

Study the clinical pharmacist influence on medication adherence & quality of life of rural type-2 diabetes mellitus patients in a tertiary care hospital

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Citation: K.V. Ramanath, M. Bhanuprakash, C. H. Nagakishore, Mahesh kumar S, Balaji D.B.S.S. Study the clinical pharmacist influence on medication adherence & quality of life of rural type-2 diabetes mellitus patients in a tertiary care hospital, Archives of Pharmacy Practice. 2012; 3(2) pp 170-180.

Abstract

Objective: To assess the impact of clinical pharmacist involvement in the medication adherence of Diabetes mellitus patients.

Methodology: A Prospective, Randomized and interventional study was carried out in the medicine department for a period of 8 months in Adichunchanagiri hospital and research centre, B.G.Nagar. The patients were grouped in to control and intervention after obtaining their consent. These patients' data was collected by using a well designed patient data collection form. The questionnaires were used to know the medication adherence behaviour and quality of life. Significance is assessed at 5 % level of significance.

Result: A total of 48 patients are enrolled in which 24 in control 24 in intervention groups. The Morisky medication adherence scale (MMAS) and medication adherence report scale (MARS) were showed P value 0.007**, <0.001**. The SF-12 for quality of life (QOL) questionnaire showed P value 0.293 in physical component summary (PCS) and 0.001** in mental component summary (MCS) respectively.

Conclusion: The present study concluded that continuous education programs/counselling is important for Diabetes mellitus patients to emphasize and re-emphasize on the disease management and this study also showed positive results in medication adherence behaviour and disease management (QOL).

Key words:

Medication Adherence, Quality of life, Diabetes mellitus.

Manuscript History:

Article Received on: 10th Sept, 2011

Revised on: 30th Dec, 2011

Approved for Publication: 2nd Mar, 2012

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Introduction

Dibetes mellitus (DM) is a group of metabolic disorders that results from defects in insulin secretion (Type I) and insulin action (sensitivity) or both (Type II). The global burden of diabetes has been estimated by WHO that 135 million people were affected in 1995, their number expectation will have reached to 299 million by the year 2025. India has the world's largest diabetes population followed by China with 43.2 million [1, 2, 3].

Medication nonadherence is a multifaceted problem especially for chronic disease people and it is one of the important factor, helps in determining the therapeutic outcome. The pharmacist educational intervention of these people will help to increase the medication adherence behaviour and quality of life [4].

Quality of life (QOL) is a broad multidimensional concept, includes subjective evaluations of both positive and negative aspects of life. Health is one of the important domain of overall quality of life. There are other domains as well—for instance, jobs, housing, schools, the neighbourhood. The concept of health-related quality of life (HRQOL) and its determinants have evolved from 1980s was helped to encompass those aspects of overall quality of life that can be clearly shown to affect health—either physical or mental [5].

The study was carried out in 750 bedded tertiary care Adichunchanagiri hospital and research centre (AH&RC) B.G.Nagar, General Medicine Department. This type of study is not conducted in our hospital. Hence, for the first time the present study was taken to assess the impact of clinical pharmacist on medication adherence, and factors influencing the medication adherence of Diabetes mellitus patients, and how that is influencing on Quality of life.

Materials and Methods

This was a prospective randomized and interventional study, Conducted for a period of 8 months. Ethical committee clearance was obtained from Adichunchanagiri Hospital and Research Centre.

Study criteria:

Inclusion Criteria

- Inpatients and outpatients of General Medicine Department who were diagnosed as Diabetes mellitus and on medication for six months.
- 18 years and above patients of either sex.
- Patients who are willing to participate in the study and sign in the consent form

Exclusion Criteria

- Patients had more than 4 chronic diseases (including DM)
- Pregnant/lactating women.

Source of data

Inpatients details from Patient case records, medication charts and lab reports and Outpatients details from Prescriptions.

Study materials:

- Informed consent form
- Patient data collection form
- Morisky Medication Adherence Scale (MMAS) questionnaire
- SF-12v2 Quality Of Life (QOL) Scale questionnaire

Study procedure:

A total of 120 prescriptions were screened, out of which 51 Diabetes mellitus patients are enrolled in the study by satisfying the inclusion criteria, in which 48 patients are completed the study and 3 patients are withdrawn from the study due to various reasons. The 48 patients were kept in two groups by simple randomization technique (odd and even numbers) after taking their consent, i.e., 24 in control and 24 in intervention groups. The control and intervention group patient's socio demographic details, their FBS and PPBS and other data related to medication adherence and QOL was collected by using MMAS-4, QOL (SF-12) questionnaires at the baseline. Both the groups were provided with dairy cards as a medication adherence remainder and asked to come for follow up every one month interval.

The intervention group patients were counselled on various aspects like disease, drugs and their management and also provided disease and drug Patient Information Leaflets at the base line. But the control groups were not counselled. Only told them to come for follow up from the date of enrolment to one month. The same method was adapted such as FBS, PPBS & medication adherence and QOL scales details recording, in the first and second follow ups. But at the second follow up the control groups were counselled orally and intervention group patients were asked to give the patient satisfaction information about pharmacist provided counselling and services, which was prepared by using a validated osteoporosis patient satisfaction questionnaire. During the 2nd follow-up the dairy cards of both group patients were collected. The obtained data was recorded and subjected for suitable statistical analysis.

Statistical Method: Descriptive statistical analysis has been carried out/adapted.

Results and Discussion

RESULTS

Table 1 shows that Out of 48 patients 24 were in intervention group, in which males were 16 (66.7%) and females were 8 (33.3%). In control group out of 24 patients, 18 (75%) were males and 6(25%) were females. This study showed that males are more Diabetics when compare to females. Because this

may be the modification of life style, stressful working environment and social habits etc.

The age group between 61-70 (37.5%) years found to be major in both intervention and control group and >70 years age group found to be less in intervention and control group. This suggests that after the age of 50 to 70 years, there are more chances of diseases due to change in the anatomical and physical functions.

The educational qualification in intervention group i.e., 14 (58.3%) patients were illiterate, and in control group have 10 (41.7%) of the primary education. This educational detail suggested that there was an existing of less educated people due to dwelling in rural areas or their low economic conditions/poverty. This point clearly suggests that there is a need of education to maintain / manage their disease.

Majority of diseased were peasants in both intervention and control group i.e., 9 (37.5%), 8(33.3%). 2(8.3%). Employed and retired were less in both control and intervention group. The occupation of these people may directly influence in their disease management. So the education about the disease management will influence to stick to the disease management strategies (eg: Stick to the medication even though having busy schedule, minimisation of forgetfulness).

The annual income was < 25,000 Rs i.e., 16 (66.7%), 13 (54.2%) in intervention and control group patients Which is one of the factors that affect the patient's medication adherence behaviour, maintaining the disease states like buying the medicines, and regular checkups? This in turn affects QOL of the patient. After educational intervention the disease management strategic was improved.

Fasting blood sugar & PPBS comparisons of Diabetes mellitus were shown in the table 2. In our study the blood sugar level between control and intervention group was found to be highly significant in the second follow up (117.38 ± 23.01) when compared to first (137.13 ± 36.63) and base line (147.88 ± 50.88) follow ups. Postprandial Blood sugar comparisons of in our study the blood sugar level between control and intervention group was found to be highly significant in the second follow up (164.58 ± 29.19) when compared to first (193.75 ± 49.94) and base line (239.08 ± 94.6) follow ups. The improvement in the blood sugar level of intervention over the control shows that there is the best positive impact on patient

Table 3 shows the MMAS scores at base line, first follow up and second follow up was found to be in control group as 3.04±1.00, 3.08±0.93 and 3.13±0.74 respectively and in intervention group 1.75±1.29, 3.08±0.72 and 3.67±0.56 respectively. In the baseline medication adherence P value <0.001**, followed by first follow up P value 1.000, followed by second follow up P value 0.007**. Statistical tests results showed a strong significant at second follow up P value as 0.007**. This clearly showed that there was a good improvement in medication adherence behaviour in intervention group because of Educational services, PILS and Dairy cards when

compared to the control group patients.

Table 4 shows the results that influence various factors in a decreasing order i.e., 1. forgetfulness was a one of the factor for 16.6 % (C), 31.6 % (I). 2. Stop taking a medicine for a while: 12.4 % (C), 29.2% (I). 3. Decided to miss out of a dose: 8.4 % (C), 15.8% (I). 4. Take less than instructed: 2.4 % (C), 6.6% (I) of groups. 5. Altering the dose: 1.6 % (C), 0(I) of groups.

At base line total scores of Diabetes mellitus group is 0.003, at first follow up scores was 0.269 and at second follow up score was <0.001.

The result showed that in the baseline there was a need of education/repeated monitoring of chronic disease conditions and its management. The first & second follow up result showed that there was a fair improvement/positive impact on the pharmacist provided education about medication adherence behaviour. This was positively influence on their QOL.

Table 5 showed In base line scores of DM patients PF, RP, BP, GH, VT, SF, RE, MH was 0.813, 0.936, 0.741, 0.178, 1.000, 0.570, 1.000, and 0.440 respectively. Similarly at first follow up PF, RP, BP, GH, VT, SF, RE, MH was 0.663, 1.000, 0.872, 0.890, 0.868, 0.537, 0.854, and 0.450. Similarly at the second follow up PF, RP, BP, GH, VT, SF RE MH was 0.193, 0.278, 0.011*, 0.339, 0.451, 0.026*, 0.001**, 0.001** respectively.

The final result suggests that the overall quality of life was improved. When compare to baseline to first follow up and from first follow up to second follow up, and baseline to second follow up. But still there is a need of continuous monitoring /work to be carried out to reduce / to manage their disease/ quality of life in a constant manner.

The Quality of life (QOL) scores of control group physical component summary (PCS) was at base line, first follow up and second follow up were found to be 35.44±4.24, 35.20±4.86 and 36.57±4.65 respectively and mental component summary (MCS) was 45.21±9.68, 45.39±9.79 and 44.64±9.94 respectively. The intervention group physical component summary (PCS) was at base line, first follow up and second follow up were found to be 34.08±5.71, 34.89±5.71 and 35.22±4.16 respectively and mental component summary (MCS) was 44.34±8.26, 44.85±8.04 and 54.56±9.73 respectively. In both PCS and MCS the baseline QOL (P value 0.354 and 0.742), followed by first follow up P value 0.843 and 0.836, followed by second follow up P value 0.293 and 0.001**. Statistical tests results show a strong significant at second follow up P value was 0.001** in MCS and in PCS there is a slight improvement but not significant. This is clearly showed that the medication adherence was indirectly improved the QOL in intervention group when compared to the control group patients.

Table 7 shows the patients satisfaction about the pharmacist provided Clinical pharmacy services and types of counselling in the management of scores (each question carries 5 marks) shows that 36.88±2.47 and the counselling type result was 21.63±1.56 respectively.

Pharmacists provide services/ information conducting studies is useful for all the patients. This shows that pharmacist is a member of health care team, and plays an important role in managing of all the chronic diseases and increases their quality of life.

Dairy cards

A dairy card was provided to control and interventional group patients as a reminder to their medications. Among 48 Diabetes Mellitus patients 29(C-14, I-15) patients were returned the provided cards and others did not. This may be due to forgetfulness, lack of education, negligence. By this study we found that this method indirectly influence on the medication adherence of the patients.

Conclusion

The present study shows that the clinical pharmacist involvement in disease management has positive impact in creating awareness about the disease, and its usage and in improving the QOL.

This study concluded that continuous education programs and counselling should be conducted for chronic diseases to emphasize and re-emphasize the importance of medication adherence and Quality of Life, reduce progression of disease and ultimately minimize hospitalization and there is a need of continuous pharmaceutical care services/monitoring to minimise the cost and to improve the better quality of life.

Future direction: Further a similar type of educational and monitoring services and providing disease PILs to other rural chronic disease patients can improve the clinical and humanistic outcomes.

Acknowledgment

Our sincere pranamas to Sri Sri Sri Dr Balaganghadharanatha maha swamiji SAC Shikshana trust. We would like to thank Dr B Ramesh, Principal, SACCP, staff and PGs of Department of Medicine AH&RC and Donald E Morisky, ScD, ScM, MSPH for providing permission to use the Morisky Medication Adherence Scale,(©MMAS-4 Item) for their timely support and suggestions at all stages of this work.

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Table 1: Distribution of Demographic details of Diabetes Mellitus patients.

Basic variables	DM Control		DM Intervention	
	N	%	N	%
Age in years				
20-30	-	-	-	-
31-40	4	16.7	0	0.0
41-50	4	16.7	5	20.8
51-60	5	20.8	8	33.3
61-70	9	37.5	9	37.5
>70	2	8.3	2	8.3
Gender				
Male	18	75.0	16	66.7
Female	6	25.0	8	33.3
BMI (kg/m²)				
<18.5	6	25.0	1	4.2
18.5-25.0	14	58.3	16	66.7
25.0-30.0	3	12.5	7	29.2
>30.0	1	4.2	0	0.0
Education				
Illiterate	6	25.0	14	58.3
Primary	10	41.7	6	25.0
High school	3	12.5	2	8.3
Pre-university	2	8.3	2	8.3
Degree+	3	12.5	0	0.0
Occupation				
Farmer	8	33.3	9	37.5
House wife	4	16.7	6	25.0
Employed	2	8.3	2	8.3
Business	5	20.8	5	20.8
Retired	5	20.8	2	8.3
Income (in Rs)				
<25000	13	54.2	16	66.7
25001-50000	5	20.8	7	29.2
5001-100000	2	8.3	0	0.0
1-1.5 lakhs	2	8.3	1	4.2
>1.5 lakhs	2	8.3	0	0.0
Total	24	100.0	24	100.0

Table 2: Comparison of Blood sugar parameters

Blood sugars	Control	Intervention	P value
FBS (mg/dl)			
• Baseline	152.46±52.52	147.88±50.88	0.760
• 1 st follow up	136.42±34.75	137.13±36.63	0.946
• 2 nd follow up	134.38±33.11	117.38±23.01	0.045*
• Baseline vs 1 st follow up	t=1.959; P=0.062	t=1.670; p=0.109	-
• Baseline vs 2 nd follow up	t=2.447; P=0.022*	t=4.090; P<0.001**	-
PPBS(mg/dl)			
• Baseline	220.83±97.01	239.08±94.6	0.513
• 1 st follow up	196.21±60.94	193.75±49.94	0.879
• 2 nd follow up	208.29±69.74	164.58±29.19	0.007**
• Baseline vs 1 st follow up	t=1.602; P=0.123	t=3.463; p=0.002**	-
• Baseline vs 2 nd followup	t=0.930; P=0.415	t=4.083 P<0.001**	-

table 2: Distribution Of Morisky Medication Adherence Scale Scores (Mmas) In DM Patients.

MMAS	DM Control	DM Intervention	P value
Baseline	3.04±1.00	1.75±1.29	<0.001**
1 st follow up	3.08±0.93	3.08±0.72	1.000
2 nd follow up	3.13±0.74	3.67±0.56	0.007**

Table 4 : Comparative distribution of MEDICATION ADHERENCE REPORT SCALE (MARS) SCORES of DM group

MARS	DM Control	DM Intervention	P value
1Q.I forget to take the medicine			
Baseline	4.17±1.31	3.42±1.32	0.054*
1 st follow up	4.17±1.20	4.54±0.88	0.225
2 nd follow up	3.96±1.20	5.00±0.00	<0.001**
2Q.I alter the dose of medicine			
Baseline	4.92±0.41	5.00±0.00	0.323
1 st follow up	4.88±0.45	5.00±0.00	0.179
2 nd follow up	4.92±0.41	5.00±0.00	0.323
3Q.I stop taking medicine for a while			
Baseline	4.38±1.06	3.54±1.14	0.012*
1 st follow up	4.42±0.97	4.42±0.97	1.000
2 nd follow up	4.75±0.61	4.83±0.38	0.572
4Q.I decided to miss out a dose			
Baseline	4.58±0.78	4.21±1.06	0.169
1 st follow up	4.54±0.78	4.67±0.70	0.562
2 nd follow up	4.79±0.51	4.88±0.34	0.507
5Q.I take less than Instructed			
Baseline	4.88±0.34	4.67±0.56	0.128
1 st follow up	4.92±0.28	4.88±0.34	0.645
2 nd follow up	4.88±0.45	4.96±0.20	0.412
Total			
Baseline	22.92±2.34	20.83±2.20	0.003**
1 st follow up	22.92±2.02	23.5±1.56	0.269
2 nd follow up	23.29±1.73	24.67±0.48	<0.001**

Table 5: Comparative distribution of QUALITY OF LIFE (SF-12v2 QOL) Domain Scores of DM

QOL Domains	Control	Intervention	P value
Physical Functioning (PF)			
Baseline	37.50±36.12	35.42±23.22	0.813
1 st follow up	39.58±36.80	35.42±28.47	0.663
2 nd follow up	38.54±35.34	26.04±29.93	0.193
Role-Physical (RP)			
Baseline	51.04±26.04	50.52±18.24	0.936
1 st follow up	51.04±25.25	51.04±18.40	1.000
2 nd follow up	50.00±24.73	57.29±21.15	0.278
Bodily Pain (BP)			
Baseline	46.88±26.90	44.79±14.71	0.741
1 st follow up	47.92±27.50	46.88±15.31	0.872
2 nd follow up	47.92±29.41	65.63±14.39	0.011*
General Health (GH)			
Baseline	38.75±29.86	28.33±22.39	0.178
1 st follow up	33.75±26.39	34.79±25.47	0.890
2 nd follow up	43.96±28.97	51.67±26.24	0.339
Vitality (VT)			
Baseline	57.29±23.86	57.29±22.70	1.000
1 st follow up	55.21±22.09	56.25±21.17	0.868
2 nd follow up	59.38±24.24	64.58±23.22	0.451
Social Functioning (SF)			
Baseline	54.17±21.70	51.04±15.60	0.570
1 st follow up	57.29±18.77	54.17±15.93	0.537
2 nd follow up	56.25±22.42	69.79±18.03	0.026*
Role-Emotional (RE)			
Baseline	50.00±20.19	50.00±20.52	1.000
1 st follow up	50.52±19.67	51.56±19.26	0.854
2 nd follow up	50.52±20.68	72.40±21.80	0.001**
Mental Health (MH)			
Baseline	65.63±16.99	61.98±15.41	0.440
1 st follow up	66.15±17.48	62.50±15.64	0.450
2 nd follow up	61.46±18.03	77.60±12.76	0.001**

Table 6: Comparative distribution of QUALITY OF LIFE (SF-12v2 QOL) PCS and MCS Scores DM patients

QOL	DM Control	DM Intervention	P value
PHYSICAL COMPONENT SUMMARY (PCS)			
Baseline	35.44±4.24	34.08±5.71	0.354
1st follow up	35.20±4.86	34.89±5.71	0.843
2nd follow up	36.57±4.65	35.22±4.16	0.293
MENTAL COMPONENT SUMMARY (MCS)			
Baseline	45.21±9.68	44.34±8.26	0.742
1st follow up	45.39±9.79	44.85±8.04	0.836
2nd follow up	44.64±9.94	54.56±9.73	0.001**

Table 7 : Distribution of Patients Satisfaction questionnaire (PSQ) in the intervention group of DM

PSQ	DM
Questions on Clinical Pharmacy Services	
Q1. How would you rate your understanding of Diabetes since your participation in this study	4.04±0.86
Q2. Were the follow up session with the pharmacist kept on time	3.88±0.74
Q3. During the appointment, was there adequate time to discuss your problem with the pharmacist	4.04±0.62
Q4. If you have questions about your DM medicines, would you trust an answer from the pharmacist	4.04±0.62
Q5. Since your participation in this study, how would you rate your understanding of your DM medication	4.38±0.71
Q6. Since your participation in this study, do you have more or less problems when it comes to taking your DM medications	4.13±0.45
Q7. How useful was the service provided by the pharmacist in this study	4.17±0.48
Q8. Has the advice given by the pharmacist affected your life in general	4.13±0.74
Q9. Do you agree that the pharmacist should continue his services in the clinic to help patients with their chronic disease medications	4.08±0.65
Total	36.88±2.47
Questions on types of counselling	
Q10. Explanation of DM	4.13±0.45
Q11. Explanation on the purpose of the medicine(s)	4.25±0.68
Q12. Advice on how best to take medicine(s)	4.42±0.50
Q13. Explanation on possible side effects	4.17±0.64
Q14. Disease/Drug pills and Diary card	4.67±0.48
Total	21.63±1.56

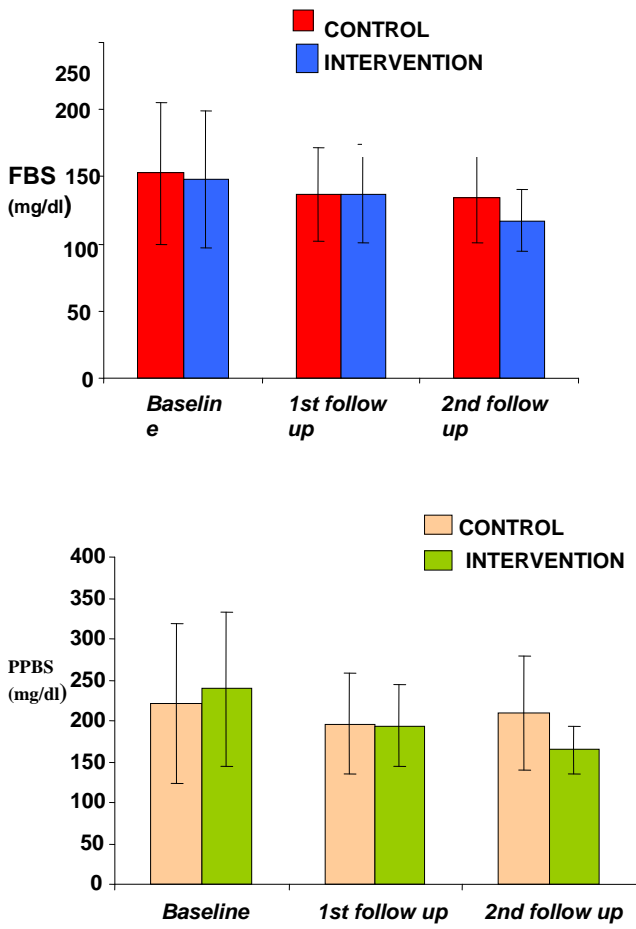


Figure1: Distribution of Blood sugar parameters

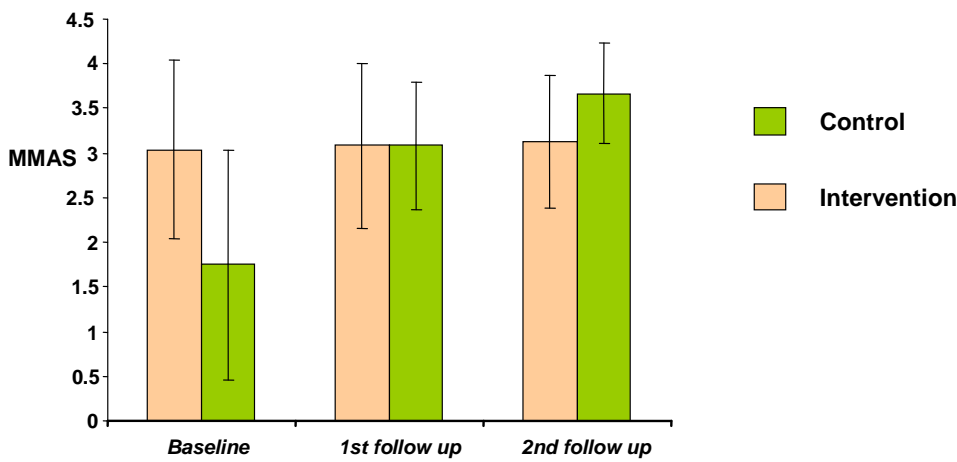


Figure 2: Morisky Medication Adherence Scale scores (MMAS) of DM patients.

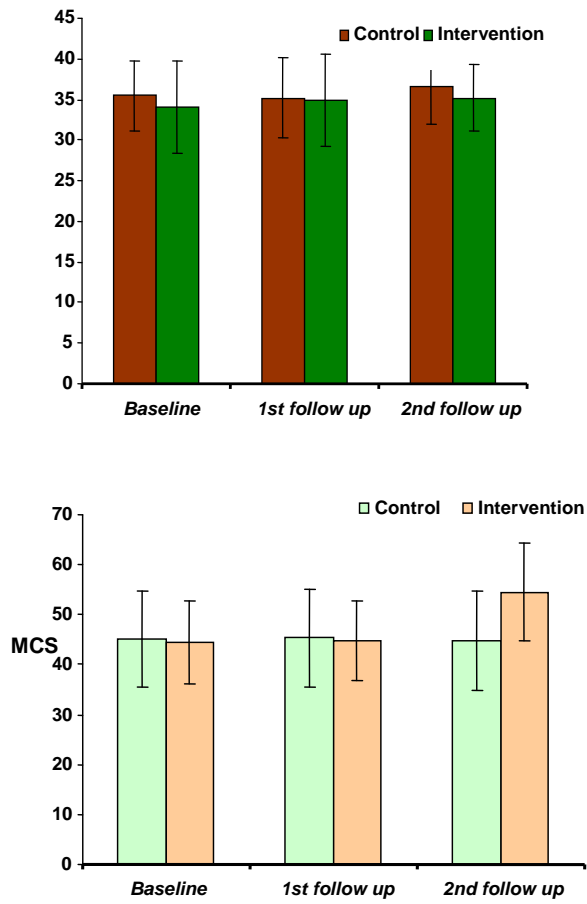


Figure 3: Comparative distribution of quality of life (SF-12v2 QOL) PCS and MCS scores of DM group

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