

Chapter 3 Results of Study

Introduction

The results of this study will be reported in the following sequence. Firstly patient selection will be discussed; thereafter the demographic characteristics will be reported. Process measures will then be reported with comparison between the intervention and control clinics as well as comparison between baseline (audit 1) and post intervention (audit 2) data. Then reporting of outcome measures will follow; again the comparison between intervention and control clinics will be done first, with comparison between baseline audit and post intervention audit thereafter. Lastly issues with regards to changes in consultation time will be reported.

Patient selection for intervention and control clinics

305 patients were approached for inclusion to the study of which 150 were usually attending the Wednesday diabetes clinic (Intervention clinic) and 155 attending the Friday diabetes clinic (control clinic). Of these patients 5 were excluded from the study for not complying with the inclusion criteria, of which four attended the Wednesday, and one the Friday clinics respectively.

Variable	Intervention n (%)	Control n (%)	p
Patients enrolled in Wednesday clinic			
Patients randomly selected in the Wednesday clinic:	150	155	0.85
Wrongly classified as Wednesday clinic patient	5	5	0.67
who were Friday clinic patients:	4	1	7**
Wrongly classified as Wednesday clinic patient	2	2	0.34
who were following up for diabetes at another clinic:	2	2	2*
No consent (refused)	1	1	1*
No consent (mental retardation)	1	1	1*

* Excluded from study

** Evaluated in Friday clinic group

Patients enrolled in the Friday clinic

Patients randomly selected in the Friday clinic:	155
Wrongly classified as Friday clinic	
patient who were Wednesday clinic patients:	2**
Patients not fulfilling inclusion criteria (diabetes	
for less than 1 year)	1*

* Excluded from study

** Evaluated in Wednesday clinic group

Five patients died during the study period, three from the intervention group and two from the control group (p = 0.44). These subjects remained included in the study for analysis.

Patient demographics

At baseline there were no statistically significant differences between the intervention and control clinics with regards to patient demographics. (Table 3.1)

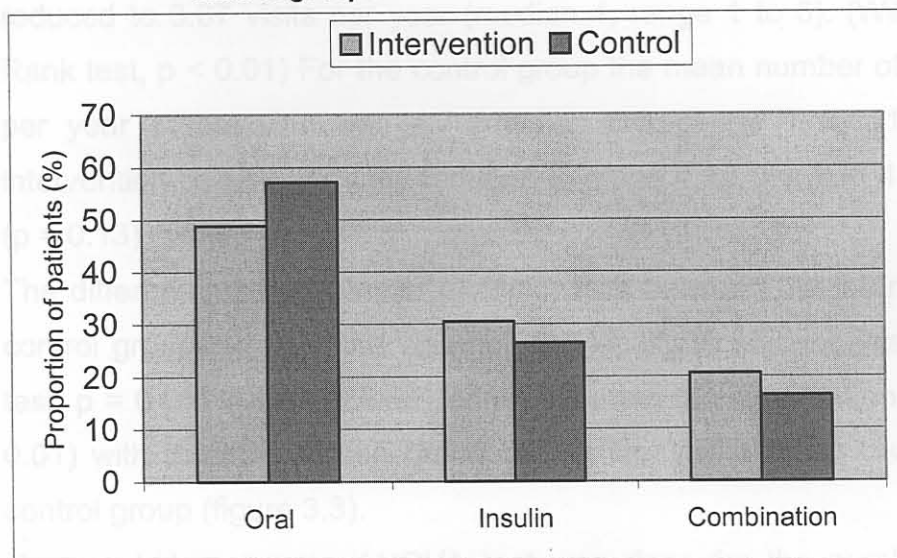
Table 3.1: Patient demographics for the intervention and control groups at baseline

Variable	Intervention n (%)	Control n (%)	p
n	141 (47)	159 (53)	
Treatment: Oral	69 (48.9)	91 (57.2)	0.35
Insulin	43 (30.5)	42 (26.4)	
Combination	29 (20.6)	26 (16.4)	
Gender: Male	52 (36.8)	57 (35.8)	0.67
	Mean (SD)	Mean (SD)	
Age	56.38 (13.00)	54.72 (14.46)	0.30
Duration of Diabetes	10.36 (7.47)	9.82 (7.72)	0.54

Treatment: The majority of patients in both the intervention and control groups were on oral treatment although a significant proportion of patients were receiving Insulin. (Table 3.1, figure 3.1) Combination therapy refers

to patients receiving both oral therapy and Insulin injections. The proportions of patients receiving oral, insulin or combination therapy within the two groups did not differ significantly ($p = 0.35$).

Figure 3.1: Treatment distribution at baseline for the intervention and control groups



Age: The age in the two groups were normally distributed, and the means did not differ significantly (table 3.1). ($p = 0.30$)

Gender: The majority of patients in both groups were female (table 3.1). The χ^2 test confirms that the proportion Male to Female in the two groups does not differ significantly. ($p = 0.67$)

Duration of Diabetes: The mean duration of diabetes between the intervention and control groups did not differ significantly (table 3.1) ($p = 0.54$). Duration of diabetes approaches a normal distribution for both groups.

In conclusion: with regards to baseline demographics the intervention and control groups did not differ significantly. The two groups can therefore be compared.

Process measures (Nominal)

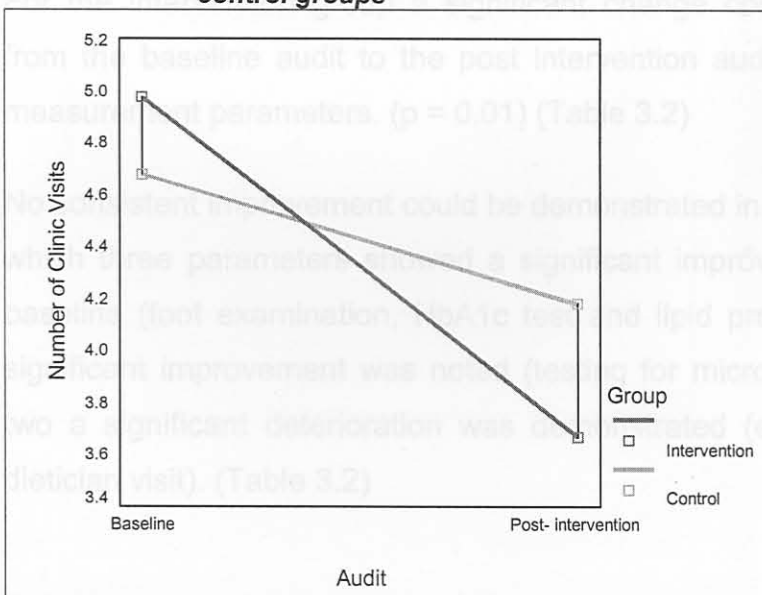
Clinic visits

The mean number of clinic visits for the intervention group at baseline was 4.97 per year (median 5.00, range 1 to 9), after the intervention it was reduced to 3.67 visits per year (median 4, range 1 to 6). (Wilcoxon Sign Rank test, $p < 0.01$) For the control group the mean number of clinic visits per year at baseline was 4.7 (median 5.0, range 1 to 11) and post intervention non-significantly reduced to mean 4.18 (median 4.00, 1 to 9). ($p = 0.13$)

The difference in the number of clinic visits between the intervention and control groups at baseline was not statistically significant (Mann-Whitney test, $p = 0.05$) but was clearly different during the intervention period ($p < 0.01$) with the intervention group having significant fewer visits than the control group (figure 3.3).

A repeated measures ANOVA test was done for the number of clinic visits, at baseline and post-intervention, between the intervention and control groups. This indicated a significant change in the number of clinic visits over time between the two groups ($p < 0.01$, with Huynh-Feldt correction) (figure 3.2).

Figure 3.2: Profile plot indicating the relationship of the number of clinic visits between baseline and post intervention audits for intervention and control groups



Other process measures (Nominal)

With the pre-intervention audit a significant difference was noted in the proportion of patients who received foot examinations, HbA1c tests and dietician visits (p values respectively 0.01, <0.01 and 0.02). For all the parameters neither the intervention nor the control group were consistently better than the other at baseline (table 3.2).

Post intervention a clear difference could be demonstrated between the intervention and control groups with the intervention group consistently significantly better than the control group (Chi² test for all six process measures $p < 0.01$) (Table 3.2).

Both the intervention and control groups showed an improvement from

Table 3.2: Comparison of process measures at baseline and post intervention for the intervention and control groups

Parameter	Intervention N=141 (%)		p	Control N=159 (%)		p
	Baseline	Post-intervention		Baseline	Post-intervention	
Foot examination	33 (23.4)	126 (89.4)	<0.01	58 (36.5)	78 (49.1)	0.04
Eye examination	45 (31.9)	99 (70.2)	<0.01	63 (39.6)	32 (20.1)	<0.01
Test for microalbuminuria	20 (14.2)	103 (73)	<0.01	15 (9.4)	24 (15.1)	0.16
HbA1c test	91 (65.5)	133 (94.3)	<0.01	66 (41.5)	114 (71.7)	<0.01
Lipid profile	29 (20.6)	99 (70.2)	<0.01	24 (15.1)	54 (34)	<0.01
Dietician visit	28 (19.8)	89 (63.1)	<0.01	51 (32.1)	22 (13.8)	<0.01
	Mean (SD)	Mean (SD)		Mean (SD)	Mean (SD)	
Score	1.745 (1.533)	4.603 (1.478)	<0.01	1.742 (1.592)	2.038 (1.382)	0.08

For the intervention group a significant change could be demonstrated from the baseline audit to the post intervention audit for all the process measurement parameters. ($p = 0.01$) (Table 3.2)

No consistent improvement could be demonstrated in the control group, for which three parameters showed a significant improvement comparing to baseline (foot examination, HbA1c test and lipid profile), for one a non-significant improvement was noted (testing for microalbuminuria) and for two a significant deterioration was demonstrated (eye examination and dietician visit). (Table 3.2)

Score of process measures

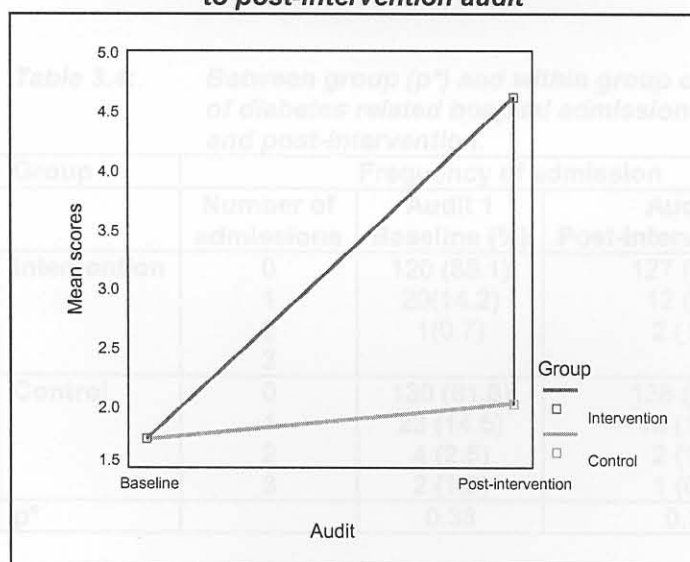
A score of the process measures was derived for each patient. One point was given to each of the process measures the patient received. (Six process measures, maximum score therefore six.)

At baseline no statistical difference could be demonstrated between the intervention and control groups ($p = 0.30$). After the intervention the intervention group scored clearly better than the control group. ($p < 0.01$) (Table 3.2)

Both the intervention and control groups showed an improvement from baseline at the post-intervention audit but only that of the intervention group was statistically significant (Intervention: $p < 0.01$, control: $p = 0.08$) (table 3.2).

A repeated measures ANOVA test indicated a significant change in scores between the two groups over time ($p = 0.000$, with Huynh-Feldt correction) (figure 3.3).

Figure 3.3: *Change in mean scores from the baseline to post-intervention audit*



Hospital admissions

The total hospital admissions (diabetes related and not related to diabetes) (table 3.3) were not significantly different for the intervention group before and during the intervention. The control group on the contrary showed significantly less admissions during the intervention period ($p = 0.02$).

Table 3.3: *Within group comparison of hospital admissions (All admissions, diabetes related and non-related) for the intervention and control groups*

Group	Frequency of admission			p
	Number of admissions	Audit 1 Baseline (%)	Audit 2 Post-intervention (%)	
Intervention	0	113 (80)	119 (84.4)	0.63
	1	21 (14.9)	14 (9.9)	
	2	6 (4.3)	5 (3.5)	
	3	1 (0.7)	0	
	4	0	1 (0.7)	
	5	0	1 (0.7)	
Control	0	113 (71.1)	130 (81.8)	0.02
	1	35 (22)	22 (13.8)	
	2	7 (4.4)	2 (1.25)	
	3	4 (2.5)	2 (1.25)	
	4	0	1 (0.6)	

For diabetes related admissions both the intervention and control groups showed a non-significant change from baseline (Table 3.4) ($p = 0.35$ and $p = 0.18$ respectively).

Table 3.4: *Between group (p^*) and within group comparison ($p^\#$) of diabetes related hospital admissions at baseline and post-intervention.*

Group	Frequency of admission			P [#]
	Number of admissions	Audit 1 Baseline (%)	Audit 2 Post-intervention (%)	
Intervention	0	120 (85.1)	127 (90.1)	0.330
	1	20(14.2)	12 (8.5)	
	2	1(0.7)	2 (1.4)	
	3			
Control	0	130 (81.8)	138 (86.8)	0.171
	1	23 (14.5)	18 (11.3)	
	2	4 (2.5)	2 (1.3)	
	3	2 (1.3)	1 (0.6)	
p [*]		0.38	0.38	

The amount of diabetes related hospital admissions between the intervention and control groups did not differ significantly at baseline nor at the post intervention audit (Table 3.4).

In the control group hyperglycaemia was the most common single cause of admission to hospital both at baseline and post-intervention, accounting for 11 (29.7%) and 10 (40%) respectively ($p = 1.00$). The number of admissions due to hyperglycaemia increased significantly from one to three for the intervention group ($p = 0.95$). At baseline hypoglycaemia were the most common cause of admission (36.4%) in the intervention group, but post-intervention only one admission were due to hypoglycaemia ($p = 0.72$) (table 3.5, figure 3.4 and 3.5). while that of the control group decreased non-significantly slightly from 11 to 10 ($p = 1.00$).

Table 3.5: *Analysis of diabetes related hospital admissions between the intervention and control groups at baseline and post intervention.*

Reason for admission	Intervention (% of admissions in group)			Control (% of admissions in group)		
	Baseline	Post-inter- vention	p	Baseline	Post-inter- vention	p
Hyperglycaemia	1 (4.5)	3 (18.7)	0.95	11 (29.7)	10 (40)	1.00
Hypoglycaemia	8 (36.4)	1 (6.3)	0.72	6 (16.3)	2 (8)	0.86
Complications:						
Acute(hyperglycaemic)	5 (22.7)	2 (12.5)	0.90	9 (24.3)	2 (8)	0.73
Chronic	8 (36.4)	6 (37.5)	0.95	11 (29.7)	11 (44)	0.95

The number of admissions for acute hyperglycaemic complications (Diabetic keto-acidosis and hyperosmolar Non-ketotic diabetic states) declined for both the intervention ($p = 0.90$) and control groups ($p = 0.73$) although not significantly.

Of the chronic complications cataract surgery was the most common reason for admission at baseline and post intervention and for both the intervention and control groups.

Figure 3.4: *Reasons for Diabetes related admissions for the intervention and control groups at Baseline audit*

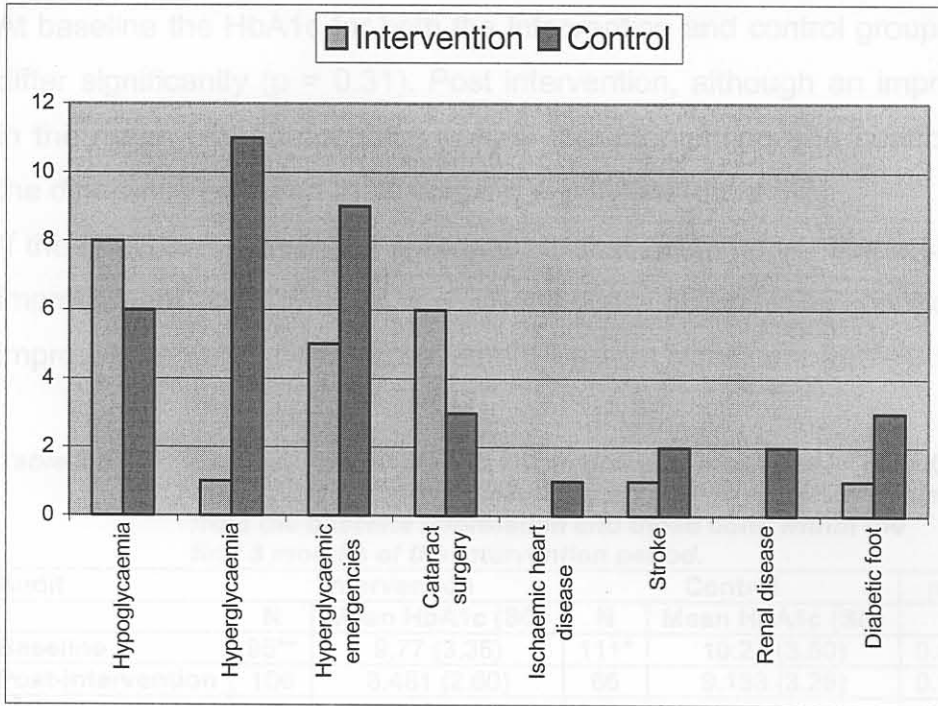
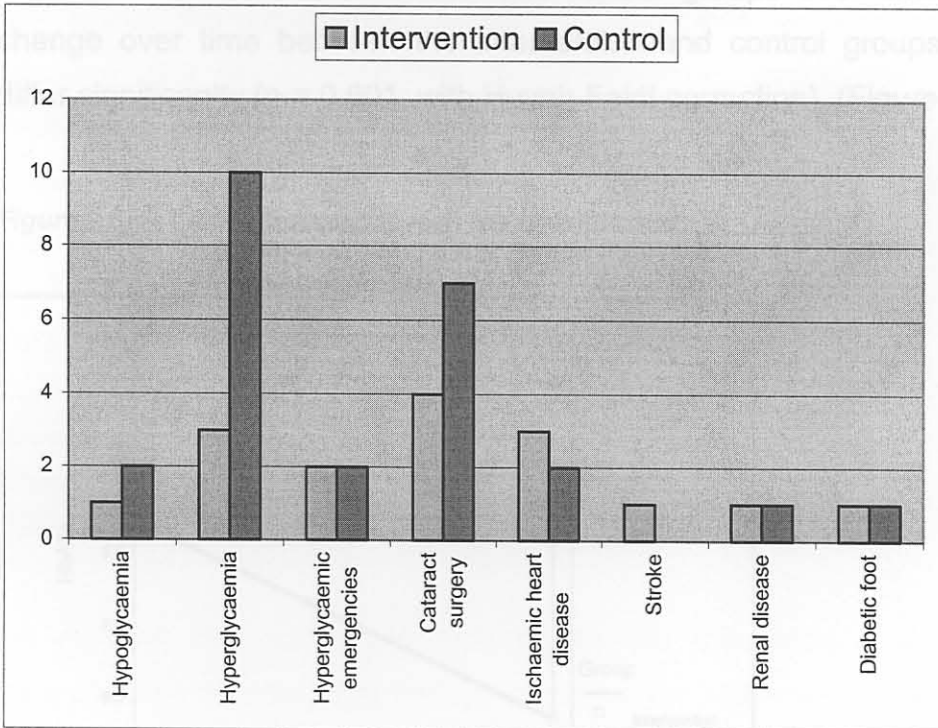


Figure 3.5: *Reasons for Diabetes related admissions for the intervention and control groups at post-intervention audit*



HbA1c

At baseline the HbA1c for both the intervention and control groups did not differ significantly ($p = 0.31$). Post intervention, although an improvement in the mean HbA1c occurred in both the intervention and control groups the difference between them was not significant (table 3.6).

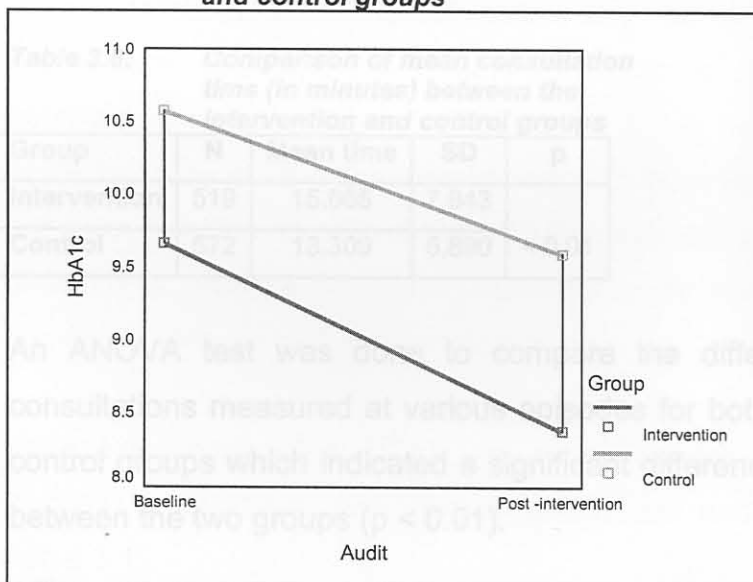
If the HbA1c at baseline is compared to that post-intervention a significant improvement occurred in the intervention group. The control group improved as well but the improvement was not significant (table 3.6).

Table 3.6: *Between group (p^*) and within group comparison ($p^\#$) of HbA1c at baseline and post-intervention. ** HbA1c results were used from the baseline information and those done within the first 3 months of the intervention period.*

Audit	Intervention		Control		p^*
	N	Mean HbA1c (SD)	N	Mean HbA1c (SD)	
Baseline	95**	9.77 (3.36)	111*	10.27 (3.60)	0.31
Post-intervention	106	8.481 (2.60)	66	9.153 (3.29)	0.14
$p^\#$		<0.01		0.06	

A repeated measures ANOVA test was done to assess the change in HbA1c between the intervention and control groups over time. HbA1c change over time between the intervention and control groups did not differ significantly ($p = 0.601$, with Huynh-Feldt correction). (Figure 3.6)

Figure 3.6: *Comparison between the baseline and post-intervention HbA1c for the intervention and control groups*



As seen in table 3.7 the proportion of patients with poor glycaemic control reduced in both the intervention and control groups and the proportion of patients with good glycaemic control increased although not statistically significant ($p = 0.17$ and $p = 0.06$ respectively). Between the two groups there were no statistically difference at baseline and post-intervention with regards to the proportion of patients with good, moderate and poor glycaemic control ($p = 0.73$ and $p = 0.34$ respectively).

Table 3.7: Percentage of patients in the intervention and control groups at baseline and post-intervention with poor, moderate and good glycaemic control

Glycaemic control	HbA1c	Baseline		Post-intervention	
		Intervention	Control	Intervention	Control
Poor control	> 9.5%	47.4	54.1	36.8	39.4
Moderate control	7.5 to 9.49%	20.0	20.7	23.6	22.7
Good control	<7.5%	32.6	25.2	39.6	37.9

Consultation time

The duration of 1092 consultations were documented for the intervention and control clinics combined. This was periodically done at baseline and throughout the intervention period. Consultations were measured at baseline and 4 times during the intervention period for both the intervention and control groups.

The overall average time spent per consultation in the intervention group was significantly longer than that of the control group (table 3.8).

Table 3.8: Comparison of mean consultation time (in minutes) between the intervention and control groups

Group	N	Mean time	SD	p
Intervention	519	15.665	7.943	< 0.01
Control	572	13.309	5.890	

An ANOVA test was done to compare the difference in duration of consultations measured at various episodes for both the intervention and control groups which indicated a significant difference in consultation time between the two groups ($p < 0.01$).

For the intervention group compared to the time spent per consultation at baseline, the time taken at various episodes throughout the intervention period was consistently longer per consultation ($p < 0.01$, < 0.01 , < 0.01 and < 0.01 respectively.) The time spent with the second and third visits were the longest (mean difference of -6.03 and -8.16 minutes from the baseline time respectively).

For the control clinic the mean duration of consultations were also longer than that measured at baseline ($p = 1.00$, < 0.01 , < 0.01 and 0.04)

Table 3.9: *Comparison of the Median time per consultation between the Intervention and control groups at different measurements*

Measurement	Median time (range)		p
	Intervention	Control	
1 (Baseline)	10 (2 – 50)	10 (2 – 35)	0.91
2	17 (8 – 35)	12 (3 – 30)	< 0.01
3	13.5 (5 – 50)	13 (4 – 43)	0.91
4	20 (5 – 52)	15 (5 – 32)	< 0.01
5	14 (4 – 42)	11 (5 – 33)	0.06

Conclusion

Patients from the Wednesday diabetes clinic were selected as the intervention group and that of the Friday clinic as the control group. Doctors attending to the Intervention clinic underwent a diabetes-training program and a structured consultation schedule was introduced in the clinic. The control clinic did not receive any intervention although patients and doctors attending this clinic were informed and their consent was obtained.

At the baseline audit of both the intervention clinic and the control clinic did not differ significantly with regards to demographic parameters, number of clinic visits, process measures, outcome measures (HbA1c and hospital admission rate) as well as consultation time.

Patient demographics: The two groups did not differ significantly with regards to treatment, age, gender distribution and duration of diabetes (table 3.1).

Process measures included: Foot examination
 Eye examination
 Test for micro-albuminuria
 HbA1c test performed
 Lipid profile done
 Dietician visited

A score derived from these process measures was calculated for each patient whose files were audited at baseline and post-intervention. At baseline the scores did not differ significantly between that of the intervention and control groups (table 3.2). A significant improvement in the score of the intervention group was seen after the mentioned interventions were implemented, compared to baseline and in comparison with the control clinic (table 3.2 and figure 3.3).

Outcome measures: Two parameters were used to measure the difference in outcome between the two groups namely the number of hospital admissions and HbA1c values.

Diabetes related hospital admissions did not differ significantly from baseline and between the groups (table 3.4). A shift in the reason for hospital admissions was seen from the baseline audit at the post-intervention audit. At baseline the most admissions were related to poor glycaemic control and hypoglycaemia while post-intervention most of the admissions were related to chronic diabetes complications (table 3.5).

HbA1c at baseline did not differ significantly between the intervention and control groups (table 3.6). Compared to the baseline HbA1c both the groups showed an improvement although this was not significant for the control group, but the intervention group did improve significantly. The change between the groups over time did not indicate significant improvement (figure 3.6).

Consultation time: Consultation time was measured on 5 occasions, at baseline and 4 times during the intervention period (every 3 months).

The overall consultation time was significantly longer for the intervention group than that of the control group during the intervention period (table 3.8). It seems that the improvement of process measures and the reduction in the number of patient visits accounts to a prolongation in consultation time. (table 3.7, 3.8)

This intervention resulted in a significant improvement of process measures in the patient care of diabetic patients with a reduction in the number of patient visits but at the expense of prolonged consultation time. Glycaemic control improved although not significantly over the duration of the intervention.

Summary of chapter

1. Baseline demographics between the intervention and the control groups did not differ significantly (table 3.1).
2. Clinic visits at baseline did not differ significantly, but a significant reduction in the number of clinic visits was shown in the intervention group comparing to baseline as well as in relation to the control group (figure 3.2).
3. A significant improvement in each of the process measures in relation to baseline and the control group was indicated (Table 3.2).
4. Overall the number of process measures each patient was expected to undergo or receive improved significantly in the intervention group when compared to baseline and to the control group (figure 3.3).
5. Diabetes related hospital admissions did not significantly changed from baseline nor did it differ between the intervention and control groups (tables 3.4).
6. Although the HbA1c improved in both the intervention and control groups, only that of the intervention group improved

significantly from baseline (table 3.6). The difference over time between the two groups was not significant (figure 3.6).

7. Consultation time in the intervention group was significantly longer than that of the control group as well as in comparison to baseline (table 3.7, 3.8).