

PhD Proposal Susan de Klerk

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THE VALIDITY AND CLINICAL UTILITY OF THE DISABILITIES OF THE ARM, SHOULDER AND HAND QUESTIONNAIRE FOR MUSCULOSKELETAL HAND INJURIES IN THE WESTERN CAPE OF SOUTH AFRICA.

PhD Proposal

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INTRODUCTION

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The Disabilities of the Arm Shoulder and Hand (DASH) Questionnaire is a well-researched evaluative and discriminative “region specific patient rated outcome measure” (PROM) used by many clinicians and researchers in the field of therapy to the upper limb.¹ The American Academy of Orthopaedic Surgeons, the Council of the Musculoskeletal Speciality Societies and the Institute for Work and Health (IWH), Toronto (Ontario) developed and published this instrument in 1996.¹ The DASH measures symptoms, and some aspect of activity and participation according to the nine domains outlined in the International Classification of Functioning, Disability and Health (ICF) in patients with musculoskeletal conditions of the upper limb.^{1,2} In their 2013 study Coenen, Kus, Rudolf, Muller, Berno, Dereskewitz and MacDermid found the DASH and the Michigan Hand Questionnaire most comprehensively cover functioning and disability as compared to other PROMs important to individuals with injury or conditions of the hand.³ Drummond, Sampaio, Mancini, Kirkwood and Stamm found that the DASH content linked well with the ICF framework but reported that additional aspects of body structure and environmental factors are not covered by the DASH.⁴ However, it is important to consider that the DASH was not developed to inform the user about the health condition in question, it was developed as a measure of the patient’s ability to function and participate in daily activities.^{1,4} Drummond et al. suggested that other instruments and clinical evaluation should be employed in addition to the DASH to address aspects such as body structure and environmental factors in intervention.⁴

Measurement instruments used in routine hand therapy practice have traditionally focused on aspects of body function and structure (such as clinician led measurement of range of motion or strength).³ Such measures are not necessarily relevant to the patient. The value of the patients’ perspective is a strongly supported notion in emerging research, legislation and guidelines on the use of PROMs, transforming health care around the world.⁵⁻⁸ The patients’ perspective is essential in providing the best quality care.⁵ In publications that are more recent a number of authors have investigated the advances in the use of instruments addressing aspects of activity and participation in addition to the predictable use of instruments that measure a single dimension such as strength or sensation.^{3,9-11} Activity and participation limitations and needs, similar to quality of life, are aspects the patient can assess best.⁶ The implementation of and call for more client centred approaches, addressing the broader understanding of health brought about by adopting the ICF as a framework, allows for the creation of evidence that is based on the patient’s perspective.¹² This has paved the way for the use of PROMs that assess aspects of activity and participation.

As PROMs ask the patient a series of questions about certain aspects of their health, an essential requirement is for the PROM to be available in the patients’ language. Most measures are developed in the English language, for use in English speaking countries.^{13,14} As people vary, based on the differences in culture, language and occupations, there is a need for measures to be adapted to different contexts.^{13,15} In 1993, guidelines for the cross-cultural adaptation of health related quality of life measures were proposed by Guillemin et al.¹³ Cross-cultural adaptation recommendations for translation and adaptation of the DASH and the QuickDASH were developed using these guidelines.¹⁵ Beaton et al recommend that when the DASH is to be used in another language, in another country; this results in change in language and culture and therefore has to be translated and culturally adapted.^{13,15} The cross cultural equivalence of the source and final versions are explained to include aspects of semantic, idiomatic, experiential and conceptual equivalence.¹³ Conceptual equivalence should

address aspects of cultural beliefs understood to be “*who people are, how they interact with the world and how they behave in certain situations*”.^{16, p. 1} There is great advantage in having an outcome measure such as the DASH, that through the methodical implementation of cross-cultural adaptation, is equivalent, irrespective of language, country or culture. Guillemin et al explains these advantages to include that through the use of the measure, the phenomenon or construct can be compared between countries and cultural groups and that it is less costly and time-consuming than developing a new measure.¹³ The process aims to ensure that the same construct is measured in the new language and in turn ensures the retention of the measurement properties of the original version.¹⁴ The process of establishing a common measure for the investigation of the construct(s) in different cultural contexts, does not end with the cross-cultural adaptation of the measure. The psychometric properties of the adapted measure have to be verified through further testing.¹⁵ The Consensus-based Standards for Selection of Health Measurement Instruments (COSMIN) provided consensus regarding the measurement properties that should be assessed.^{17,18} These include the following types of validity: face, content, criterion, cross-cultural, construct (including convergent, discriminant and known group validity), structural, predictive and longitudinal validity (responsiveness).^{17–20} Establishing these is however an ongoing process and each requires many clinical measurement studies.¹⁴

Clinical utility understood to be the appropriateness, accessibility, practicability and acceptability of a measure²¹, is an important property to consider with the same rigour, as the DASH only holds value if it is used. The DASH has been translated into 50 languages from around the world in accordance the recommendations from the developers.¹⁵ Of the 50 language versions, 17 are from developing contexts^a, four from the African continent. A systematic review of the cross-cultural adaptation of the DASH, completed in 2008, included only English language publications (n = 9); eight of nine from developed contexts.²² It can therefore be argued that there is a bias in research on the topic, towards developed countries. In South Africa, the routine use of measures of activity and participation remains low.^{23,24} De Klerk, Buchanan and Pretorius found that 36.6% of participants (n=81) in their study did not use the DASH at all and 40% used it infrequently.²³ Participants offered reasons for non-use, which in the case of the DASH was mostly due to time constraints and lack of applicability in the practice context.²³ Time constraints is not an unfamiliar reason for non-use of PROMs and has been documented by many authors.^{4,11,25} In contrast, the quick administration time of the DASH has been reported by researchers.^{9,22} It is however worth exploring the notion of lack of applicability and time constraints (aspects of clinical utility) associated with the use of such a rigorous instrument, with well-established psychometric properties, in this context.

RESEARCH CONTEXT AND RATIONALE

Intervention in the South African context is complicated by the diversity in culture, language and occupations. The Western Cape is the fourth largest South African province and has a population of six million people constituting 11% of the total population of 56.7 million people.²⁶ In the total population white (9.2%), coloured (9.0%) and Indian people (2.6%)^b are in the minority with a black African majority of 79.2%.²⁷ South Africa has 11 official national languages and additional indigenous languages without official status. In the Western Cape the three most predominantly spoken languages are Afrikaans (49.7%), isiXhosa (24.7%) and English (20.3%). There is a high incidence of trauma and violence; South Africa is believed to be one of the most violent nations in the world.²⁸ Inter personal violence is the method used to deal with conflict; the impact of 46 years of apartheid with contributing political violence and oppression in South Africa is considered to be causative of this occurrence.²⁹ Interpersonal violence dominates the injury profile in South Africa, and in 2007 it was found to be seven times the global average.²⁸ Seedat, Van Niekerk, Jewkes, Suffla, and Ratele reported violence and unintentional injuries to be the second leading cause of all death and disability adjusted life years lost in South Africa in 2000.³⁰ Traumatic injuries sustained due to road traffic accidents also prove to be greater in the South African context than the global rate.²⁸ Work related accidents are also high. In 1993, a total of 242 424 accidents in the workplace were reported

^a Developing country context is understood to be middle income (upper and lower) and low income countries according to the World Bank Rankings⁵²

^b The racial classification is employed by the national census of South Africa; the use thereof must not be regarded as the authors' approval of the practice of racial classification.

(33.4 accidents per 1000 workers).³¹ Manual labourers (blue collar workers) constitute the largest percentage of the South African workforce and injuries to the fingers were most reported amongst this group of workers (24%) and in 57% of cases led to permanent disability.³¹

Acts of interpersonal violence and trauma contribute to the high burden of hand injuries seen in this context. In the absence of clear epidemiological information on the incidence of traumatic hand injuries in South Africa, the author looked to findings on the occurrence of upper limb injuries internationally. These are believed to account for a fifth (20%) of all injuries presented to emergency departments of hospitals.³² Dias and Garcia-Elias also identified that injuries to the hand are often associated with poverty and deprivation, as found in South Africa.³² Considering the high incidence of trauma and violence in South Africa, it is postulated that this number may well be exceeded in this context. Pietrobbon reviewed hand injuries treated in South African hospitals between 1992 and 1994.³³ She noted that assaults accounted for the largest number of injuries and resulted in complex traumatic injuries, tendon and nerve injuries, fractures and burns.³³ Tendon injuries were most predominant and accounted for 33% of the injuries treated during this period.³³ Van Stormbroek surveyed 106 South African community service occupational therapists and more than half (51.1%) indicated that they treat complex traumatic hand injured patients at least once a month.³⁴ De Klerk et al noted that in their sample of 81 South African occupational therapists, diagnoses that were seen most commonly in routine daily practice were nerve injuries (90.1% of therapists), fractures (88.8%) and tendon injuries (85.1%).²³ Hand injuries are therefore a daily occurrence in hand therapy practice in the South African context.

The population of interest in the current study are the Afrikaans and isiXhosa speaking individuals, receiving occupational therapy for musculoskeletal hand injuries in government hospital and / or health care facilities within the Western Cape. Afrikaans is spoken by 13.5% of the population and most widely used in the Western and Northern Cape of South Africa.³⁵ Blignaut however highlights that there is great variation in language that is “*fed by differing social, cultural, geographical, situational and psychological contexts*”.^{36,p.20} As a result the variety of Afrikaans spoken in the Western Cape, often referred to as Kaaps or Western Cape Afrikaans, is a colloquial language, spoken by ranging communities classified as *coloured*^b during Apartheid.³⁷ There is an existing Afrikaans version of the DASH, without evidence of cross cultural adaptation or psychometric properties, but no cross culturally adapted Kaaps or Western Cape Afrikaans version of the DASH.³⁸ isiXhosa is spoken by 17.6% of the population, in both the Western and Eastern Cape.³⁵ There is a newly translated isiXhosa version of the DASH, without evidence of cross cultural adaptation or psychometric properties.³⁸ It is essential to ensure the semantic, idiomatic, experiential and conceptual equivalence as well as the psychometric properties including validity and reliability of any PROM but specifically the DASH in this context.^{13-15,22,39} By using PROMs that have been cross cultural translated and adapted, in addition to the evaluation of psychometric properties, the ‘*patient’s perspective and experiences about their illness is in the forefront of the clinical and research processes*’.^{14,p.1}

PROBLEM STATEMENT

There is a lack of evidence on the validity and clinical utility of the DASH as a measure of activity and participation for hand injured clients in developing country contexts, and more specifically the Western Cape of South Africa.

AIM AND OBJECTIVES

This research aims to establish the validity and clinical utility of the Western Cape Afrikaans and isiXhosa DASH as a measure of activity and participation for hand injured clients in the Western Cape of South Africa.

Achieving the following objectives will address the aim:

1. To systematically review the available evidence on the validity and clinical utility of the DASH in developing country contexts.
2. To translate and cross- culturally adapt the DASH into Afrikaans for the Western Cape of South Africa.

3. To evaluate the construct validity (specifically the content, face and structural validity) of the Western Cape Afrikaans DASH in a sample of hand injured clients in the Western Cape of South Africa.
4. To evaluate the construct validity (specifically the content, face and structural validity) of the existing isiXhosa DASH in a sample of hand injured clients in the Western Cape of South Africa.
5. To explore the clinical utility of the Western Cape Afrikaans and isiXhosa DASH in routine clinical practice amongst a sample of Occupational Therapists in the Western Cape of South Africa.

METHODS

A sequential mixed method study design will be followed with quantitative and qualitative components across 4 phases. ⁴⁰

PHASE 1: SYSTEMATIC REVIEW

RESEARCH AIM

This systematic review aimed to determine the validity and clinical utility of the DASH questionnaire as a measure of activity and participation in patients with musculoskeletal hand injuries in a developing country context.

METHODS

PROTOCOL AND REGISTRATION

This review was registered with the international prospective register of systematic reviews (PROSPERO) as number CRD42016045635. The systematic review protocol was designed using Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) 2015 statement and the Protocol for systematic reviews of measurement properties by Terwee, de Vet, Prinsen and Mokink. ^{41,42}

LITERATURE SEARCH

A comprehensive search of key electronic databases, including MEDLINE (PubMed), EBSCOHost (Academic Search Premier, CINAHL, and Africa Wide), Scopus, Web of Science and Google Scholar was conducted. Grey literature were considered as far as possible.

The search strategy consisted of a collections of search terms for the following characteristics:

1. DASH questionnaire (Construct of interest)
2. Patients with musculoskeletal hand injuries (Target population)
3. Validity and clinical utility (Measurement properties)

The search strategy can be found in Appendix 1.

ELIGIBILITY CRITERIA

Table 1: Eligibility criteria for systematic review

Inclusion criteria	Exclusion criteria
<ul style="list-style-type: none"> - Studies which included the self-report DASH questionnaire. - The study population of adults (age ≥ 18) with musculoskeletal hand injury. - The study population from a developing country context. Studies in which the country 	<ul style="list-style-type: none"> - Studies evaluating the effectiveness of interventions where the DASH questionnaire was used as an endpoint without studying the measurement property in question.

- is not mentioned in the article, author affiliation was checked and verified.
- The aim of the study was the evaluation of the measurement property validity or clinical utility.
 - Studies which provided indirect evidence on the measurement property validity, e.g. from studies in which the instrument (DASH) was used in the validation process of another instrument.
 - Both unpublished (grey literature) and studies published as a full text original article were included.
 - Articles in any language could have been included as very few developing countries have English as a first language.
 - Studies from the inception of the DASH questionnaire to date: 1996 – 2016.

SELECTION OF ABSTRACTS AND FULL TEXT ARTICLES

The search was carefully documented and included the names of the databases searched, interfaces used to search the databases, dates of the search, the exact search terms, limits set and the number of articles retrieved for each database. Covidence.org, a free online platform was used to manage the review. Search results were imported into Covidence.org and duplicates were removed. Articles were initially scanned for relevance based on the title and abstract; the principle investigator (PI) applied inclusion criteria based on the abstracts and the titles of the search results. In addition, the PI did a hand search of the reference lists of the included articles for inclusion of additional documents in the review. After this screening process the number of excluded articles were recorded. The full text for the remaining articles were uploaded to Covidence.org. Two reviewers (the PI and a 2nd reviewer) independently screened the articles retrieved in the searches for relevance using the eligibility criteria. The results were recorded. The reviewers met to discuss their findings. Where discrepancies arose, it was discussed to reach consensus. In the case of disagreement between the two reviewers, a third reviewer was available to make the final decision about whether to include the study or not. The number of included and excluded documents were recorded and the documents were allocated to the relevant folder in Covidence.org. The PRISMA 2009 flow diagram was used to depict the search and selection process.⁴³

DATA EXTRACTION

Following the analysis of the full text articles by two reviewers based on the eligibility criteria, the PI extracted the following data: Characteristics of the study populations in which the measurement properties were assessed such as age, gender, condition, setting, country, and language. In addition, the PI extracted information on how validity and clinical utility were ascertained in the included studies.

EVALUATION OF THE METHODOLOGICAL QUALITY OF THE INCLUDED ARTICLES

The methodological quality of the selected studies was independently assessed by two reviewer using a combination of three tools: The critical appraisal tool (The COSMIN checklist) developed by the COSMIN group, the checklist to operationalize measurement characteristics of PROMs by Francis et al; and aspects of the Multi-dimensional model of clinical utility by Smart.^{21,44,45} The scoring system, developed for the COSMIN checklist was applied to calculate the quality score for each measurement property of cross-cultural validity. This scoring system comprises a 4-point rating scale in order to classify each of the measurement properties as excellent, good, fair or poor. A dichotomised scoring system was used to

rate the properties of construct and content validity as well as clinical utility in terms of respondent burden and presentation, appropriateness and acceptability, by identifying whether the relevant properties were addressed in the publication. If the ratings were different, these were discussed and resolved through consensus. A third reviewer³³ was available to independently appraise these articles. Properties were scored according to the “worst score counts” method, i.e. if one item per box is scored “poor” then the overall score for that particular measurement property was poor.^{18,44}

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RISK OF BIAS IN INDIVIDUAL STUDIES

The risk of bias were considered by scoring the methodological quality of each of the measurement properties under review according to the COSMIN checklist. This included, but was not limited to ascertaining the percentage of missing responses. A high percentage of missing responses were considered an indication of selection bias.⁴⁶

DATA SYNTHESIS

The eligibility criteria that were applied during this review, aimed to ensure that the included studies were sufficiently similar with regard to study population. The setting, as well as the language version of the instrument did however differ. The similarities were judged based on the data extracted. The methodological quality of the measurement properties under review, demonstrated in each of the studies were reported according the COSMIN criteria as described above. The number of studies by quality rating for each psychometric property were reported. The aspects of clinical utility that were reported on, as well as the number of studies that reported on clinical utility were summarised in a table format.

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To ascertain if the DASH is a suitable measurement instrument to measure aspects of activity and participation of hand injured patients in a developing country context, the number of studies in which the validity of this instrument is investigated, the methodological quality of these studies, and (the consistency of) the results of the studies were taken into account. Conclusions were drawn regarding the usefulness of this measure in a developing context. Recommendations were made for practice and future research.

OVERALL CONCLUSION

This phase of the research has been completed and the manuscript: *The validity and clinical utility of the Disabilities of the Arm Shoulder and Hand Questionnaire for hand injuries in developing country contexts: A Systematic Review* was published in the Journal of Hand Therapy in November 2017.³⁸

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Some of the main findings from this review that informs the additional phases of this research are:

1. There is no evidence of the cross-cultural adaptation or validity of the current Afrikaans version of the DASH.
2. There is a newly translated and cross-culturally adapted isiXhosa version of the DASH.
3. There is no published evidence of the validity of the isiXhosa version of the DASH.
4. There is no evidence of the clinical utility of the DASH in the South African context.

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PHASE 2: TRANSLATION AND CROSS-CULTURAL ADAPTATION OF THE DASH INTO AFRIKAANS FOR THE WESTERN CAPE^c.

RESEARCH AIM

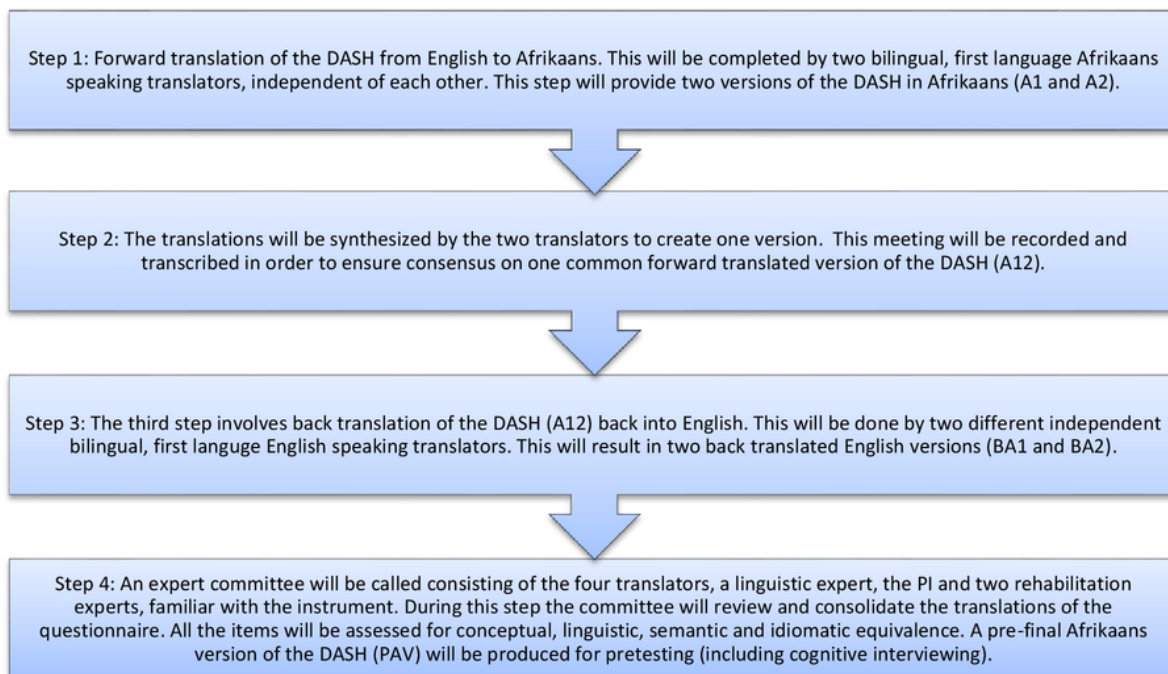
This research aims to translate and cross culturally adapt the original English DASH into Afrikaans for the Western Cape.

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^c For the purpose of this proposal, the term *Afrikaans* is understood to refer to Kaaps, Western Cape Afrikaans or Afrikaans for the Western Cape.

METHODS

The method for translation and cross-cultural adaptation as recommended by the IWH will be followed.¹⁵ The IWH will be contacted for permission to translate and adapt the DASH into Afrikaans for the Western Cape. The process includes several steps outlined in the diagram below:



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Figure 1 Translation and Cross cultural adaption of the DASH

SELECTION OF TRANSLATORS

Translators, without a background in medicine or health, will be required for each step of the translation and cross cultural adaptation process outlined in Figure 1 above. For step 1 and 2, two translators are required. They should be bilingual (Afrikaans and English) first language Afrikaans speaking individuals. For step 3, two translators should be bilingual (English and Afrikaans) first language English speaking individuals. Step 4 requires the four translators involved in step 1, 2, and 3, a linguistic expert, the PI and two rehabilitation experts familiar with the instrument. This group will be referred to as the Expert committee. The linguistic expert should be a person who studies language, specifically English and Western Cape Afrikaans. The linguist should be bilingual (Afrikaans and English) and study every aspect of the language, including how words evolve over time, the sound of the language, vocabulary and grammar. The two rehabilitation experts should be bilingual (Afrikaans and English) occupational therapists or physiotherapists in the field of hand therapy familiar with the DASH.

PRETESTING AND COGNITIVE INTERVIEWING

Pretesting and cognitive interviewing will be done on a convenience sample of ≥ 30 participants with hand injuries, as per the IWH guidelines.¹⁵ Inclusion criteria are that the participants must be Afrikaans first language speakers attending occupational therapy outpatients at government health care facilities within the Western Cape of South Africa. Facilities in close geographical proximity of the Faculty of Medicine and Health Science, Stellenbosch University, Tygerberg Campus will be selected. These could include Bishop Lavis Rehabilitation Centre and Elsies River Day hospital. Participants must have a musculoskeletal hand injury. After seeking consent, socio-demographic information (including age, gender, educational

level and employment status) in addition to information about the nature of the hand injury, will be obtained from the participants. Participants will then be required to complete the pre-final version of the Afrikaans DASH (PAV), during which the PI will conduct cognitive interviews with each participant.

METHOD

Cognitive interviewing is a tool developed in the 1980's to assist in the understanding of the cognitive processes when answering questionnaires in order to improve the design of the questionnaire toward minimizing response error.^{47,48} This technique is widely used during the cross-cultural translation and adaptation of the DASH in developing countries^{39,49-52} and advocated by experts in the field of cross-cultural translation and adaptation of PROMs.^{14,53} *Think aloud interviewing* and *verbal probing techniques* are two main subtypes of cognitive interviewing techniques.^{47,48} Think aloud interviewing expects the participant to "think aloud" as they answer each item on the questionnaire. The interviewer documents the thoughts and/or thought processes that leads the participant to answer the question. Disadvantages of this approach is that it requires participants training, participant resistance can be expected and there is a reported burden on the participant.^{47,48} Verbal probing techniques involve the use of cognitive probes once the participant has answered the question. The basic categories of probes include comprehension / interpretation, paraphrasing, confidence judgement, recall, specificity and general.^{47,48} As the advantages of verbal probing include control of the interview and ease of training of the participant, this technique will be employed during this phase of the research. The PI will make use of retrospective verbal probing by asking the probe questions during a debriefing session once the participant has answered all 30 items of the Afrikaans DASH (PAV).^{47,48} Participant responses will be recorded. The record of responses will be captured in an Excel spreadsheet by documenting issues raised regarding test items by each interviewee as well as an overall comment on whether the questionnaire as a whole seemed relevant or burdensome.

OVERALL CONCLUSION

During a final expert committee (the same committee outlined in step 4 above) meeting the pretesting phase will be concluded. The expert committee will consider: 1) the original question, 2) a description of the problems encountered during the cognitive interviewing process, specifically in relation to the categories of probes, and 3) possible resolutions to the problems encountered.^{47,48} This will conclude the final Afrikaans version of the DASH.

PHASE 3: EVALUATION OF THE VALIDITY OF THE AFRIKAANS FOR THE WESTERN CAPE AND ISIXHOSA DASH

4 RESEARCH AIM

The third phase of the research aims to address the third and fourth objective of the study, namely evaluating the construct validity, specifically face, content and structural validity of both the Afrikaans and isiXhosa versions of the DASH.

31 CONTENT AND FACE VALIDITY

Evaluation of the face and content validity of the Afrikaans DASH will commence following the finalisation of the translation process for the Afrikaans DASH in Phase 2. The same method of content and face validity testing will be used for both the Afrikaans and the isiXhosa DASH.

METHOD

Item-objective congruence (IOC) scoring will be employed.^{54,55} IOC scoring is the process by which a group of content experts rate individual test items to establish congruency with the objectives recorded by the IWH during the development of the DASH.^{54,55} A convenient sample of two groups of four content experts each^{52,55} will be recruited and will be referred to as Group Afrikaans (Afr) and Group isiXhosa (Xhs).

Table 2: Inclusion and exclusion criteria for face and content validity Phase 3

Group	Inclusion criteria	Exclusion criteria
Afr (n=4)	Occupational therapist, physiotherapist and/or orthopaedic surgeons familiar with the DASH	none
	Mother tongue Afrikaans speaking individuals	
Xhs (n=4)	Occupational therapists, physiotherapist and/or orthopaedic surgeons familiar with the DASH	none
	Mother tongue isiXhosa speaking	

The experts will be required to rate the respective versions of the DASH toward calculating the item-objective congruence (IOC) value for each of the test items.^{52,54,55} The content experts will be asked to score each item as follows.

Table 3: Item-objective congruency scoring^{52,54,55}

+1	Clearly measuring	Congruent
0	Degree to which it measures the content is unclear	Questionable
-1	Clearly not measuring	Incongruent

Data analysis will be done by calculating the IOC value for each item. The sum of the scores from each content expert will be divided by the number of experts in each group.^{52,54,55} In order to demonstrate satisfactory content validity, an IOC value of ≥ 0.5 is expected.^{52,54} The content experts will be asked to comment on the face validity of the respective versions. The face and content validity of the Afrikaans and isiXhosa DASH can be completed concurrently or sequentially depending on availability of the content experts.

STRUCTURAL VALIDITY

The COSMIN group defines structural validity as a confirmation, through investigation, of either unidimensionality or multidimensionality of test items.¹⁹ Multidimensionality implies that sub-scales can be demonstrated and unidimensionality confirms that all the items of the measure is reflective of a single construct.¹⁹ The DASH items were designed to be summed into a single score, therefore the underlying assumption is that all the items measure different aspects of the same construct. The unidimensionality of the English DASH has been challenged by a number of authors.^{39,56-58} Principal component analysis will be used to explore the unidimensionality of the Afrikaans and isiXhosa DASH.

METHOD

Table 4: Method structural validity Phase 3

Principal component analysis of:		
	Afrikaans DASH	isiXhosa DASH
Sampling	A convenience sample of two hundred (n=200) hand injured patients will be recruited, when newly referred for occupational therapy treatment in selected government care settings within the Western Cape of South Africa.	A convenience sample of two hundred (n=200) hand injured patients will be recruited, when newly referred for occupational therapy treatment in selected government care settings within the Western Cape of South Africa.
Informed consent	Written and verbal informed consent will be obtained from participants.	Written and verbal informed consent will be obtained from participants.
Inclusion criteria	<ul style="list-style-type: none"> Age ≥ 18 yrs. Literate in Afrikaans (mother tongue Afrikaans) 	<ul style="list-style-type: none"> Age ≥ 18 yrs. Literate in isiXhosa (mother tongue isiXhosa)

Exclusion criteria	<ul style="list-style-type: none"> • Upper extremity condition of a neurological nature 	<ul style="list-style-type: none"> • Upper extremity condition of a neurological nature
Instrumentation	<p>The DASH questionnaire consisting of 30 items will be completed by each recruited participant in this cross-sectional study toward establishing structural validity. The questionnaire should be self-administered. Participants will be asked to complete all 30 items. Items are scored on a scale from one to five, rating their ability to have performed activities over the past week. In order to calculate the score, no more than three questions can be omitted. The scores range from 'no difficulty' or 'no symptoms' to 'severe difficulty' or 'severe symptoms'. An overall score is then calculated ranging from 0 (no disability) to 100 (severe disability).</p> <p>Test administrators (occupational therapists) will also be required to complete a form containing socio-demographic information on each of the participants (Appendix 2). Training will be provided on this process.</p>	
Data management	<p>The completed questionnaires will be stored in a file and collected from the various settings at regular intervals. The informed consent forms will be filed separately and both the completed questionnaires and informed consent forms will be kept in a locked cabinet. Only the PI will have access. They will be kept separate to the informed consent form, which will be filed in a separate file and both kept in a locked cabinet to which no one has access but the PI. A data capturer will be used to record the data. Confidentiality will be ensured by not including patients' names on the forms. Responses for each item of the 30 items will be recorded separately. The data will be entered into Microsoft Excel and fifty percent of the captured data will be checked for accuracy by the PI through random selection of questionnaires and verification of the captured data in the Excel spread sheet. Regular meetings will be held with the data capturer to ensure that questions are addressed throughout the process.</p>	
Data analysis	<p>Data analysis will be done using SPSS version 19. Descriptive statistics (frequencies and percentages) will be used to summarise the socio-demographic information obtained during data collection. Principal component analysis will be used on both data sets (Afrikaans and isiXhosa DASH). The Kaiser–Meyer–Olkin (KMO) measure of sampling adequacy will be used; KMO values of greater than 0.5 will be acceptable. Independent factors will be obtained with the Varimax rotation method.</p>	

OVERALL CONCLUSION

After completion of Phase 3 of this study, there will be two new versions of the DASH (Afrikaans for the Western Cape and isiXhosa) with evidence of construct validity.

PHASE 4: QUALITATIVE EXPLORATORY STUDY BY MEANS OF FOCUS GROUP INTERVIEWS.

RESEARCH AIM

Phase 4 of this study aims to explore the clinical utility of the Afrikaans and isiXhosa DASH in routine clinical practice amongst a sample of occupational therapists in the Western Cape of South Africa

METHOD

A focus group of 6 – 8 occupational therapists, will be purposively sampled. Selection criteria include that they should have been involved in phase 2 and/or 3 of this research. They will be eligible for selection if they, over the past year collected data for the purpose of this research by administering the Afrikaans and/or isiXhosa DASH to hand injured clients. They will be informed about the aim of this phase of the study and written consent will be obtained prior to data collection.

The aim of the focus group is to explore the clinical utility of the Afrikaans and the isiXhosa DASH in routine clinical practice within their respective settings. Clinical utility has many dimensions, this research will however consider the aspects

described by Smart in a Multi-dimensional Model of Clinical Utility.²¹ These aspects include: Appropriate, Accessible, Practicable and Acceptable. The questions will focus on these aspects and involve an in-depth exploration thereof. For example, questions regarding Appropriate will explore the effectiveness and relevance of the DASH by questioning the importance for clinical decision making or the impact on existing treatment processes.²¹ The qualitative data will be gathered across two 60 minute focus group interviews. Interviewees' confidentiality will be maintained and interviews will be recorded and stored safely by the PI.

DATA ANALYSIS

Data will be transcribed verbatim for inductive thematic analysis. The qualitative data analysis process described by Creswell will be followed.⁵⁹

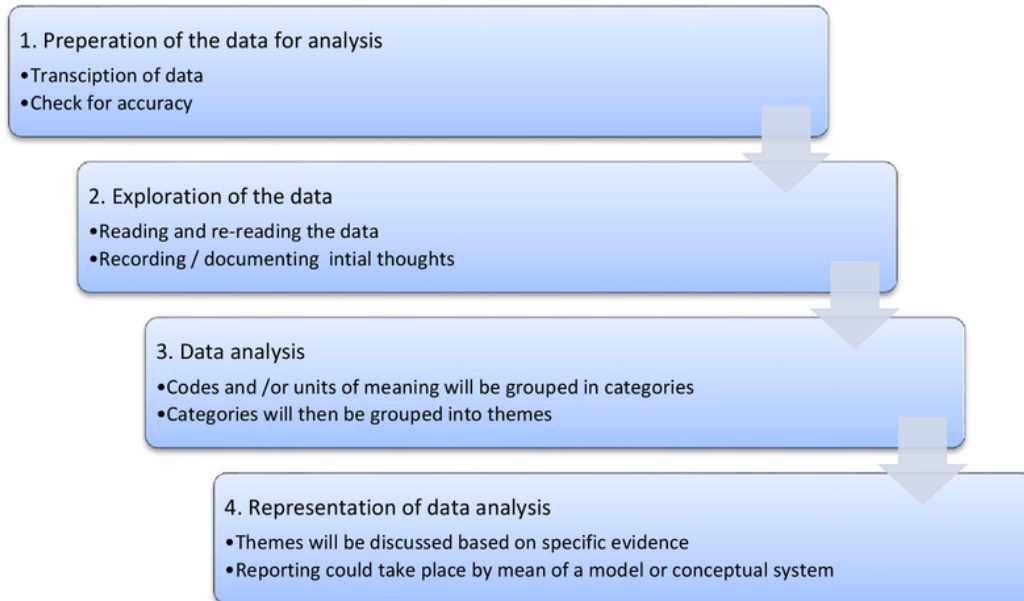


Figure 2: Process of qualitative data analysis

Trustworthiness will be upheld by employing strategies of credibility, transferability, dependability and confirmability.⁶⁰

Member checking will be done by providing the participants with summaries of the focus group interviews following participation in this phase. This approach will ensure that credibility is upheld. In addition, draft of codes will be made available to participants. The PI will ensure that a final member check is done as this phase concludes, to ensure the representativeness of the data.⁶⁰ In order to enable the reader to make an informed decision regarding the transferability of the findings from this phase of the research the PI will make use of thick description.⁶⁰ The following will be made explicit: the context in which the research will be conducted and participant characteristics (including but not limited to previous experience with administration of the DASH and type of hand injuries encountered in their practice setting). Person triangulation of the data will be used in order to ensure dependability.⁶⁰ The PI will seek similar themes or units of meaning from at least three participants during data analysis. The data analysis process will include an audit trail as it progresses. The PI will make use of journaling or a note book to ensure reflexivity during the data analysis process. The following will be documented: preconceptions, biases and beliefs on the part of the PI, problems or frustrations regarding the research process and any questions that may arise.⁶⁰

OVERALL CONCLUSION

This phase of the research will conclude an account of the perceived clinical utility of the DASH, from the perspective of occupational therapists that have used it in clinical practice. This will add a qualitative description of the utility of the DASH in the developing context of South Africa.

ETHICAL CONSIDERATIONS

Appropriate institutional ethics will be sought from the Health Research Ethics committee of Stellenbosch University. The participants in all the phases of this research may not directly benefit in any way from their participation. Therapists who participate in this research may learn how to use the DASH and are likely to gain insight into its usefulness for hand therapy practice. The community of occupational therapists working in this field, as well as isiXhosa and Afrikaans speaking hand injured patients will benefit through the dissemination of the research findings, as it will add to the growing body of evidence of occupational therapy practice in the field of hand therapy within the South African context.

Confidentiality will be maintained through keeping personal information confidential at all times. All information will be kept in a safe place, to which only the PI has access. Participants will be assigned a code on the DASH questionnaire (phase 2 and phase 3), the debriefing interview questionnaire (phase 2) or the item-objective congruency score (phase 2) they completed in the various phases of this research, ensuring that the participants' names are not on the documents. During phase 4 (qualitative focus group) of the study, pseudonyms will be used towards maintaining confidentiality when transcribing the data. The original recording of the interviews will be removed (deleted) once all the data have been transcribed and checked for accuracy. During the research process as well as dissemination of the research the PI will not disclose any information that may have an impact on the careers of participating occupational therapists or other professionals involved in any phase of this study.

The patients that are involved as research participants in this study (phase 2 and 3) will be duly informed regarding the research process and their contribution. Permission towards their participation will be sought from the relevant Western Cape Department of Health bodies. The information they provide by means of completing the DASH questionnaire will be kept confidential at all times and will have no effect on their planned occupational therapy intervention. During phases 2 – 4 of this research informed consent will be required towards participation. Potential participants will be provided with an informed consent form detailing the purpose and methods involved in the research to allow them to make an informed decision as to whether they wish to participate. The PI will assure occupational therapists and other professionals involved in the research of confidentiality and participants will be made to feel safe at all times. Demographic information, provided in any phase of this research will be handled without prejudice and as such justice will be upheld.

SIGNIFICANCE OF THE STUDY

This study will be first of its kind in the South African context. There have been no validity or clinical utility studies on the DASH in the South African context. There is also no research evidence on the cross-cultural adaptation of the DASH to the South African context. MacDermid states that the process of cross-cultural adaptation could ensure inclusivity in conducting research and clinical outcome measurement.¹⁴ This study is significant as the research will address how the DASH will perform as a measure of activity and participation in the culturally and occupationally varied context of South Africa amongst isiXhosa and Afrikaans speaking hand injured patients. The results and conclusions from this research will allow us to describe how activity and participation is potentially different due to culture and context in addition to how useful it is. Patients will benefit as their perspective will be captured and considered during hand therapy intervention. Practitioners in the field of hand therapy will benefit, as there will be a valid outcome measure to inform hand therapy practice and research. Tangible outputs include two official and recognized translated and culturally adapted version of the DASH for use in the South African context.

LIMITATIONS OF THE STUDY

A possible limitation could include the potential heterogeneous nature of hand injuries among the patients included in the study. The sample could include a range of conditions, some more distal and some more proximal in nature, which in turn could impact the factor analysis. A further limitation is that this study includes initial evaluation of psychometric properties of the Afrikaans and the isiXhosa DASH and that other aspects, such as reliability, other types of validity e.g. concurrent or known groups validity and responsiveness should also be studied toward further validating the instrument in this context. Cano and Hobart however reflects that *"establishing clinically meaningful content validity from the onset by defining, conceptualizing, and operationalizing the constructs intended to be measured is a vital step"* in the process of psychometric testing.^{61, p.288}

ESTIMATED TIME FRAME

Time	Description
July – Dec 2016	<ul style="list-style-type: none"> Started systematic review PROSPERO registration Completion of the Systematic review
Jan – Apr 2017	<ul style="list-style-type: none"> Completion of manuscript of Systematic review for publication Submitted manuscript for peer review to the Journal of Hand Therapy
Apr – Nov 2017	<ul style="list-style-type: none"> Complete and hand in proposal Proposal approval and registration Complete and hand in ethics application Complete and apply for permission from Western Cape Department of Health facilities.
Nov – Apr 2018	<ul style="list-style-type: none"> Commence and complete Phase 2 Prepare manuscript for publication Submit for peer review
May 2018 – Apr 2019	<ul style="list-style-type: none"> Commence and complete Phase 3 Prepare manuscript(s) for publication Submit for peer review
May 2019 – Nov 2019	<ul style="list-style-type: none"> Commence and complete Phase 4 Prepare manuscript for publication Submit for peer review
Dec 2019 – May 2020	<ul style="list-style-type: none"> Final summaries Final thesis submission

BUDGET

Item	Description / Motivation	Unit Cost	No. of units	Total cost
Personnel costs				
<i>Research assistantship</i>	Occupational therapists working in the areas where data collection will be done, have to be trained to collect the data. They will be provided with information packs	R100	10	R1000.00
<i>Transcribing costs</i>	The cognitive interviews, done as part of the cross-cultural adaptation of the DASH as well as the qualitative data form the focus group interviews have to be transcribed for data analysis	R15 per 1 minute recording; R900 / hour	20 hours	R18 000.00
<i>Consultation services (statistical)</i>	Biostatistical consultations are needed for statistical analysis of the quantitative data	R230 per hour	20 hours	R4 600.00

Equipment				
<i>Laptop computer</i>	A laptop computer (with docking station) is needed for the management and execution of the research project.	R22 000	1	R22 000.00
Materials and supplies				
<i>EndNote referencing software</i>	EndNote referencing system will be used throughout the research project to manage references and reference articles in subsequent manuscripts	R4 000	1	R4 000.00
<i>Copying</i>	The DASH questionnaires have to be copied for completion for each phase of the research. The questionnaire comprises 6 pages.	R0.50 per page	400	R1 200.00
Translations services	The guidelines for cross cultural translation for the DASH entails a detailed process of forward and backward translation of the questionnaire, and involves a number of translators	R12 000	1	R12 000.00
Research travel	Traveling to and from the sites where the research will be conducted (Western Cape, longest distance to and from Worcester).	R 3.18 per kilometre	1500km	R4 770.00
Conference attendance and accommodation				
<i>OTARG conference, September 2017, Ghana</i>	An abstract has been submitted for this conference toward disseminating results from the completed systematic review, relevant to the African continent.	R25 000	1	R25 000.00
<i>WFOT conference May 2018, Cape Town, South Africa</i>	An abstract has been accepted for this conference toward disseminating results from the completed systematic review as well as the research process.	R15 000	1	R15 000.00
<i>IFSHHT conference, May 2019, Berlin, Germany</i>	An abstract will be submitted for attendance of this conference towards disseminating preliminary results as well as networking with key persons in the field and meetings with internationally based supervisor.	R40 000	1	R40 000.00
Total				R142 970.00

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