019, Morso et al, 2011, Piironen et al, 2016 and Pilz et al, 2014). To overcome this problem the following guidelines were followed in many of the studies, including the isiZulu translation – firstly, the closest possible translation for a specific word was used, secondly, the closest possible

translated meaning for a phrase was used, and thirdly, sentence structure was adjusted to convey the closest possible meaning to the English version.

The word “sometime”, in question one¹ and question two² in the isiZulu translation process was disputed by the back translators, because back translator two (BT2) and back translator one (BT1) translated it to mean “other time” and “sometime” respectively. An intense debate ensued between the back translators and the expert committee and eventually all of them agreed that “other time” and “sometime” actually means the same thing in isiZulu, and therefore the term “kwezinye izikhathi” was accepted and included in the final translation of questions one and two. Similar difficulties were experienced with question one and question two in the Finnish (Piironen et al, 2016) and the Dutch (Bier et al, 2017) translation studies with the phrase “spread down my leg(s). The Finnish translated “spread down” as “radiate”, and “legs” as “lower extremity”, because in Finnish the word “legs” refers to the extremity without a foot. The Dutch translated “legs” as “to one/both legs” to include the ‘s’ written in brackets in the original version.

Question three³ challenged both the forward and back translators regarding the translation of the correct tense of the word “walked”, as well as translating the phrase “my back pain”. Minor changes like adding “wami” which changed the back translation from “the back pain” to “my back pain” and changing “ngihamba” – “I’m going” to “ngihambe” – “to go” made the sentence structure and tense of the isiZulu version much more accurate. No other translation studies had problems with translating question three.

The phrase “more slowly” in question four⁴ was translated by the forward translators to mean “long time” (isikhathi eside), instead of “more slowly”. After much discussion in the expert committee, it was decided that there is no other way to translate this phrase into isiZulu, so “isikhathi eside” was used. No other translation studies had similar problems.

¹ “My back pain has spread down my leg(s) at some time in the last 2 weeks”

² “I have had pain in the shoulder or neck at some time in the last 2 weeks”

³ “I have only walked short distances because of my back pain”

⁴ “In the last 2 weeks, I have dressed more slowly than usual because of back pain”

The phrase “physically active” in question five⁵ challenged both the forward and back translators, as well as the expert committee in this study. A lengthy debate around the meaning of “physically active” occurred - “does *physically active* mean exercise or activities of daily living (ADL’s)?” It was initially translated by the forward translators as “avocavoce” meaning mostly exercise with a bit of other activity, but after some discussion the expert committee came to the consensus that the phrase should be translated to mean being physically active during ADL’s and not doing specific exercises. “Anyakazise” was used instead, changing the meaning to general activity and not specific exercises. Similar difficulties were experienced in the German (Aebischer et al, 2015), Swedish (Betten et al, 2015) and Italian (Maggiani et al, 2019) translation studies, whilst the Finnish (Piironen et al, 2016) study described the phrase as difficult for Finnish laymen to understand. Ultimately the expert committees in these studies decided to keep the wording as close to the original English version as possible, so as not to lose the meaning entirely.

Back translator one (BT1) and back translator two (BT2) produced different translations of question six⁶, back translating the word “engikhathazayo” to mean “stressful” and “worry” respectively. The expert committee queried this difference, debating if this term in isiZulu really conveyed the meaning of “worrying”. After much discussion, it was decided that worrying and stressful are the same concept in isiZulu, so the word “engikhatazayo” was used to cover both meanings. This is similar to the French (Bruyere et al, 2012) translation who do not have an equivalent word for “worry” in their vocabulary. In contrast the Danish (Morso et al, 2011) and Finnish (Piironen et al, 2016) studies both experienced some difficulty with the time factor in this question, which may have caused some ambiguity in their final translations. The Danish translation eventually translated this question as “I have been worried a lot of the time” and the Finnish translated it as “I have often been concerned about my condition”. Similarly, the Brazilian Portuguese (Pilz et al, 2014) study found that this question was not understandable by more than 20% of the patients in their first pretest, so they had to adapt it to “worrying thoughts have been going through my mind a lot of the time due to the pain in my back”.

No specific word exists in isiZulu for the word “terrible” in question seven⁷, so the forward translators used the word “sebubukhulu”. The back translators back translated

⁵ “It’s not really safe for a person with a condition like mine to be physically active”

⁶ “Worrying thoughts have been going through my mind a lot of the time”

⁷ “I feel that my back pain is terrible and it’s never going to get any better”

it to mean “the back pain has increased or gotten bigger”. The expert committee wanted to ensure that the translated question must mean “the back pain is terrible” and “not increasing”, so after much discussion, the word “sebubukhulu” was removed and “kakhulu” added, making the final translation the closest to the original meaning in isiZulu. Only the Finnish (Piironen et al, 2016) study had a similar experience, as there are a number of meanings for the word “terrible” in Finnish, but none correspond to the meaning of the word in English. They therefore used “very difficult” in their translation.

The forward and back translators struggled to translate question eight⁸, experiencing difficulty finding appropriate isiZulu words for the phrase “in general” and the word “enjoy”. After much discussion the expert committee restructured the translated sentence to as close as possible to the original meaning as possible. No other studies reported similar challenges with translating this question.

“Bothersome” in question nine⁹ is not a word usually used in Africa, so the forward translators translated it to mean “bother” or “trouble” (“kukuhlophe kangakanani”), which the expert committee agreed meant the same thing and was closest to the original study. No equivalent words in the Finnish (Piironen et al, 2016) and the Danish (Morso et al, 2011) studies were found, so a word closest to the original meaning was used, and they back translated it to mean “disruptive” and “irritation” respectively.

Therefore, finding the closest meaning to certain phrases and certain words without changing the meaning of the original construct seemed to be the biggest challenge in all of the abovementioned translation studies, including the isiZulu version.

All the translation challenges and changes to the isiZulu version were addressed and approved by the expert committee prior to testing the validity, reliability and usability of the translated tool. This process occurred in all the translated versions as well as in the development of the original STarT back screening tool (Hill et al, 2008).

⁸ “In general, I have not enjoyed all the things I used to enjoy”

⁹ “Overall, how bothersome has your back pain been in the last 2 weeks”

5.2. PHASE TWO: VALIDATION

5.2.1. Demographic characteristics

South Africa has one of the most complex and diverse populations on the African continent, with 79% of the population black Africans, nine percent coloured or white and three percent Indian (Stats SA, 2017). South Africa also has 34 established languages (30 living and 4 extinct) and after the constitution was amended in 1996, 11 official languages were recognized. The average South African speaks 2.84 of these languages and uses more than one language in a single conversation (The 11 languages of SA, 2019). Different regions of South Africa consist of different cultures and languages, with almost one quarter (23%) of the population speaking isiZulu as their home language, and 58% speaking it as their second language. English is the dominant language in major cities across South Africa but is only spoken as a second language by black Africans in most other areas in the country, including Witbank/eMalahleni, Mpumalanga, where up to 24% speak isiZulu, and where this study took place (The 11 languages of SA, 2019).

The majority of the sample population were female (77%) in the 50 to 59yr age category. Many of the other translation/validation studies also showed a higher percentage of females in their sample population, but in the 40 to 49yr age category (Hill et al, 2008, Morso et al, 2011, Piironen et al, 2016 and Raimundo et al, 2017). This correlates well with the literature which shows a higher prevalence of low back pain onset in women between the ages of 30 and 50 years of age (Nicholas et al, 2011 and Yoshimoto et al, 2017), which does not differ in the developed versus the developing world (Louw et al, 2007).

This study showed that a majority of the sample population were only high school educated (53%) which was similar to the Swedish (64%) (Betten et al, 2015), Portuguese (32%) (Raimundo et al, 2017)) and Brazilian Portuguese (60%) (Pilz et al, 2014) studies. None of the other translation studies, including the original English study examined the education levels of their sample populations, suggesting the assumption that education levels would not influence their translation process. This assumption could be true in developed countries but may not ring true in developing countries.

A number of the translation studies identified employment status in their participants (Hill et al, 2008, Karstens et al, 2015, Piironen et al, 2016 and Robinson et al, 2017)

highlighting the majority of patients being employed or receiving disability benefits, whereas the majority of participants (60%) in this study were unemployed and receiving no employment or disability benefits. This difference is to be expected as this study is one of the only studies done in developing Africa, where resources are limited, income inequality exists and the majority of the population do not have access to disability benefits or unemployment funds (UNDP, 2017). With the exception of the Brazilian-Portuguese study (Pilz et al, 2014), most of the other studies were done in developed countries, where disability grants and unemployment benefits are easily available like the UK that provides extensive financial assistance in the form of Universal Credit, Disability Living Allowances and Employment and Support Allowances (GOV.UK, 2019). Socio-economic status affects physical and mental well-being as well as quality of life (APA, 2019), and in developing Africa, limited resources, income inequality and poverty lead to a lower socio-economic status. Lower socio-economic status is increasingly associated with negative physical and psychological health outcomes (APA, 2019), which in turn affects family and community well-being.

This population sample was not attending the primary health care clinic specifically for their back pain, whereas many of the other translation studies had patients seeking treatment specifically for low back pain at private outpatient physiotherapy clinics (Abedi et al, 2015, Hill et al, 2008, Karstens et al, 2015, Morso et al, 2011 and Piironen et al, 2016). The majority of this population sample was stratified into the high-risk group, which may suggest that the patients are either not actively seeking treatment for their back pain, in contrast to those in many of the other translation studies or, are not getting the correct treatment when their back pain begins. The possibility also exists that the staff at the local primary care clinics in Mpumalanga are not educated on the correct treatment pathways for these patients and thus do not know that these patients should be referred for physiotherapy or interdisciplinary treatment.

The legacy of apartheid presents a significant challenge for the education and health systems in South Africa, where equal education opportunities were not provided for all race groups. African people were on the receiving end of this inequality, which has thus resulted in lower educational levels for the majority of black people, a lack of educational resources and a shortage of qualified teachers (UK Essays, 2016). This has led to a lack of basic information regarding health and wellness, particularly amongst those above the age of 50 years (UK Essays, 2016). This correlates with the majority of this study's participants (77% in the 50-59yr age category), and the age prevalence of NSLBP (30-60yrs) (Maher et al, 2017). In a survey on healthcare system

efficiency, South Africa was ranked last among 19 countries and only spent 8.8% of its GDP on healthcare in 2017, whilst the US spent 19.1% and France 11.5% (Fin24, 2017). Resources at most government healthcare facilities in South Africa are severely limited, and along with increased staff shortages and poor dissemination of information to the public results in poor patient care (Medical Brief, 2016). Many of the participants in this study demonstrated lower levels of education, which could suggest that they do not have access to basic healthcare information, due to the abovementioned education inequalities and healthcare challenges. Apartheid also resulted in language barriers being created amongst its' people, with most non-black South Africans not proficient in indigenous languages like isiZulu, and many black South Africans not proficient in English. Therefore, in order to obtain reliable information, questionnaires must be available in the language a person is proficient in, and hence this study.

5.2.2. Content Validity

The two components of content validity were measured: item content validity (I-CVI) and scale content validity (S-CVI). Item content validity for relevance was excellent, however clarity, simplicity and ambiguity were found to be satisfactory, as one expert failed to rate two of the questions a 3 or 4 which is required for an excellent item content validity rating. Scale content validity (S-CVI) was considered acceptable. Measuring a questionnaire's content validity measures the questionnaire's quality, which is a necessary part of developing an appropriate tool. This suggests that acceptable content validity ensures that the content is relevant and appropriate, particularly when culturally adapting a specific tool.

Content validity was tested using four language experts and a specific scoring scale to minimize the subjective nature of testing content validity. One translation study (Bier et al, 2017) and the original English tool (Hill et al, 2008) specifically tested content validity, but based their content validity scores on floor and ceiling effects (Bier et al, 2017). For floor and ceiling effects to be present, some items need to be missing in the lower and upper ends of the scale, which results in limited content validity (Terwee et al, 2007). Floor and ceiling effects were not tested in this study, as the recommended sample size (Terwee et al, 2007) to test these effects on is at least 50 patients, and this study's sample size was only 30.

Other outcome measure translation studies (Morris et al, 2012) tested face validity and content validity simultaneously, using a group of patients to report on the ease of understanding and ease of completing the translation. This study did not test face

validity, as it is an even more subjective test than content validity (Bolarinwa, 2015), but used a panel of experts to test content validity, and the sample population to report on usability of the isiZulu tool.

Criterion-related (predictive and concurrent) validity as well as construct validity were the most frequently tested forms of validity tested in other outcome measure translation studies (Mphahlele et al, 2008, Sharafi et al, 2017 and Tsang Chi Chung et al, 2017). They were not tested in this study, due to the fact that the STarT back tool is a screening tool and does not predict future change (predictive validity), and there is a lack of a single reference standard tool already translated into isiZulu that screens for similar constructs (construct validity).

5.2.3. Test-Retest Reliability

According to this study, the test-retest reliability of the preliminary isiZulu STarT back screening tool shows acceptable reliability with an ICC of 0.73 (95% CI 0.38 – 0.82) for the total score, which is similar to that of the original version for the total score (ICC of 0.73 95% CI 0.57- 0.84) (Hill et al, 2008). The Brazilian-Portuguese (Pilz et al, 2000), Portuguese (Raimundo et al, 2017), Finnish (Piironen et al, 2016) and German (Karstens et al, 2015) studies also demonstrated acceptable reliability with ICC ranging from 0.70 to 0.78.

5.2.4. Internal Consistency

Internal consistency in this study (Cronbach's alpha) showed less than acceptable results for both the total score (0.68) and the psychosocial subscale (0.68). This was less than the original English version (0.74 total score and 0.74 psychosocial subscale) (Hill et al, 2008), as well as the Brazilian-Portuguese (Pilz et al, 2000), Portuguese (Raimundo et al, 2017), Finnish (Piironen et al, 2016), French (Bruyere et al, 2014), Persian (Abedi et al, 2015) and Japanese (Matsudaira et al, 2016) versions. Internal consistency measures how well items in a tool measure the same thing, and this is achieved through good construct definitions (Terwee et al, 2007). The difference in the results could be due to the way the constructs of the original English version were translated, with many words and phrases not existing in the isiZulu language. It could also be due to a less educated sample population not understanding the translated concepts clearly, particularly the negative wording of some of the questions (Bolarinwa, 2015). Thus, the isiZulu translation shows less than acceptable internal consistency compared to the original version and other translations, with lower correlation between items in the total scale and the psychosocial scale. This results

in less than acceptable reliability of the tool, which suggests the need to retest the translated tool on a different sample population.

5.2.5. **Usability**

Usability of the isiZulu preliminary translated tool was measured by examining the ease of understanding the questions of the translated tool (33% of the sample population rated it very easy), the ease of completion of the questions (40% rated it very easy), and the time taken to complete the questionnaire (43% completed it in 10 minutes). All the other translated versions (Abedi et al, 2015, Aebischer et al, 2015, Betten et al, 2015, Bier et al 2017, Bruyere et al, 2012, Gusi et al 2011, Karstens et al, 2015, Luan et al, 2014, Maggiani et al, 2019, Morso et al 2012, Piironen et al, 2016, Pilz et al 2000 and Raimundo et al 2017) as well as the original English version (Hill et al, 2008) tested the usability of their tools on a small sample size ($n = 12 - 30$), and also found good acceptability, ease of understanding and ease of completion. The participants in this study took longer to complete the questionnaire than the other versions (5-10 minutes). This could possibly be due to either the lower education levels noted in the sample population, or due to this being the first time this sample population has been exposed to any form of health questionnaire.

5.3. **Conclusion**

Overall, the isiZulu version of the STarT back screening tool showed good psychometric properties and usability and can thus be effectively applied in an isiZulu NSLBP population.

CHAPTER 6

6. CONCLUSION AND RECOMMENDATIONS FOR FUTURE RESEARCH

6.1 CONCLUSIONS

Non-specific low back pain has become a significant problem worldwide, both for patients and for clinicians. Addressing the risk of developing chronic NSLBP has therefore become an important part of the treatment of NSLBP. The STarT back screening tool was developed to identify and address risk factors that can predict the long-term course of NSLBP, and it stratifies primary care patients into risk subgroups, assisting clinicians in determining appropriate treatment interventions. The tool was developed for the English language population and has been translated into 35 languages around the world. This study translated and validated the STarT back screening tool into isiZulu.

Established guidelines for the translation process were followed, and a preliminary isiZulu translation was produced which showed good linguistic accuracy. The preliminary isiZulu translation was tested on a sample population of isiZulu NSLBP patients, and they reported good understanding and ease of completing the tool. The translated tool also showed good content validity, acceptable test-retest reliability and less than acceptable internal consistency. The preliminary isiZulu translation of the STarT back screening tool can therefore be used in an isiZulu population of NSLBP patients.

6.2 STRENGTHS OF THIS STUDY

The translation phase of this study followed internationally recognized guidelines and used first language isiZulu speakers throughout the process, which strengthened the linguistic accuracy of the translation.

A wide inclusion-criterion for the validation phase, and the fact that patients were recruited from a variety of geographical out-patient clinics contributed to the external validity and reliability of the study.

An appropriate sample size for testing content validity, reliability and internal consistency was used.

6.3 **LIMITATIONS OF THIS STUDY**

This study was unable to measure criterion or construct validity as there is a lack of a single reference standard tool translated into isiZulu that tests similar constructs for stratification of NSLBP in a primary care setting, against which the isiZulu tool could be tested. The OMPSQ is the closest reference standard used in other translation studies like the Finnish and the French studies, as well as in the development of the original English version, but no isiZulu translation of the OMPSQ exists.

The sample size of this study was considerably smaller than recommended by Terwee et al (2007), and smaller compared to most of the other translation studies, which could have affected the validation results. Psychometric validation could therefore be improved with a larger sample size.

As in many of the other translation studies, the isiZulu STarT back screening tool did not test the treatment effect that NSLBP patients were receiving between the first and the second test. The original STarT back screening tool was not designed to gather this type of information, so other outcome measures could be used alongside the isiZulu translation to address these limitations.

The isiZulu translation was only tested in the Mpumalanga province of South Africa, where many but not the majority of isiZulu speaking people reside, but it is still suitable for most isiZulu speakers countrywide despite possible regional language and cultural differences.

6.4 **CLINICAL RECOMMENDATIONS**

isiZulu is the most spoken language in South Africa, so the widespread use of the isiZulu STarT back screening tool will have a significant effect on the way NSLBP is treated. The isiZulu STarT back screening tool provides a systematic approach to clinical decision-making, assisting the matching of patients to the correct treatment path, without missing patients at risk for chronicity. Therefore, training clinicians, particularly primary health care providers at local clinics and private practices in the implementation and use of the isiZulu STarT back screening tool is likely to improve clinical decision-making, improve treatment for patients with NSLBP, particularly those in the high-risk subgroup, and possibly improve physiotherapy referrals as needed.

6.5 **RECOMMENDATIONS FOR FUTURE STUDIES**

It will be necessary to conduct another study to evaluate the psychometric properties in a larger, representative sample. Translation and validation of the OMPSQ into isiZulu, which then could be used as a reference standard to test the isiZulu STarT back screening tool would assist in fully validating the tool.

It will also be necessary to test the clinical effectiveness and cost-effectiveness of the isiZulu translation as well as the original English version in the South African context by comparing this stratified approach to a non-stratified best practice approach. This would determine if stratified care leads to a significant decrease in health care costs and faster recovery times in South Africa specifically.

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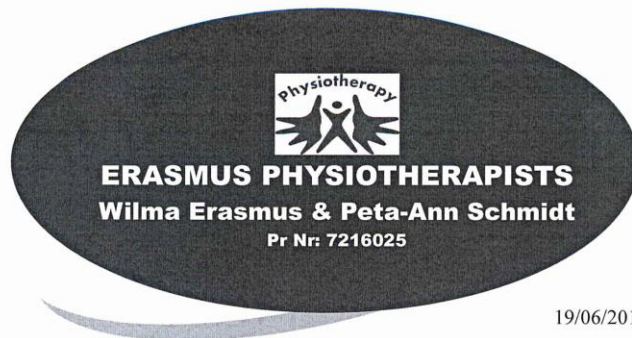
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APPENDIX 1

▪ LETTER OF PERMISSION FROM ERASMUS PHYSIOTHERAPISTS



Highveld Medical Centre
22 Frans Quass Street
Ext 12 Witbank 1035
PO Box 2103
Witbank 1035

Phone: 013 656 4176
Fax: 013 6903254
E.mail: wilmae@mweb.co.za

19/06/2017

To whom it may concern,

Re: Permission to use my Physiotherapy practice as a site for an MSc research project

I hereby grant Peta-Ann Schmidt permission to use my Physiotherapy practice as a site for her MSc research project titled: Cross-cultural adaptation & Validation of the STarT back screening tool in isiZulu.

Yours sincerely

Wilma Erasmus
MSc Physiotherapy

APPENDIX 2

LETTER OF PERMISSION FROM MPUMALANGA DEPARTMENT OF HEALTH

nhrd @ hst. org. za



health
MPUMALANGA PROVINCE
REPUBLIC OF SOUTH AFRICA



MPUMALANGA
THE PLACE OF THE RISING SUN

No. 3, Government Boulevard, Riverside Park, Ext. 2, Mbombela, 1200, Mpumalanga Province
Private Bag X11285, Mbombela, 1200, Mpumalanga Province
Tel: +27 (13) 766 3429, Fax: +27 (13) 766 3458

Litiko Letemphilo Departement van Gesondheid UmNyango WezeMaphilo

Letter of Support Signed by Chief Director (CD)/CEO/District Manager (DM)/Programme Manager (PM)

1. Name & contact no. of Applicant	Peta-Ann Schmidt 0833645107		
2. Title of Study:	Cross-cultural adaptation + validation of the START back screening tool in isiZulu		
3. Aim and population target:	To validate the START back screening tool in an isiZulu population of non-specific low back pain patients		
4. Period to undertake the study	From:	October 2017	to: August 2018
5. Resources Required from Facility/Sub-district/Community			
5.1: Facility Staff Required to assist with the Study	Yes	NO	
	How many:		
	Nurses:		
	Doctors:		
	Other, please specify:		
5.2: Patient Records/Files	Yes	NO	
5.3: Interviewing Patients/ participants at Facilities	Yes	NO	
5.4: Interviewing Patients/ participants at Home	Yes	NO	
5.5: Resource Flow (Are there benefits to Patients/community)	Yes	NO	
	Please list: transport costs + use of translated tool		
5.6: Resource Flow (Are there benefits to Facility/District)	Yes	NO	
	Please list: use of translated tool		
6. Availability of Required Clearance			
6.1: Ethical Clearance	Yes	Pending	NO
	Clearance Number:		
6.2: Clinical Trial	Yes	Pending	NO
	Clearance Number:		
6.3: Vaccine Trial	Yes	Pending	NO
	Clearance Number:		
6.4: Budget	Yes		NO
	Source of fund: Medical Research Endowment Fund		
Declaration by Applicant: I Mr/Ms/Dr/Prof/Adv. Peta-Ann Schmidt Wits University + SASP agree to submit/present the result of this study back to the CEO/Institution/District.			
Comment by CEO/DM/PM:		Supported / Not Supported	
will benefit the hospital (Physio services). P. Medonics			
Signature of CEO/CD/DM/PM		DEPARTMENT OF HEALTH WITBANK HOSPITAL PRIVATE BAG X7206, WITBANK MPUMALANGA PROVINCE	
Name:			
Please email completed form to: JerryS@mpuhealth.gov.za or ThembaM@mpuhealth.gov.za			

Please note that this letter is not an approval to undertake a study, but a support letter from the Department of Health, i.e. the CEO/District Manager acknowledges to have been consulted on the study



health
MPUMALANGA PROVINCE
REPUBLIC OF SOUTH AFRICA

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Litiko Letemphilo

Departement van Gesondheid

UmNyango WezeMaphilo

Enquiries: Themba Mulungo (013) 766 3511

Ms. Peta-Ann Schmidt
P.O. BOX 2188
Witbank
1035

Dear Ms. Peta-Ann Schmidt

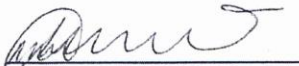
**APPLICATION FOR RESEARCH & ETHICS APPROVAL: CROSS-CULTURAL
ADAPTATION & VALIDATION OF THE STaT BACK SCREENING TOOL IN ISIZULU**

The provincial health research committee has approved your research proposal in the latest format you sent.

- Approval Ref Number: MP_201710_004
- Approval period: 01/11/2017 – 31/08/2018
- Facilities: Rob Ferreira

Kindly ensure that the study is conducted with minimal disruption and impact on our staff, and also ensure that you provide us with the soft or hard copy of the report once your research project has been completed.

Kind regards


MS. TZ. MADONSELA
MPUMALANGA: PHRC

2017/11/14
DATE



APPENDIX 3

▪ ENGLISH STarT BACK SCREENING TOOL

Patient name: _____ Date: _____

Thinking about the **last 2 weeks** tick your response to the following questions:

		Disagree	Agree
1.	My back pain has spread down my leg(s) at some time in the last 2 weeks	☐	☐
2.	I have had pain in the shoulder or neck at some time in the last 2 weeks	☐	☐
3.	I have only walked short distances because of my back pain	☐	☐
4.	In the last 2 weeks, I have dressed more slowly than usual because of back pain	☐	☐
5.	It's not really safe for a person with a condition like mine to be physically active	☐	☐
6.	Worrying thoughts have been going through my mind a lot of the time	☐	☐
7.	I feel that my back pain is terrible and it's never going to get any better	☐	☐
8.	In general I have not enjoyed all the things I used to enjoy	☐	☐
9.	Overall, how bothersome has your back pain been in the last 2 weeks ?		
	Not at all Slightly Moderately Very much Extremely		
	☐ ☐ ☐ ☐ ☐		
	0 0 0 1 1		

Total score (all 9): _____ **Sub Score (Q5-9):** _____

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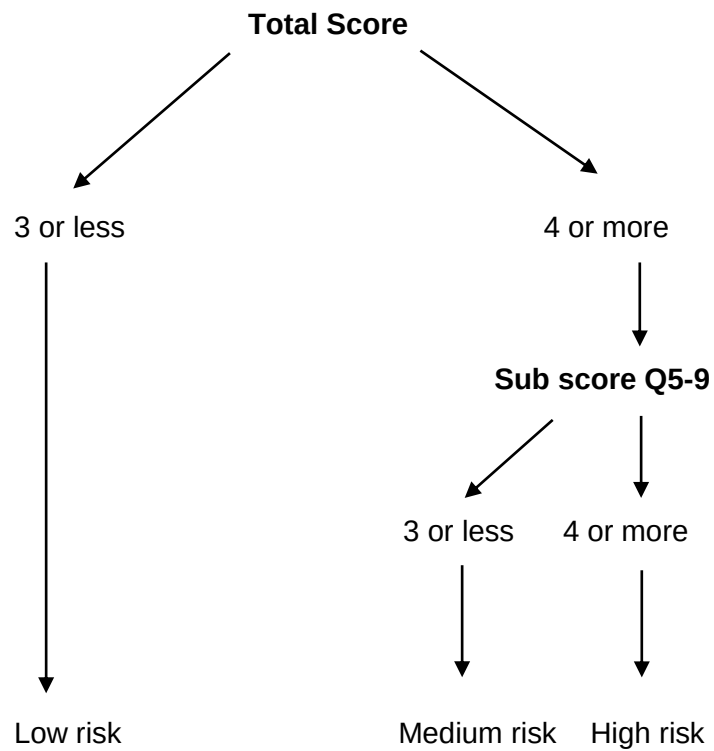
Funded by Arthritis Research UK

APPENDIX 4

▪ STarT BACK SCREENING TOOL SCORING SYSTEM

© Keele University 01/08/07

Funded by Arthritis Research UK



APPENDIX 5A

▪ DEMOGRAPHIC QUESTIONNAIRE (English)

DEMOGRAPHIC QUESTIONNAIRE

NO: _____

Gender: Male ☐
Female ☐

Age: 18-20 yrs ☐
21-29 yrs ☐
30-39 yrs ☐
40-49 yrs ☐
50-59 yrs ☐
60 yrs or older ☐

Highest level of education achieved: Primary school ☐
High school ☐
University ☐

Occupation: _____

Employment status: Employed (40 hours or more per week) ☐
Employed (less than 40 hours per week) ☐
Not employed ☐
Retired ☐
Disabled/not able to work ☐

Previous history of back pain or injury: _____

APPENDIX 5B

▪ DEMOGRAPHIC QUESTIONNAIRE (isiZulu)

IPHEPHAMBUZO

NO.: _____

Ubulili:

Owesilisa ☐

Owesifazane ☐

Ubudala: 18-20 iminyaka ☐
21-29 iminyaka ☐
30-39 iminyaka ☐
40-49 iminyaka ☐
50-59 iminyaka ☐
60yrs yeminyaka noma ngaphezulu ☐

Izinga eliphezulu lezemfundo kufinyelelwa: Isikole samabanga aphansi ☐
Isikole sebanga eliphezulu ☐
Inyuvesi ☐

Umsebenzi: _____

Zezoquqashwa: Ngisebenza (amahora angu 40 noma ngaphezulu evikini) ☐
Ngisebenza (amahora angaphansi kuka 40 ngeviki) ☐
Angasebenzi ☐
Umhlala phansi ☐
Ukhubazekile ☐

Uke walimala ngaphambi kwalokhu: _____

APPENDIX 6

▪ POST RETEST EVALUATION QUESTIONNAIRE (English/isiZulu)

POST-RETEST EVALUATION QUESTIONNAIRE/POST-RETEST KOKUHLAZIYWA LWEMIBUZO(ENGLISH/ZULU)

NO:.....

1. Were there any changes in your back pain in the past two weeks? / Kwakungekho izinguquko zakho ubuhlungu emuva esikhathini esidlule amasonto amabili?

2. Did you suffer any additional injuries to your back in the past two weeks? / Ingabe ukulimaza emuva yakho esikhathini esidlule amasonto amabili?

3. Please rate the ease of understanding/comprehension of the translated questionnaire on the following scale, with 1 being easy to understand and 10 being difficult to understand / Sicela ukukala ukuthi kulula kanjani kwaba ukuqonda lwemibuzo.

Easy to understand

Difficult to understand

Kulula ukuqonda

Kunzima ukuqonda

1 2 3 4 5 6 7 8 9 10

4. Please rate the ease of completing the tool on the following scale, with 1 being easy to complete and 10 being difficult to complete / Sicela ukukala ukuthi kulula kanjani kwaba ukuqedela lwemibuzo.

Easy to complete

Difficult to complete

Lula ukuqedela

Kunzima ukuqedela

1 2 3 4 5 6 7 8 9 10

5. How long did it take to complete the questionnaire / Kwakudingeka isikhathi ukuze uqedele uhlu lwemibuzo

5 minutes/amaminithi ☐

10 minutes/amaminithi ☐

15 minutes/amaminithi ☐

20 minutes/amaminithi ☐

6. Any suggestions to improve the clarity of the translated tool? / Noma iziphi iziphakamiso ukuthuthukisa ukuqond lwemibuzo

APPENDIX 7

▪ FORWARD TRANSLATOR INFORMATION LETTER

FORWARD TRANSLATOR INFORMATION DOCUMENT

Dear Translator

I, Peta-Ann Schmidt, am a 2nd year Masters' student in Physiotherapy at the University of Witwatersrand. As part of my studies I am doing research on a physiotherapy back pain questionnaire.

I would like to invite you to participate in this research study

The importance of this study

Questionnaires form an important part of physiotherapy treatment, and assist physiotherapists in understanding patients' signs and symptoms, as well as in guiding the correct choice of treatment program.

The aim of this study is to translate the STarT back screening tool/questionnaire from English into Zulu and then test the translated Zulu version for its validity and reliability or its correctness and understandability.

There is no direct benefit to participating in this study, however once its correctness and understandability have been established, the tool/questionnaire can be used by all physiotherapists in South Africa. This will enable physiotherapists to understand their patients' signs and symptoms better and determine a more appropriate choice of treatment.

What are you, the translator, expected to do?

Should you agree to participate in this study, you will be asked to translate the English version of the STarT back screening tool/questionnaire into Zulu. After translating the questionnaire, you will be asked to participate in a discussion with another translator and the researcher to develop a new screening tool. You will then be asked to join an expert committee of methodologists, health professionals, language professionals and other translators from Wits University and Witbank/eMalahleni to discuss the pre-final version of the translated screening tool that will be tested on a patient population.

Participation is voluntary and refusal to participate will not have any negative consequences. You may withdraw from the study at any time without fear of suffering any negative repercussions.

What are the risks of taking part in this study?

There are no risks that you will be exposed to. Each participant will receive feedback on their participation in the study. You will be compensated monetarily for your time.

Confidentiality

Information obtained from participants will be used only for the purpose this study is intended for.

More information requests

Should you have any questions or need more information, I am readily available to clarify any queries and handle your concerns. Alternatively, you can contact me on 0833645107 or email me at paschmidt@mweb.co.za.

Should you have any ethical related concerns, please contact Professor P Cleaton-Jones at peter.cleaton-jones@wits.ac.za or at 011-717 2700/2656/1234/1252 at the Human Research Ethics Committee of the University of Witwatersrand.

If you are willing to participate in this study, kindly complete and sign the attached consent form

Kind regards
Peta-Ann Schmidt

APPENDIX 8

▪ FORWARD TRANSLATOR INFORMED CONSENT LETTER

CONSENT TO PARTICIPATE IN THE FORWARD TRANSLATION OF THE ISIZULU VERSION OF THE STarT BACK SCREENING TOOL

I, _____ hereby consent to be a participant in the forward translation of the isiZulu version of the STarT Back screening tool.

I acknowledge the fact that I did receive enough information and had the opportunity to ask questions with regards to the benefits and possible risks of participating, to make an informed decision about the above and that this was made without duress.

Signed: _____ Date: _____

APPENDIX 9

▪ BACKWARD TRANSLATOR INFORMATION LETTER

BACKWARD TRANSLATOR INFORMATION DOCUMENT

Dear Translator

I, Peta-Ann Schmidt, am a 2nd year Masters' student in Physiotherapy at the University of Witwatersrand. As part of my studies I am doing research on a physiotherapy back pain questionnaire.

I would like to invite you to participate in this research study

The importance of this study

Questionnaires form an important part of physiotherapy treatment, and assist physiotherapists in understanding patients' signs and symptoms, as well as in guiding the correct choice of treatment program.

The aim of this study is to translate the STarT back screening tool/questionnaire from English into Zulu and then test the translated Zulu version for its validity and reliability or its correctness and understandability.

There is no direct benefit to participating in this study, however once its correctness and understandability have been established, the tool/questionnaire can be used by all physiotherapists in South Africa. This will enable physiotherapists to understand their patients' signs and symptoms better and determine a more appropriate choice of treatment.

What are you, the translator, expected to do?

Should you agree to participate in this study, you will be asked to back translate the newly developed Zulu version of the STarT back screening tool/questionnaire into English. After back translating the questionnaire, you will be asked to join an expert committee of methodologists, health professionals, language professionals and other translators from Wits University and Witbank/eMalahleni to discuss the pre-final version of the translated screening tool that will be tested on a patient population.

Participation is voluntary and refusal to participate will not have any negative consequences. You may withdraw from the study at any time without fear of suffering any negative repercussions.

What are the risks of taking part in this study?

There are no risks that you will be exposed to. Each participant will receive feedback on their participation in the study. You will be compensated monetarily for your time.

Confidentiality

Information obtained from participants will be used only for the purpose this study is intended for.

More information requests

Should you have any questions or need more information, I am readily available to clarify any queries and handle your concerns. Alternatively, you can contact me on 0833645107 or email me at paschmidt@mweb.co.za.

Should you have any ethical related concerns, please contact Professor P Cleaton-Jones at peter.cleaton-jones@wits.ac.za or at 011-717 2700/2656/1234/1252 at the Human Research Ethics Committee of the University of Witwatersrand.

If you are willing to participate in this study, kindly complete and sign the attached consent form

Kind regards
Peta-Ann Schmidt

APPENDIX 10

▪ BACKWARD TRANSLATOR INFORMED CONSENT LETTER

CONSENT TO PARTICIPATE IN THE BACK TRANSLATION OF THE ISIZULU VERSION OF THE STarT BACK SCREENING TOOL

I, _____ hereby consent to be a participant in the back translation of the isiZulu version of the STarT Back screening tool.

I acknowledge the fact that I did receive enough information and had the opportunity to ask questions with regards to the benefits and possible risks of participating, to make an informed decision about the above and that this was made without duress.

Signed: _____ Date: _____

APPENDIX 11

▪ LETTER OF PERMISSION TO TRANSLATE THE ORIGINAL STaRT BACK SCREENING TOOL

From: kathfen [kathfen@gmail.com]

Sent: Monday, March 13, 2017 1:04 PM

To: Peta-Ann; Romy; Jonathan

Subject: Re: Permission to translate and validate the STaRT back tool into the Zulu language

Follow Up Flag: Follow up

Flag Status: Flagged

Hi Jonathan and Peta Ann,

Sorry I've been really slack on this. Go for it Peta Ann. You may want to be in contact with Romy Parker from UCT too.

Warmest,

Kath

On Mar 13, 2017 11:42 AM, Jonathan Hill <j.hill@keele.ac.uk> wrote:

Hi Peta-Ann

Thanks for offering to translate the SBT into Zulu...

I have already given permission to Kath to do this.... Kath could you let us know how that's going?

Many thanks

Jonathan
Dr Jonathan Hill
NIHR Senior Lecturer in Physiotherapy
Research Institute for Primary Care and Health Sciences
Keele University
Staffordshire
ST5 5BG
UK
+44 (0)1782 733900
Fax 01782 733911
<http://www.keele.ac.uk/pchs/>
NIHR School for Primary Care Research

Established in 2006, with revised membership in 2009, the National Institute for Health Research (NIHR) School for Primary Care Research (SPCR) is a partnership between eight leading academic centres for primary care research in England. The SPCR's main aim of increasing the evidence base for primary care practice, is achieved through high quality research and strategic leadership. For more information on our programmes of research and training, please visit our website: sPCR.nihr.ac.uk

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On 12 March 2017 at 15:16, Peta-Ann Schmidt <paschmidt@mweb.co.za> wrote:

To whom it may concern

I would like to ask permission to do my MSc Research on the translation and validation of the Keele STarT back tool into the Zulu language. I am an MSc student at Wits University in Johannesburg South Africa.

If there is any advice you could give me regarding the best way to approach this process, it would be greatly appreciated.

Thank you

Yours sincerely

Peta-Ann Schmidt
MSc Student Wits University Johannesburg South Africa

APPENDIX 12A

▪ PARTICIPANT INFORMATION DOCUMENT (ENGLISH)

Dear Participant

I, Peta-Ann Schmidt, am a 2nd year Masters' student in Physiotherapy at the University of Witwatersrand. As part of my studies I am doing research on a physiotherapy back pain questionnaire that has been translated from English to Zulu.

I would like to invite you to participate in this research study.

The importance of this study

Questionnaires form an important part of physiotherapy treatment, and assist physiotherapists in understanding patients' signs and symptoms, as well as in guiding the correct choice of treatment program.

The aim of this study is to translate the STarT back screening tool/questionnaire from English into Zulu and test the translated Zulu version for its validity and reliability or its correctness and understandability.

There is no direct benefit to participating in this study, however once its correctness and understandability have been established, the tool/questionnaire can be used by all physiotherapists in South Africa. This will enable physiotherapists to understand their patients' signs and symptoms better and determine a more appropriate choice of treatment.

What are you, the participant, expected to do?

Should you agree to participate in this study, you will be asked to fill out the translated Zulu version of the STarT back screening tool/questionnaire. After a period of two weeks, you will be asked to fill out the tool/questionnaire again. Transport costs will be reimbursed. As a participant, your identity will remain protected. The study will take approximately 20 minutes of your time.

Participation is voluntary and refusal to participate will not have any negative consequences. You may withdraw from the study at any time without fear of suffering any negative repercussions.

What are the risks of taking part in this study?

There are no additional risks that you will be exposed to. Each participant will receive feedback on their participation in the study. There is no monetary reward for participating in this study.

Confidentiality

To ensure confidentiality of participants is maintained, study numbers will be used instead of participant names. Each participant will be assigned a study number. The key to these study numbers will be kept in the possession of the researcher only. Participants are to write their names only on the consent form attached.

Information obtained from participants will be used only for the purpose this study is intended for.

More information requests

Should you have any questions or need more information, I am readily available to clarify any queries and handle your concerns. Alternatively, you can contact me on 0833645107 or email me at paschmidt@mweb.co.za.

Should you have any ethical related concerns, please contact Professor P Cleaton-Jones at peter.cleaton-jones@wits.ac.za or at 011-717 2700/2656/1234/1252 at the Human Research Ethics Committee of the University of Witwatersrand.

If you are willing to participate in this study, kindly complete and sign the attached consent form

Kind regards
Peta-Ann Schmidt

APPENDIX 12B

▪ PARTICIPANT INFORMATION LETTER (isiZulu)

IMINININGWANE YOMNCEDISI

Mncedisi

Ngingu Peta-Ann Schmidt, umfundi wase Wits University eGoli. Ngenza uphenyo ngobuhlungu bomgogodla ngesi Zulu. Ngizocela ukuthi sisebenzisane kuloluphenyo.

Lolusesho luzosetshenziswa ngesiZulu, ukuze lincede odokotela (physiotherapists') ukuzoqonda ubuhlungu bomgogodla, bakwazi ukukhetha umuthi okuyiwona olungele lobo buhlungu.

Angeke uthole lutho ngokungenela lophenyo kodwa uma umgogodla wakho sewuhloliwe, kuzosetshenziswa lapha eMzansi Afrika ukunceda abanye abantu kancono.

Uzogcwalisa ngesiZulu imibuzo yobuhlungu bomgogodla bese emva kwamaviki amabili, kuzofuneka ubuyele ukuzophendula imibuzo futhi. Ozohamba ngako kuzokhokhelwa. Angeke waziwe, futhi kuzothatha 20 imizuzu.

Uma ungenela losesho kuyintando yakho, ungayeka noma kunini, ngaphandle kokusolwa. Akunangozi ekwenzeni loku, uzothola imiphumela ebewubuzwe yona.

Ukugcina imiphumela yakho kuyimfihlo, azonikezwa inombolo. Igama lakho lizobhalwa efomini kuphela. Imiphumela izosetshenziswa kulophenyo.

Uma ufuna ukwazi kabanzi ngishayeke ucingo kulenombolo: 0833645107 noma ubhalele ku-email paschmidt@mweb.co.za.

Uma ufuna ukungenela lasesho, ngicela ugcwalise ifomu elilandelayo.

Ngiyabonga

Yimi u-Peta-Ann Schmidt

APPENDIX 13A

▪ PARTICIPANT INFORMED CONSENT LETTER (English)

CONSENT TO PARTICIPATE IN THE TESTING OF THE ISIZULU VERSION OF THE STarT BACK SCREENING TOOL

I, _____ hereby consent to be a participant in the testing of the isiZulu version of the STarT Back screening tool.

I acknowledge the fact that I did receive enough information and had the opportunity to ask questions with regards to the benefits and possible risks of participating, to make an informed decision about the above and that this was made without duress.

Signed: _____ Date: _____

APPENDIX 13B

▪ PARTICIPANT INFORMED CONSENT LETTER (isiZulu)

IMVUMO YOKUBAMBA ICHAZA EKHUMUSHWENI ISIZULU KU STarT BACK SCREENING TOOL

Mina, _____ ngiyavuma ukuthatha incacheba
ekuhloleni kwesiZulu se STarT back screening tool.

Ngiyavuma ukuthi ngilutholile ulwazi nethuba lokubuza imibuzo kanye nenzuzo nezingozi
zokuthatha incacheba, ukwenza isinqumo kokungenhla ukuthi akweziwanga ngempogelwelo.

Vuma: _____ Usuku: _____

APPENDIX 14

▪ T1 FORWARD TRANSLATION

THE STarT BACK SCREENING TOOL

Igama lesiguli: _____ Usuku: _____

Qabanga ngamaviki amabili andlulile bese uphendula lemibuzo elandelayo.

Yala Vuma

1. Ubuhlungu bomgogodla behlele emilenzeni kwezinye izikhathi kulamaviki amabili andlulile.
2. Benginobuhlungu emahlombe nasentanyeni kwesinye isikhathi emavikini amabili andlulile.
3. Ngihambe ibanga elimfushane ngenxa yobuhlungu bomgogodla wami.
4. Kulamaviki amabili andlulile ngithathe isikhathi eside ukugqoka kunasemihleni ngenxa yobuhlungu bomgogodla.
5. Akuphephile ukuba umuntu okulesimo esinjengesami ukuba avoqavoqe umzimba.
6. Imicabango engikhathazayo ibiloku isenqondweni yami ngasosonke isikhathi.
7. Ngizwa sengathi ubuhlungu bomgogodla wami sebukhulu kanti futhi angeke busabangcono.
8. Empeleni angizijabulisanga ngezinto engivame ukuzijabulisa ngazo.
9. Kuko konke kukuhluphe kangakanani ubuhlungu bomgogodla wakho kulamaviki amabili andlulile?
Lutho Kancane Hayi njalo Kakhulu Ngokwedlulele

APPENDIX 15

▪ T2 FORWARD TRANSLATION

THE STarT BACK SCREENING TOOL

Igama lesiguli: _____ Usuku: _____

Qabanga ngamaviki amabili andlulile bese uphendula lemibuzo elandelayo.

Yala Vuma

1. Emavikini amabili adlule ubuhlungu bomgogodla sebehlele ezinyaweni.
 2. Nginobuhlungu emahlombe noma entanyeni ose kunamaviki amabili.
 3. Ngihamba amabanga amafishane ngenxa yobuhlungu bomgogodla.
 4. Kulamaviki amabili endlule ngigqake kanzane kunojujwayelekile ngenxa yobuhlungu bomgogodla.
 5. Akuphephanga neze ukuthi umuntu onalokungula kwami ukuthi azivozavaze.
 6. Esikhathini esiningi kunemizabango engikhathazayo agifikelayo enqodweni yami.
 7. Ngizwa agathi lobuhlungu bomgogodla obusabisayo angeke buze bube nzono.
 8. Agnisazijbuleli izinto ebensingi jabulisa esikhathini esendlule.
 9. Bukhuluphe kangakanani lobuhlungu bomgogodla kulamaviki ambili endlule
- | | | | | |
|-------|---------|------------|---------|---------------|
| Lutho | Kancane | Hayi njalo | Kakhulu | Ngokwedlulele |
|-------|---------|------------|---------|---------------|
-

APPENDIX 16

▪ T12 SYNTHESIS OF T1 and T2 FORWARD TRANSLATIONS

THE STaRT BACK SCREENING TOOL

Igama lesiguli: _____ Usuku: _____

Qabanga ngamaviki amabili andlulile bese uphendula lemibuzo elandelayo.

Yala Vuma

1. Ubuhlungu bomgogodla behlele emilenzeni kwezinye izikhathi kulamaviki amabili andlulile.
2. Benginobuhlungu emahlombe noma entanyeni kwesinye isikhathi emavikini amabili andlulile.
3. Ngihamba amabanga amafishane ngexa yobuhlungu bomgogodla.
4. Kulamaviki amabili andlulile ngithathe isikhathi eside ukugqoka kunasemihleni ngenxa yobuhlungu bomgogodla.
5. Akuphephile neze ukuba umuntu okulesimo esinjengesami ukuba avoqavoqe umzimba.
6. Imicabango engikhathazayo ibiloku isengondweni yami ngasosonke isikhathi.
7. Ngizwa sengathi ubuhlungu bomgogodla wami sebukhulu kanti futhi angeke busabangcono.
8. Empeleni angizijabulisanga ngezinto engivame ukuzijabulisa ngazo.
9. Kuko konke kukuhluphe kangakanani ubuhlungu bomgogodla wakho kulamaviki amabili andlulile?

Lutho Kancane Hayi njalo Kakhulu Ngokwedlulele

APPENDIX 17

▪ BT1 BACK TRANSLATION

THE STarT BACK SCREENING TOOL

Igama lesiguli: _____ Usuku: _____

Patient's name: _____ Date: _____

Qabanga ngamaviki amabili andlulile bese uphendula lemibuzo elandelayo

Think about the past two weeks and answer the following questions.

		Yala Disagree	Vuma Agree
1.	Ubuhlungu bomgogodla behlele emilenzeni kwezinye izikhathi kulamaviki amabili andlulile. The back pain was sometimes felt down your legs during the past two weeks	☐	☐
2.	Benginobuhlungu emahlombe noma entanyeni kwesinye isikhathi emavikini amabili andlulile I sometimes felt pain on my shoulders or on my neck during the past two weeks.	☐	☐
3.	Ngihamba amabanga amafishane ngenxa yobuhlungu bomgogodla I walk short distances because of the back pain.	☐	☐
4.	Kulamaviki amabili andlulile ngithathe isikhathi eside ukugqoka kunasemihleni ngenxa yobuhlungu bomgogodla. In the past two weeks, it took me longer than it usually takes me to dress up, because of the back pain.	☐	☐
5.	Akuphephile neze ukuba umuntu okulesimo esinjengesami ukuba avoqavoqe umzimba. It is not safe for someone with the same condition as mine to do physical exercises.	☐	☐
6.	Imicabango engikhathazayo ibiloku isemngondweni yami ngasosonke isikhathi. My mind has been preoccupied with stressful thoughts at all times.	☐	☐
7.	Ngizwa sengathi ubuhlungu bomgogodla wami sebubukhulu kanti futhi angeke busabangcono.	☐	☐

It feels like the back pain has increased and like it will not get better

8. Empeleni angizijabulisanga ngezinto engivame ukuzijabulisa ngazo.

☐☐

Actually, I did not enjoy the things I usually enjoy to do .

9. Kuko konke kukuhluphe kangakanani ubuhlungu bomgogodla wakho kulamaviki amabili andlulile?

In overall, to what extent did your back pain bother you during the past during two weeks?

Lutho

Kancane

Hayi njalo

Kakhulu

Ngokwedlulele

Not at all

A little bit

Not frequently

A lot

Extremely

☐☐☐☐☐

APPENDIX 18

▪ BT2 BACK TRANSLATION

THE STarT BACK SCREENING TOOL

Igama lesiguli: _____ Usuku: _____

The name of patient: _____ Date: _____

Cabanga ngamaviki amabili adlulile bese uphendula lemibuzo elandelayo.

Think about the past two weeks and then answer these following questions.

		Yala Refuse	Vuma Agree
1.	Ubuhlungu bomgogodla behlele emilenzeni kwezinye izikhathi kulamaviki amabili adlulile. The pain of the back went down to the legs at other times in the two weeks gone past.	☐	☐
2.	Benginobuhlungu emahlombe noma entanyeni kwesinye isikhathi emavikini amabili adlulile. I was having a pain on the shoulders or on the neck at the other time in the two weeks gone past.	☐	☐
3.	Ngihamba amabanga amafishane ngenxa yobuhlungu bomgogodla. I walk distances that are short because of pain of the back.	☐	☐
4.	Kulamaviki amabili adlulile ngithathe isikhathi eside ukugqoka kunasemihleni ngenxa yobuhlungu bomgogodla. In these two weeks gone past I took a long time to dress up compared to other days because of the pain of the back.	☐	☐
5.	Akuphephile neze ukuba umuntu okulesimo esinjengesami ukuba avocavoce umzimba. It is not safe that a person who is in this condition that is like mine that he/she must exercise his/her body.	☐	☐
6.	Imicabango engikhathazayo ibiloku isemqondweni yami ngasosonke isikhathi. The thoughts that trouble me have been in my mind all the time.	☐	☐

- | | | Yala
Refuse | Vuma
Agree |
|----|---|--------------------------|--------------------------|
| 7. | Ngizwa sengathi ubuhlungu bomgogodla wami sebubukhulu kanti futhi angeke busabangcono. | | |
| | I feel like the pain of my back is now bigger yet again it will never be better. | ☐ | ☐ |
| 8. | Empeleni angizijabulisanga ngezinto engivame ukuzijabulisa ngazo. | | |
| | Actually I did not make myself happy with things I usually make myself happy with | ☐ | ☐ |
| 9. | Kuko konke kukuhlophe kangakanani ubuhlungu bomgogodla wakho kulamaviki amabili adlulile? | | |

All in all how much trouble did the pain of your back cause in these past two weeks?

Lutho	Kancane	Hayi njalo	Kakhulu	Ngokwedlulele
Nothing	Little	Not always	A lot	Too much
☐	☐	☐	☐	☐

APPENDIX 19

PRELIMINARY ISIZULU STarT BACK SCREENING TOOL

THE ISIZULU STarT BACK SCREENING TOOL Code: _____

Date: _____

Cabanga ngamaviki amabili adlulile bese uphendula le mibuzo elandelayo.

		Yala	Vuma		
1.	Ubuhlungu bomgogodla wami behlele emilenzeni kwezinye izikhathi kula maviki amabili adlulile.	☐	☐		
2.	Benginobuhlungu emahlombe noma entanyeni kwezinye izikhathi emavikini amabili adlulile.	☐	☐		
3.	Ngihambe amabanga amafushane ngenxa yobuhlungu bomgogodla wami.	☐	☐		
4.	Kula maviki amabili adlulile ngithathe isikhathi eside ukugqoka kunasemihleni ngenxa yobuhlungu bomgogodla.	☐	☐		
5.	Akuphephile neze ukuba umuntu okulesi simo esinjengesami anyakazise umzimba.	☐	☐		
6.	Imicabango engikhathazayo ibilokhu isemqondweni wami izikhathi eziningi.	☐	☐		
7.	Ngizwa sengathi umgogodla wami ubuhlungu kakhulu, futhi ngeke usaba ngcono.	☐	☐		
8.	Angizange ngizithokozele izinto engivame ukuzijabulisa ngazo njengenjwayelo	☐	☐		
9.	Kuko konke kukuhlophe kangakanani ubuhlungu bomgogodla wakho kula maviki amabili adlulile?				
	Neze	Kancanyana	Kancane	Kakhulu	Ngokwedlulele
	☐	☐	☐	☐	☐

APPENDIX 20

▪ EXPERT ITEM CONTENT VALIDITY RATING

Expert Item Content Validity Rating of the isiZulu STarT Back Screening Tool

Please rate each question on the isiZulu STarT Back Screening Tool as follows:

▪ Relevance

1= not relevant

2= question needs some revision

3= relevant but needs minor revision

4= very relevant

* Clarity

1= not clear

2= question needs some revision

3= clear but needs minor revision

4= very clear

▪ Simplicity

1= not simple

2= question needs some revision

3= simple but needs minor revision

4= very simple

* Ambiguity

1= doubtful

2= question needs some revision

3= no doubt but needs minor revision

4= meaning is clear

Questions	Relevance	Clarity	Simplicity	Ambiguity
1				
2				
3				
4				
5				
6				
7				
8				
9				

APPENDIX 21

▪ ETHICAL CLEARANCE CERTIFICATE



R14/49 Ms P Schmidt

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL) CLEARANCE CERTIFICATE NO. M170717

NAME: Ms P Schmidt
(Principal Investigator)
DEPARTMENT: School of Therapeutic Sciences
Department of Physiotherapy
Medical School

PROJECT TITLE: Cross-cultural adaptation and validation of the STarT
back-screening tool in isiZulu

DATE CONSIDERED: 28/07/2017

DECISION: Approved unconditionally

CONDITIONS:

SUPERVISOR: Ms V Naidoo

APPROVED BY: 
Professor CB Penny, Co-Chairperson, HREC (Medical)

DATE OF APPROVAL: 19/09/2017

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary on 3rd floor, Phillip V Tobias Building, Parktown, University of the Witwatersrand, Johannesburg.
I/We fully understand the conditions under which I am/we are authorised to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated from the research protocol as approved, I/we undertake to resubmit to the Committee. **I agree to submit a yearly progress report.** The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. In this case, the study was initially reviewed in July and will therefore be due in the month of July each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

Principal Investigator Signature _____

Date _____

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

APPENDIX 22

▪ LIST OF OTHER TRANSLATED LANGUAGES

1. Afrikaans
2. Arabic
3. Brazilian-Portuguese
4. Chilean-Spanish
5. Chinese (Traditional)
6. Croatian
7. Danish
8. Dutch
9. Estonian
10. Finnish
11. French
12. German
13. Greek
14. Hebrew
15. Hungarian
16. Hindi
17. Indonesian
18. Italian
19. Japanese
20. Korean
21. Mandarin
22. Nepali
23. Norwegian
24. Persian
25. Polish
26. Portuguese
27. Punjabi
28. Russian
29. Spanish
30. Swedish
31. Tamil
32. Turkish
33. Urdu
34. Welsh
35. Yoruba

APPENDIX 23

▪ S-CVI CALCULATION

$$\begin{aligned} & \text{I-CVI relevance} + \text{I-CVI clarity} + \text{I-CVI simplicity} + \text{I-CVI ambiguity} \div 4 \\ &= 1.0 + 0.94 + 0.94 + 0.94 \div 4 \\ &= 3.82 \div 4 \\ &= 0.955 \end{aligned}$$

APPENDIX 24

TURN-IT-IN REPORT

Research report

ORIGINALITY REPORT		
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17	Betten, Carola, Christofer Sandell, Jonathan C. Hill, and Annelie Gutke. "Cross-cultural adaptation and validation of the Swedish STarT Back Screening Tool", European Journal of Physiotherapy, 2015.	<1%
18	Jasper D. Bier, Raymond W.J.G. Ostelo, Bart W. Koos, Arianne P. Verhagen. "Validity and reproducibility of the modified STarT Back Tool (Dutch version) for patients with neck pain in primary care", Musculoskeletal Science and Practice, 2017	<1%
19	eprints.keele.ac.uk	<1%
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Akbarzadeh Baghban, Ali Montazeri, and Mohamad Parnianpour. "Translation and validation of the Persian version of the STarT Back Screening Tool in patients with nonspecific low back pain", Manual Therapy, 2015.

10	shura.shu.ac.uk	<1%
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13	"Handbook of Work Disability", Springer Nature America, Inc, 2013	<1%
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16	Jena Pauli, Angela Starkweather, Jo Lynne	
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41	Azimi, Parisa, Sohrab Shahzadi, Shirzad Azhari, and Ali Montazeri. "A validation study of the Iranian version of STarT Back Screening Tool (SBST) in lumbar central canal stenosis patients", Journal of Orthopaedic Science. 2014. Publication	<1 %
42	Lina Elsabbagh, Tasneem Al-Atwi, Dhair Aldossary, Ali M. Alshami et al. "Cross-cultural adaptation and validation of the STarT Back Tool for Arabic speaking adults with low back pain in Saudi Arabia", Journal of Orthopaedic Science, 2019 Publication	<1 %
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45	Robinson, Michael E., and Steven Z. George. "Screening for problematic low back pain: STarT", Pain. 2012. Publication	<1 %
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47	fysio.dk Internet Source	<1 %
48	Karstens, Sven, Katja Krug, Jonathan C. Hill, Christian Stock, Jost Steinhäuser, Joachim Szecsenyi, and Stefanie Joos. "Validation of the German version of the STarT-Back Tool (STarT-G): a cohort study with patients from primary care practices", BMC Musculoskeletal Pain ", Spine. 2014. Publication	<1 %
49	Jonathan C. Hill, Kate M. Dunn, Martyn Lewis, Ricky Mullis, Chris J. Main, Nadine E. Foster, Elaine M. Hay. "A primary care back pain screening tool: Identifying patient subgroups for initial treatment", Arthritis & Rheumatism, 2008 Publication	<1 %
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