THE RELATIONSHIP BETWEEN OBJECTIVELY MEASURED PHYSICAL ACTIVITY AND PARAMETERS OF DISEASE CONTROL IN AN AFRICAN POPULATION OF TYPE 2 DIABETES MELLITUS

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A research report submitted to the Faculty of Health Science, University of the Witwatersrand, in fulfilment of the requirements for the degree of Master of Medicine in the branch of Internal Medicine.

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DECLARATION

I, Muhammad Abid Siddiqui, declare that this research report is my own work. It is being submitted for the degree of Master of Medicine in the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other University.

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ABSTRACT

BACKGROUND: The incidence of type 2 Diabetes Mellitus (T2DM) is increasing rapidly. This is possibly due to increasing obesity, reduced level of activity, sedentary lifestyle, aging population and industrialization.

AIM: The primary objective of this study is to ascertain the level of activity using a pedometer in patients with T2DM. The secondary objectives are: (1) to correlate the baseline level of activity with body mass index (BMI), HbA1c and blood pressure (BP), (2) to assess whether 7000 steps a day influence HbA1c and BP over a 3-month period.

METHOD: We screened 110 patients; 95 patients (n=95) completed the study. At the first visit HbA1c, BMI and BP were measured. At the end of the first month baseline physical activity (PA) was recorded using pedometers. Patients were divided into two groups: active (n=50) and control (n=45). Patients in the active group were asked to walk a minimum of 7000 steps/day. The control group were asked to continue their usual activity. These patients were followed up monthly over a period of 3 months. At each visit BMI, BP and step counts were recorded. HbA1c was measured only at the first and last visit.

RESULT: Activity levels increased significantly in the active group throughout the study. Mean step count for the control group at baseline was 2923.1 ±1136.9, which increased to 3431.2 ±1251.7 by the end of the study. Mean step count for the active group at baseline was 4609.9±1702.1, which increased to 7244.8±1419.4 by the end of the study. The difference between control and active group was statistically significant ($p < 0.001$). Systolic and diastolic BP decreased significantly in both groups ($p= 0.017$) for systolic BP and ($p= 0.002$) for diastolic BP but no interaction found between the groups as systolic and diastolic BP decreased at the same rate over time in both groups. HbA1c decreased by 1.04% in active group, this difference was statistically highly significant ($p <0.001$)

CONCLUSION: Increase in activity levels decreases HbA1c by 1.04 percentage point over 3 months in T2DM ($p<0.001$), which is statistically significant.

KEYWORDS: Pedometers; Physical activity; T2DM; HbA1c; BMI

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Dedicated to my family especially my daughter, colleagues and patients who have inspired my research.

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ABBREVIATIONS

ACSM	American College of Sports Medicine
ADAPT	Alberta Diabetes and Physical Trail
BMI	Body Mass Index
BP	Blood Pressure
CDC	Centres for Disease Control and Prevention
DPP	Diabetes Prevention Programme
DSMEP	Diabetic Self –Management Education Programme
DBP	Diastolic Blood Pressure
GDM	Gestational Diabetes Mellitus
HbA1c	Glycated Haemoglobin
HDL-C	High density lipoprotein cholesterol
IGT	Impaired glucose tolerance
IDF	International Diabetes Federation
Kg	Kilogram
m	Metre
PA	Physical Activity
SBP	Systolic Blood Pressure
T1DM	Type 1 Diabetes Mellitus
T2DM	Type 2 Diabetes Mellitus
UKPDS	United Kingdom Prospective Diabetes Study

SUBMISSABLE PAPER

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HbA1c

BMI

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CONCLUSION: Increase in activity levels decreases HbA1c by 1.04 percentage point over 3 months in T2DM ($p<0.001$), which is statistically significant.

KEYWORDS: Pedometers; Physical activity; T2DM; HbA1c; BMI

1.0 INTRODUCTION

The incidence of type 2 Diabetes Mellitus (T2DM) is increasing rapidly. This is possibly due to increasing obesity, reduced level of activity, sedentary lifestyle, aging population and industrialization.[1]

In the USA in 2010, the prevalence of diabetes was estimated to be 0.2% in individuals aged less than 20 years and 11.3 % in individuals older than 20 years.[1] Diabetes increases with age. It is the fifth leading cause of death worldwide. In 2010 about four million people died as a result of complications due to diabetes.[1]

There are three and half million South Africans with diabetes (approximately 6% of the population) and many remain undiagnosed.[2] Worldwide, more than 400 million people have diabetes. The International Diabetes Federation (IDF) has predicted that this figure will increase to 552 million by 2030.[2] It is expected that the greatest increase would be in the African continent and it is predicted that by 2030 the prevalence of diabetes in Africa would almost have doubled. Besides the important causative factors mentioned above, there is a cultural belief among most African communities that weight gain is a reflection of social achievement, wellbeing and honour.[2]

T2DM occurs almost exclusively in the adult population and its main feature is insulin resistance, manifested as hyperinsulinaemia and hyperglycaemia. It is strongly associated with family history, obesity and physical inactivity which accounts for 90% of all diabetes.[3] The typical patient with T2DM is sedentary, overweight, and middle aged or older.[3,4] In Type 1 diabetes (T1DM) there is autoimmune destruction of pancreas leading to a failure to secrete insulin.[3]

Regular physical activity (PA) is necessary for the prevention and management of T2DM and is associated with a lower incidence of all cause and cardiovascular disease mortality in patients with diabetes.[5] The Diabetes Prevention Programme (DPP) found that a minimum of 150 min/week of moderate-intensity PA, such as brisk walking, was more efficient than metformin or placebo in the prevention of T2DM in pre-diabetics.[6] Similarly, Heimrich et al., described an inverse relationship between energy consumption in leisure-time PA and the development of T2DM in former college students.[7]

The advantages of regular PA in diabetes are: (1) better glycaemic control (2) weight reduction and (3) improved insulin sensitivity.[8,9] The latter being integral to the prevention of cardiovascular complication, as impaired insulin activity can lead to elevated triglycerides,

reduced high density lipoprotein cholesterol, increased secretion of very low-density lipoprotein cholesterol, and hypertension.[10]

The United Kingdom Prospective Diabetes Study (UKPDS), showed that intensive glucose control with metformin decreased glycated haemoglobin (HbA1c) by 0.6%. This reduction was associated with a 32% decrease risk of diabetes-associated complications and 42% decrease in the mortality rate.[11]

There is no doubt that PA is beneficial to patients with diabetes. However, the minimum degree and frequency of activity required to achieve favourable outcomes has not been fully explained. While the Centres for Disease Control and Prevention (CDC) and the American College of Sports Medicine (ACSM) have suggested a minimum of 30 minutes of moderate-intensity PA on most days of the week,[12] Tudor-Locke et al., believe that walking 10 000 steps/day is effective.[13]

Even though the health benefits of moderate PA in diabetes has been established, the compliance with exercise is sadly low. Pedometers may be used as a motivational tool to encourage people with T2DM to increase their PA.

The primary objective of this study was to ascertain the level of activity using a pedometer. The secondary objectives were: (1) to correlate the baseline level of activity with body mass index (BMI), HbA1c and blood pressure (BP), (2) to assess whether 7000 steps a day influence HbA1c and BP over a 3-month period.

2.0 METHODS

This was a prospective observational study conducted at the diabetic clinic at Chris Hani Baragwanath Academic Hospital from August 2015 to January 2016. The study was aimed at African male and female diabetic patients between the ages 18-65 years attending the diabetic clinic. This study was approved by Wits Human Research Ethics committee (Medical). Inclusion criteria:

1) T2DM- 18-65 years old
2) Signed consent
3) Patient having HbA1c measured as standard care in the clinic

Exclusion criteria:

1) Patients with T1DM
2) Patients having any disability that may affect walking such as amputation of leg
3) Patients with co- morbid cardiovascular disease

A sample size of 75 was obtained using mean change and standard deviation in HbA1c for intervention and control group at the 5% significance level and 80% power.[14] However, the sample size was increased to 110 to account for maximum number of variables that may be included in regression analysis. A sample size of 15 is required for each variable added to the model. Patients were screened randomly from the diabetic clinic over a period of 2 months from July 2015 to Sept. 2015 which were further followed up for total period of 4 months. Ninety-five patients completed the study. Fifteen participants were excluded from the study because they lost to follow up. Health variables like bodyweight in kilogram (kg) and height in metres (m) were measured with patients wearing light clothing and no shoes. BP was measured in a sitting position with a Welch Allyn monitor. HbA1c was measured on a DCA Vantage analyser.

At the first visit, patients were informed about the study and were given an information sheet containing a brief description of the study. All patients enrolled in the study were given a multi-function pedometer and a step count log.

Patients were advised to wear the pedometer throughout the day with an exception during sleeping and bathing, and the number of steps were recorded every evening before sleeping. Patients were told to attach the pedometer to the belt at the level of waist.

Baseline activity was ascertained at the end of the first month, after which the participants were divided into two groups, active and control.

Participants with a higher step count in the first month, and those willing to increase their steps to 7000 per day were included in the active group, the rest were in the control group. Participants in active group were given a plan to increase their daily physical activity by starting regular morning or evening walk, to participate in sporting activity, to join exercise club or even to join the gym if possible. The control group were asked to continue their usual activity and to log their steps. Both groups were followed up for the next 3 months. At each visit the patients BP and weight were recorded, and a new step log issued. HbA1c was only measured at the first visit and last visit.

2.1 STATISTICAL METHODS

IBM SPSS version 23 was used to analyse the data. A p value <0.05 was considered as statistically significant. Categorical variables were compared between the two groups using Pearson's chi square test. Independent samples t-tests were used to compare normally distributed continuous variables between two groups. Pearson's correlation coefficient was used to assess strength of relationships between continuous variables. Repeated measures ANOVA testing was used to assess changes over time within and between groups. A time x group interaction which was statistically significant indicated a treatment effect. Profile plots were used to show the direction and trends of the effects over time between the groups.

3.0 RESULTS

Demographics

Ninety-five participants were analysed. Their age and gender by group are shown in Table 1 below. There was no difference between the groups in term of age and gender. Mean age for control group was 54.1 years compared to 55.2 years for active group.

Table 1: Demography

			Study Arms		p value
			Control	Active	
Gender	Male	N	14	17	0.764
		n %	31.1%	34.0%	
	Female	N	31	33	
		n %	68.9%	66.0%	
Age	N		45	50	
	Mean		54.1	55.2	0.468
	Standard Deviation		7.4	6.9	

The primary objective was to ascertain the level of activity using pedometer. There was a significant difference in step counts at baseline between the two groups. The difference in step

counts between male and females, and between different age groups, in both arms was not significant, except in the control group at month 3 there was a significant difference between step counts in males and females (p=0.045). (Table 2 and Table 3).

Table 2: Average step counts between male and female in both groups

		Study Arms					
		Control		p value	Active		p value
Average steps		Gender			Gender		
		Male	female		Male	Female	
Month 1	Mean	3357.8	2726.8	0.085	4681.8	4572.8	0.833
	Standard Deviation	1001.9	1154.5		1530.4	1805.8	
Month 2	Mean	3551.6	3067.5	0.139	6058.7	6598.9	0.134
	Standard Deviation	876.3	1044.3		1131.5	1211.7	
Month 3	Mean	3721.9	3013.8	0.045	7121.3	6859.5	0.452
	Standard Deviation	1159.3	1023.5		1347.6	1046.9	
Month 4	Mean	3781.4	3273.0	0.211	7134.7	7301.5	0.698
	Standard Deviation	949.9	1350.4		1273.6	1504.7	

Table 3: Average step counts between different age groups in both arms

		Study Arms							
		Control			p value	Active			p value
Average steps		Age group				Age group			
		<=50	51-60	>60		<=50	51-60	>60	
Month 1	Mean	3163.2	2762.5	2863.8	0.599	5170.6	4690.6	3799.9	0.146
	Standard Deviation	1031.7	1197.1	1215.1		1567.1	1884.1	1071.9	
Month 2	Mean	3294.9	3042.8	3385.2	0.630	6604.7	6466.9	6081.8	0.560
	Standard Deviation	811.8	1004.5	1264.9		675.5	1510.0	686.6	
Month 3	Mean	3108.1	3162.7	3498.6	0.630	7256.3	6945.6	6619.7	0.424
	Standard Deviation	852.8	1170.1	1318.0		805.5	1189.4	1365.9	
Month 4	Mean	3411.4	3317.6	3626.1	0.809	7481.0	7005.4	7574.5	0.437
	Standard Deviation	1371.8	1247.5	1184.6		1074.1	1119.4	2236.8	

Table 4 shows the mean number of steps measured at each time point using a pedometer by study arms. Mean step counts for control group was 2923.1± 1136.9 steps compared to 4609.9± 1702.1 steps for active group at baseline which increased to 3431.2± 1251.7 steps and 7244.8± 1419.4 steps respectively at the end of the study. The difference was highly statistically significant at all time points ($p< 0.001$) with the active group taking significantly more steps than the control group.

Table 4: Mean step counts from months 1 to 4

Average steps	Study Arms					
	Control			Active		
	n	Mean	Standard Deviation	n	Mean	Standard Deviation
Month 1	45	2923.1	1136.9	50	4609.9	1702.1
Month 2	45	3218.1	1010.8	50	6415.2	1201.5
Month 3	45	3234.1	1105.1	50	6948.5	1150.9
Month 4	45	3431.2	1251.7	50	7244.8	1419.4

The secondary objective was to correlate the baseline level of activity with BMI, HbA1c and BP.

There was no significant difference between the active and control group in terms of baseline values. Mean BMI for control group was 33.93± 5.84 kg/m² compared to 32.60± 6.92 kg/m² for active group (p=0.317). Similarly mean HbA1c for control group was 9.85± 2.38% compared to 9.86± 2.40 % for active group (p=0.989). (Table 5)

Table 5: Baseline BMI, HbA1c and blood pressure

Group Statistics						p value
Baseline	Study Arms	N	Mean	Std. Deviation	Std. Error Mean	
Weight (kg)	Control	45	89.076	16.0405	2.3912	0.264
	Active	50	85.248	17.0379	2.4095	
BMI (Kg/m^2)	Control	45	33.934	5.8443	.8712	0.317
	Active	50	32.603	6.9276	.9797	
HbA1c %	Control	45	9.8573	2.38969	.35623	0.989
	Active	50	9.8640	2.40508	.34013	
SBP (mmHg)	Control	45	147.16	19.454	2.900	0.694
	Active	50	148.90	23.211	3.283	
DBP (mmHg)	Control	45	85.58	10.319	1.538	0.906
	Active	50	85.84	11.164	1.579	

There was also no correlation between average number of steps at baseline and BMI, Systolic BP(SBP), Diastolic BP(DBP) or HbA1c (Table 6).

Table 6: Correlation of baseline activity with BMI, HbA1c and BP

Baseline		Average Steps
BMI (kg/m^2)	Pearson Correlation	.014
	Sig. (2-tailed)	.891
	N	95
SBP (mmHg)	Pearson Correlation	.106
	Sig. (2-tailed)	.307
	N	95
DBP (mmHg)	Pearson Correlation	.074
	Sig. (2-tailed)	.476
	N	95
HbA1c %	Pearson Correlation	-.103
	Sig. (2-tailed)	.322
	N	95

The other secondary objective was to assess whether 7000 steps a day influence HbA1c and BP over a 3-month period.

HbA1c

1. Whether being in the active group versus the control group influences HbA1c over a 4-month period was analysed

There was a highly significant interaction between time and treatment group ($p<0.001$), indicating that the two study arms did not behave the same way over time for HbA1c. Figure 1 below shows that the active arm reduced their HbA1c over the two time points while the value in the control arm increased.

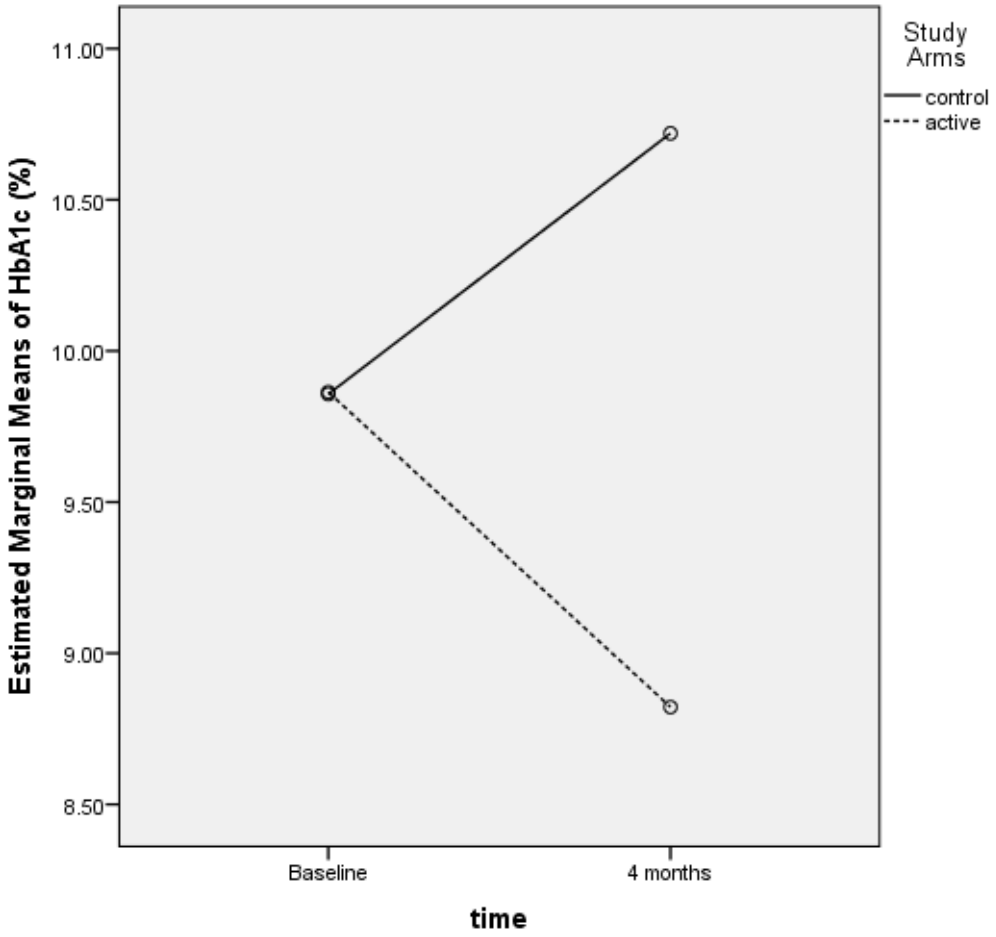

Figure 1: Estimated Marginal Means of HbA1c over a 4-month period in the control and active arms.

The change in HbA1c and BMI over the 4-month period was calculated and compared between the treatment groups. The HbA1c change on average was 0.86 % increase in the control arm and 1.04% decrease in the active arm. This was highly significantly different between the arms ($p < 0.001$) The BMI change was positive for both groups and was not different between the arms. (Table 7)

Table 7: Change in HbA1c and BMI over 4 months period

Group Statistics						P value
Change	Study Arms	n	Mean	Std. Deviation	Std. Error Mean	
HbA1c %	Control	45	.8622	1.12337	.16746	<0.001
	Active	50	-1.0420	1.27633	.18050	
BMI (Kg/m^2)	Control	45	.2170	.90158	.13440	0.611
	Active	50	.1209	.93103	.13167	

Blood Pressure

2 Whether being in the active group versus the control group influences BP over a 4-month period was assessed

When comparing SBP between the two arms, there was no interaction between time and study arm for SBP (p=0.866) meaning that the SBP changed at the same rate over time in both groups. There was a significant time effect (p=0.017) meaning that there was a general decrease in SBP over time. Figure 2 below shows this decrease in both groups over time.

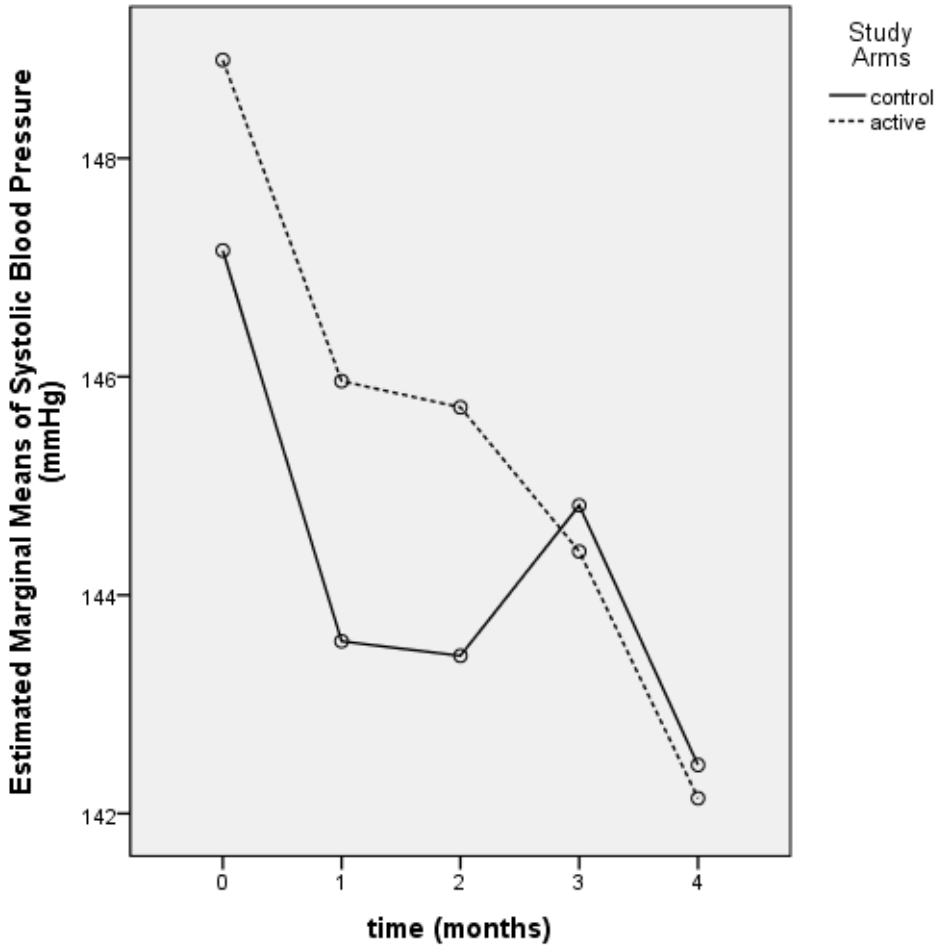

Figure 2: Estimated Marginal Means of SBP between the two arms

There was no interaction between time and study arm for DBP (p=0.331), meaning that the DBP changed at the same rate over time in both groups. There was a significant time effect (p= 0.002) meaning that there was a general decrease in DBP over time. Figure 3 below shows this decrease over time in both groups.

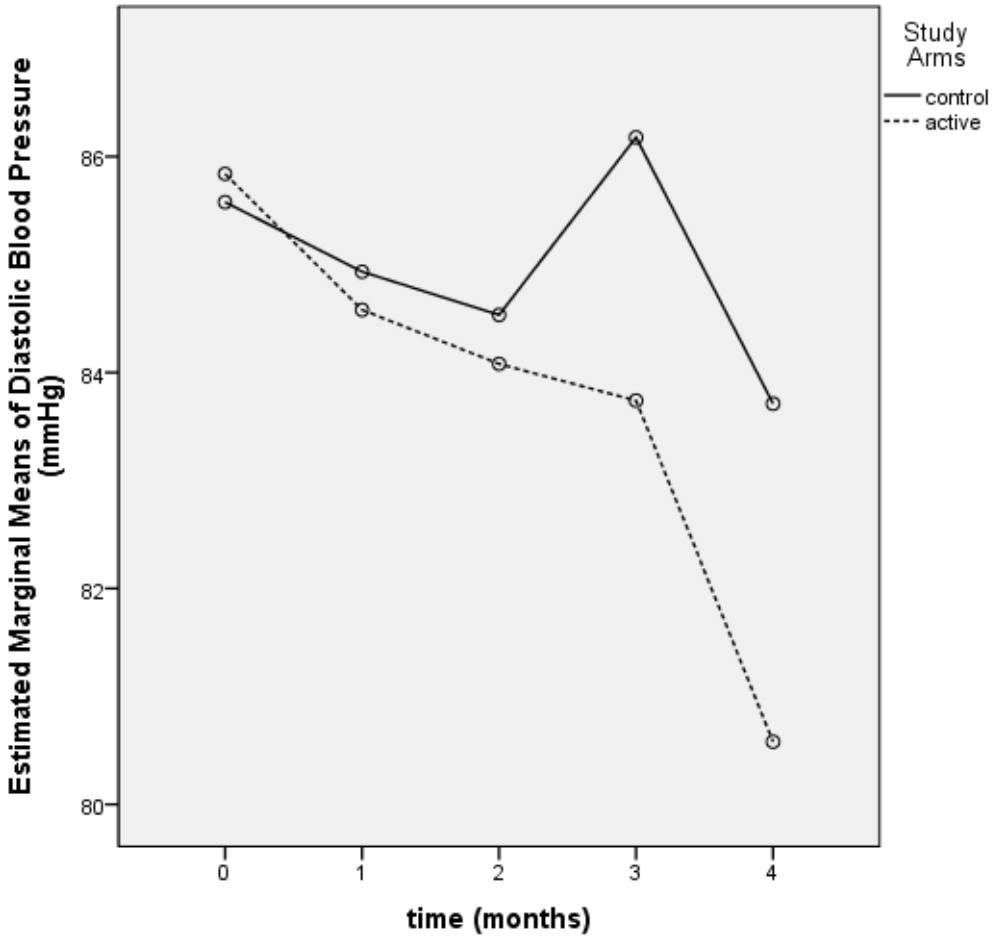

Figure 3: Estimated Marginal Means of DBP between the two Arms

In both groups there was a weak negative correlation between change in steps and change in HbA1c – meaning that as the steps increased, the HbA1c decreased (as in the active group) or that as the steps decreased, HbA1c increased (as in the control group).

However, the change in steps in the control group over the entire study period was much lower than the change in steps in the active arm. (Mean = 508 in control and 2634 in the active arm). Similarly, the change in HbA1c was positive (i.e. an increase) in the control arm (mean = 0.8622) and negative in the active arm (i.e. a decrease) (mean = -1.042). Figure 4 explains this phenomenon – the control arm (white circles) were mainly above the horizontal line meaning they increased in HbA1c, and most of the white circles are in the right-hand box meaning they increased in steps. The few in the left-hand block are influencing the relationship (correlation) to be negative i.e. they increased HbA1c while decreasing steps. In contrast, the active group are mainly in the lower right-hand quadrant which shows that they decreased HbA1c while increasing steps.

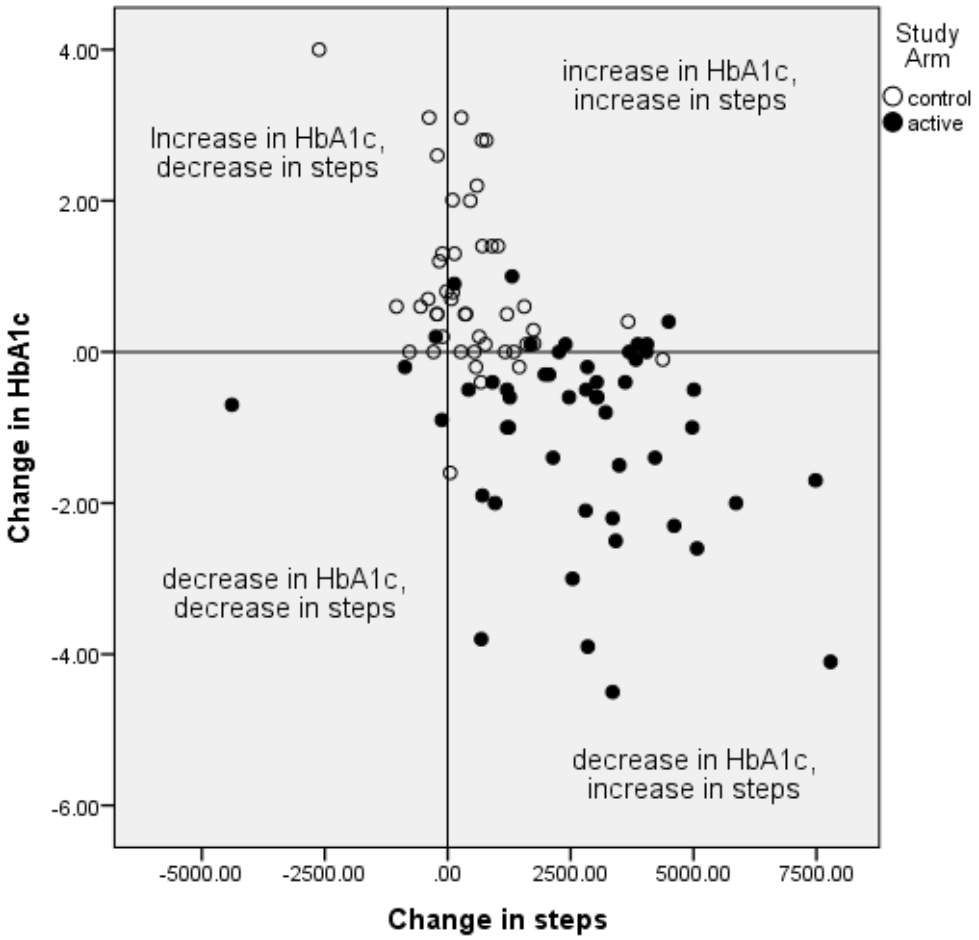

Figure 4: Correlation between change in steps and change in HbA1c

4.0 DISCUSSION

There was a significant difference in step counts at baseline between the two groups. Although most of the patients in active group were more active at baseline, their physical activity increased significantly throughout the study, suggesting that pedometer-based motivation has significant impact on step counts in active group. (Table 4)

There was no significant difference in BMI, HbA1c and BP between the two groups at baseline. (Table 5) We did not find any correlation between average number of steps at baseline and BMI, SBP, DBP or HbA1c. (Table 6)

There was a significant decrease in SBP and DBP in both groups during the course of study, but no interaction was found between the groups as SBP and DBP decreased at the same rate in both groups over this time period. The active group had a greater trend in a decrease in DBP as compared to the control, but this difference was not statistically significant, as depicted in figure 2 and 3 respectively. This decrease in blood pressure did not require any change in treatment.

The HbA1c changed significantly over the course of three months in the active group. On average, the HbA1c increased by 0.86 percentage point in the control group and decreased by 1.04 percentage point in the active group, this was highly significant ($p<0.001$). (Table 7) In control group HbA1c increased despite some increase in step counts, possibly due to progression of disease or compliance issue. The increase in physical activity to 7000 steps per day had significant effect on HbA1c. This decrease in HbA1c is higher than the decrease shown in the metformin arm of the UKPDS, a decrease of HbA1c by 0.6 percentage point.[11] The UKPDS was associated with a 32% decrease risk of diabetes associated complications and 42 % decrease in mortality.[11]

Our study differs from a pedometer-based behavioural modification programme in T2DM, where 92 patients with T2DM patients that were enrolled from the Ghent University Hospital, showed no noticeable immediate or short-term disparities in health outcomes between the control and intervention group. But the study highlighted an important threshold of ≥4000 steps/days to influence HbA1c.[14]

Our results confirm that community or clinic- based PA programmes may be employed as a useful strategy for management of T2DM. Our study's results are more favourable than a meta-analysis by Plotnikoff, et al, where community-based PA programmes were associated with a reduction in HbA1c by 0.32% ($p=0.06$).[15] Their research was organised in various countries that included various ethnic and cultural groups. Most of the research (16/22

publications) in this meta- analysis were randomised controlled trials. These studies across various ethnic and cultural groups, demonstrated that community- based programmes using PA as a main component can effectively decrease HbA1c level, reduce weight and increase PA levels. If our study was conducted over a longer duration, we may have shown a decrease in weight and/or BMI. In both study groups most of the patients were on Metformin, Insulin (Actrapid, Actraphane, Protophane), Angiotensine Converting Enzymes Inhibitors (ACEI), Asprin and Zocor. Five patients in active group and one patient in control group were also taking sulphonylureas.

Out of 50 patients in active group, 30 were taking more than 50 units (u) of insulin/day with a minimum of 14u and maximum of 184 u/day. Similarly in control group 32 out of 45 patients were taking more than 50u of insulin/day with a minimum of 10u and maximum of 132 u/day. Insulin therapy could possibly be an explanation for the increase in BMI in both groups. (Table 7)

5.0 LIMITATIONS

- Small sample size,
- Study was conducted over a short period of time
- Lack of prescribed plan for exercise to achieve a target of 7000 steps/day
- Did not look at other factors which may influence the measurement of HbA1c like anaemia or chronic kidney disease
- Also did not look at any change in treatment that influences the HbA1c during the study period.

6.0 CONCLUSION

This study demonstrates that even in sedentary diabetic populations, that a passive and inexpensive tool such as a pedometer may positively influence PA to significantly achieve a meaningful reduction in HbA1c of 1.04% ($p<0.001$) without a prescribed exercise programme from health care providers. This could taranslate to other tools that could measure step counts e.g. cell phones or watches.

We suggest that a study like this could be conducted over a longer period of time to gauge any positive benefit on metabolic parameters such as BP and weight, and to see if these changes are sustainable with continued PA.

7.0 FUNDING

There was no sponsorship of any kind as it was a self-funded project. Dr. Bhana, the supervisor supplied the pedometers for this research.

8.0 CONFLICT OF INTEREST

None declared.

9.0 REFERENCES

1. Shaw JE, Sicree RA, Zimmet PZ. Global estimates of the prevalence of diabetes for 2010 and 2030. Diabetes research and clinical practice. 2010 Jan 1;87(1):4-14.

2. Prevalence of diabetes in South Africa [Internet]. Health24. 2013 [cited 28 February 2015]. Available from: http://www.health24.com/Medical/Diabetes/About-diabetes/Diabetes-tsunami-hits-South-Africa-20130210

3. Peirce NS. Diabetes and Exercise. British Journal of Sports Medicine.1999;33(3):161-172. https://doi.org/10.1136/bjsm.33.3.161

4. Blair SN, Kohl IH, Barlow CE, et al. Changes in physical fitness and all-cause mortality: a prospective study of healthy and unhealthy men. JAMA 1995;273(4):1093–8.

5. Gregg EW, Berkoff RB, Caspersen CJ, et al. Relationship of walking to mortality among US adults with diabetes. Archives of internal medicine. 2003;163(12):1440-1447. https://doi.org/10.1001/archinte.163.12.1440

6. Knowler WC, Barrett-Connor E, Fowler SE, et al. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. The New England journal of medicine. 2002;346(6):393-403. https://doi.org/10.1056/NEJMoa012512

7. Helmrich SP, Ragland DR, Leung RW, et al. Physical activity and reduced occurrence of non-insulin-dependent diabetes mellitus. The New England journal of medicine. 1991;325(3):147-152. https://doi.org/10.1056/NEJM199107183250302

8. Boule NG, Haddad E, Kenny GP, et al. Effects of exercise on glycemic control and body mass in type 2 diabetes mellitus: a meta-analysis of controlled clinical trials. Jama. 2001;286(10):1218-1227.

9. Yamanouchi K, Shinozaki T, Chikada K, et al. Daily walking combined with diet therapy is a useful means for obese NIDDM patients not only to reduce body weight but also to improve insulin sensitivity. Diabetes care. 1995;18(6):775-778.

10. Beller GA. Coronary heart disease in the first 30 years of the 21st century: challenges and opportunities: The 33rd Annual James B. Herrick Lecture of the Council on Clinical Cardiology of the American Heart Association. Circulation. 2001;103(20):2428-2435. https://doi.org/10.1161/01.CIR.103.20.2428

11. Effect of intensive blood-glucose control with metformin on complications in overweight patients with type 2 diabetes (UKPDS 34). UK Prospective Diabetes Study (UKPDS) Group. Lancet.1998;352(9131):854-865.

12. Pate RR, Pratt M, Blair SN, et al. Physical activity and public health. A recommendation from the Centers for Disease Control and Prevention and the American College of Sports Medicine. Jama. 1995;273(5):402-407.

13. Tudor-Locke C, Bassett DR, Jr. How many step/day are enough? Preliminary pedometer indices for public health. Sports medicine. 2004;34(1):1-8.

14. Van Dyck D, De Greef K, Deforche B, et al. The relationship between changes in steps/day and health outcomes after a pedometer-based physical activity intervention with telephone support in type 2 diabetes patients. Health education research. 2013;28(3):539-545. https://doi.org/10.1093/her/cyt038

15. Plotnikoff RC, Costigan SA, Karunamuni ND, et al. Community-based physical activity interventions for treatment of type 2 diabetes: a systematic review with meta-analysis. Frontiers in endocrinology. 2013;4:3.
https://doi.org/10.3389/fendo.2013.00003

APPENDICES

Appendix A: Research Protocol

STUDY TITLE: The Relationship between Objectively Measured Physical Activity and Parameters of Disease control in an African Population of type 2 Diabetes Mellitus

NAME AND QUALIFICATIONS OF RESEARCHERS

Muhammad Abid Siddiqui, MBBS Dip (PEC) SA

Supervisor: Dr Sindeep Bhana

PREVALENCE

The incidence of Type 2 Diabetes Mellitus (T2DM) is increasing rapidly. This is possibly due to increasing obesity, reduced level of activity, sedentary lifestyle, aging population and industrilization.[1]

In the USA in 2010, the prevalence of diabetes was estimated to be 0.2% in individuals aged less than 20 years and 11.3 % in individuals aged more than 20 years.[1] Diabetes increases with age. It is the fifth leading cause of death worldwide. In 2010 about 4 million people died as a result of diabetes.[1]

There are three and half million South Africans with diabetes (roughly 6% of the population) and many more still undiagnosed.[2] Worldwide, more than 400 million people have diabetes. The International Diabetes Federation (IDF) has predicted that this figure will increase to 552 million by 2030.[2] It is expected that the greatest increase would be in the African continent and it is predicted that by 2030 the prevalence of diabetes in Africa would almost have doubled.[2] Besides the important causative factors mentioned above, there is a cultural belief among most African communities that weight gain is a reflection of achievement, wellbeing and honour.[2]

TYPES OF DIABETES

Diabetes can be divided in to two major types.[3, 4]

1) T1DM (5% - 10 %)
2) T2DM (90% - 95%)

Gestational diabetes (GDM) is a less common form, associated with a 40 % - 60% increased risk of developing T2DM in the next 5 – 10 years. Pancreatic disease and genetic defects in

insulin action can also cause diabetes. Genetic and environmental causes are highly associated with the development of T2DM.[4]

PATHOPHYSIOLOGY

The characteristic of T2DM are: (1) impaired insulin secretion (2) insulin resistance (3) excessive hepatic glucose production, and (4) abnormal fat metabolism. Obesity, especially visceral or central is also prevalent in T2DM, (more than 80% of diabetics suffer from obesity). In the initial stage of the disease, glucose tolerance remains near normal despite insulin resistance, because the pancreatic beta cells compensate by increasing insulin output.[5]As insulin resistance and compensatory hyperinsulinemia increase, the pancreatic islet cells in

certain individuals fail to maintain higher insulin secretion level resulting in impaired glucose tolerance (IGT), which is represented by elevated post prandial glucose level. Further decreases in insulin secretion and ongoing hepatic glucose production, lead to overt diabetes and ultimately the beta cells fails completely.[5]

EFFECT OF PHYSICAL ACTIVITY ON T2DM

Regular physical activity (PA) is necessary for the prevention and management of T2DM and is associated with a lower incidence of all cause and cardiovascular disease mortality in patients with diabetes.[6] The Diabetes Prevention Programme found that a minimum of 150 min/week of moderate-intensity PA, such as brisk walking, was more efficient than metformin or placebo in the prevention of T2DM in pre-diabetics.[7] Similarly, Heimrich et al., described an inverse relationship between energy consumption in leisure-time PA and the development of T2DM in former college students.[8]

The advantages of regular PA in diabetes are: (1) better glycaemic control (2) weight reduction and (3) improved insulin sensitivity.[9, 10] The latter is integral to the prevention of cardiovascular complication, as impaired insulin activity can lead to elevated triglycerides, reduced high density lipoprotein cholesterol (HDL-C), increased secretion of very low-density lipoprotein cholesterol, and hypertension.[11]

The United Kingdom Prospective Diabetes Study (UKPDS), showed that intensive glucose control with metformin decreased Glycated Haemoglobin (HbA1c) by 0.6%. This reduction

was associated with a 32% decrease risk of diabetes-associated complications and 42% decrease in the mortality rate.[12]

In one study, 92 T2DM patients were enrolled from the Department of Endocrinology of the Ghent University Hospital. They were selected, at random, to either intervention group or control group.[13]

They observed no noticeable immediate or short-term disparities in health outcomes between the control and intervention groups. Nonetheless, they highlighted an important threshold of ≥4000 steps/day. HbA1c levels improved significantly above that threshold in 18 patients. But since this threshold was not associated with any other health outcome. To explain their results, they suggested that since these patients were managed by endocrinologists in a University Hospital, it is possible that they were so well treated (mean baseline HbA1c = 7.3%), that it was difficult to establish any additional benefits.

The authors of this study postulate that even though the difference in HbA1c in their research was less than 0.6% between the groups (≥4000 steps/ day vs. <4000 steps/day), it is possible that increased reduction in cardiovascular complications can be expected as PA is linked to other cardiovascular benefits and weight reduction.

There is no doubt that PA is beneficial to patients with diabetes. However, the minimum degree and frequency of activity required to achieve favourable outcomes has not been fully explained. While the Centres for Disease Control and Prevention (CDC) and the American College of Sports Medicine (ACSM) have suggested a minimum of 30 minutes of moderate-intensity PA on most days of the week,[14] Tudor-Locke et al., believe that walking 10 000 steps/day is effective.[15]

Even though the health benefits of moderate PA in diabetes has been established, the compliance with exercise is obviously low. To address this issue, low cost pedometers and cell phones may be used as monitoring device which may provide immediate feedback on the level of PA.

In another study the effect of self-help PA programme was studied on adults with T2DM over the course of three months.[16]

The effectiveness was identified by using cardiovascular indicators, HbA1c, anthropometric factors like weight and body fat, and activity levels.

Participants were assigned, at random, to an intervention group and a control group. Individuals in the intervention group visited the usual Diabetic Self-Management Education programme (DSMEP) and were given a copy of the book, *Manpo-Kei*, (Manpo-kei is a Japanese term for pedometer or step-counter), a concise hand-out summarising the key points of the device. Participants in the control group attended the DSMEP only.

The conclusion of this study was that the use of a pedometer can be a convenient strategy to encourage diabetics to improve PA. In contrast to their conclusion, they also indicated that attendance at a DSMEP alone may be sufficient to improve PA among diabetics.[16]

The Alberta Diabetes and Physical Activity Trial (ADAPT) studied the effectiveness of public health PA interventions delivered through print and telephone modes compared to standard PA educational materials.[17]

In this study two hundred and eighty-seven participants were recruited using a multi-strategy approach (mainly using general advertising strategies) and were assigned, at random, to three groups. Study inclusion criteria were participants eighteen years or older, diagnosed with T2DM, having regular access to a telephone and without any language barrier.

They concluded that no significant effects on PA or HbA1c levels were seen in T2DM adults. Steps/day significantly improved in the print-based material group and the pedometer with telephone counselling group, for females. They suggested that it is possible that the theoretical methods and the intervention approaches utilized in their study were not enough to promote changes, and also not applicable for their overall study population.[17]

Community–based PA programmes can be employed as a useful strategy for the management of T2DM.

Plotnikoff, et al conducted a systematic review with meta-analysis to examine the effectiveness of community-based PA programmes for management of T2DM in adult populations.[18] In this review, twenty-two eligible studies (publications from 2002 to June 2013) were selected in which the PA components/ approach accounted for more than half of the whole intervention. The research was organised in various countries that included various ethnic and cultural groups. Most of the research (16/22 studies) was a randomised control trial. The primary outcomes were different in the various studies; PA, weight and HbA1c were the primary outcomes in 9, 4 and 11 studies respectively.

On the whole this study demonstrated that community-based programmes using PA as a main component, can effectively decrease HbA1c levels, reduce weight and increase PA levels. Eleven studies, that demonstrated HbA1c as a primary outcome measure, were analysed. The meta-analysis showed community-based PA programmes were associated with a reduction in HbA1c by 0.32%. This was very close to statistical significance (p=0.06).

The different strategies utilized to promote PA was very different and ranged from organised group educational programmes, yoga classes, telephone advice, Young Men's Buddhist Association (YMBA) membership, motivational methods and providing access to gym equipment.

Their review suggested that including resistance training as part of PA programme could improve functional status and glycaemic control by promoting muscle strength, lean muscle mass and bone mineral density.

The authors believe that in light of the fact that they included various ethnic groups, ranges of age groups (ages 52-73), with higher proportion of females (64%), their findings are perhaps generalizable.

Overall, their findings demonstrate that community-based PA interventions effectively increase PA and decrease HbA1c levels.[18]

This study aims to measure the PA/step counts using pedometers and its relationship with parameters of disease control such as body mass index (BMI), HbA1c and blood pressure (BP).

STUDY AND OBJECTIVES

STUDY AIM:

Is to measure the level of activity in patients with T2DM at Chris Hani Baragwanath Academic Hospital in Soweto.

PRIMARY OBJECTIVE:

1. Ascertain level of activity using a pedometer

SECONDARY OBJECTIVES:

1. To correlate the baseline level of activity with BMI/ HbA1c/ BP
2. To assess whether 7000 steps a day influence HbA1c and BP over a 3-month period.

METHODS:

Study Design: Prospective, Observational trial.

Site of Study: Diabetic clinic at Chris Hani Baragwanath Academic Hospital

Study Population: African male and female patients between the ages 18-65 years attending diabetic clinic.

Population size: A sample size of 75 was obtained using mean change and standard deviation in HbA1c for the intervention and control group at 5 % significance level and 80% power.[13] However, the sample size was increased to 110 to account for maximum number of variables that may be included in regression analysis. A sample size of 15 is required for each variable added in the calculation.

Population Classification: Participants will be assessed over the 1st month to ascertain baseline activity and thereafter the population will be divided in to two groups, active and control. The active group will be asked to aim for at least 7000 steps per day over the next 3 months and control group to continue their routine daily activity.

Inclusion Criteria:

1. T2DM: 18-65 years old
2. Signed consent
3. Patient must have HbA1c measured as standard care in the clinic

Exclusion Criteria

1. T1DM
2. Any disability that may affect walking such as amputation of leg

Variable Measurements:

Body weight in kilogram (kg) and height in metres (m) will be measured wearing light clothing and without shoes. BMI will be calculated as the weight in kg divided by the square of height in metres. Normal BMI is 18.5 to 24.9 kg/m^2. According to World Health Organisation's definition, a BMI greater than or equal to 25 is overweight and a BMI greater than or equal to 30 is obesity.

BP will be measured with the person in a seated position with an automated monitor. Normal BP is between 120/80 to 139/89 mm of Hg.

HbA1c will be done at the beginning and at the end of the study. Normal value is less than 6.5%.

Data Analysis Plan: For continuous variables such as HbA1c, weight and BP, mean and standard deviation as summary measures will be used. For categorical variables like gender, frequency tables will be used.

Histogram will be used for continuous variables and pie chart for categorical variables such as race and gender.

To compare between control and active groups a t- test will be used to compare variables such as HbA1c, weight and BP, assuming that data would be normally distributed, otherwise Mann-Whitney U test will be used.

ANOVA or Kruskal-Wallis will be used to investigate the mean difference of HbA1c, weight and BP between different groups.

DATA COLLECTION

Timing:

	Nov 2014	Dec 2014	Jan 2015	March 2015	May 2015	June 2015	July 2015	Aug 2015	Sept 2015	Oct 2015	Feb 2016
Literature	✓	✓	✓								
Preparing Protocol		✓	✓	✓	✓						
Protocol assessment					✓	✓					
Ethics					✓						
Collecting Data						✓	✓	✓	✓		
Data Analysis										✓	✓
Writing										✓	✓

FUNDING

There is no sponsorship of any kind for this project. It will be self-funded. Dr Bhana, the supervisor has 300 pedometers.

LIMITATIONS:

1. Patients may not achieve 7000 steps.
2. Patients may be lost to follow up.
3. Lost or malfunctioning of pedometers.

ETHICS: Approved, No M150402

REFERENCES

1. Shaw JE, Sicree RA, Zimmet PZ. Global estimates of the prevalence of diabetes for 2010 and 2030. Diabetes research and clinical practice. 2010 Jan 1;87(1):4-14.
2. Prevalence of diabetes in South Africa [Internet]. Health24. 2013 [cited 28 February 2015]. Available from: http://www.health24.com/Medical/Diabetes/About-diabetes/Diabetes-tsunami-hits-South-Africa-20130210.
3. American College of Sports Medicine ADA. Exercise and Type 2 Diabetes [Internet]. [cited 28 February 2015]. Available from: http://www.abne.org.br/profissionais/Exercise_and_Type_2_Diabetes__American_College_of.18.pdf.
4. American Diabetes Association. Diagnosis and classification of diabetes mellitus. Diabetes care. 2013 Jan 1;36(Supplement 1):S67-74.
5. Kahn SE. The importance of β-cell failure in the development and progression of type 2 diabetes. The Journal of Clinical Endocrinology & Metabolism. 2001 Sep 1;86(9):4047-58.
6. Gregg EW, Gerzoff RB, Caspersen CJ, Williamson DF, Narayan KV. Relationship of walking to mortality among US adults with diabetes. Archives of internal medicine. 2003 Jun 23;163(12):1440-7.
7. Knowler WC, Barrett-Connor E, Fowler SE, Hamman RF, Lachin JM, Walker EA, Nathan DM. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. The New England journal of medicine. 2002 Feb;346(6):393-403.
8. Helmrich SP, Ragland DR, Leung RW, Paffenbarger Jr RS. Physical activity and reduced occurrence of non-insulin-dependent diabetes mellitus. New England journal of medicine. 1991 Jul 18;325(3):147-52
9. Boulé NG, Haddad E, Kenny GP, Wells GA, Sigal RJ. Effects of exercise on glycemic control and body mass in type 2 diabetes mellitus: a meta-analysis of controlled clinical trials. Jama. 2001 Sep 12;286(10):1218-27.

10. Yamanouchi K, Shinozaki T, Chikada K, Nishikawa T, Ito K, Shimizu S, Ozawa N, Suzuki Y, Maeno H, Kato K, Oshida Y. Daily walking combined with diet therapy is a useful means for obese NIDDM patients not only to reduce body weight but also to improve insulin sensitivity. Diabetes care. 1995 Jun 1;18(6):775-8.
11. Beller GA. Coronary heart disease in the first 30 years of the 21st century: challenges and opportunities: The 33rd Annual James B. Herrick Lecture of the Council on Clinical Cardiology of the American Heart Association. Circulation. 2001 May 22;103(20):2428-35.
12. UK Prospective Diabetes Study (UKPDS) Group. Effect of intensive blood-glucose control with metformin on complications in overweight patients with type 2 diabetes (UKPDS 34). The Lancet. 1998 Sep 12;352(9131):854-65.
13. Van Dyck D, De Greef K, Deforche B, Ruige J, Bouckaert J, Tudor-Locke CE, Kaufman JM, De Bourdeaudhuij I. The relationship between changes in steps/day and health outcomes after a pedometer-based physical activity intervention with telephone support in type 2 diabetes patients. Health education research. 2013 Mar 13;28(3):539-45.
14. Pate RR, Pratt M, Blair SN, Haskell WL, Macera CA, Bouchard C, Buchner D, Ettinger W, Heath GW, King AC, Kriska A. Physical activity and public health: a recommendation from the Centers for Disease Control and Prevention and the American College of Sports Medicine. Jama. 1995 Feb 1;273(5):402-7.
15. Tudor-Locke C, Bassett DR. How many steps/day are enough?. Sports medicine. 2004 Jan 1;34(1):1-8.
16. Diedrich A, Munroe DJ, Romano M. Promoting physical activity for persons with diabetes. The Diabetes Educator. 2010 Mar;36(1):132-40.
17. Plotnikoff RC, Karunamuni N, Courneya KS, Sigal RJ, Johnson JA, Johnson ST. The Alberta Diabetes and Physical Activity Trial (ADAPT): a randomized trial evaluating theory-based interventions to increase physical activity in adults with type 2 diabetes. Annals of Behavioral Medicine. 2012 Aug 25;45(1):45-56.
18. Plotnikoff RC, Costigan SA, Karunamuni N, Lubans DR. Community-based physical activity interventions for treatment of type 2 diabetes: a systematic review with meta-analysis. Frontiers in endocrinology. 2013 Jan 29;4:3.

Appendix B: Data Collection Sheet

DATA COLLECTION SHEET

Participant Number					
Hospital Number					
Surname					
Name					
Gender	☐ **Male**			☐ **Female**	
Date of Birth/ Age	**/ /**			**Age**	
Hypertensive	☐ **Yes**			☐ **No**	
Date of diagnosis of DM	**/ /**				
Current Treatment		**YES**	**NO**		
Metformin					
Sulfonylureas					
Insulin (Total Units)					
Aspirin					
Diuretic					
ACE-I					
ARB					
CCB					
β blocker					
α blocker					
Statin					
	Baseline	End of Month 1	End of Month 2	End of Month 3	End of Month 4
Weight					
Height					
BMI					
HBA1C					
SBP					
DBP					
Average Number of steps covered					

APPENDIX C: PARTICIPANT INFORMATION SHEET

PARTICIPANT INFORMATION SHEET

Title of study: The relationship between objectively measured physical activity and markers of disease activity in an African Population of type 2 Diabetes.

Introduction: Hello, How are you?

My name is Dr. Muhammad Abid Siddiqui and I am a staff member in the Department of internal medicine. Research is just the process to learn the answer to a question. In this study I would like to find out the effect of physical activity on patients with type 2 diabetes on parameters of disease control like Body mass index (BMI), Blood Pressure (BP) and Glycated Haemoglobin (HbA1c), as previous studies have shown that increase in physical activity has beneficial effects on BMI, BP and HbA1c.

BMI: is a measurement of body fat based on height and weight that applies to both adult men and women. Normal BMI is 18.5 to 24.9 kg/m^2

Blood Pressure: is the pressure of blood within the arteries and normal BP is between 120/80 to 139/89.

HbA1c: is a blood test that shows how well your diabetes is being controlled and provides an average of your blood sugar control over the past 2- 3 months. Normal value is less than 6.5%.

I would like to invite you to participate in this study which is considering the use of pedometer to assess the level of Physical Activity.

What is involved in participating in the study?

- This study is for a period of 4 months. Participants of the study will be assessed over the 1^{st} month to ascertain baseline activity and thereafter will be divided in to two groups, active and control at random.
- You will be given a pedometer, a small metre to measure daily step counts. You should wear this pedometer throughout the day (clipped to clothing or belt at waist), except for sleeping and bathing and to record every day in the evening the steps accumulated during the day in an activity log.

- First visit will be for about 30 to 40 minutes including signing of consent form and the demonstration about how the pedometer will work. Thereafter everyone will be seen every month for about 10 minutes for the next 3 months as per normal diabetic clinic visit.
- There is no additional treatment for the study and you should follow your usual eating habits but some of you would be asked to be more active.
- No additional investigations are required for the study except some routine blood test like HbA1c at the beginning and at the end of the study.

Risks for participating in the study:

- There is no risk involved while participating in this study.

Participation:

- Your participation in the study is voluntary.
- You can withdraw from the study at any time without giving any reason, for which you will not be penalized and you will continue to receive the same treatment as before.
- Translator or interpreter will be present in case of language problem.

Confidentiality:

- Efforts will be made to keep personal information confidential. Absolute confidentiality cannot be guarantee.
- Data will be available to patients and supervisor.
- Results will be made available for M med and journal publication.

Contact Details:

- In case you need any further information or concern about the study, you can contact the following persons:
  1) Dr.Muhammad Abid Siddiqui (Researcher) Tel: 083 441 6972
  2) Dr Sindeep Bhana (Supervisor) Tel: 011 933 8000

- For any concern or complaints regarding the ethical issues surrounding the study or other direct queries you can contact HREC Chair/Administrator on the following address:
  HREC (Medical) contact details: Prof P Cleaton Jones, Tel 011 717 2301, email peter.cleaton-jones1@wits.ac.za
  Ms Z Ndlovu Administrative Officer 011 717 2700/1234/1252 zanele.ndlovu@wits.ac.za

Thank you for taking the time to read this information sheet.

Appendix D: Consent Form

CONSENT FORM: USE OF CLINICAL INFORMATION FOR RESEARCH

Dear Patient,

You are currently admitted to **the study with a title of "The relationship between objectively measured physical activity and parameters of disease control in an African population of type 2 diabetes mellitus", to assess the level of activity using pedometers. From** time to time such research involves the use of patient records from which information is extracted. The use of such information is subject to the following:

1. Approval from the Human Research Ethics Committee (Medical) of the University of the Witwatersrand.
2. Identity of a patient from whose file information is extracted is never revealed to anyone but the researcher unless specific consent is obtained to do so. The information gathered does not contain the name of the patient but only a coded number so as to maintain anonymity.

Whilst we are not currently involved in research that requires us to use any information now, this may change in the future when you may have already been discharged. We would like to obtain your consent to use information from your file for the purpose of research, subject to the aforementioned conditions. If you choose not to give consent, this will not compromise your treatment in any way. If at any time you choose to withdraw consent you are free to do so and will not be prejudiced in any way.

Should you wish to contact us at any stage regarding consent, contact **Dr Muhammad Abid Siddiqui** at **(083**) **441 6972.**

A. Consent Given

I_____ hereby give consent for my records to be used as per the above mentioned conditions for the purposes of research:

PATIENT: _____ DATE: _____

B. Consent Not Given

I _____ do not give consent for my records to be used:

PATIENT: _____DATE: _____

Appendix E: Ethics Clearance Certificate

R14/49 Dr Muhammad Abid Siddiqui

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M150402

NAME: (Principal Investigator)	Dr Muhammad Abid Siddiqui
DEPARTMENT:	Internal Medicine Chris Hani Baragwanath Academic Hospital
PROJECT TITLE:	The Relationship between Objectively Measured Physical Activity and Markers of Disease Severity in an African Population of Type 2 Diabetes
DATE CONSIDERED:	24/04/2015
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Dr Sindcp Bhana
APPROVED BY:	Professor P Cleaton Jones, Chairperson, HREC (Medical)
DATE OF APPROVAL:	03/06/2015

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Secretary in Room 10004, 10th floor, Senate House, University.

I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned

contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. **I agree to submit a yearly progress report**

Principal Investigator Signature Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

APPENDIX F: TURNITIN REPORT

a0042575:Final_Paper.docx

ORIGINALITY REPORT

9%	7%	8%	7%
SIMILARITY INDEX	INTERNET SOURCES	PUBLICATIONS	STUDENT PAPERS

PRIMARY SOURCES

1	www.ncbi.nlm.nih.gov Internet Source	2%
2	Araiza, P.. "Efficacy of a pedometer-based physical activity program on parameters of diabetes control in type 2 diabetes mellitus", Metabolism, 200610 Publication	1%
3	www.sio-triveneto.it Internet Source	1%
4	Submitted to University of Witwatersrand Student Paper	1%
5	R. C. Plotnikoff, N. Karunamuni, K. S. Courneya, R. J. Sigal, J. A. Johnson, S. T. Johnson. "The Alberta Diabetes and Physical Activity Trial (ADAPT):A Randomized Trial Evaluating Theory-Based Interventions to Increase Physical Activity in Adults with Type 2 Diabetes", Annals of Behavioral Medicine, 2012 Publication	1%
	archinte.ama-assn.org	

6	Internet Source	1%
7	www.princetoncme.com Internet Source	1%
8	Submitted to University of Leeds Student Paper	1%

Exclude quotes	On	Exclude matches	< 1%
Exclude bibliography	On		

PLAGIARISM DECLARATION

1. I know that plagiarism means taking and using the ideas, writings, works or inventions of another as if they were one's own. I know that plagiarism not only includes verbatim copying, but also the extensive use of another person's ideas without proper acknowledgement (which includes the proper use of quotation marks). I know that plagiarism covers this sort of use of material found in textual sources and from the Internet.

2. I acknowledge and understand that plagiarism is wrong.

3. I understand that my research must be accurately referenced. I have followed the rules and conventions concerning referencing, citation and the use of quotations as set out in the Departmental Guide.

4. This assignment is my own work, or my group's own unique group assignment. I acknowledge that copying someone else's assignment, or part of it, is wrong, and that submitting identical work to others constitutes a form of plagiarism.

5. I have not allowed, nor will I in the future allow, anyone to copy my work with the intention of passing it off as their own work.

Name: _____ Student #:_____

Signed: _____ Date: _____