Original Article

Impact of Mental Ill Health on Medication Adherence Behaviour in Patients Diagnosed with Type 2 Diabetes

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Abstract

The prevalence and cost of type-2-diabetes mellitus (T2DM) are escalating globally. The comorbidities between T2DM, depression and anxiety are common. Achieving high adherence to therapy, supported by lifestyle adjustment is the gold standard for good diabetes management. This study aimed to explore the impact of mental ill-health on medication adherence behaviors in patients diagnosed with T2DM. Participants were recruited from a single general medical practice in Birmingham, and randomly allocated into group A and group B. All participants had their HbA1c and blood pressure (BP) measured, their medication adherence, depression, and anxiety screened at each consultation. Of 64 patients, those with secondary school education, physically active, unemployed, did not have online access to resources, were mentally healthy and from Pakistani ethnicity, had better diabetes medications adherence. Regression analysis showed a significant statistical difference ($p<0.05$) in the unintentional diabetes medication adherence and anxiety scores favoring group A. BP showed a significant difference between baseline and endpoint but no difference was observed between groups. The use of Morisky® software has allowed the screening of the underlying cause of medication adherence, depression, and anxiety promptly. The study identified the importance of medication adherence in diabetes and the impact this has on HbA1c and mental health. The study also proposed two algorithms, one for T2DM patients in general and one for patients from the Muslim faith, and showed how clinicians can adapt their consultations to meet the needs of an individual.

Keywords: Type 2 diabetes mellitus, Pakistani and bangladeshi, Depression and anxiety, Muslim diabetes patient, Independent prescriber pharmacist, Medication adherence

Introduction

The association between chronic long-term conditions such as type 2 diabetes mellitus (T2DM) and mental ill-health (MIH) is well known and well defined in the Diagnostic and Statistical Manual of Mental Disorders [1-3]. Many authors have investigated the correlation between the two conditions, to establish if one can lead to the other. A recent study measuring the relationship between depression and prevalence of T2DM in a community setting showed that most medications used for the treatment of depression can lead to weight gain, and consequentially increase the patient's risk to develop or worsen T2DM [4]. The authors also concluded that for the patient diagnosed with depression, the risk for T2DM increased by 20% and further increased after the initiation of medications. Another study showed that the risk of depression increased in T2DM patients diagnosed with diabetic neuropathy [5-7] concluded that the possible pathway is indirect, due to obesity as a result of loss of motivation for physical activity, emotional eating, and the side effects of the used medication.

Kumar found that the presence of T2DM is related to structural changes in the brain and linked insulin resistance to a depressed mood [8, 9]. Pouwer *et al*. [10] identified the link between stress, depression, and anxiety, and increasing the risk of T2DM. The increased risk was reported to be a result of changes in behavior leading to poor lifestyle choices such as altered eating patterns, poor food choices, consumption of a large amount of food, or more frequent meals. This is further compounded by physical inactivity, and self-medicating with high alcohol consumption. Another pathway they described was that behavior changes due to mental disorders can cause a long-term activation of the hypothalamic-pituitary-adrenal axis, leading to a sympathetic nervous system effect on appetite causing a knock-on effect of increasing obesity and therefore potentially resulting in T2DM.

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How to cite this article: Bibi N, Wara B, Morrissey H, Ball P. Impact of Mental Ill Health on Medication Adherence Behaviour in Patients Diagnosed with Type 2 Diabetes. Arch. Pharm. Pract. 2021;12(4):6-16. https://doi.org/10.51847/3Cr5E7T8Cw

Aim

This study aimed to explore the impact of mental ill-health, on medication adherence behaviors in patients diagnosed with T2DM.

Materials and Methods

This was a cohort observational study where the study population was randomly divided into cohort A (received three consultations, three months apart) and group B (received two consultations, 6 months apart). Ethics approval was received from the Health Research Authority (HRA) through the Integrated Research Application System (IRAS). The population (n=64) was recruited out of all patients (n=71) on the register of one general medical practice in Birmingham, UK. The study process is set out in **Figure 1**. Patients were recruited through invitation letters posted to their homes by the clinic's administration staff. The invitation letter included the participant information sheet and the selection criteria. Those who responded to the invitation were contacted by the surgery to be booked in for a consultation with the researcher. At the beginning of the consultation, the researcher explained the study procedures and duration, then, the researcher confirmed the patient's eligibility to participate. Those admitted were then asked to sign the consent form if they were still interested to participate. They were then moved to the waiting room, where they were given the demographics questionnaire for self-completion. This was collected at the beginning of the baseline consultation. Further demographics and previous HbA1c records were collated from a patient electronic medical record (EMR). Patient adherence to therapy was screened using the Morisky® 8-items electronic tool (MMAS-8©) twice; once for all their medications and again for diabetes medications only [11]. The Clinically Useful Depression Outcome Scale (CUDOS©) was used to screen for depression and the Clinically Useful Anxiety Outcome Scale (CUXOS©) was used to screen for anxiety [12-15]. Patients were asked to score their well-being on a scale from 1-5 where 1 least sense of well-being and 5 is the maximum sense of wellbeing. A medicine use review was then conducted and a care plan was developed, including any required education sessions or referrals. Patients were then randomly segregated into group A and group B using a randomization table generated in Microsoft® Excel™. All the data collected throughout the study were then analyzed for trends between the two groups and by demographics.

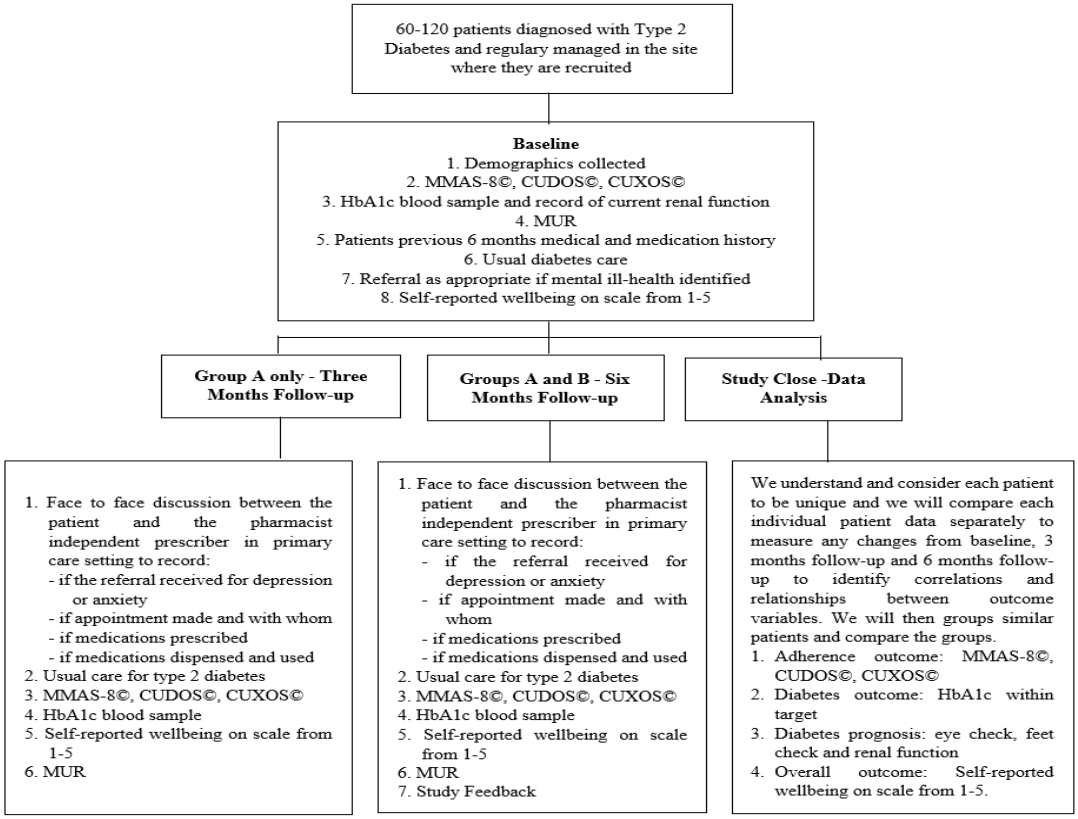


Figure 1. Diagrammatic Illustration of the Study Plan

Patient's records were reviewed to take note of the dates of, and reasons for, the most recent visits (during the past 12 months) to their endocrinologist, optometrist, or podiatrist, most recent HbA1c results, and most recent BP measurement. When HbA1c and BP recent records, (within the past 4 weeks), were not found, an HbA1c test was ordered and BP

was measured. The sample was calculated based on an improvement by one score point in patients' medication adherence as 6 patients in each group. This was multiplied by 5 as the minimum (n=30 patients per group) and by 10 as the maximum (60 patients per group) to accommodate withdrawals. Recruitment continued for 6 months which enabled the intervention to be concluded within 12 months. Patients were eligible if they were diagnosed with T2DM, able to self-consent, and 18 years of age or over. To prevent unnecessary stress on patients, those who were diagnosed with conditions such as severe dementia or severe mental illness or undertaking acute treatment for cancer were not invited.

Results and Discussion

Out of 71 patients who were eligible to participate, 64 (90%) signed the informed consent to voluntarily enroll in the study. The consultations at the initial enrolment were termed 'baseline (BL)', the 3-months consultations were termed 'midterm (MT)' and the 6-months consultation was termed 'endpoint (EP)'.

Table 1 provides the descriptive summary of the study population by all measurable output variables.

Table 1. Overall mean values, SD (+/-) with minimum and maximum values at baseline and endpoint.

Variables	BL				EP			
			Range				Range	
	Mean	SD+/-	Min	Max	Mean	SD+/-	Min	Max
HbA1c	8	1.7	6.4	13	7.7	1.7	5.8	12.7
MMAS-8© Diabetes medications intentional	3.4	1.1	0	4	3.3	0.7	2	4
MMAS-8© Diabetes medications unintentional	3.5	0.7	0.8	4	3.7	0.5	1.8	4
CUDOS©	1	0.2	1	2	1	0	1	1
CUXOS©	1	0.2	1	2	1	0	1	1
MMAS-8© Chronic diseases medications intentional	3.6	0.8	1	4	3.9	0.3	3	4
MMAS-8© Polypharmacy unintentional	3.5	0.6	2	4	3.7	0.4	2.8	4
BP (systolic)	123.9	13	98	159	126.8	14.6	100	175
BP(diastolic)	78.2	7.2	59	93	81	6.6	60	100

Morisky score-8© = MMAS-8, Clinically useful depression outcomes scale = CUDOS, Clinically useful anxiety outcomes scale = CUXOS, SD(+/-) = standard deviation, BP = blood pressure.

Data was then analyzed by all variables comparing group A to group B's measurable outcomes **(Table 2)**. Group A showed a better adherence mean score for both diabetes medications and chronic diseases medications in both the physically active and inactive patients. The unemployed also showed a higher mean adherence score in the two groups. Other factors identified were; secondary school education, access to resources, not smoking, no diagnosis of MIH, and Bangladeshi heritage.

CUDOS mean percentage was lower (better) in group A physically active (0.18%), group B unemployed (0.14%), group A patients with secondary school education, those with no access to resources, smokers, those who are treated for mental illness and patients from Bangladeshi heritage (0.17%, 0.18%, 0%, 0.17%, 0% respectively).

There were no significant differences between groups and variants in the CUXOS mean scores, however, only patients from Pakistani heritage from group A remained above 1% till the end of the study.

Wellbeing means the self-reported score was higher (better) in group B physically inactive (5), group A unemployed (4.75), group A patients with primary school education, those with no access to resources in group A (4.18), smokers in group A (4.67), those who are treated from mental illness from group B (4.5) and patients from Bangladeshi heritage in group B (4.67).

Table 2. Means and SD(+/-) for all measurable parameters by study variables for groups A and B

	Active	Inactive	Employed	Unemployed	Education Primary	Education Secondary	Access to the internet	No access to the internet	Smoker	Non-smoker	MIH	No MIH	Pakistani	Bangladeshi

Diabetes medications adherence																															
Group	BL	EP	BL	EP	BL	EP	BL	EP	BL	EP	BL	EP	BL	EP	BL	EP	BL	EP	BL	EP	BL	EP	BL	EP	BL	EP	BL	EP	BL	EP	BL	EP
A	Mean	6.32	7.4	6.67	7.25	5.92	7.23	7.00	7.59	6.83	7.34	6.27	7.46	6.83	7.50	6.20	7.34	7.67	7.33	6.37	7.46	6.00	7.25	6.62	7.44	6.60	7.39	6.08	7.46		
	N	28	28	3	3	12	12	8	8	19	19	12	12	19	19	11	11	3	3	28	28	6	6	26	26	26	26	6	6		
	SD +/-	1.87	0.86	2.31	1.30	2.06	1.24	0.53	0.82	1.65	0.91	1.87	0.88	1.25	0.86	2.54	0.85	0.58	0.58	1.90	0.89	2.16	1.07	1.76	0.85	1.60	0.95	2.72	0.51		
B	Mean	7.15	7.16	7.58	6.75	6.66	6.61	7.43	7.50	7.17	7.04	7.31	7.28	7.02	6.74	7.23	7.80	6.60	7.30	7.30	7.16	7.44	6.38	7.18	7.21	7.04	7.13	7.96	7.04		
	N	28	28	3	3	14	14	7	7	23	23	9	9	21	21	10	10	5	5	26	26	4	4	28	28	26	26	6	6		
	SD +/-	1.18	1.19	0.72	1.73	1.69	1.35	0.64	0.80	1.05	1.24	1.38	1.17	1.27	1.33	1.32	0.39	1.67	0.89	1.01	1.20	0.66	1.74	1.19	1.11	1.19	1.20	0.10	1.35		
Chronic diseases medications adherence																															
A	Mean	7.07	7.69	7.33	7.00	7.00	7.46	7.00	7.75	7.11	7.62	7.00	7.54	7.24	7.55	6.98	7.70	7.33	7.25	7.07	7.66	7.38	7.67	7.03	7.59	7.13	7.56	6.92	7.79		
	N	28	28	3	3	12	12	8	8	19	19	12	12	19	19	11	11	3	3	28	28	6	6	26	26	26	26	6	6		
	SD +/-	1.09	0.45	1.15	0.00	0.84	0.49	1.31	0.46	1.12	0.49	1.03	0.49	0.92	0.49	1.34	0.46	0.58	0.43	1.13	0.47	0.61	0.52	1.15	0.48	0.97	0.49	1.52	0.40		
B	Mean	7.05	7.61	7.58	7.50	6.39	7.30	7.57	8.00	7.15	7.57	7.08	7.83	6.86	7.52	7.73	7.95	7.15	7.55	7.13	7.69	7.69	7.38	7.05	7.68	6.95	7.57	7.75	7.96		
	N	28	28	3	3	14	14	7	7	23	23	9	9	21	21	10	10	5	5	26	26	4	4	28	28	26	26	6	6		
	SD +/-	1.28	0.61	0.52	0.66	1.54	0.64	0.81	0.00	1.12	0.57	1.52	0.41	1.36	0.60	0.70	0.11	1.27	0.87	1.26	0.45	0.47	0.60	1.28	0.53	1.29	0.57	0.50	0.10		
CUDOS© scores																															
A	Mean	0.54	0.18	0.00	0.33	0.50	0.17	0.25	0.50	0.74	0.21	0.17	0.17	0.47	0.21	0.36	0.18	0.00	0.00	0.46	0.25	1.00	0.17	0.38	0.23	0.42	0.27	0.83	0.00		
	N	28	28	3	3	12	12	8	8	19	19	12	12	19	19	11	11	3	3	28	28.0	6	6	26	26	26	26	6	6		
	SD +/-	0.96	0.39	0.00	0.58	0.90	0.39	0.46	0.53	1.10	0.42	0.39	0.39	0.77	0.42	0.92	0.40	0.00	0.00	0.84	0.44	1.10	0.41	0.85	0.43	0.86	0.45	1.17	0.00		
B	Mean	2.21	0.36	1.00	1.00	2.64	0.43	1.00	0.14	2.22	0.48	2.11	0.22	2.86	0.43	1.00	0.30	4.00	0.40	1.88	0.38	1.25	0.50	2.32	0.39	2.46	0.38	1.00	0.50		
	N	28	28	3	3	14	14	7	7	23	23	9	9	21	21	10	10	5	5	26	26	4	4	28	28	26	26	6	6		
	SD +/-	4.30	0.49	1.00	0.00	5.58	0.51	1.15	0.38	4.03	0.51	4.40	0.44	4.80	0.51	1.63	0.48	7.87	0.55	3.13	0.50	1.50	0.58	4.31	0.50	4.46	0.50	1.10	0.55		
CUXOS© scores																															
A	Mean	0.21	0.07	0.00	0.33	0.33	0.17	0.13	0.13	0.11	0.05	0.33	0.17	0.26	0.11	0.09	0.09	0.00	0.33	0.21	0.07	0.33	0.00	0.15	0.12	0.19	0.08	0.17	0.17		

			B		Wellbeing scores	A			B		HbA1c	A			B	
N	SD +/-	Mean	N	SD +/-	Mean	N	SD +/-	Mean	N	SD +/-	Mean	N	SD +/-	Mean	N	SD +/-
28	0.63	1.39	28	3.40	4.21	28	0.92	3.96	28	0.74	8.45	28	2.02	7.50	28	1.03
28	0.26	0.18	28	0.39	4.71	28	0.46	4.36	28	0.62	8.03	28	1.92	7.34	28	1.30
3	0.00	4.33	3	7.51	4.00	3	1.00	3.67	3	1.15	7.53	3	1.06	9.83	3	2.24
3	0.58	0.00	3	0.00	4.33	3	1.15	5.00	3	0.00	8.10	3	1.68	9.10	3	2.70
12	0.89	1.57	14	4.24	3.92	12	0.90	3.93	14	0.73	8.26	12	1.96	7.68	14	1.34
12	0.39	0.14	14	0.36	4.50	12	0.67	4.36	14	0.63	8.03	12	1.67	7.93	14	2.03
8	0.35	0.71	7	0.95	4.25	8	0.89	3.86	7	0.69	8.76	8	2.71	7.54	7	0.79
8	0.35	0.00	7	0.00	4.75	8	0.46	4.71	7	0.49	8.35	8	2.97	7.13	7	0.83
19	0.32	1.43	23	3.19	4.16	19	0.96	3.91	23	0.79	8.16	19	1.95	7.70	23	1.40
19	0.23	0.17	23	0.39	4.68	19	0.58	4.39	23	0.58	7.76	19	1.75	7.49	23	1.48
12	0.89	2.22	9	5.26	4.08	12	0.90	4.00	9	0.71	8.63	12	2.05	7.67	9	1.20
12	0.39	0.11	9	0.33	4.58	12	0.51	4.44	9	0.73	8.43	12	2.09	7.44	9	1.62
19	0.73	1.71	21	3.87	4.16	19	0.96	4.00	21	0.84	8.14	19	1.73	7.56	21	0.90
19	0.32	0.19	21	0.40	4.63	19	0.50	4.43	21	0.60	7.81	19	1.51	7.71	21	1.74
11	0.30	1.70	10	4.03	4.18	11	0.87	3.80	10	0.63	8.83	11	2.37	8.08	10	1.98
11	0.30	0.10	10	0.32	4.64	11	0.67	4.40	10	0.70	8.52	11	2.44	7.08	10	0.74
3.00	0.00	2.60	5.00	5.81	2.67	3.00	0.58	3.80	5.00	0.84	8.00	3	0.87	8.06	5	2.47
3.00	0.58	0.40	5.00	0.55	4.67	3.00	0.58	4.20	5.00	0.45	7.83	3	1.26	6.86	5	0.63
28.0	0.63	1.54	26.0	3.50	4.29	28.0	0.81	4.00	26.0	0.75	8.17	28	1.86	7.57	26	1.06
28.0	0.26	0.12	26.0	0.33	4.64	28.0	0.56	4.42	26.0	0.64	7.84	28	1.78	7.41	26	1.32
6	0.52	3.50	4	6.35	4.33	6	1.03	4.50	4	1.00	8.48	6	2.56	9.00	4	2.35
6	0.00	0.25	4	0.50	4.83	6	0.41	4.50	4	1.00	8.37	6	2.00	8.73	4	1.90
26	0.61	1.39	28	3.40	4.12	26	0.91	3.86	28	0.71	8.26	26	1.84	7.50	28	1.06
26	0.33	0.14	28	0.36	4.62	26	0.57	4.39	28	0.57	7.89	26	1.87	7.30	28	1.38
26	0.63	1.50	26	3.51	4.15	26	0.92	3.88	26	0.77	8.45	26	2.12	7.47	26	0.94
26	0.27	0.15	26	0.37	4.65	26	0.56	4.42	26	0.58	8.14	26	2.00	7.57	26	1.64
6	0.41	2.33	6	5.24	4.17	6	0.98	4.17	6	0.75	7.68	6	0.69	8.63	6	2.29
6	0.41	0.17	6	0.41	4.67	6	0.52	4.33	6	0.82	7.27	6	1.00	7.01	6	0.48

Regression Analysis

The medication adherence scores were split into intentional and unintentional, which distinguished participants' behavior toward their diabetes medications adherence **(Figures 2a and 2b)**. There was no significant difference seen between the groups, however, a potentially important pattern of improvement was observed for group A whereas group B was seen to fall. This demonstrates the value of an additional, midterm encounter impacting patients' intentional behavior toward their medication adherence.

Chronic disease medications intentional adherence scores showed a greater improvement in group B participants when compared to group A. However, these results show that an extra encounter did not prove to be beneficial with the chronic

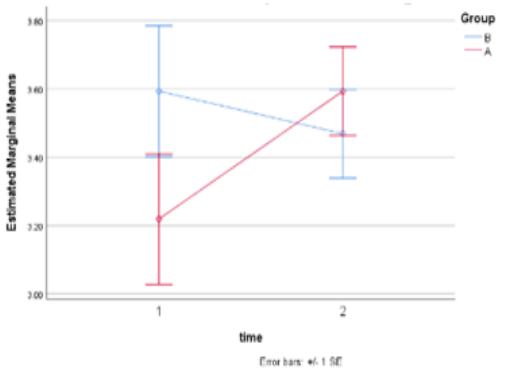
disease medication as both groups reached the same point of improvement **(Figure 2c and 2d)**.

Improvement in CUDOS© and CUXOS© scores was greater when patients were reviewed over a longer period (6-months) compared to those seen every 3-months **(Figure 2e and 2f)**.

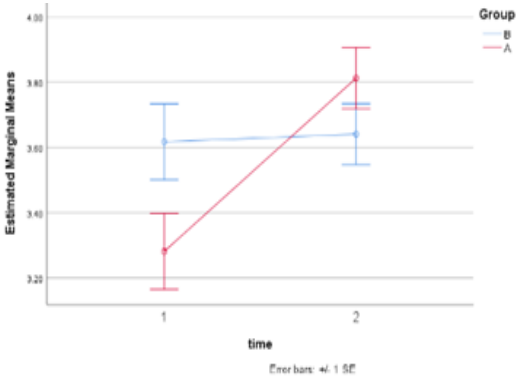
Wellbeing scores were self-reported, there was no statistical difference between the groups however group A displayed better wellbeing scores when compared to group B. This showed the importance of having frequent encounters (3-monthly) and the sense of being reassured by healthcare professionals **(Figure 2g)**.

The difference between baseline and endpoint for HbA1c shows no statistical difference, therefore, indicating no need for a further encounter **(Figure 2h)**.

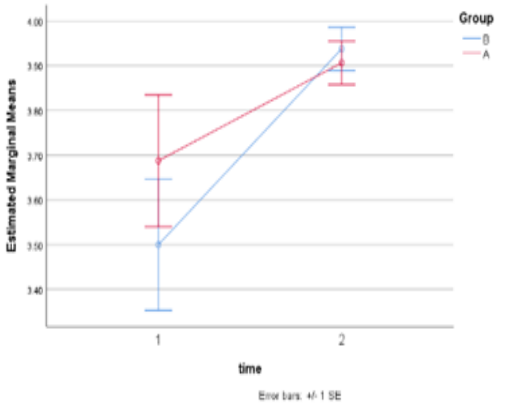
For BP, both systolic and diastolic had raised in both groups but remained within range, with group A being slightly lower than group B. The results show a statistical difference between time points but no difference between the groups **(Figure 2i and 2j)**.



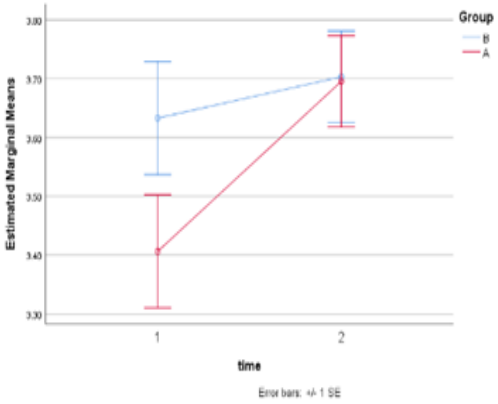
a) Diabetes medication intentional adherence scores



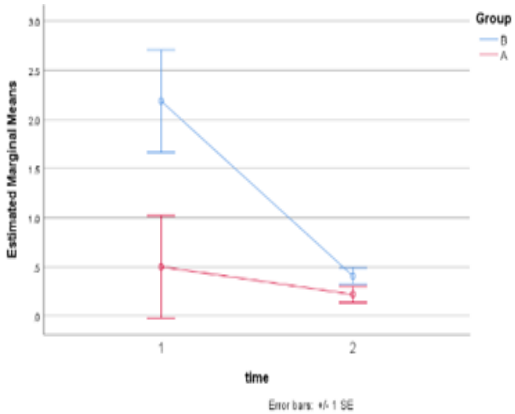
b) Diabetes medications unintentional adherence scores



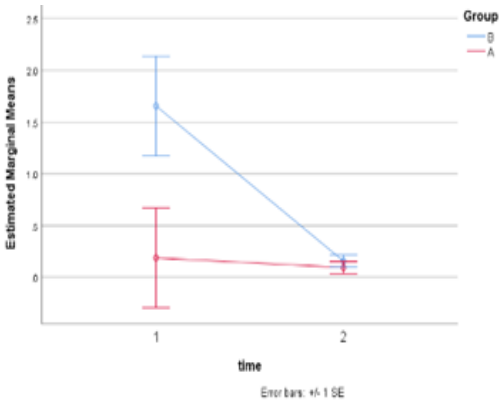
c) Chronic disease medication intentional adherence score



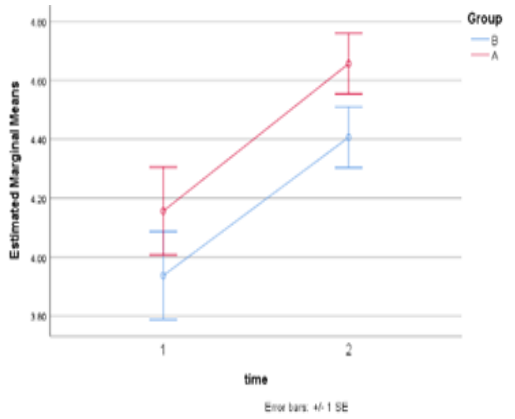
d) Chronic disease medications unintentional adherence scores



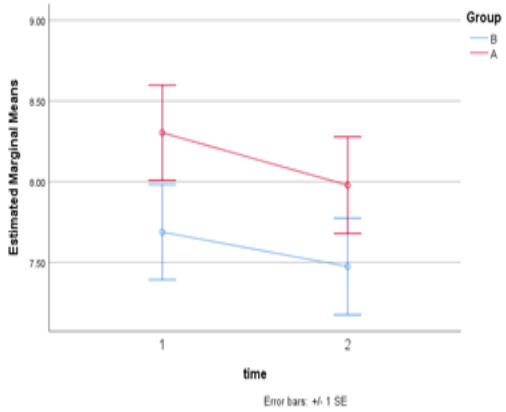
e) CUDOS© scores



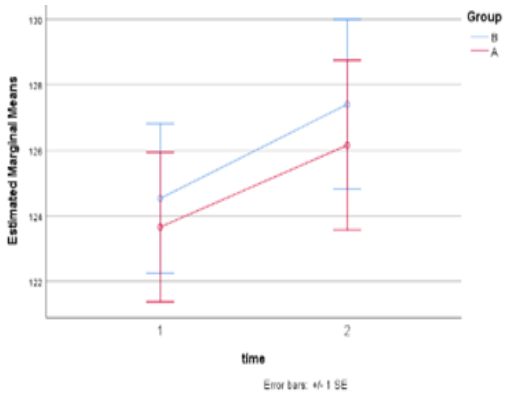
f) CUXOS© scores



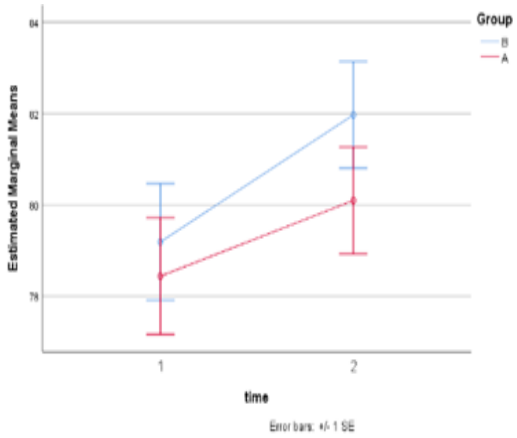
g) Wellbeing score



h) HbA1c results



i) BP systolic readings



j) BP diastolic readings

Figure 2. Regression analysis by groups

Thematic Analysis

Using Braun *et al*. [16], the qualitative data were analyzed using a thematic approach. There were 12 identified themes. **(Table 3)**. Those themes were used to develop the two proposed models for primary care **(Figure 3)**.

Table 3. Themes identified from the 64 cases at the end-point

Domain	Themes	Baseline results from Cases	Endpoint results Cases
Knowledge	Awareness of condition prognosis.	31	51
	Awareness of how medications work.	15	58
	Awareness of the impact of lifestyle.	8	51
	Awareness of treatment step-up pathways.	7	48
Self-care and disease prognosis	Category 1: High self-care efficacy and favorable disease prognosis (disease markers are within the patient target range, good adherence to medications and lifestyle advice, no mental health issues).	11	47
	Category 2: High self-care efficacy and poor disease prognosis (disease markers are out of the patient target range, good adherence to medications and lifestyle advice, no mental health issues).	27	12
	Category 3: Poor self-care efficacy and favorable disease prognosis (disease markers are within the patient target range, low adherence to medications and lifestyle advice, mental health issues).	4	0
	Category 4: Poor self-care efficacy and poor disease prognosis (disease markers are out of patient target range, low adherence to medications and lifestyle advice, mental health issues).	23	5
Future needs	Ongoing monitoring required - patient at risk of non-adherence to therapy and lifestyle	28	5
	Ongoing monitoring required – patient at risk of mental health problems or illnesses	11	0

	Ongoing monitoring required – patients require frequent health checks.	48	26
Study impact	Benefit from participating in the study (self-reported wellbeing score).	45	62

Prediction Model

Based on the thematic analysis, coupled with case characteristics and grouping, it was possible to identify four possible prediction phenomena. Patients who displayed this phenomenon shared some characteristics as illustrated in **Table 4**.

Table 4. Patients shared characteristics at baseline

Phenomenon	High self-care efficacy and favorable disease prognosis	High self-care efficacy and poor disease prognosis	Poor self-care efficacy and favorable disease prognosis	Poor self-care efficacy and poor disease prognosis
Age (years)	Median: 53 Mean: 54 Mode: 48	Median: 56 Mean: 55 Mode: 66	Median: 59 Mean: 59 Mode: 59	Median: 60 Mean: 59 Mode: 65
Gender (M/F)	F= 7 M=4	F= 15 M=11	F= 1 M=3	F= 12 M=11
Intentional medications adherence ranges	Median: 4 Mean: 4 Mode: 4	Median: 3 Mean: 3 Mode: 4	Median: 4 Mean:4 Mode: 4	Median: 4 Mean: 3.75 Mode: 4
Unintentional medication adherence	Median:4 Mean: 4 Mode: 4	Median:3 Mean:3 Mode: 3	Median: 4 Mean: 3.75 Mode: 4	Median: 3.75 Mean: 3 Mode: 4
Depression	0%-10%	11%-20%	0-10%	11-20%
Anxiety	0%-10%	11%-20%	0%-10%	11%-20%
Wellbeing	Median: 4 Mean: 4 Mode: 4	Median: 4 Mean: 4 Mode: 4	Median: 4 Mean: 4 Mode: 4	Median:4 Mean: 4 Mode:4
Number of conditions	<3	4-5	4-5	<6
Number of medications	2-10	2-10	2-10	4-14
HbA1c (%)	Median: 6.7 Mean: 6.8 Mode: 6.5	Median: 7.6 Mean: 7.9 Mode: 7.7	Median: 7.6 Mean: 7.6 Mode: 7.1	Median:7.7 Mean: 8.8 Mode: 7.7
BP (mmHg)	Median: 126/80 Mean: 123/85 Mode: N/A	Median: 126/80 Mean: 124/80 Mode:128/80	Median: 127/85 Mean: 128/85 Mode: N/A	Median: 128/77 Mean: 124/77 Mode: 137/78
COVID-19 impact	Yes	Yes	Yes	Yes
Phenomenon probability	Possible	Possible	Impossible	Possible

The phenomena are confirmed as possible when shared by 90% or more of the participants' characteristics. Four possible models were identified and were used to develop the research recommendations.

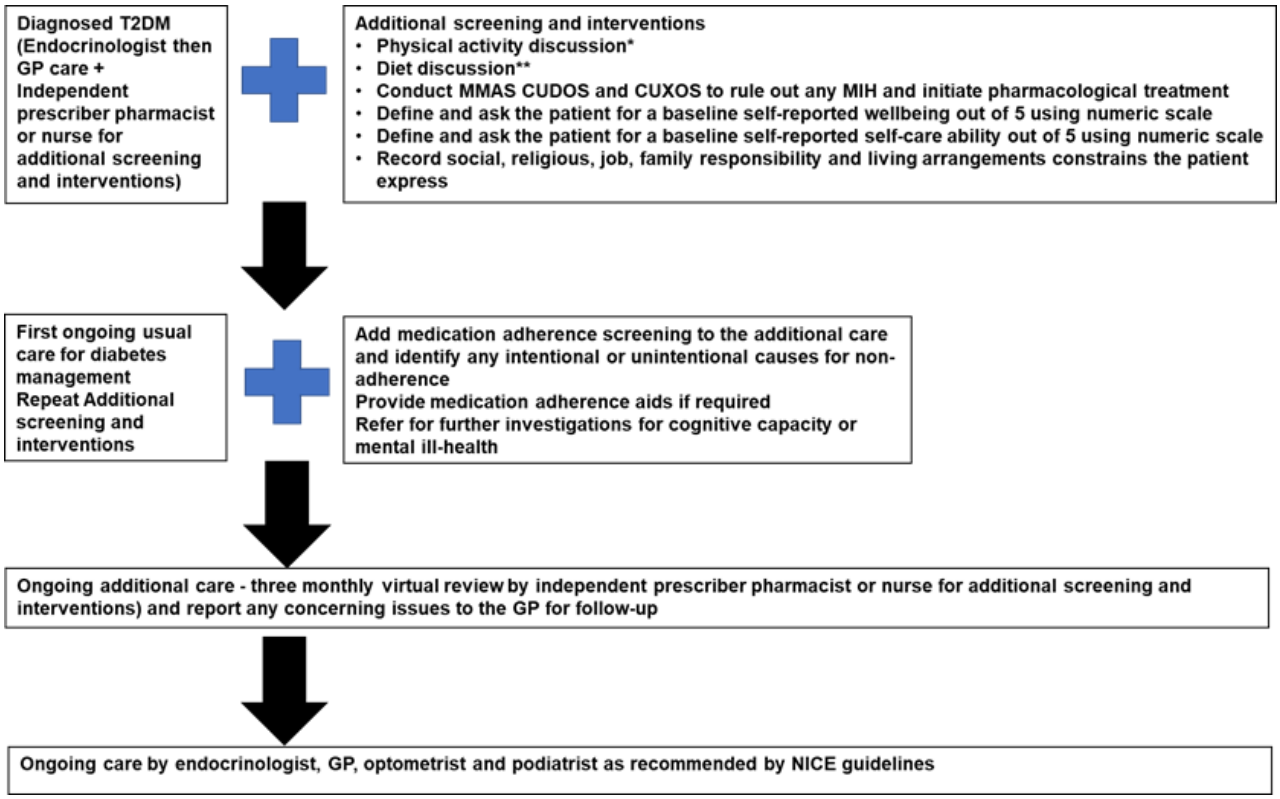
Impact on T2DM management in Bangladeshi and Pakistani patients

Figure 3a displays a pictorial illustration for diabetes care for participants from the southeast Asian population of the Muslim faith. Based upon study findings, various adaptations are required t to manage T2DM at an optimum level of glycaemic control. Various religious, and personal views of participants were seen as restricting certain physical activities which need to be highlighted to the clinician to recognize and develop achievable goals as per the current guidelines NG28 [17]. The study shows the importance of health education in the population group of Southeast Asians. Participants mainly had a background of primary or secondary education, which it was established the difference between the Pakistani and Bangladeshi heritage populations, and the difference in approach required to achieve optimal diabetes control. As seen in the algorithm, the power of a group session would enable a better understanding of dietary intake as well as physical activity sessions. This population showed individuals with a large number of children from multi-occupant households. The idea of a group session can allow

household members to come and participate as a group and in essence, take the same message home together. It needs to be highlighted that these group sessions are founded on, and respectful of the participants' cultural and religious background, therefore gender-specific groups, and when appropriate, age-specific groups will be required due to the religious beliefs of individuals. Both ethnic groups' definitions, beliefs, and behaviors towards physical illness, mental illness, and wellbeing are derived from a combination of their own cultures and religion. Accordingly, physical activities, dietary plans, screening for adherence, and mental illness needs to be established in ways that work around those identified issues to make them practical and achievable.

Impact of practice improvement for T2DM in primary care

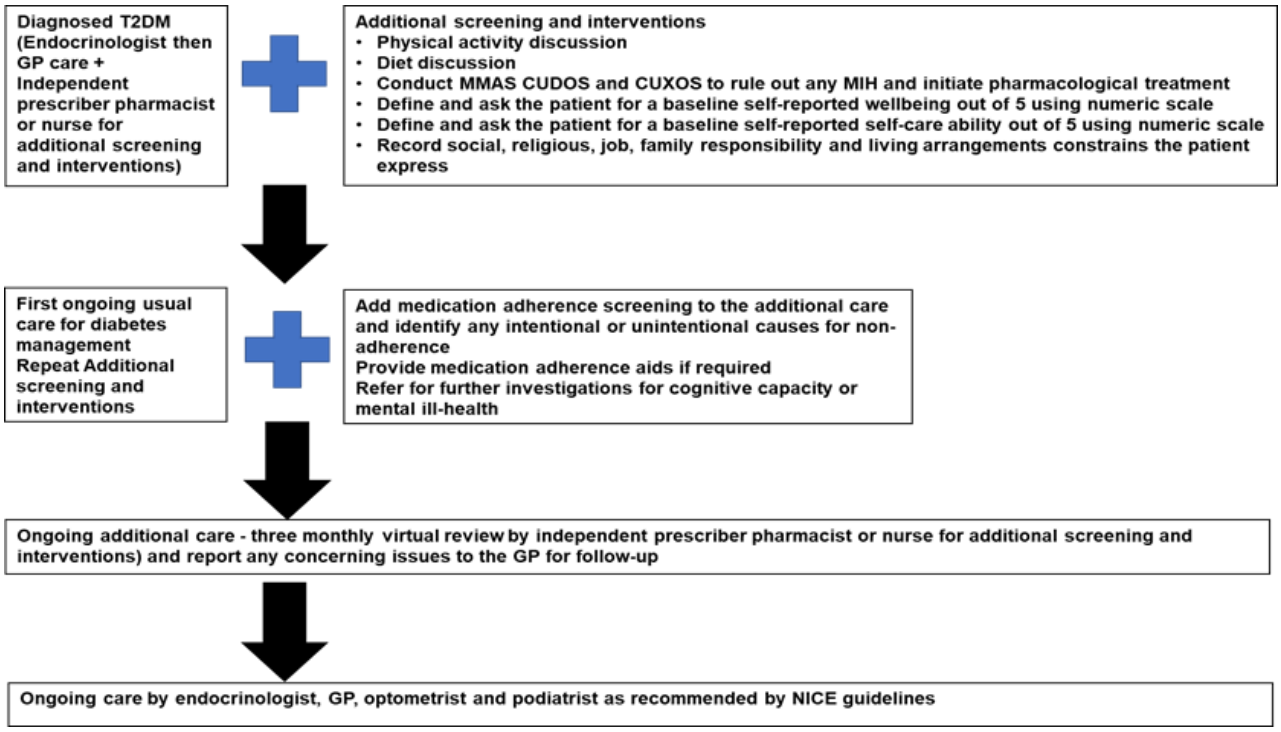
This study has shown how three monthly reviews do not allow the progression of an impact in glycaemic control or MIH but showed improvement in physical activity, diet, and wellbeing [18]. However, this was only observed for 6 months which is not sufficient to accomplish behavior change. A four-monthly review by independent prescribers (from GP or community-based) is proposed to complement the usual care described in NICE guidelines including diet and physical health advice **(Figure 3b)**.



a) Prototype algorithm for patients diagnosed with T2DM tailored to Muslim Pakistani and Bangladeshi patients

* Physical activity discussion: -Consider gardening, walking to work or shopping, -Consider activities that can be undertaken at the comfort of an individual's house using alternative gym such as use of house furniture e.g., kitchen benches, food instead of weight etc

**Diet discussion: -Consider that Pakistani and Bangladeshi patients differ culturally and consume different, -Food in different diary, fat and carbohydrate (complex and simple) proportions, -Consider portion control advise during cultural and religion events to compensate for type of consumed food to avoid upsetting culture trends



b) Prototype algorithm for patients diagnosed with T2DM

Figure 3. Prototype algorithms

Limitation

This study had some limitations: Funding was the first hurdle. Numerous applications were rejected as it appeared a project led by a pharmacist was not considered by many funders as clinical research because it was led by an independent prescribing pharmacist, not a doctor or a nurse.

Cultural sensitivity and norms also affected the study results, as all patients recruited were from Bangladeshi or Pakistani origin where essential aspects of the study remain stigmatizing and labeling if they are disclosed; aspects such as MIH, smoking, and alcohol consumption. Additionally, there were cultural appropriateness issues where participants feel societal obligations to participate in, or avoid, which are determinant for poor diabetes control such as food as the center of social gathering and celebrations, and gender restriction or obligations, such as the type of physical activity undertaken and large household responsibilities for females. This may have led to participants not being willing to disclose those aspects or respond to the questions, based upon their personal, cultural and religious beliefs.

Site selection impact was also experienced. The area where the site is located in Birmingham is mostly populated by people of Southeast Asian origin.

Conclusion

The assessment of T2DM, depression, and anxiety was seen to be important to review in all encounters, however, the study has shown that a longer (6-months) interval between reviews was more beneficial than 3-months, whereas, with T2DM review, a significant difference was seen when the patient review was every 3-month compared to 6-months. The study demonstrated that current guidelines do not account for ethnicity and religion, or how these two factors can influence glycaemic control. This pilot study demonstrated clear potential for the use of MMAS-8© Widget and CUDOS©/CUXOS© screening. The structure within the NHS in recent years has dramatically changed allowing more pharmacists to be employed in primary care. The tools can be used as part of the structured medication reviews (SMR) to enable the detection of adherence issues.

ACKNOWLEDGMENTS: The use of the MMAS-8 for this study was granted by Dr Donald Morisky. The MMAS-8 Scale, content, name, and trademarks are protected by US copyright and trademark laws. Permission for use of the scale and its coding is required. A license agreement is available from MMAR, LLC., Donald E. Morisky, ScD, ScM, MSPH, donald.morisky@moriskyscale.com. (© 2006 Donald E. Morisky)
CONFLICT OF INTEREST: None
FINANCIAL SUPPORT: None
ETHICS STATEMENT: The Health Research Authority (HRA), the Integrated Research Application System (IRAS) approved the study ethics application on 9/9/2019, reference number 19/NW/0508.

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