Chapter 2
Hypothesis and Methods

Summary of study methods

This is a Quasi-experimental study with a controlled before and after design, comparing two clinics with similar characteristics. Both clinics were initially audited in a cross sectional way to acquire baseline data on quality of patient care. The average consultation time was measured at the same time at baseline. A structured consultation schedule and a physician education program were introduced in one of the clinics. A second audit, at the end of the one-year intervention period was done to determine the efficacy of the intervention.

Aim of the study

To measure the efficacy of a physician education program and a structured consultation schedule to improve the quality of diabetes patient care at Kalafong hospital.

Study Question

Does the introduction of a structured consultation schedule and a physician education program improve the quality of diabetes care at Kalafong Diabetes clinic?

Hypothesis

1. A structured consultation schedule and a physician education program will improve the quality of diabetes care at Kalafong hospital diabetes clinics.

2. A structured consultation schedule does not significantly prolong consultation time.

Study design

This is a Quasi-experimental study with a controlled before and after design.

Setting

Two diabetes clinics at one tertiary care hospital.

Comparators

The quality of patient care delivered by physicians taking care of diabetic patients in two diabetic clinics was compared to each other. The clinics take place on Wednesdays and Fridays respectively and use the same premises and nursing staff. A consultant physician, one registrar and two medical officers run each of these clinics, and were not allowed to cross over to the other clinic during the study period. Each clinic deliver services to their own patients, and patients are not allowed to move to the other clinic unless on special request of the patient. The two clinics were very similar to each other with regards to patient characteristics and delivery of patient care at baseline, and can therefore be compared to each other.

Selection process

The Wednesday diabetes clinic was selected as intervention clinic and the Friday clinic as control clinic. From each clinic a sample of patients were selected randomly to evaluate the interventions on the intervention and control clinics.

Audit and Intervention

1. Audit of clinical records of diabetic patients attending the Kalafong diabetic clinics, the Wednesday (intervention) and the Friday (control) clinics, done at baseline before the introduction of the intervention. Notes made in every patient's record file during the 12 months before enrolment were audited at baseline.

2. Measuring consultation time per patient for both the intervention and control groups at baseline.

3. Introduction of the intervention, which included a structured consultation schedule as well as a training program for physicians attending to diabetic patients in the Wednesday (intervention) clinic. This was continued for a one-year period.

4. A second audit of clinical records of both Wednesday (intervention group) and Friday (control group) diabetic clinic patients, 12 months after the first audit, to assess the efficacy of the structured consultation changes and the education program.

5. During each 3 months of this study a measurement of the time spent per patient consultation was done for both the Wednesday and Friday clinics (intervention and control groups).

Audit of files

This was done on 2 occasions, at the beginning of the study (baseline audit) as well at the end of 1 year (post-intervention audit). This was done to compare and assess if patient care improved or not.

An independent physician with knowledge of diabetes audited 150 files of diabetic patients of both the Wednesday (intervention) and Friday (control) clinics. These files were randomly selected for audit.

Figure 2.1: *Schematic representation of the study design*
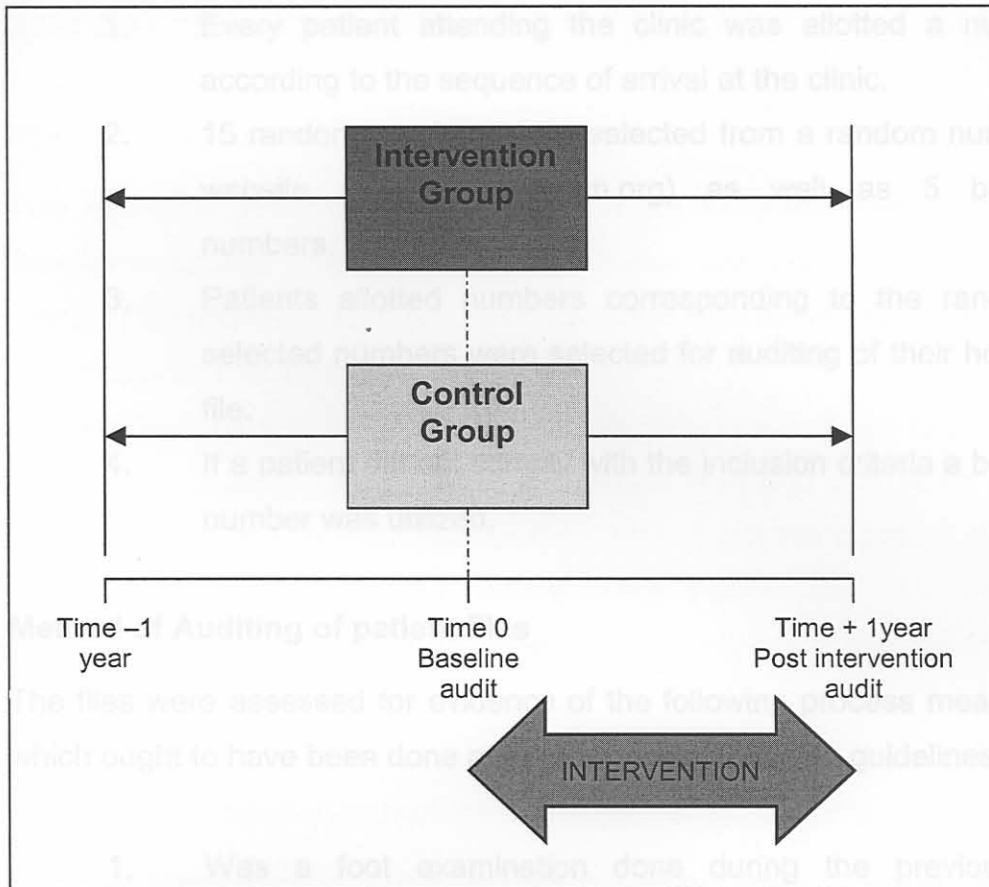
Selection of files for auditing

Inclusion criteria for patient files to be selected for audit was:

1. Duration of diabetes more than 1 year
2. Attending the Kalafong diabetes clinic for 1 year or longer or
3. 4 or more clinic visits at Kalafong diabetes clinic
4. Patients voluntary consent obtained that his or her hospital file data may be used anonymously

Exclusion criteria for selection of patient files for audit were:

1. Duration of diabetes less than 1 year
2. Less than 4 previous clinic visits at Kalafong diabetes clinic
3. New patients to a Kalafong diabetes clinic, or a patient of one of these clinics for less than 1 year
4. No consent given for audit of patient file

Randomisation was executed as follows:

1. Every patient attending the clinic was allotted a number according to the sequence of arrival at the clinic.
2. 15 random numbers were selected from a random numbers website (http//www.random.org) as well as 5 backup numbers.
3. Patients allotted numbers corresponding to the randomly selected numbers were selected for auditing of their hospital file.
4. If a patient did not comply with the inclusion criteria a backup number was utilized.

Method of Auditing of patient files

The files were assessed for evidence of the following process measures, which ought to have been done according to the SEMDSA guidelines:

1. Was a foot examination done during the previous 12 months?
2. Were the eyes examined, or was the patient sent for ophthalmologic assessment during the previous 12 months?
3. Was the patient's urine assessed for micro-albuminuria during the previous 12 months?
4. Was the patient sent for dietary counselling during the past 12 months?
5. Was an HbA1c done during the past 12 months?
6. Was a Lipid profile done during the past 12 months?

In addition the following were also noted from the files:

1. Admissions to hospital wards during the previous 12 months and the reasons therefore.
2. Number of clinic visits during the past 12 months.
3. The patient's current therapy: oral/ Insulin/ combination.

All this data were collected on a precompiled data collection form (see addendum 1)

Assessment of average consultation time

This was done at baseline and repeated every 3 months. Timing of these assessments was changed to include busier and quieter times of the month. This allowed evaluation of consultation time during each section of the structured consultation schedule.

An average time spent per patient was calculated for both the intervention and control groups. The physicians recorded start and end times at the beginning and end of each consultation from which the duration of each consultation were calculated. These were pooled and the average consultation time determined for the doctors working in the Wednesday (intervention) and Friday (control) clinics.

Structured consultation schedule and physician training program

Both the training program and the structured patient care schedule were based on the SEMDSA Guidelines for the management of type two Diabetes (the latest South African guidelines at the start of this study). [33] All procedures and special investigations planned for this study were according to these clinical practice guidelines.

An interactive training program was introduced for all doctors working in the Intervention Diabetes clinic (Wednesday). This consisted of regular sessions for the mentioned doctors. None of these sessions were compulsory, but it was stated that doctors working in the intervention diabetes clinic would strongly benefit from these sessions.

These sessions included theoretical knowledge transfer as well as a practical approach towards diabetes care.

Topics included the following:
1. Glycaemic control in type 1 and type 2 diabetes.
2. Diabetic foot problems, prevention and diagnosis.

3. Diabetic eye problems, spectrum, diagnosis and prevention.
4. Macrovascular disease in diabetics, spectrum and how to reduce the risk
5. Dietary advice for diabetics.
6. Risk and management of micro-albuminuria.
7. Educating the diabetic

A change was instituted at the diabetic clinic, from the previously totally independent approach (where each doctor saw patients without constraint, and himself decided on examinations and special investigations) to a more structured approach.

This structured approach aimed to make the care more homogeneous.

Each patient was scheduled to attend the clinic quarterly. Every 3 months a different focus was set.

First quarterly visit
1. Proper foot examination
2. Education on foot care
3. HbA1c

Second quarterly visit:
1. Dietician consultation
2. Advice on medication use
3. BMI calculation
4. Evaluation of Cardiovascular risk factors and advice.

Third quarterly visit:
1. Urine Albumin: Creatinine ratio
2. Serum Urea, Creatinine and Electrolytes, Lipid profile and HbA1C

Fourth quarterly visit:
1. Eye assessment or referral to eye clinic
2. ECG

A new more user-friendly diabetes patient record form was introduced to structure the consultation. (See addendum 2)

Data management

All audit data was captured on a form designed on Microsoft Access; this program was also used to produce a data spreadsheet. All data cleaning and editing was done in Excel; thereafter data was transferred to SPSS statistical computer package, for analysis.

Statistical analysis

For comparison of the number of clinic visits and number of hospitalisations, between the study and control groups the Mann Whitney and Wilcoxon non-parametric test were used.

For comparison of variables with nominal frequencies Chi-square tests were done.

A score was compiled for each patient from the process measures the patient received. One point was awarded for each of the six process measures. The scores were analysed with the repeated measures ANOVA test.

The consultation times at different episodes were compared between the intervention and control groups as well as in relation to baseline for which an ANOVA test was used.

Continuous data done repeatedly on the same subjects was compared utilizing the repeated measures ANOVA test.

An α level of <0.05 was considered significant for all statistical interferences.

Time schedule

January 2002:   Baseline audit on hospital records of selected subjects from both the intervention and control groups.

Initiation of the physician education program.

Baseline assessment of time per consultation.

	Motivation and Information session for clinic staff and physicians.
February 2002:	Introduction of structured consultation schedule. Started with part 1 of the consultation schedule.
March 2002:	First assessment of time per consultation. Second part of physician education program.
May 2002:	Started with part 2 of structured consultation schedule.
June 2002:	Second assessment of time per consultation. Third part of physician education program
August 2002:	Started with part 3 of the structured consultation schedule.
September 2002:	Third assessment of time spent per consultation. Part 4 of physician education program.
November 2002:	Started with part 4 of the structured consultation schedule.
January 2003:	Fourth assessment of time spent per consultation.
February 2003:	Second audit of patient records.
April 2003:	Data analysis.
May 2003:	Preparation of dissertation.
June 2003:	Preparation of publication.
April 2004:	Presentation of results at SEMDSA congress

Ethical aspects

The protocol for this study was presented for assessment and approval to the Ethics committee of the Faculty of Human Health Sciences of the University of Pretoria. (Protocol number: 196/2001)

No Doctor's notes were audited prior to written informed consent was obtained from participating patients (See addendum 3) and doctors (See addendum 4).

All participating doctors and patients participated out of free will and without additional remuneration.

With regards to patients:

1. All patients received at least the same care than that provided before the start of the study.

2. All patients attending the Wednesday clinic (whether their hospital records were audited or not) was managed according to the structured consultation schedule.

3. Patient data utilized as process and outcome measures was and will remain to be treated anonymously.

4. If it becomes clear after the study that the care given to patients attending the Wednesday clinic is better than that in the Friday clinic, the structured consultation schedule and physician education program will be introduced in the Friday clinic and continued in the Wednesday clinic.