CHAPTER 3:
RESEARCH DESIGN AND METHODOLOGY

3.1 RESEARCH DESIGN

In this randomised controlled, prospective study both qualitative and quantitative research methods were used as outcomes measures.

- Quantitative Experimental design – a pre-test-post-test randomized experimental design was used.
- This included qualitative element in the form of focus groups and
- Qualitative assessment surveys of adaptations in the home during a home visit

With this design, all conditions were the same for both the experimental and control groups, with the exception that the experimental group was exposed to additional treatment intervention. The experimental group was subjected to quantitative (before and after testing; and standard and experimental intervention) and qualitative (focus groups to establish course of intervention at home) methods and a survey of adaptations in their homes. The control group received quantitative input (before and after testing and standard intervention).

Maturation and history are potential problems for internal validity in this design and interaction of pre-testing and treatment poses a threat to external validity. Maturation occurs when biological and psychological characteristics of the research participants change during the experiment, thus affecting their post-test scores. History occurs when participants experience an event (external to the experimental treatment) that affects their post-test scores. Interaction of pre-testing and treatment comes into play when the pre-test sensitizes participants so that they respond to the treatment differently than they would with no pretest [67].

All the outcome measures used in this study have been reported extensively as outcome measures that are not influenced by history and the interaction of pre-testing and treatment. That a certain amount of maturation will inevitably occur in

the study population is to be expected but this should however be minimal as the study runs over four months only.

The study population consisted of male and female RA patients who attend the CHBH RA clinic on a Thursday.

A flow chart of the study design is illustrated in Figure 1.

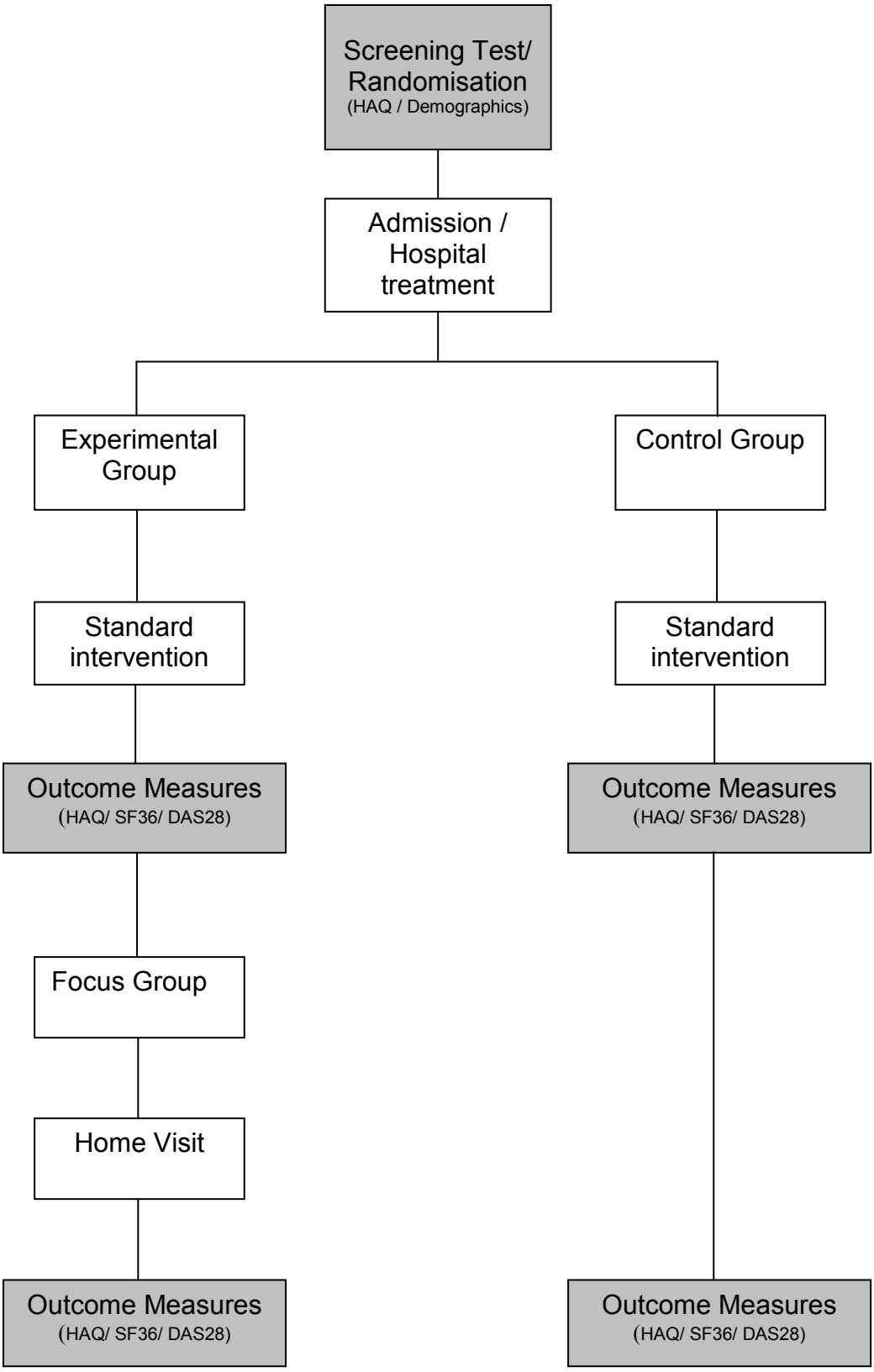

Figure 1: Flow Chart of Study Design

3.2. STUDY POPULATION

Patients were recruited from the weekly CHBH arthritis clinic. The following inclusion and exclusion criteria were used.

Inclusion criteria:

- Patients fulfilling at least 4/7 of the ACR criteria for RA [6]
- 18 years $\leq$ age $\leq$ 60 years
- Residing within Soweto
- Patients with moderate physical disability defined as assessed by HAQ scores between 20 (DI= 1.0) and 40 (DI= 2.0) [43] (it should be noted that patients who attend the clinic are in different stages of the disease. Inclusion was based on their DI and not the stage of their disease. It was felt that patients with this DI have the greatest potential for improvement).

Exclusion criteria as:

- Recent or planned surgery
- Bed or wheelchair bound
- Other sources of disability or co-morbidities that might interfere with function e.g. Cardiac disease.

3.2.1 Sample Size

The study was powered to detect a clinically relevant change in the patients outcome measures of the HAQ-DI of 0.5 points assuming a standard deviation of 0.467 units (range from 0 to 2, (sd = $\sqrt{2}$ (range/6) = 0.467) and testing at the 0.05 level of significance. A sample of at least 20 patients per group will have 90% power to detect a clinically relevant difference.

3.3 SCREENING AND RANDOMISATION PROCEDURE

3.3.1 The Screening Procedure

On the specific Thursdays, noted under dates between January and June 2005 (Appendix A) the principal Investigator, an OTA (trained in rheumatology) and a professional nurse screened patients for the study. The diagnoses of RA was

confirmed by patient records containing the ACR classification. Between 80 – 100 patients who attended the CHBH RA clinic were asked to complete the HAQ. Some patients were able to complete the forms independently. Others who required assistance due to poor vision, illiteracy or difficulty holding the pen were helped by one of the team members to complete the forms. (Studies have shown that responses are similar when the instrument is self-administered or administered by a nurse-assessor or physician at interview [28]). Valid candidate questionnaires were separated according to the inclusion and exclusion criteria. All the valid questionnaires were then scored.

Once four patients had been selected, they were asked to read the information leaflet and sign informed consent (Appendix B). Patients were not told whether they were in the control or experimental group.

Patients were to be admitted to hospital then for one-week intensive OT rehabilitation. They were not admitted immediately. All the necessary documentation for admission was completed by a doctor in the clinic and given to patients. They were asked to return on the Sunday evening for admission. Rehabilitation would start on the Monday morning.

Between 2 and 4 patients were admitted each week to keep the groups small and manageable and allow for individual treatment sessions.

3.3.2 The Randomisation Procedure

Depending on the Thursday on which the patients were screened they were either placed in the control or experimental group. All the Thursdays that fell between January and July 2005 were written on individual pieces of paper. One date plus one coloured tag (blue and green) were pulled simultaneously from a box. The dates pulled out with the blue tags were the days that indicated the experimental group and the green the control group.

The randomisation of subjects after completing the screening HAQ was as follows: After scoring all the valid questionnaires a randomised selection of 4 patients was done. The professional nurse selected 4 forms from the ones held out to her, with

closed eyes. All forms were held up side down during the selection. The OTA called the subjects selected. Once all four were identified, they were removed from the queue to give consent. A brief but thorough explanation of the study was given. Subjects were then given the opportunity to be admitted or to decline to be admitted to the study at this stage. Some subjects did decline and reasons given were: family commitments, prior arrangements or failing to see the direct benefit the study might hold for them. The professional nurse then randomly selected another candidate according to the method mentioned above.

3.4 SCHEDULE OF VISITS AND ASSESSMENTS

3.4.1 Time Schedule

Data collection for this study started in January 2005. Subjects were selected on Thursdays between January 2005 and July 2005. All further follow ups were completed by November 2005. (Appendix A)

The research procedures for assessment and treatment used are outlined in Tables 1 and 2.

Table 1: Schedule of Assessments

	Visit 1 Screening	Visit 2 Hospital admission (one week)					Visit 3 Focus group (Experimental Group only)	Visit 4 Home Visit (Experimental Group only)	Visit 5 End of Treatment
Procedure	Day -10 to -1	Day 0 - 4					Week 3-5	Week 8-10	Week 20 (± 1week)
		0	1	2	3	4			
Screening HAQ	✓								
Eligibility Criteria	✓								
Informed consent	✓								
Demogra-phics	✓	✓							
Physical examination by physician		✓							
Patients particulars		✓							
Disease duration		✓							
Resources available		✓							
ESR				✓					✓
Tender and swollen joint count				✓					✓
HAQ						✓			✓
SF-36						✓			✓
Qualitative surveys							✓	✓	✓

Table 2: Schedule of OT Treatment

	Visit 1 Screening	Visit 2 Hospital admission (one week)					Visit 3 Focus group (Exp group only)	Visit 4 Home Visit (Exp Group only)	Visit 5 End of Treatment
Procedure	Day -10 to -1	Day 0 - 4					Week 3-5	Week 8-10	Week 20 (± 1week)
		0	1	2	3	4			
Exercise class		✓	✓	✓	✓	✓			
Making AD - Tap turner - Extended sponge			✓	✓					
Splinting			✓	✓					
Joint protection education					✓				
Energy saving principles					✓				
Discussion of home programmes						✓			
Reflecting on coping strategies							✓		✓
Setting goals for further improvement							✓		
Evaluating application of AD/EC use								✓	
Evaluation of the home								✓	
Adjustments made in home environment								✓	
Activities demonstrated								✓	

3.5 THERAPEUTIC INTERVENTIONS

3.5.1 In-Patient Care

Both groups received in-hospital rehabilitation that consisted only of OT with daily exercise groups, joint protection education, energy saving principles, splinting of tender and swollen joints, correcting deformity, making/issuing assistive devices and giving subjects a home exercise programme (Table 2). This programme has been developed over several years at the hospital based on the OT's role in RA principles [2].

The in-hospital OT intervention consisted of two sessions every day. Subjects started with an exercise group in the OT department every morning after breakfast. This group was run by either the principal investigator or a trained OTA.

The exercise group on the Monday started with an informal discussion on: Who does exercise at home? Why they do it? Explaining the benefits of reduced early morning stiffness (EMS) reduced pain and improved mobility of the joints. The exercise programme consisted of a 5 minute warm up marching on the spot. Then it focussed on moving through full active range of motion (AROM) in all the joints from head to toe (or as much AROM as subjects could get during the session). It ended with a 5 minute tone down that included stretches and breathing techniques. After the first session the painful joints were identified. Early morning stiffness was monitored before the exercises session along with improvement of painful joints. Each session throughout the week aimed to improve the AROM in all problematic joints. The repetitions during the exercise groups also increased from Monday through to Friday. Subjects were encouraged to repeat the exercise session by themselves in the ward in the evenings.

The second session for each subject on a Monday was done individually to establish if any splinting would be required during the week.

The second group session on a Tuesday and Wednesday was devoted to the making of assistive devices. Subjects were provided with the material and demonstration to make a wooden tap turner on one day (using a small plank and

screws) and an extended sponge on the other day (using a sponge and a wooden hanger). Either the principal investigator or a qualified OTA supervised these sessions. Subjects kept the devices and were encouraged to use them in the ward during the admission and then to continue to use them at home.

Figure 2: Groups making the extended sponges

Figure 3: Groups making the extended sponges.

The second session on a Thursday was an education session. Subjects attended the general group education session at the RA clinic where the OT, a physiotherapist, social worker, podiatrist, rheumatology nurse and Arthritis Foundation members discuss their roles in the multi-disciplinary team (MDT). The OT focussed on joint protection techniques, energy saving principles and the use of assistive devices.

The second session on a Friday was the re-evaluation of the HAQ-DI and the first completion of the SF 36. Subjects were informed on the outcome and asked to comment on their experiences of the week.

Subjects received approximately 8 hours of group treatment during the week, and 1 to 2 hours of individual treatment. During the one-week admission, subjects were assessed by a doctor and adjustments to medication were made if necessary. They were then discharged on the Friday with follow-up dates and the encouragement to implement what they were taught, at home.

3.5.2 Focus Groups

Subjects in the experimental groups returned one month after discharge for a focus group.

This was included for assessment of OP. The first assumption of client-centered assessment is that clients know what they want in terms of their occupational performance. This assumption allows therapists to trust clients to identify the problems that interfere with optimum occupational performance. A second assumption of the client-centered approach is that the only relevant frame of reference for therapy is that of the client. While the therapist may have knowledge and expertise about certain aspects of disability and therapy, he or she can never fully understand the values, beliefs, and experiences of the client, and must therefore accept the client's reports as the most relevant source of information. Furthermore, this assumption suggests that the more open-ended the assessment is, the greater the opportunity to hear the client's unedited, uncensored experience of occupation. The third assumption of the client-centered approach is that the therapist cannot actually promote change; he or she can only create an

environment that facilitates change. The most valuable role for the therapist is to support the client through the changes he or she wishes to make, with information, ideas, suggestions, resources, and trust in his or her ability to succeed in making the desired change [47].

As the evidence for the effectiveness of a comprehensive OT programme in RA is uncertain, the inclusion of a focus group was to assist in the customisation of the comprehensive intervention offered and ensure a client centred approach. Rather than anticipating how subjects experienced the intervention, the subjects in the experimental group were given an opportunity to give feedback in a group setting. Questions involved asking open ended questions and developing an analysis from the information supplied by participants [68]. Asking the questions "what do you struggle with?" and "what is important to you?" changed the approach to be more patient-centred. This provided the opportunity for the therapist to facilitate change and an opportunity for the subjects to pursue personally identified goals and discuss the attainment of these in a group setting [20] enabling shared decision-making [20, 23].

Other advantages of the groups are:

- Treatment in groups are more effective [20]
- Builds group cohesion and support from peers [20]
- Considers the individual needs and impact of the disease as expressed by the subjects themselves [44].
- Provides an opportunity for modelling in group setting where subjects can learn from each other [20].
- Provides an opportunity for supplementary questions to verify information [29].

The focus group sessions were administered by 2 OTs, one facilitating the group and the other observing and scribing. (See Appendix C for structure of group). All groups were videotaped. There was also an OTA present to help with translation. The aim of the group was to establish how the subjects were coping with the disease since leaving the hospital and what home environment adaptations they still felt necessary to improve their level of functioning.

The group session started by asking subjects how they were coping at home. The home implementation of what they had learnt in the hospital was discussed followed by a discussion on problems still experienced by each patient. Each room in the house and activities in that room were discussed (See Appendix C for questions asked during the group).

Thereafter the subjects were asked to formulate personal objectives on how they could improve the quality of their day to day task performance during the following two weeks prior to the home visit by the OT. This was to encourage subjects to continue applying the joint protection and energy conservation techniques and to facilitate further self-management of the disease.

The trustworthiness of the data is obtained through triangulation with quantitative scores, focus group and home visit information. Rich, thick description is used to convey the findings [68].

3.5.3 Home Based Intervention

Home visits were carried out by the researchers to the homes of the experimental group eight to ten weeks after discharge. A survey of the adaptations used by the subjects and made by the researcher was completed using a checklist.

The focus of the home based intervention was to further assist subjects and empower them within their home environment. As all of the subjects in the study come from an economically deprived social environment, environmental adaptations had to be cost effective. Subjects were encouraged to use what was available within their environment to make changes rather than to rely on expensive methods for adjustments. An individual checklist was compiled for each subject after the focus group based on their identified problems and goals. This was used to facilitate the focus of the home visits. The structure of the home visit was a room to room inspection in the house with the emphasis placed on goals and feedback identified by the subject in the earlier focus group sessions (Appendix D for example).

3.5.3.1. Evaluation of the Home

The same OT, OTA and professional nurse that had been treating the subjects thus far made the home visits. Each home visit lasted approximately 90 minutes.

Kielhofner emphasises that, to understand the human occupation, we must understand the physical and social environment in which it takes place [69]. Thus, in order for us to really understand what further intervention would be required, we needed to do the home visits.

Figure 4: A Subjects house in Protea North, Soweto

During the home visit, the OT assessed any adaptations that had already been made and implemented the modifications discussed with the subject during the focus groups. Resources available to the client were noted.

Some photographs of the home and changes made by the team were taken.

Figure 5: Illustrating how using cement bricks that were lying around could be used to raise the work surface for a better ergonomically adjusted washing position.

3.5.3.2 Adjustments Made

The restoration of performance can be achieved through adaptation, not just of the person's skill, but the way in which the activity is performed [58].

The provision of further assistive devices, adaptations to the patient's work area or task adjustments were only made if the subject's method of executing an activity was considered harmful to their joints and not simply as a matter of convenience for the subject.

Principles of ergonomics, energy conservation, task simplification and joint protection were all considered. The checklist compiled during the focus group further guided the adjustments made by the home-visit team.

When adjusting the task area, an attempt was made to use what the subjects had in their environment e.g. raising a work surface with bricks that were lying around (Figure 5), or using chairs to raise a work surface.

3.5.3.3 Demonstration of Activities

Subjects were asked to demonstrate activities they had reported to be problematic during the focus group. Whether or not subjects had achieved their personal objectives were also noted. Reinforcement of existing techniques being used were also consolidated in the subjects' home environment.

3.6 OUTCOME MEASURES USED FOR STUDY POPULATION

3.6.1 Demographic Data

The following demographic data was collected from patients; Age, gender, address, disease duration, recent surgery and other medical problems. Disease

duration for each patient was defined as the time of onset of painful joints and collected from patients' clinic records, as reported by the patient. (Appendix E)

3.6.2 Health Assessment Questionnaire

The HAQ measures disability and provides a disability index (HAQ-DI) [28, 29, 30]. This self-administered instrument looks at 8 categories of function: dressing and grooming, rising, eating, walking, hygiene, reaching, grasping and other activities. Patients are asked to grade their ability to perform certain tasks on a scale of 0 – 3, where 0 = without ANY difficulty, 1= with SOME difficulty, 2 = with MUCH difficulty and 3 = UNABLE to. (Appendix F)

This test is widely used in research done by OTs' on the effectiveness of treatment as it considers functional ability in occupational performance [14, 16, 17]. The HAQ is also routinely used at CHBH RA clinic. For the purpose of this study we chose to score all 20 items to calculate a total out of 60, not 24, thus making the measurement more sensitive to change [45, 46]. The category score is the mean of the item scores in that category. The disability index (DI) is calculated by adding the scores and dividing by the total number of questions answered [42]. The range is from DI=0 meaning no disability, to DI=3 meaning completely disabled [29]. Mild disability is considered a DI score ≤ 1.0, moderate 1.0 ≤ DI ≤2.0 and severe disability DI ≥ 2.0 [43].

We did not weight the HAQ scores to account for the use of assistive devices (as usually done), as this has a negative effect on the item score by increasing it. One of the reasons for this is that we felt it was preferable to consider only the degree of task performance regardless of the use of technical assistance. In doing so, we accepted the analysis of Van der Heide and colleagues, who demonstrated that functional disability and assistance reflect separate dimensions of physical function [45, 70]. Issuing AD to subjects is a part of OT intervention and it would be contradictory to then weight that HAQ score negatively for the use of these.

3.6.3 Short Form 36

The first SF 36 [31] assessments were done during the admission period and again at follow-up at week 20 (± 1 week). This test was done to measure both physical and mental health status. In addition to the disability score provided by the HAQ-DI, the SF36 offers a further spectrum of components influenced in the subjects' OP. We obtained four physical health scales test scores: physical functioning (PF), role-physical (RP), bodily pain (BP) and general health (GH), and also four mental health scales test scores: vitality (VT), social functioning (SF), role-emotion (RE), and mental health (MH), all of which affect occupational performance. The SF-36 version 2 was used in this study [32]. (Appendix G)

The raw SF 36 scores were transformed to 0 – 100 scale using the following formula [32]:

$$\text{Transformed Scale} = \frac{\left[\text{(actual raw score – lowest possible raw score)}\right]}{\left[\text{(possible raw score range)}\right]} \times 100$$

All measurements of the HAQ and SF-36 at the end of week one and at Week 20 (± 1 week), were done by a trained OTA, thus blinding the researcher. This improves the validity of the assessments and prevents bias by the principal researcher.

3.6.4 Disease Activity Score-28

Overall disease activity was measured using the DAS28. This was done during admission and again at final follow-up. The measurement at final follow-up was done to see whether improvement can be attributed to the comprehensive OT intervention or improvement in the disease activity itself. It further deals with the threat to internal validity by controlling for maturity and history (e.g. medical treatment remission) of participants [67]. All tender and swollen joint counts for the DAS28 were performed by one of two rheumatologists at the hospital.

For the purpose of this study, the DAS28 with 3 variables (DAS28-3V) was used (28 swollen joint count, 28 tender joint count, ESR). Balsa et al found a high

correlation between the DAS28 and DAS28-3V when compared to the ACR disease activity criteria [71]. Excluding the general health assessment on a visual analogue scale by the patient makes the score more objective. It has been proposed that in established RA it is better to use the DAS index with 3 variables as global health or patient global assessment of disease activity can be considered in relation to mixed variables that combine the effects of the disease process and damage [71].

The levels of disease activity were defined as follows:

- A patient is considered to be in disease remission when their DAS28 < 2.6
- low disease activity DAS28 2.6≤3.2
- moderate disease activity 3.2< DAS28 ≤5.10
- or high disease activity DAS28 >5.1

A change of 1.2 of the DAS28 in an individual patient is considered a significant clinical change [33].

3.6.5 Reassessment of Subjects

Both groups of subjects returned in to the hospital for a final evaluation at 20 weeks (± 1 week). This allowed for completion of data collection for all groups within one year as there were time constraints. It has previously been shown that the best results occur over 4 months [26]. Both qualitative (HAQ-DI and SF36) and quantitative outcome measures were repeated. In addition disease activity was re-evaluated using the DAS28.

The subjects were asked to evaluate the OT intervention. This was done in the form of structured questions and an informal discussion, noted down by the researcher. Subjects were asked what aspects of the intervention they felt benefited them the most:

- If they were still exercising daily?
- If they where using the AD made and issued?
- Did they feel that that they were coping better with their RA than before?

3.7 STATISTICAL ANALYSIS

3.7.1 Statistical Methods: Qualitative and Quantitative

As mentioned before, for the primary objective (HAQ-DI), a sample of *at least* 20 subjects per group will have at least 90% power to detect a clinically relevant difference in change from baseline of 0.5 points on the disability index (HAQ-DI) according to the HAQ. Assuming a standard deviation of 0.467 units (range from 0 to 2, (sd = $\sqrt{2}$ (range/6) = 0.467) and testing at the 0.05 level of significance.

In the data analysis, groups were compared at baseline, 1-week and at week 20 ± 1 week with respect to their change in HAQ-DI, DAS28 and SF36, from baseline, using an analysis of covariance (ANCOVA). A p value of 0.05 was determined as significant. ANCOVA is used to reduce the error of variance and thus produce more powerful tests than in a design with no pre-test. It also helps eliminate systematic bias [67].

All observed parameters were analysed and reported on. A Welch t-test was used for the reason that some of the parameters variances of groups were different. It deals with unequal variances. Furthermore should variances be equal, the Student t-test is a special case of the Welch t-test. The Welch t-test was used to compare groups at baseline and initial assessment with respect to:

- demographic information
- HAQ scores
- DAS28
- SF 36

A paired t-test was used to compare baseline scores with end of hospital stay and baseline with final follow-up scores within the:

- Control group
- Experimental group

A Fisher Exact test was used to calculate the significance in both groups' access to resources and their evaluation of the OT intervention.

3.7.2 Qualitative data

In order to identify themes all discussions during the focus group sessions were transcribed. The groups were also video taped to review afterwards to ensure no information was missed.

The first step in coding was to make sense of all the data by analysing significant statements and generating meaningful units [68]. This was done by watching all the videotapes and comparing these with the scribed notes from the groups. The researcher was guided by perceptions held by the subjects, their way of thinking about the disease and rehabilitation, and activities brought up in the groups. All phrases pertaining to the disease and disability as well as improvement and problems experienced were noted and clustered together. Finally the specific themes were coded according to the frequency in which they occurred.

To ensure trustworthiness of the coding process, a sample of the groups was coded by the original scribe and values added in percentage of appearance. This was compared to the themes extracted by the main researcher. Both main themes correlated, as well as the theme constructs, within 7% of each other.

3.7.3 Analysis of Home Based Intervention

Descriptive statistics in terms of percentages were used to analyse the home visits. The number of assistive devices issued was noted along with the frequency of each specific AD issued. The number of times of area and task adjustment, along with frequency of each, was also noted. The frequency was divided by the number of subjects in the experimental group that completed the study (n=29) to calculate the percentages of these area and task adjustments.

3.8 ETHICS

Ethical clearance was obtained from Wits Ethical Committee for study on Human Subjects prior to the study (Appendix H). Admission to the study was voluntary and all subjects signed informed consent. Special permission was also obtained from the experimental group subjects to videotape the focus groups and photograph them. All subjects could withdraw from the study at any given time.