CHAPTER 3: RESEARCH METHODOLOGY AND RESULTS

3.1 INTRODUCTION

The purpose of this study was to develop and test an appropriate, valid, time limited, but effective interview based multidimensional questionnaire to evaluate the hand function and occupational status of clients suffering from rheumatic diseases whom attended the Rheumatology out patient clinic at Kalafong hospital in Pretoria.

This study was needed as the researcher had critically reviewed related tests and/or questionnaires that were reported in the literature up until 2000 and none were found to be appropriate to use with this specific cohort of clients. Most of the clients were illiterate, of the African culture and not sufficiently conversant in English to complete the existing tests/questionnaires effectively.

The study consisted of a number of steps, which developed as the research progressed. For clarity these are summarized in the following diagram:

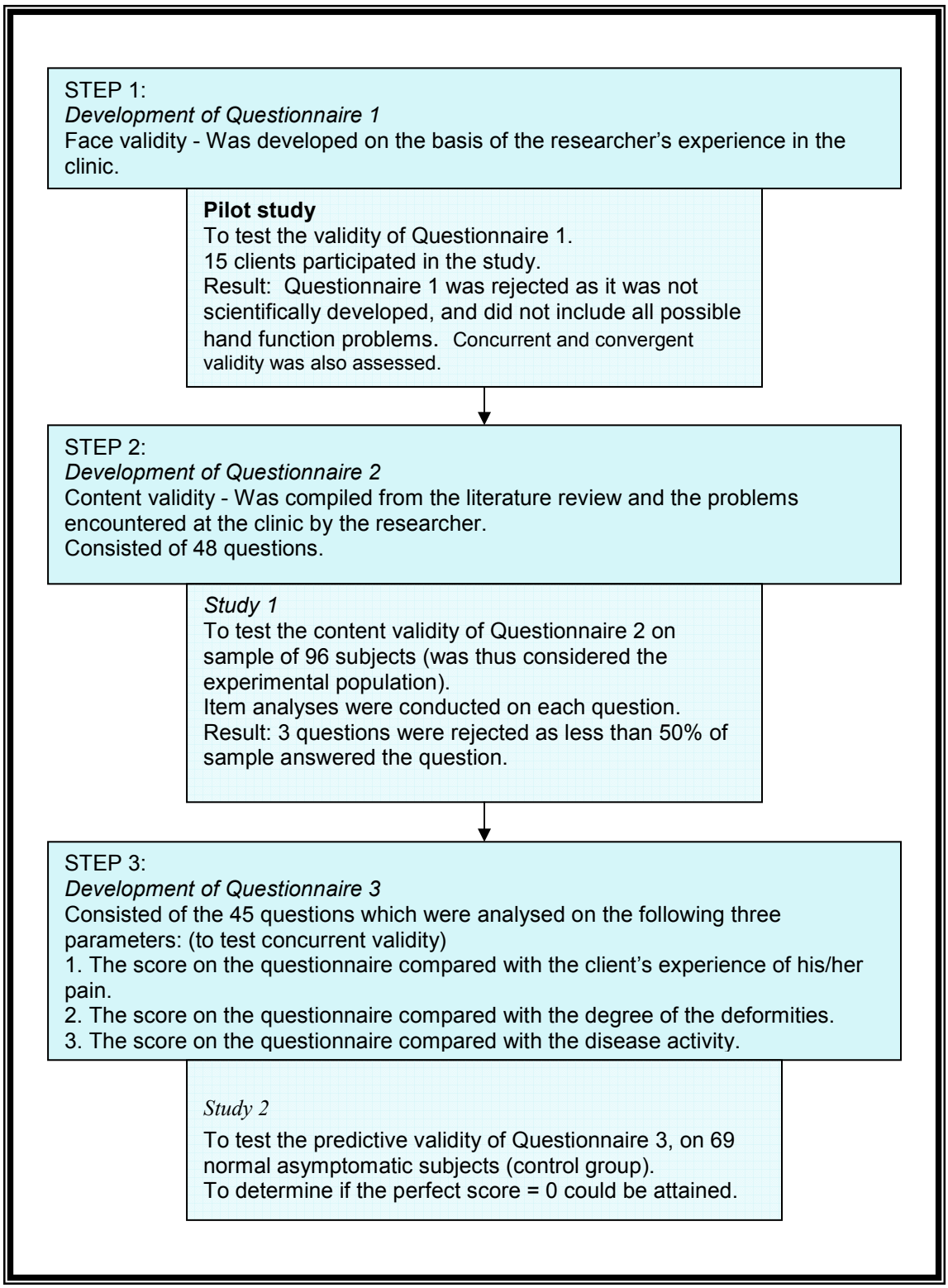


Figure 3.1: Illustration of the steps that evolved in the development of the questionnaire.

3.2 STEP 1

3.2.1 DEVELOPMENT OF QUESTIONNAIRE 1

3.2.1.1 Introduction

The researcher developed Questionnaire 1 when no available assessment was found to be suitable in the literature. The goal of developing the new questionnaire was to collect appropriate data quickly from the specific cohort of clients attending the Kalafong hospital rheumatology out patient clinic. Content validity was established for the specific population at the beginning of the project (Trochim 2006).

3.2.1.2 Questionnaire Design

The researcher designed Questionnaire 1 using a descriptive questionnaire development design. The purpose of a descriptive design is essentially fact-finding and description (Oppenheim, 1992). Each question in Questionnaire 1 was designed to describe an aspect of functional ability and/or occupational performance as it is influenced by hand function limitations. An example of one of the questions is: *I find it difficult to fasten or undo my buttons because of my hands.*

This step in the questionnaire design used face validity, (Trochim 2006) which was the first step of ensuring content validity, as Questionnaire 1 was developed based on the researcher's experience and her perception of what was needed to do a quick efficient screening. The researcher made a list of all the difficulties the clients had mentioned

during an OT assessment. These items were ranked and the most common ones were included in Questionnaire 1.

Twenty four questions were included in the questionnaire, which would keep it short and easy to administer. In considering convergent validity (Trochim 2006) the questions were formulated similar to those used in the Sickness Impact Profile (SIP). The question content included the areas and categories of the SIP that related to hand function, namely Body Care and Movement, Social Interaction, Communication, Emotional Behaviour, Sleep and Rest, Eating, Work, Home Management and Recreation and Pastimes (Gilson, et al. 1975). The SIP was chosen because the format of the questions was easily understood and answered. Seven questions that mentioned pain as contributing to the loss of a skill or function were included in the questionnaire. The questionnaire was designed in English.

The researcher asked the staff in the Kalafong OT department (OT's and OTA's) for their opinions and the Sotho and Zulu speaking staff members agreed that this format would be easily managed by the clients who came to this hospital.

Before the questionnaire could be tested in the pilot study, it had to be translated into the languages most common spoken by the cohort of clients attending the Kalafong out patient Rheumatology clinic, viz. Afrikaans, Sotho and Zulu (Appendix A). The original English questionnaire items were translated back and forth into the other three languages by professional translators until they were satisfied that the translated items were

linguistically correct. Afrikaans was included in the choice of languages because it is one of the eleven official languages and from time to time there were clients from different cultural backgrounds, who spoke Afrikaans, who came to the Kalafong out patient Rheumatology clinic.

3.2.2 PILOT STUDY

3.2.2.1 Study Population

The questionnaire was piloted on 15 clients who attended the Rheumatology clinic at Kalafong hospital.

A convenience sampling technique was used. The next 15 clients who were referred for an OT assessment, who complied with the inclusion criteria and agreed to participate, were included in the pilot study. The criteria for including clients were:

1. Clients had to be between the ages of 18 and 69 years,
2. Clients with a rheumatic disease affecting hand function,
3. Clients with active disease as well as those in remission.

3.2.2.2 Research method

Administration of Questionnaire 1

Since the illiteracy rate of the client population seen at this specific clinic was high, it was decided to make this an interviewer-administered questionnaire. Due to the researcher's inability to fluently speak either of the commonly spoken African languages in the area, an OTA was trained to complete the questionnaire with the clients. The OTA

training included familiarizing her with the questions included in this questionnaire and explaining the answer key. One fact that was emphasised during the training was that she may repeat questions to the client, but she may not change the intent. During the initial phase of the research, the OT was in the same room as the client and the OTA when the questionnaire was administered. The same OTA was involved with the study throughout. Prior to being referred to occupational therapy, the client initially went to the Rheumatology clinic on referral from the primary care physicians. After the first visit, clients could only attend the clinic by appointment. The client was seen by the rheumatologist, who completed the Ritchie index as part of his consultation. The Rheumatologist then referred the client for an occupational therapy assessment and intervention.

The OT and OTA met with each of the 15 clients to be included in the pilot study. The OTA explained the research project using a standard format in their preferred language and obtained permission for participation in the study. Clients who were literate were given the information sheet and in the case of illiterate clients, the OTA read the client information sheet, explained the project in their language of preference and consenting clients signed the consent form (Appendix B). All clients agreed to participate. However, the procedure in place for any refusal was that those clients would not complete the questionnaire, but proceed with the rest of their OT evaluation and intervention.

After permission was obtained, the OT and OTA completed an initial interview to gather the background information. The subjects's age, language and hand of choice as well as diagnosis was recorded on the general information sheet (Appendix C).

The OTA then administered Questionnaire 1 (Appendix A) in the subject's home language. The client's responses were recorded on a record sheet as either "*yes*" or "*no*". (Appendix D)

Concurrent validity was further ensured by comparing the questionnaire to

- the Ritchie Index. This index evaluated the pain a client experienced in 14 different joints. Eleven of these joints were recorded separately for left and right side, thus leading to 25 individual scores that were summed to give a total score. The higher this total score, the higher the level of pain a client experienced. At this stage it was assumed the theoretical constructs of pain and hand function were negatively related.

Convergent validity was further ensured by comparing the questionnaire to

- The SHE. The hand function evaluation measured 15 tasks by recording the time it took a person to complete each task, in seconds as it was expected that clients with hand function impairment would take longer to do these activities. Each task was considered of equal value in the total score and therefore the time taken for each of the 15 tasks was recorded. Five of the tasks were recorded separately for left and right hand, thus leading to 20 results per client. At this stage it was

assumed the theoretical constructs of hand function measured in time and by questionnaire were positively related.

After the OTA completed the questionnaire the OT administered the SHE. The SHE was administered to all clients, as this was the accepted clinic practice.

Data collection

Three sets of data were collected

- The data from Questionnaire 1

  Questionnaire 1 was scored by awarding one point for each "yes" answer and zero points for "no" answers. A maximum of 24 would thus indicate total dysfunction. High scores on the questionnaire indicated more severe difficulty and low scores less difficulty.

- The Ritchie index

  The rheumatologist recorded each client's Ritchie index score on the Ritchie scoring sheet during his consultation with the client. (Appendix E) The OT transcribed these scores onto her own record form because the form the physician completed had identifying data, and the researcher wanted to ensure the confidentiality of the clients included in the study. (Appendix F)

- SHE Scores

  The SHE scores were obtained by recording the time it took the client to complete

each of the tasks included in the test, and these results were recorded on the SHE record form (Appendix G). An example of one of the tasks in the SHE was "*The fastening of buttons on a button board*". All 20 time reading scores were summed and averaged into a single score. The higher this score, the more hand function difficulty the person experienced.

3.2.2.2 Data Analysis

- **Descriptive Data**

  The descriptive study included analysing the clients in the sample according four variables viz. diagnostic groups, language, hand preference and gender using percentages.

- **Analytical Data**

  The score each subject in the pilot study obtained on questionnaire 1 was correlated with their Ritchie Index for joint tenderness score and the score they obtained on the SHE. A correlation co-efficient was calculated between each pair of scores using the Pearson product moment correlation. I.e. Questionnaire 1 correlated to Ritchie Index and Questionnaire 1 to SHE score.

  These correlations were done to determine whether the pain a subject experienced, was related to the score they obtain on Questionnaire 1. Thus subjects with high scores on Questionnaire 1 (indicating severe difficulty) would also score high on the pain scale.

It was initially also anticipated that clients with a high score on the SHE (indicating severe hand function difficulties) would also score high on Questionnaire 1.

Statistical significance levels were calculated from the correlation score in each case.

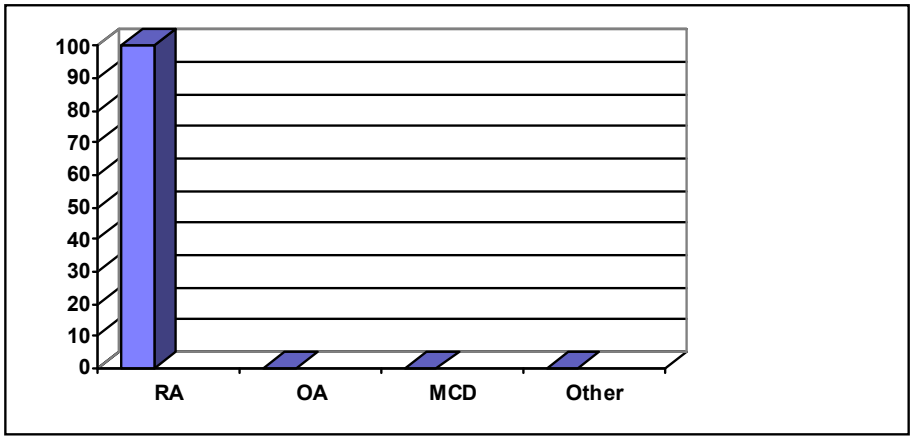
3.2.2.3 Results of the Pilot Study

Fifteen subjects with hand function limitations due to a rheumatic disease were assessed during the pilot study. They ranged in age from 18 to 69 years old.

- **Descriptive data**

  Four demographic variables namely, the different diagnostic groups, language preference, hand preference and gender were analysed.

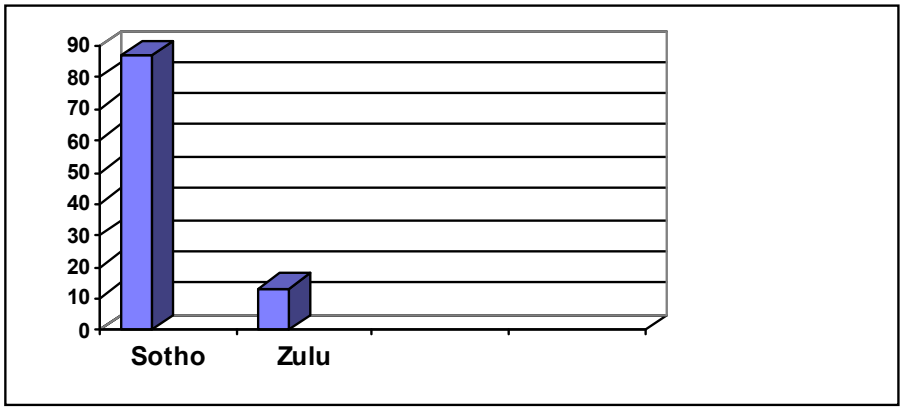
  The percentage for each variable mentioned was calculated. Figures 3.2 to 3.5 represent the findings of the sample (n = 15).



N = % of clients out of a total pilot study sample of 15 cases

Figure 3. 2 Distribution of the different diagnostic groups

All clients seen in the pilot study had Rheumatoid Arthritis (RA). This correlates with the literature in that the most common rheumatic diagnosis is RA (Ritchie et al. 1968); Melvin, 1989; Melvin & Ferrell, 2000).



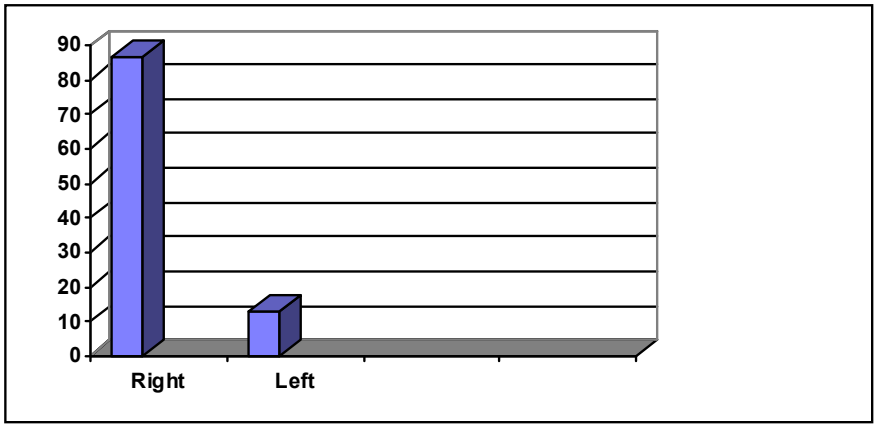
N = % of the total number of clients included in the pilot study (i.e. 15)

Figure 3.3: Distribution of language preference

Sotho = 86,7% (n = 13)

Zulu = 13,3% (n = 2)

Of the 15 clients, 2 answered the Zulu version of Questionnaire 1 and 13 the Sotho version.



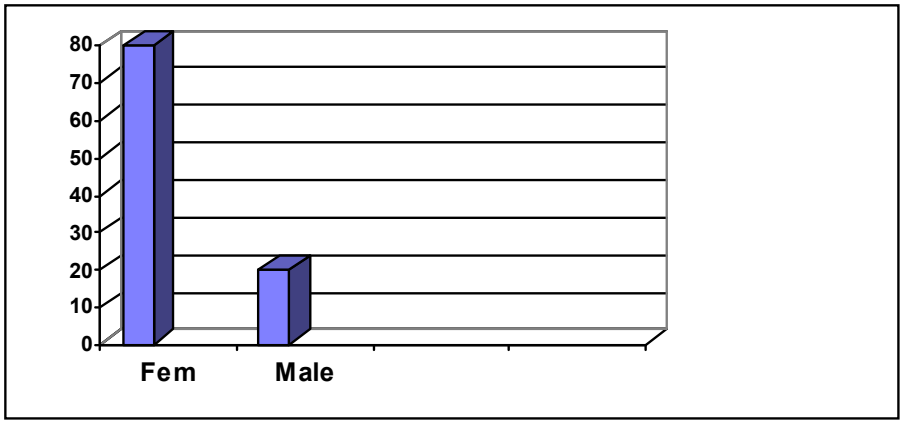
N = % of total number of clients included in the pilot study (i.e. 15)

Figure 3. 4: Distribution of hand preference

Right handed = 86,7% (n = 13)

Left handed = 13,3% (n = 2)

Two subjects were left handed and 13 right dominant, which is in keeping with the general population, where right-handedness is more common than left-handedness. (Hunter, 1995)



N = % of total number of clients in the pilot study (i.e. 15)

Figure 3.5: Distribution of gender

Fem. (Female) = 80,0% (n = 12)

Male = 20,0% (n = 3)

The gender variable of 12 females and three male subjects also correlates with the literature in that RA is more common in females than males (Schumacher, 1988; Melvin, 1989; Melvin & Ferrell, 2000).

- **Analytical Data**

Questionnaire I versus Ritchie index of joint tenderness

The correlation co-efficient was calculated between the Ritchie index of joint tenderness score and the Questionnaire 1 score.

The Pearson product moment correlation test yielded that a high correlation existed (r = 0,84), which meant that 72% (r^2 = 0,71) of the one variable could be explained by the other variable, with the significance level being p = 0,00. This means that pain in the form of joint tenderness is highly indicative of the incapacity measured by Questionnaire 1. Thus the questionnaire showed good concurrent validity with pain.

Questionnaire I versus the SHE

The relationship between the score of Questionnaire 1 and the SHE was also determined by calculating the correlation coefficient. A correlation of r = 0.61 was obtained which indicates a low correlation between these two variables. Only 36% (r^2 = 0,38) of the variation in the one can be explained by the other. In spite of this low correlation, it was found to be significant (p = 0,02), where $p \leq 0,05$ indicates a statistically significant correlation. Even though the correlation calculated was statistically significant, this only meant that the statistical calculations were accurate and the occurrence was not by chance. The only assumption that could be made from this analysis between the SHE and Questionnaire 1, was that if the score on the one assessment was high, it would

also be high on the other assessment and vice versa. Convergent validity was therefore not as high between the two tests.

The researcher was convinced that each test has its place in the approach to rheumatology clients. One aspect that made a comparison between the SHE and the Questionnaire 1 difficult was that the SHE measured performance in seconds compared to the answers received by the SOQ and a score of between 0 and 24. Thus the content of what was being measured in the questionnaire differed from that of the SHE.

While the results of the pilot study were disappointing no development would be achieved without a pilot study to test an initial design. The statistical analyses lead to the following conclusions and speculations;

- A high and significant correlation and concurrent validity existed between pain in the form of joint tenderness as measured on the Ritchie Index and Questionnaire 1.
- A low, but significant correlation and convergent validity existed between the results of the SHE and Questionnaire 1, which may suggest potential for the questionnaire to be a screening device to determine the need for more in-depth standardised testing.

However on critical review, the following problems were identified:

- the questionnaire was randomly compiled on "gut" feel without any scientific basis for inclusion or exclusion of questions. This led to not all potential problems being included.
- the factors influencing hand function were also not well analysed to ensure that all were covered by the questions asked.

With the above in mind it appeared that the results of the pilot study suggested that the information that had been included in questionnaire 1 could be used as the basis for the development of questionnaire 2 in Step 2 of the study.

3.3 STEP 2

The purpose of this step was to design a valid and sensitive measure based on best evidence and not clinical experience alone, to determine the functional ability of the specific cohort of clients attending the rheumatology clinic at the Kalafong hospital. Thus both content and criterion-related validity needed to be investigated (Trochim 2006).

It was planned that Questionnaire 1, which had been evaluated in the pilot study, would form the basis of the new questionnaire 2 but it would be expanded to include more questions.

3.3.1 DEVELOPMENT OF QUESTIONNAIRE 2

3.3.1.1 Introduction

The pilot study findings led the researcher to look at Questionnaire 1 more critically. Even though the 24 questions included in this questionnaire incorporated most of the categories mentioned in the SIP, it did not examine all the skills that influence hand function and its impact on the client's occupational performance.

Another objective of this research project was to design an assessment that would incorporate a multidimensional approach. It was therefore important to include the other dimensions, e.g. psychological impact, medical symptomatology as well as pain into the questionnaire. Thus the researcher decided to revisit the literature and gather further information regarding hand function difficulties as reported in rheumatology clients which included these additional dimensions.

The statistician also recommended that the questionnaire be expanded to enable an item analysis of each question and that the final questionnaire include more than one question per focus area, so if questions need to be eliminated based on the results of the item analyses, there will be sufficient questions remaining to cover all important aspects.

3.3.1.2 Questionnaire design

To further establish content validity (Trochim 2006) the researcher then made another more comprehensive list of all the difficulties that were mentioned in the literature as seen in rheumatology clients with hand involvement. The additional questions were

generated by analysing the performance skills needed to do the activities mentioned. These questions were again ranked and then compared to the ones already included in the questionnaire. The ones already included were eliminated and the rest were then included in Questionnaire 2.

The questions all followed the same format as discussed in the Pilot Study, (3.2.1.2, p. 29) to ensure that it would still meet the criteria set out at the onset of the study to design a questionnaire specific for the population served at this hospital.

The emphasis remained on how each aspect was influenced by hand function limitations. An example of one of the new questions is: *"I often feel irritated and frustrated, because of my hands"*.

Questionnaire 2 now consisted of 48 questions. Even though the format remained the same as for Questionnaire 1, the researcher again checked with the staff in the OT department (OT's and OTA's) for their opinions and the Sotho and Zulu speaking staff members agreed that this format would still be easily managed by the clients who came to this hospital. The researcher therefore decided to maintain this design for Questionnaire 2 and to test it during Study 1.

As Questionnaire 2 was designed in English, it had to be professionally translated into Afrikaans, Sotho and Zulu again (Appendix H) and then translated back and forth into the other three languages by professional translators until they were linguistically correct.

Afrikaans was again included in the choice of languages, because there were sometimes clients from different cultural backgrounds, who spoke Afrikaans, who came to Kalafong hospital. After the professional translation, a Sotho speaking and a Zulu speaking OTA and an Afrikaans speaking OT then read the translated questionnaires to verify whether the translations still used language that would be understood by the clients attending the Rheumatology clinic. This was extremely important step as one of the initial reasons for undertaking this research was to develop an assessment for these clients, the majority of whom did not speak English. The literature also stressed the advantages of assessing a client in their first language (Hill et al. 1990).

3.4 STUDY 1

Study 1 evaluated the responses to Questionnaire 2. An analysis of the questions was conducted to determine the relevance to this questionnaire to the experimental population The questionnaire was compared to the Arthritis Profile (Appendix I), the Ritchie Index (Appendix J),and the researchers assessment of the nature of the disease activity and severity of the client's deformities (only hands) to further confirm the concurrent validity.

3.4.1. RESEARCH METHOD

3.4.1.1 Sampling technique and selection of the sample for study 1

The sampling technique and selection of the sample was the same as for study 1

A convenience sampling technique was used. Over a period of 6 months, all the clients who were referred for an OT assessment from the Kalafong Rheumatology out patient

clinic, and who complied with the criteria below and agreed to participate were included in study 1.

3.4.1.2. Inclusion and exclusion criteria

The following criteria were used to include subjects into the sample:

1. Only those with a rheumatic disease affecting hand function,
2. Clients with active disease as well as those in remission,
3. Clients between the ages of 18 and 69 years old. (Scrimgeour, 1983)
4. Clients of both genders.

Questionnaire 2 was initially administered to 50 clients who attended the rheumatology clinic at Kalafong hospital. However after the researcher consulted with the statistician it was decided to extend the sample to improve the quality of the statistical analysis, to a 95% percent probability level. An additional 46 clients were included. The total sample size was 96.

3.4.1.3 Ethical considerations

Clients were only included in the study if they agreed to participate after having been informed about the research procedure as set out in the information sheet and signed the consent form. The explanation was done by the OTA who has been involved with the study and the rheumatology clinic. It was done in the client's language of choice.

3.4.2 RESEARCH PROCEDURE

3.4.2.1 Administration of Questionnaire 2

Questionnaire 2 (Appendix H) was discussed and practised with the OTA responsible for administering it with the clients. The same OTA was used for both the pilot study and the rest of the research. She worked at and was familiar with the rheumatology clinic routine. This was done because inter-rater reliability was not yet established for Questionnaire 2 and by using the same OTA for all data collection relating to Questionnaire 2; the researcher controlled the variable of gathering all the information in a consistent manner.

Questionnaire 2's key was changed to having five options for each answer, and not only the simple "yes" and "no" used in Questionnaire 1. The five options were:

- Yes
- No
- Sometimes
- Don't Know
- Not Applicable

This was done for a number of reasons. One of the criteria for excluding an item was if more than 50% of the sample considered that item to be not applicable. Some clients also only had difficulty sometimes and there might be instances where a client really did not know the extent to which an item might be a problem. However, the OTA was instructed to give the client initially only the two options "*yes*" and "*no*" initially. The other three

were only used in cases where a client could really not give a definitive "*yes*" or "*no*" answer. The statistics literature stated that people in general tend to choose the less direct answer when given the choice. This might lead to all questions being answered as "*sometimes*" or "*don't know*".

3.4.2.2 Scoring of Questionnaire 2

Questionnaire 2 was scored by awarding one point for each "*yes*" or "*sometimes*" answer and zero points for "*no*" answers. Questions with "*Don't Know*" answers were excluded for that analysis. "*Not Applicable*" answers were not awarded a score, but were taken into consideration during the statistical analysis, where one of the criteria was the number of clients who considered an item appropriate. A maximum of 48 would thus be the highest score obtainable on questionnaire 2 and would indicate total dysfunction. High scores on the questionnaire indicated more severe difficulty and low scores less difficulty.

3.4.2.3 Other assessment scores /tools used together with Questionnaire 2

3.4.2.3.1 Arthritis Profile (Appendix I)

An arthritis profile, completed by the referring rheumatologist, accompanied each questionnaire and gave a summary of the client's medical condition.

3.4.2.3.2 General Information Sheet (Appendix C)

A general information sheet was completed by the researcher on each client. This included background information, nature of the disease activity, severity of the client's

deformities (only hands) and the client's own rating of their level of pain (As obtained from the OTA).

3.4.2.3.3 Ritchie Index (Appendix J)

The rating of pain was on a scale from 0-3, where 0 = no pain, 1 = slight, 2 = mild and 3 = severe (Ritchie et al. 1968). The researcher (OT) based this pain scoring system on the Ritchie-Index (Ritchie et al. 1968). This was done because the rheumatologist used the Ritchie Index at the clinic. It was also the task of the OTA to explain this scale to the clients. The researcher and OTA discussed the way she was to explain the terms: "slight, mild and severe" to the clients according to Ritchie's scoring, where 0 = the joints are not tender at all or no pain exists. 1 = the joints are tender when used or touched. 2 = the joints are so tender that the client winces when using or touching them and 3 = the joints are so tender that the client winces and withdraws the hands when the joints are touched.

3.4.3 DATA COLLECTION

The subjects attended the rheumatology clinic where the rheumatologist completed their arthritis profile. The subjects complying with the criteria for inclusion in the research project were identified and the researcher completed a general information sheet for each.

The OTA then explained the procedure to each subject and obtained their consent. She also explained the pain scale and each subject's rating was noted on the general information sheet.

3.4.4 DATA ANALYSIS

The final procedure to establish content validity of the questionnaire was carried out at this stage. This was done in Study 1, where the first analysis undertaken was to determine whether more than 50% of the population answered any question as "*Not Applicable*". The statistician determined that any question answered by more than 50% of the respondents as "*Not Applicable*" would be excluded, as it would not be possible to be generalised to the population. Thereafter item analyses were done on each of the remaining questions. These were done on each question to statistically motivate the inclusion or exclusion of a question in the final questionnaire. This was to ensure that the final questionnaire only included the questions relevant for this population and would be sensitive in determining the influence hand function problems have on functional ability.

The first item analysis was done to determine whether the answer to a question could in fact distinguish between a high and a low score on the questionnaire. In other words, each question was analysed by comparing the answer to that specific question, to the total score of the questionnaire. Two way tables were drawn up for "yes" and "no" answers compared to "high" and "low" scores on questionnaire 2. Each question was analysed this way.

3.4.4.1 Comparison of Low and High Scores versus Yes and No answers:

Table 3.1 Low/high score on questionnaire 2

	Low	High
Yes		
No		

A subject who scored high on the questionnaire should have more "*yes*" answers and a subject who scored low, should have more "*no*" answers. No questionnaire can be statistically sound, if this first and most basic principle is not met. It has to be determined through statistical analysis that the questions included in the questionnaire can measure the functional difficulty or wellness of the population. It defeats the purpose of the entire research project if these tables did not eliminate questions that could not measure the factors analysed.

3.4.4.2 Comparison of Active and Remission of the disease versus Yes and No answers:

The second item analysis was done to determine whether the answer to a question could distinguish between those clients with active disease and those in remission.

Here the "*yes*" and "*no*" answers were compared to subjects with active disease and those in remission.

Table 3.2 Disease activity

	Active	Remission
Yes		
No		

It was expected that people with active disease would have more *"yes*" answers and people in remission would have more "*no*" answers.

3.4.4.3 Comparison of Mild and Severe Deformities versus Yes and No answers:

The third analysis was done to determine whether the answer to a question could distinguish between mild and severe affliction (deformities). Each question was analysed by comparing the "*yes*" and "*no*" answers to mild and severe deformities.

Table 3.3 Severity of deformities

	Mild	Severe
Yes		
No		

This table was drawn up to determine whether the questions would be able to give a clear picture of the influence deformities have on occupational performance. It was believed by the researcher that many clients are seen with severe ROM limitations, and are still able to perform most of the functional tasks. The researcher attempted to statistically prove that deformities are NO indication of functional ability.

3.4.4.4 Comparison of Mild and Severe levels of pain versus Yes and No answers:

The last item analysis was done to determine whether the answer to a question could distinguish between mild and severe pain levels.

Table 3.4 Level of pain

	0 & 1	2 & 3
Yes		
No		

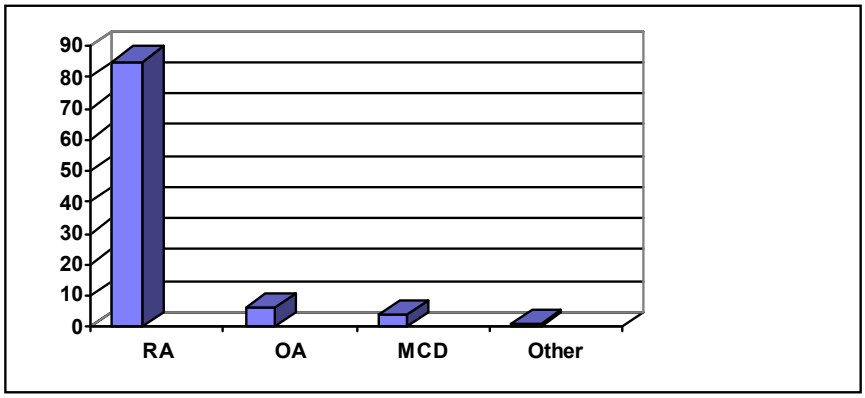
It is hypothesized that pain is one of the biggest contributing factors in functional limitations. One would therefore expect high pain levels to have more "*yes*" answers and low pain levels to have more *"no*" answers.

3.4.5 RESULTS OF STUDY 1

The following results were obtained from descriptive and statistical analyses of Questionnaire 2, which was administered to 96 rheumatology subjects with hand function problems, included in Study 1. The subjects included ranged in age from 20 to 68, with a mean age of 44,45 years.

3.4.5.1 Descriptive data

The descriptive data gives a picture of the demographics of the sample investigated.



N = % of clients out of a total sample of 96 cases

Figure 3. 6: Distribution of the different diagnostic groups

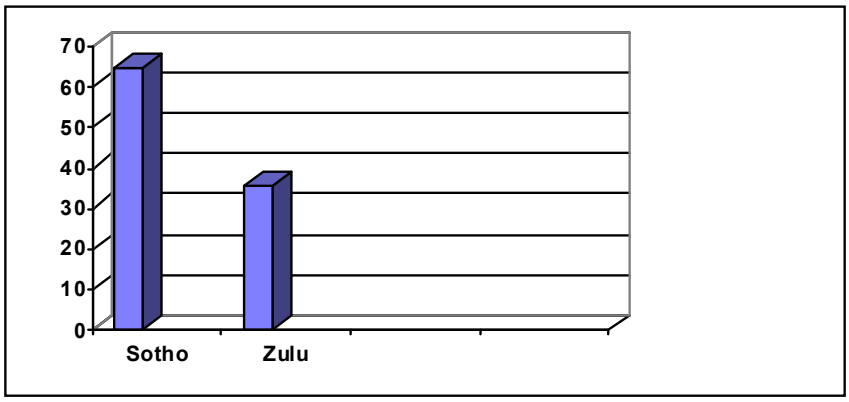
RA = 88,5% (n = 85)

OA = 6.2% (n = 6)

MCD = 4.2% (n = 4)

Other = 0,1% (n = 1)

Of the 96 subjects evaluated, 85 had a diagnosis of Rheumatoid Arthritis; six had Osteo-Arthritis and only four had Mixed Connective Tissue Disease. One case fell into the "other" category.



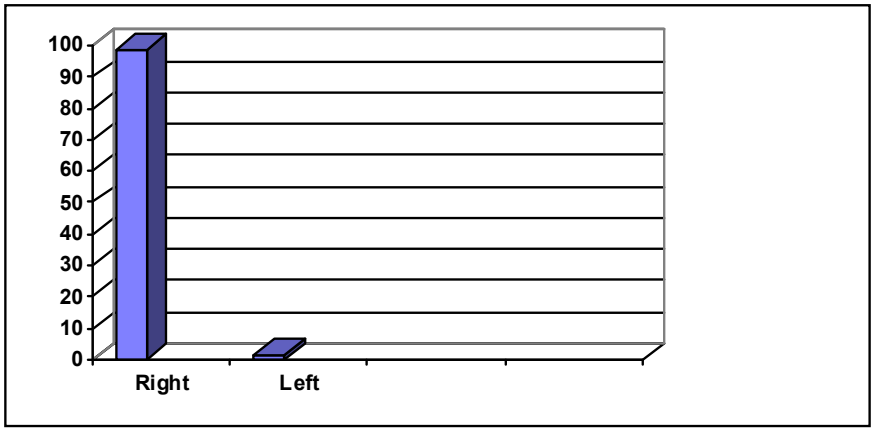
N = % of the total number of subjects (i.e. 96)

Figure 3. 7: Distribution of language preference within sample

Sotho = 64,6% (n = 62)

Zulu = 35,4% (n = 34)

The questionnaire was available in four languages, namely English, Afrikaans, Sotho and Zulu. Almost 65% (64,6%) of the people assessed, chose to answer the Sotho version of the questionnaire, which is in keeping with the language spoken in and around the area served by Kalafong hospital.



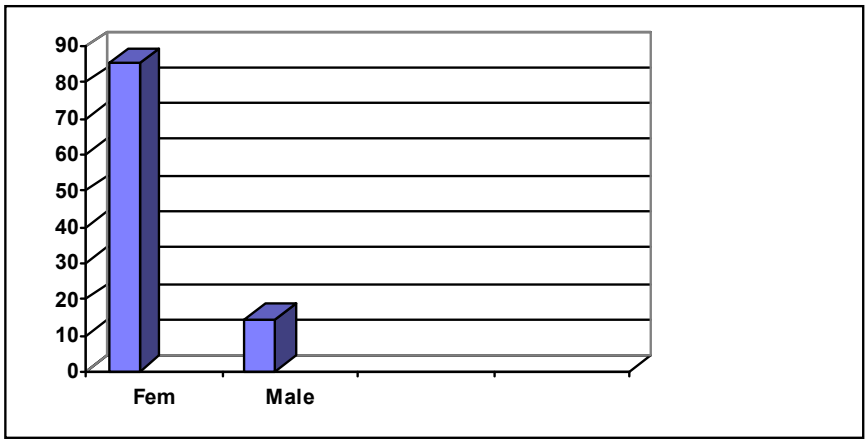
N = % of total number of subjects (i.e. 96)

Figure 3. 8: Distribution of hand preference within sample.

Right handed = 97.9% (n = 94)

Left handed = 2.1% (n = 2)

Ninety-seven comma nine percent of the subjects were right handed with 2,1% being left handed.



N = % of total number of subjects (i.e. 96)

Figure 3.9: Distribution of gender within sample.

Fem. (Female) = 85,4% (n = 82)

Male = 14,6% (n = 14)

Since RA and OA affect females more than males, it was not surprising that 85,4% of the rheumatology clients included in the study were female.

3.4.5.2 Questionnaire 2

Questionnaire 2 as it was used in Study 1 consisted of 48 questions. On the recommendation of the statistician it was decided to discard questions if more than 50 % of the clients answered that question as "*Not Applicable*". Three questions were discarded because more than 50% of the clients answered these three questions as "*Not Applicable*". These questions were:

Question 46: Because of my hands, I have difficulty in driving a car.

Question 47: I find it difficult to handle the cards whilst playing, because of my hands.

Question 48: Because of my hands, I can't participate in counter games anymore.

Analysis of the questions was done on the remaining 45 questions for the 96 subjects.

3.4.5.3 Analysis of each question in the test

To establish concurrent validity for the remaining 45 questions, they were analysed in terms of the four variables mentioned above. For each question four tables have been compiled to show the two-way analysis for the specific item being analysed.

The data in table 3.5 demonstrates how each of the 45 questions were analysed in order to distinguish between severe or mild functional difficulties. The number of clients scoring within the lower third of the total possible score and those in the higher third were calculated. By comparing these two groups with the answers obtained on the questions, analyses could be done to determine whether or not the questions were sensitive outcome measures. When a question can determine between the low and high thirds of the score

obtained, it should have mostly *"no*" answers for the low third and mostly "*yes*" answers for the high third. When only these questions are to be included in the final questionnaire, a high score obtained will indicate severe functional difficulty and a low score mild functional difficulty.

The second variable in table 3.5 demonstrates whether a question could distinguish between the disease activity namely whether the disease was active or in remission. If a question was sensitive in terms of disease activity, there had to be more "*yes*" answers from clients with active disease and more "no" answers from those in remission.

The third variable in table 3.5 reviews the severity of the illness as seen in the deformities, was analysed. This was included because many OT's feel that they see numerous clients with severe deformities (more than 50% loss of ROM, with swan-neck and/or boutonniere or Z-deformities) who still do most of their ADL independently. On the other hand the opposite was also true, many clients with mild deformities are almost totally dependent in terms of ADL. It was the aim of this specific statistical analysis, to determine whether a question could distinguish between the impact mild or severe deformities have on hand function and occupational performance. Questions sensitive to the severity of the deformities should have more "*no*" answers from subjects with mild deformities and more "yes" answers from those with severe deformities.

The fourth variable in table 3.5 for each question reflects the summary of the two-way tables done for each question compared to the level of pain as experienced by the client.

The nought and one scores for pain were combined into the "lower" level of pain and the two and three scores were combined into the "higher" level of pain. These were then again compared to the "yes" and *"no*" answers to the questions. For a question to be sensitive in terms of pain, one would expect more "no" answers for the "lower" level of pain and more "yes" answers for the "higher" level of pain.

The significance levels for each item were calculated. P values were calculated to determine the significance or lack of significance of the data (Brink, 1996).

To make sure the questionnaire had high concurrent validity, it was decided that those questions that could not distinguish between the variables mentioned, would be eliminated. None of the questions were eliminated based on this assumption.

The results for each question will now be presented. (Appendix K: Summary of Item Analyses Results) All results in green reject the null hypotheses listed on page 7 that states that questionnaire 2 is a valid method to evaluate the functional ability of rheumatology clients at Kalafong hospital. Results in black show accept the null hypotheses, or are not statistically significant.

Table 3. 5 Analysis of Questions: Functional Difficulty

	Functional Difficulty		**Severity of Deformities**		**Disease Activity**		**Pain**	
	n	**p**	**n**	**p**	**n**	**p**	**n**	**p**
Question 1- *I find it difficult to fasten or undo my buttons*	**61**	**0.00**	87	0.00	**89**	**0.00**	**85**	**0.00**

Question 2 - *I find it difficult to fasten or undo my zips*	**48**	**0.00**	**70**	**0.00**	**71**	**0.00**	**69**	**0.00**
Question 3 - *I find it difficult to hold the soap while washing,*	**57**	**0.00**	**86**	**0.00**	**87**	**0.00**	**84**	**0.00**
Question 4 - *I find it difficult to open or close taps*	**64**	**0.00**	91	0.01	**93**	**0.00**	**89**	**0.00**
Question 5 - *I find it difficult to put on/take off my shoes,*	**63**	**0.00**	89	0.03	**91**	**0.00**	**87**	**0.00**
Question 6 - *I find it difficult to tie the shoelaces*	**59**	**0.00**	81	0.00	**83**	**0.00**	**79**	**0.00**
Question 7 - *I find it difficult to fasten or undo the buckles of my shoes*	**59**	**0.00**	80	0.00	**82**	**0.00**	**78**	**0.00**
Question 8 - *make it impossible for me to hold my toothbrush.*	**63**	**0.00**	**89**	**0.04**	**91**	**0.00**	**87**	**0.00**
Question 9 - *I can't open any bottles*	**62**	**0.00**	88	0.01	**90**	**0.00**	**86**	**0.00**
Question 10 - *I find it difficult to shave*	**12**	**0.01**	16	0.08	**16**	**0.00**	**15**	**0.01**
Question 11. - *I find it difficult to put on make up.*	**62**	**0.00**	**91.**	**0.00**	93	0.04	**89**	**0.00**
Question 12 - *I find it difficult to wash my hair*	**64**	**0.00**	93	0.00	**95**	**0.01**	**91**	**0.00**
Question 13 - *I find it difficult to towel dry my hair*	**64**	**0.00**	93	0.00	**95**	**0.00**	**91**	**0.00**
Question 14. - *I have problems holding my washing cloth whilst bathing/washing*	**63**	**0.00**	**90**	**0.02**	**92**	**0.00**	**88**	**0.00**
Question 15 - *I find it difficult to pull my pants up when going to the toilet.*	**59**	**0.00**	**85**	**0.00**	**86**	**0.00**	**83**	**0.00**
Question 16 - *I find it difficult to pull my pants down when going to the toilet.*	**63**	**0.00**	93	0.11	**93**	**0.00**	**89**	**0.00**
Question 17 - *I find it difficult to pick up pots and pans when cooking*	**59**	**0.00**	81	0.01	**90**	**0.00**	**86**	**0.00**
Question 18 - *I can't hold the spoon/fork to stir the food whilst preparing it.*	**62**	**0.00**	91	0.01	**93**	**0.00**	**89**	**0.00**
Question 19 - *I have a problem sweeping the floor, because I can't hold the broomstick.*	**60**	**0.00**	**90**	**0.00**	**91**	**0.00**	**89**	**0.00**
Question 20 - *I can't hand wash my clothes*	**64**	**0.00**	92	0.02	**92**	**0.00**	**90**	**0.00**

Question 21 - *I find it difficult to hold the shopping basket*	**63**	**0.00**	92	0.01	93	0.00	**90**	**0.00**
Question 22.- *I have difficulty in carrying a plastic shopping bag.*	**62**	**0.00**	91	0.00	92	0.01	**89**	**0.00**
Question 23. - *I can no longer pick up the kettle*	**62**	**0.00**	89	0.00	91	0.03	**87**	**0.00**
Question 24 - *It's difficult to pull up the blankets*	**62**	**0.00**	90	0.00	**92**	**0.00**	**88**	**0.00**
Question 25 - I *have difficulty in holding a cup to drink from*	**61**	**0.00**	**90**	**0.00**	92	0.11	**88**	**0.00**
Question 26 - *It is difficult to turn a key,*	**63**	**0.00**	**92**	**0.00**	**94**	**0.00**	**90**	**0.00**
Question 27 - *I can't pick up and carry around a pot of pap. (>5kg)*	**63**	**0.00**	90	0.03	92	0.03	**88**	**0.00**
Question 28 - *The problems I have with my hands forced me to change jobs*.	**62**	**0.00**	91	0.00	93	0.00	**89**	**0.00**
Question 29 - *I only eat the food that I can easily handle with my painful hands.*	**64**	**0.00**	93	0.00	**95**	**0.00**	**91**	**0.00**
Question 30 - *I can barely pick anything up with my painful hands*	**63**	**0.00**	90	0.01	**92**	**0.00**	**88**	**0.00**
Question 31 - *Because of my hands I do not work at all.*	**60**	**0.00**	88	0.00	**90**	**0.00**	**86**	**0.00**
Question 32.- *Because of my hands I do not use sign language when I talk.*	**58**	**0.00**	80	0.07	**82**	**0.00**	**78**	**0.00**
Question 33.- *I find it difficult to fall asleep*.	**63**	**0.00**	93	0.01	**94**	**0.00**	**90**	**0.00**
Question 34 - *I wake up during the night,*	**64**	**0.00**	92	0.07	**94**	**0.00**	**90**	**0.00**
Question 35. - *I feel self-conscious because my hands look ugly, so I usually stay at home.*	**61**	**0.00**	90	0.02	**92**	**0.00**	**88**	**0.00**
Question 36. - *I keep my hands in the same position for long times, because they are too painful to move*.	63	0.00	91	0.00	93.	0.00	89	0.00
Question 37 - *Because I have pain in my hands most of the time, I think about my hands a lot.*	64	0.00	93	0.03	95	0.00	91	0.00

Question 38. - *I expect other people to do things for me, because my hands are very painful.*	**63**	**0.00**	92	0.00	94	0.06	**90**	**0.00**
Question 39 - *My hands make me irritated and I am then impatient with my family.*	**62**	**0.00**	91	0.00	**93**	**0.00**	**89**	**0.00**
Question 40 - *I often feel irritated and frustrated, because of my hands.*	61	0.00	91	0.00	92	0.00	89	0.00
Question 41 - *I have a problem holding my cutlery while eating*	**65**	**0.00**	**92**	**0.02**	**94**	**0.00**	**90**	**0.00**
Question 42 - *I can no longer hold my pen to write,*	**60**	**0.00**	**83**	**0.00**	**85**	**0.00**	**81**	**0.00**
Question 43 - *I can't do my hobby anymore.*	**61**	**0.00**	89	0.15	91	0.00	**87**	**0.00**
Question 44 - *I can no longer hold the books to read.*	**57**	**0.00**	80	0.15	**82**	**0.00**	**87**	**0.00**
Question 45 - *I do not feel like doing a hobby anymore*	**62**	**0.00**	90	0.04	**92**	**0.00**	**88**	**0.00**

Less than half the subjects answered Question 10: *I find it difficult to shave, because of my hands.* The analysis of this question showed it was a gender specific activity. Twenty-four male subjects were included in the study. Therefore the question was answered by more than 50% of the applicable subjects.

This analysis suggests that the questions now included in questionnaire 2 are more relevant to use to assess the functional ability of clients at the Kalafong Rheumatology outpatient client.

Forty two of the 45 questions are able to distinguish effectively between both severe and mild difficulties and high and low pain. Only questions 36, 37 and 40 are only sensitive

to high difficulty and high pain but not low difficulty and low pain, high deformity and active disease and not low deformity and disease in remission. They were removed to retain the concurrent validity of the questionnaire.

Thirty four questions were also sensitive to distinguishing between active disease and disease in remission. But only 10 questions could distinguish efficiently between severe and mild deformity. Therefore this questionnaire does not have concurrent validity with severity of deformity. .

3.5 STEP 3

The final process in determining the concurrent validity (Trochim 2006) was carried out with this questionnaire. Significance was set at a 1% level of significance: ($p \leq 0,01$) to achieve this. Three questions were removed because they were inappropriate or not answered by 50% of the sample, and the questionnaire was now called questionnaire 3. As this represented the final version of the questionnaire it was renamed the Steinmann-Obermeyer Questionnaire (SOQ).

During step 3, the score obtained by the SOQ was compared to the three external measures collected during the assessment of the subject: The patient's rating of their pain, and the rheumatologist's assessment of the severity of disease and disease activity.

3.5.1 ASSESSMENT TOOLS

3.5.1.1 The Steinmann Obermeyer Questionnaire (SOQ)

The SOQ consisted of 45 questions, which were relevant to the population assessed. (Appendix L)

3.5.1.2 Ritchie Index

See 3.4.1.2 – The pain rating scale is the same joint tenderness index used for Study 1 and 2.

3.5.1.3 Degree of deformities

The degree of deformities, or also termed the severity of the disease, was determined by the rheumatologist at the clinic. The criterion used was, clients with less than 50% loss of ROM in the joints of the hands were termed mild and those with more than 50% loss of ROM were considered severe.

3.5.1.4 Disease activity

Disease activity was determined by blood results taken by the rheumatologist. The blood tests that contributed most to this were the C-reactive Protein (CRP), Erythrocyte Sedimentation Rate (ESR), Full Blood Count (FBC) and Rheumatoid Factor (RF).

3.5.2 RESEARCH PROCEDURE

The same sample of 96 rheumatology clients who completed questionnaire 2 was used to obtain the data for the comparison between the SOQ and the variables of pain, severity of the disease and disease activity described above. This information was collected from the patients' files.

3.5.3 DATA ANALYSES

3.5.3.1 SOQ versus Pain

The composite score for each subject was obtained for the SOQ by excluding the results of the 3 questions that were removed from the questionnaire 2. The raw scores obtained on the SOQ were calculated as a percentage and then compared with the client's own rating of his/her level of pain. The pain levels were divided into two categories, namely high and low. The pain scores of zero and one were combined into the "low pain" category and the two and three pain scores made up the "high pain" category. These two categories were compared with the high and low scores on the questionnaire.

3.5.3.2 SOQ versus Severity of Disease

The composite score obtained on SOQ was again calculated as a percentage and compared with the severity of the subjects' disease. The mild and severe deformities as classified by the rheumatologist were compared to the high and low scores on the questionnaire.

3.5.3.3 SOQ versus Disease Activity

The raw score obtained on SOQ was again calculated as a percentage and compared with the disease activity. The two categories of disease being "*active*" and "*in remission*" were compared to high and low scores on the questionnaire.

3.5.4 RESULTS OF STEP 3

3.5.4.1 The SOQ versus pain

After the item analyses were completed, the SOQ score was compared to the level of pain experienced by the client. It was hypothesised that a significant correlation exists between a client's experience of his/her pain and the results obtained by the SOQ. The results supported this.

Table 3.6: Total SOQ score versus the level of pain.

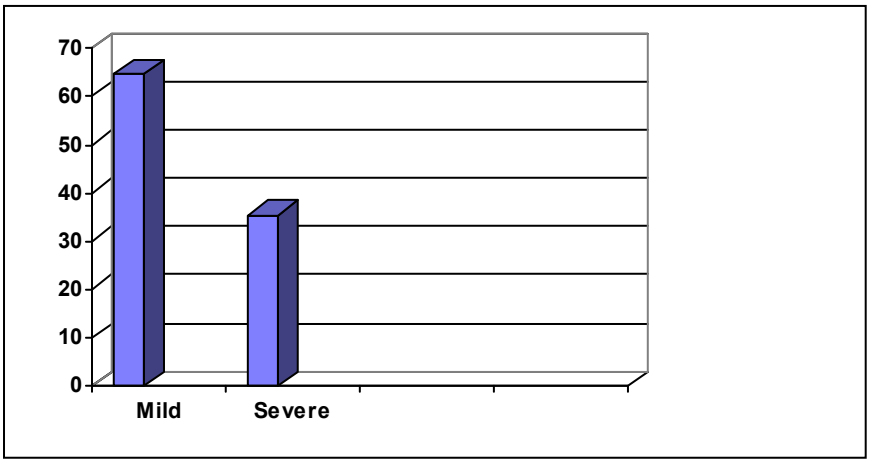
	LOW PAIN (0 & 1)	**HIGH PAIN (2 & 3)**	**p value**
MEAN	0,3060	0,8514	p = 0,00
N	32	60	

Significant was set at a 1% level of significance: ($p \leq 0,01$)

The data of 92 subjects was analysed, 32 clients scored low on the questionnaire and reported low pain. Sixty subjects scored high on the questionnaire and reported high levels of pain. The mean as seen in Table 3.6 indicate that for low pain the score should be as close to nought as possible and for high pain should be as close to one as possible. This was the case, which meant that a very good relationship existed between the outcome of the questionnaire and the subject's own experience of their pain threshold. ($p \leq 0.00$).

The null hypothesis stated under objective 1.4.4 (p. 7) was rejected: There is a significant correlation between the patient's assessment of their level of pain and the score obtained by the SOQ indicating good concurrent validity.

3.5.4.2 SOQ and Severity of Disease



N = total number of rheumatology clients included in the study (i.e. 96)

Figure 3.10: Distribution of severity of the disease

Mild = 64,6% (n=62)

Severe = 35,4% (n=34)

Table 3.7: Total SOQ score versus the severity of disease.

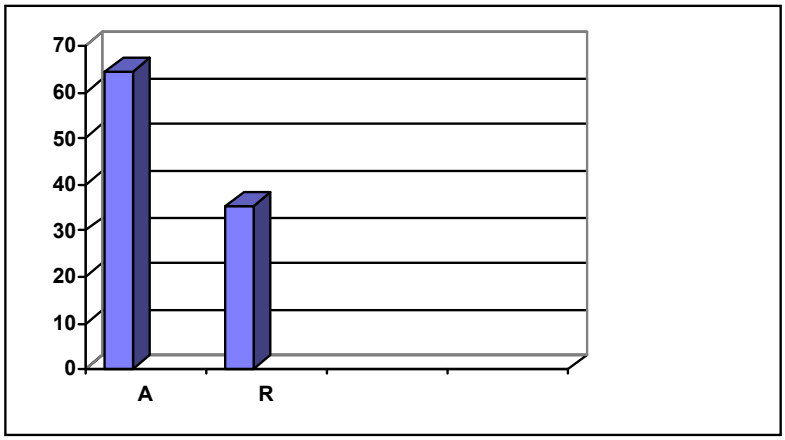
	MILD	SEVERE	p value
MEAN	2,1388	2,7014	p = 0,00
N	62	34	

Significant set at a 1% level of significance: ($p \leq 0,01$)

If the severity of the disease as seen in the deformities were correlated to their functional ability, the above score for mild disease should be close to nought and for severe disease should be close to one. As can be seen from the results, this was not the case. This is what the researcher expected, since she has hypothesised that the severity of the disease is not an indication of a clients functional difficulties.

The null hypothesis stated under objective 1.4.2 (p. 7) was accepted: There is no significant correlation between the severity of disease as classified by less or more than 50% ROM in the hand joints, and the score obtained by the SOQ indicating discriminative validity.

4.5.3.3 SOQ and disease activity



N = % of total number of rheumatology clients included in the study (i.e. 96)

Figure 3.11: Distribution of disease activity

A = Active

R = Remission

Active = 64,6% (n=62)

Remission = 35,4% (n=34)

Table 3.8: Total questionnaire 3 score versus the disease activity.

	REMISSION	ACTIVE	p value
MEAN	0,2905	0,8126	p = 0,00
N	34	62	**p value**

Significant was set at a 1% level of significance ($p \leq 0,01$)

The data of 96 subjects was analysed, 34 clients scored low on the questionnaire and was reported to be in remission. Sixty two subjects scored high on the questionnaire and had active disease. The mean as seen in Table 3.58 indicate that for remission the score should be as close to nought as possible and for active, it should be as close to one as possible. This was the case, which meant that a very good relationship existed between the outcome of the questionnaire and the client's disease activity. ($p \leq 0{,}00$)

The null hypothesis stated under objective 1.4.3 (p. 7) was rejected: There is a significant correlation between the disease activity as classified the CRP, ESR, FBC and RF, and the score obtained by the SOQ indicating high concurrent validity.

The above results indicate that the questionnaire outcome can be compared with the subject's own pain rating and their disease activity. In other words, these two components can give an indication of a client's functional difficulties. The severity of the disease as measured by the deformities in their hands, on the other hand, gives no indication of their functional limitations. Therefore concurrent validity only exists with the pain and disease activity scores.

3.6 STUDY 2

To establish the predictive validity of the study, it was decided to verify the finding that a raw score of zero indicated no dysfunction. The questionnaire was administered to 69 age and gender matched control subjects who had never been diagnosed as having rheumatic disease.

3.6.1 STUDY POPULATION AND PROCEDURES

3.6.1.1 Control group

The next set of data was obtained by administering the SOQ to the control group of 69 asymptomatic individuals to determine what the perfect raw score on the questionnaire would be if completed by a subject with no hand pathology. The researcher felt this raw score should be zero but needed to prove it scientifically. In theory this means that a raw score of zero would indicate no dysfunction or the person was asymptomatic in terms of rheumatic disease. A raw score of 45 would indicate total disability and dysfunction. Subjects used for this part of the study, where matched for age and gender with subjects who completed Questionnaire 2.

The control subjects were selected from the same population, i.e. the areas served by Kalafong hospital, but were recruited from the pool of people who visited the hospital on a daily basis to bring family members or friends to the hospital. The researcher was very careful to select the control subjects from a pool of people who did not themselves come to the hospital to seek medical assistance. The criteria applied to this group were the same in terms of age and gender (matched to the study group) as for the study group, but the distinguishing criterion was that the control group should not be suffering from any kind of illness or disease that would affect their hand function in any way.

The same OTA who participated in the study thus far, also administered this part of the research. The control subjects were invited to participate and the OTA explained the purpose of the research project and read them the information sheet following the exact

procedure as describe in study 1. The information sheet (Appendix B) was adapted to explain the use of the questionnaire and the consent form was the same for this group (Appendix M) and consent was obtained before administering the SOQ. If a subject refused consent, the questionnaire was not administered. Once the subject had signed the consent form the OTA administered the SOQ in their language of choice. No other procedures were administered or information obtained.

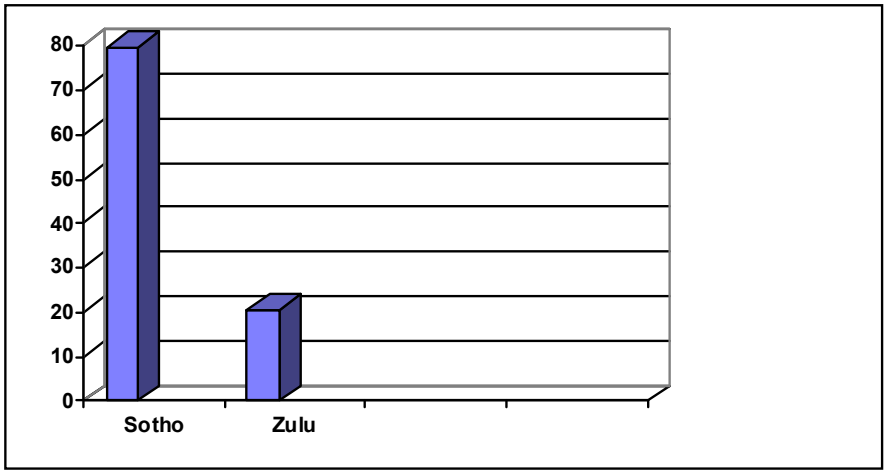
Statistically a minimum of 50 subjects was required to establish a 95% level of significance, but it was possible to obtain a bigger sample and after consultation with the statistician it was decided that this could only benefit the reliability of the results.

3.6.2 DATA ANALYSIS

All subjects answered all the questions as "*no*" and thus scored zero as their total raw score on the SOQ, which indicated that the control subjects had no hand function problems. Mean scores were calculated for this data.

3.6.3 RESULTS OF STUDY 2

3.6.4.1 Descriptive Data

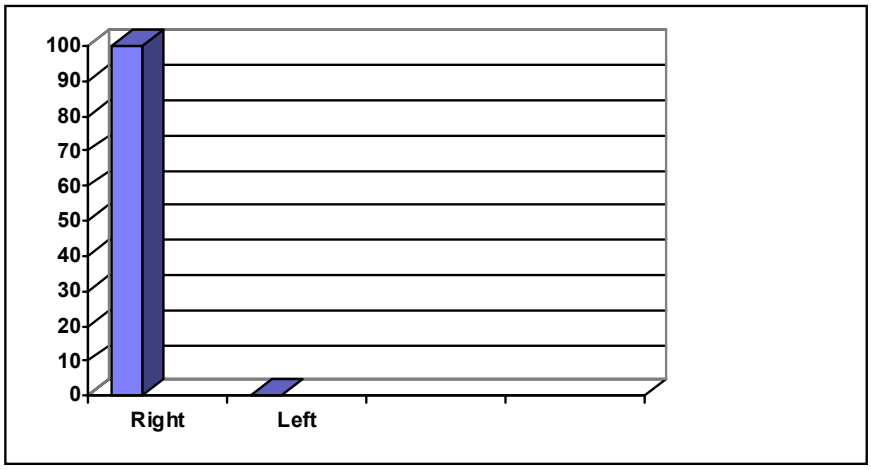


N = % of the total number of control subjects included in the study (i.e. 69)

Figure 3.12: Distribution of language preference: Control group

Sotho = 79,7% (n = 55)

Zulu = 20,3% (n = 14)



N = % of total number of control subjects included in the study (i.e. 69)

Figure 3.13: Distribution of hand preference: Control group

Right handed = 100% (n = 69) Left handed = 0% (n = 0)

This differed from the study group because the study group included a small percentage of people who are left handed.

Table 3.9: Statistical analysis of the total score on SOQ for normal subjects

	Normal Subjects
Standard deviation	0,00
Mean	0,00

N = 69

For the total raw score to equal nought (in other words indicate an absence of functional difficulty) the mean score in the table should be as close to nought as possible. The mean score equalled nought, which supported the fact that a SOQ raw score of zero meant no functional difficulty.

Predictive validity was assumed as no significant difference between the means of the client group and normal subjects was established statistically as all subjects scored 0.

3.7 CONCLUSION

The questionnaire developed as the research progressed as illustrated in Figure 3.1. Each step in this evolution was numbered to clarify the progression and also for the easy understanding of the reader. The research methodology and statistical analyses were included together to simplify the understanding of the project progression. The results obtained verified the validity of the questionnaire for use with the population served by Kalafong hospital in Pretoria.

The initial 24 question questionnaire developed to collect appropriate data efficiently

about the specific cohort of clients attending the Rheumatology clinic at Kalafong hospital for the purpose of directing OT was based on hearsay and clinical observations. After testing in the pilot study, it was face validity proved to be inadequate although the weak correlations indicated that it may have some value.

Content validity was further established in Questionnaire 2, which was developed using the literature and best evidence to ensure that the items were appropriate and multi dimensional and focused on disturbances resulting from limited hand function as a result of rheumatic disease. This questionnaire included 48 questions and was tested for its relevance for this cohort of clients. Questionnaire 2 was tested on a sample of 96 subjects who all agreed to participate and met all the ethical consideration. This part of the research project was done in support of objective 1.4.1 (p.7). The analysis excluded 3 questions as they were marked inappropriate or answered by less than 50% of the sample. Concurrent validity was established by the statistical analysis which supported that the questions were most appropriate to the sample in terms of functional difficulty and painand least appropriate to identifying deformity.

The remaining 45 questions formed the final daft and were renamed SOQ. The raw scores of the SOQ were recalculated as percentages and the SOQ, and concurrent validity was further tested against pain, degree of deformity and disease activity.

A predictive validity study was done when the SOQ was administered to an asymptomatic sample the score equalled 0. This was tested on a sample of 69 control

group subjects and the results supported the fact that a score of 0 indicated no functional difficulty. No statistical analysis could confirm this as the value was 0.