

Intervention Program Concerning Quality of Life of Diabetic Patients with Lower Limb Prosthesis

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Abstract

Background: Diabetes and associated amputation are major challenges that threaten patient's quality of life (QoL). Well fitting prosthesis is considered as a turning point in restoring amputee's life through improving physical functioning, body image, work capacity, and social participation. **This study was aiming to** evaluate the effect of intervention program on quality of life of diabetic patients with lower limb prosthesis. A quasi experimental design was utilized to meet the aim of the study. The study was conducted on a purposive sample of 60 diabetic patients with lower limb prosthesis who were divided into study and control groups. The study was conducted at Orthopaedic Industries Work Shop's clinics that is affiliated to Agouza Rehabilitation & Rheumatology Center of the Army. **Data were collected using** 1) Interviewing Questionnaire including the following parts: A) Socio demographic characteristics, B) Patient's clinical data sheet, C) Patients' level of knowledge regarding diabetes and prosthesis. 2) Quality of life of diabetic patients with prosthesis questionnaire. **The result** of this study showed that there were highly statistically significant differences between study and control groups post intervention regarding total knowledge about diabetes and prosthesis, which represent ($p < 0.001$). Additionally, there were highly statistically significant differences between study and control groups post intervention regarding total dimensions of quality of life, which represent ($p < 0.001$). As well as, majority of study group had moderate level of quality of life post intervention. This study concluded that the implementation of intervention program had a positive effect on quality of life of diabetic patients with lower limb prosthesis. **This study recommended** that development of preparatory psycho-educational program for diabetic patients with limb amputation prior to using prosthetic limb to enhance psychosocial adjustment after using prosthesis.

Key words: Diabetes, Intervention program, Lower limb prosthesis, Quality of Life.

Introduction

Living with diabetes is very demanding both mentally and physically. A complete change in life routines is needed in form of more regular healthy life-styles, adherence to daily medication, scheduled visits to various types of healthcare professionals, repeated physical examinations, and laboratory tests. These life modifications places serious constraints on patients' daily life

and threaten life satisfaction (Chew, Mohd-Sidik and Shariff-Ghazali, 2015).

Lower limb amputation confronts the individual with a multitude of evolving physical and psychosocial problems such as impairments in physical functioning, pain, prosthesis use, changes in employment status, and alterations in body image and self concept. Such stressors challenge the individuals' ability to maintain emotional well-being and may produce maladaptive reactions

(Magurová, Majerníková, Hloch, Tozan, and Goztepe, 2012).

Quality of life (QoL) is major health outcome that directs all health interventions, it is a wide-ranging concept that is affected not only by people`s health status, but also by their social settings, psychosocial state, level of independence, and their relationship to the environment in which they live (Mohammed and Shebl, 2014).

Quality of life is negatively affected by the association between diabetes and amputation due to long term disability that result. Lower limb prosthesis is a device that designed to replace the function or appearance of the missing lower limb as much as possible. Well fitting prosthesis maximize physical function, update mental map of body image, increase social reintegration and improve quality of life (Falvo, 2014).

It is important to understand role of behavioral, cultural and lifestyles related factors that affecting the management of diabetes and prosthetic limb (Mustapha et al., 2014).The goals of nursing role are to design program aimed to mange pain, restore physical functioning, enhance diabetes self care, promote independence, improve psychological status, emphasize on self-acceptance and incorporation of prosthesis as a part of self, and increase social participation (El Sebaee & Mohamed, 2011).

Significance of the study:

Association between amputation and underlying diabetes are frightening for both the patients and their concerns because of their effect on physical, social, financial and emotional life aspects, which lead to psychological upset as well as

create social problems. Lower limb prosthesis is considered as a turning point in amputees life that increase his physical ability and modify his psychosocial profile. In Egypt, The International Diabetes Federation (IDF) estimated that 7.5 million people have diabetes and around 2.2 million have prediabetes. unfortunately no available census found regarding number of amputees or prosthesis users in Egypt. So, this study will be helpful in providing better understanding to the experience of diabetic patients with lower limb prosthesis and providing an intervention program designed to handle serious health problems, maintain emotional wellbeing and increase life satisfaction.

Aim of the Study:

The aim of this study was to:

Evaluate the effect of intervention program on quality of life of diabetic patients with lower limb prosthesis.

This aim achieved through:-

- 1- Assessing quality of life of diabetic patients with lower limb prosthesis.
- 2-Developing and implementing intervention program to enhance quality of life of diabetic patients with lower limb prosthesis
- 3- Evaluating the effect of the intervention program on quality of life of diabetic patients with lower limb prosthesis.

Research Hypothesis

The current study hypothesized that: The intervention program has positive

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effect on the quality of life of diabetic patients with lower limb prosthesis.

Subjects and Methods

A- Research design:

This study was conducted through using a quasi experimental design.

B- Setting:

The study was conducted at Orthopaedic Industries Work Shop's clinics. It is affiliated to Agouza Rehabilitation & Rheumatology Center of the Army.

Subject:

A Purposive sample of 60 diabetic patients with lower limb prosthesis was selected according to certain inclusion criteria. The study subjects were divided into two groups: study group (who received the intervention program) and control group.

Inclusion criteria:

Adult (both sexes), having a unilateral (transtibial and transfemoral) amputation for diabetic cause, first time to use prosthesis, one month after completing prosthetic training, healthy proper limb, different educational levels and who agree to participate in the study.

D-Tools of data collection

A- Interviewing Questionnaire:

It was designed by the researcher in simple Arabic language after reviewing related literature. It included three parts as follow:

Part I: Socio demographic characteristics;

It included data such as; age, gender, marital status, educational level, occupation, income, health insurance, prosthesis cost and residence.

Part II: Patient's clinical data sheet;

It dealt with medical background of diabetic patients with limb prosthesis that contains 2 parts:

1- Patient's past history; it included medical and surgical history regarding diabetes, amputation and family history regarding amputation and prosthesis.

1- Physical assessment; that included side, and level of amputation, type of prosthesis, prosthesis daily use and diabetes treatment and complications.

Part III: Patients' level of knowledge regarding diabetes and prosthesis;

It was designed to assess patient's level of knowledge regarding diabetes (definition, investigations, complications, prevention of diabetic foot, management). This part also included patient's knowledge regarding prosthesis (types, components, residual limb care, prosthesis use, prosthesis care, and follow up). This part included 20 items, the maximum score for each item was 3 degree and the minimum score was 1, arranged as following: yes =3, No=2, and don't know=1 for positive statements, while items numbers 2, 5, 6, 10, 11, 12, 14, and 19 were negative statements in which no=3, yes=2, and I don't know=1. The total score equals 60

Total score was considered as the followed:

≥ 60% (≥ 44 grades) was satisfactory level of knowledge.

<60% (>44 grades) was unsatisfactory level of knowledge.

B- Quality of Life of diabetic patients with prosthesis questionnaire;

It was developed by the researcher that used to assess the quality of life dimensions for diabetic patients with lower limb prosthesis. It included physical, psychological, social and environmental and overall quality of life. It included 5 categories:

1- Physical dimension included 6 subcategories that were related to pain (8 items), residual limb problems (10 items), prosthesis problems (12 items), diabetes (7 items), activity of daily living (4 items) and work (6 items).

2- Psychological dimension that included 18 items, social dimension that included (9 items), environmental dimension (7 items) and overall quality of life (2 items).

Each item had five responses (almost - most – sometimes – very little & never) except:-

-Pain frequency had 7 responses (All time - More than one time /day- 4-6 times/week - 2-3 times/ week- Once/ week- never).

Pain intensity and overall quality of life had visual numeric scale (1-10).

Scoring:

Each sentence had score ranging from 1-5 (1=almost, 2= most, 3=sometimes, 4=very little & never= 5) except:

- In physical dimension, all items of Activity of Daily Living and items number 4, 5, 6, 7 of diabetes were positive statements that had score (5=almost, 4= most, 3=sometimes, 2=very little & never= 1).

-Pain frequency that had score ranging from 1-7 in which

All time =1 More than one time /day =2

4-6 times/week=3 2-3 times/ week =4

Once/week= 5 Once or twice/ month=6 Never= 1.

-Pain intensity that had score ranging from 1-10 in which:

Mild (1-3), Moderate(4 -6), Severe (7 -10).

Tools validity and reliability

To achieve the criteria of trustworthiness of the tools of data collection in this study, the tools were tested and evaluated for their face and content validity, and reliability. Face and content validity were tested by five experts from faculty members in the nursing and medical field from Ain Shams University and Agouza Rehabilitation & Rheumatology Center of The Army. They were from different academic categories, i.e., 2 professors and 3 assistant professors. Different specialties were represented such as

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Psychiatric/Mental Health Nursing, Medical-Surgical Nursing, and Physical Therapy. To ascertain relevance, clarity, and completeness of the tools, experts elicited responses were either agree or disagree for the face validity. The items on which 80% or more of the experts have agreed were included in the proposed tool.

• Pilot Study:

The pilot study was conducted on six diabetic patients with limb prosthesis (10% of total sample), to ensure the clarity of questions, applicability of the tools and the time needed to be filled in. Those patients were included in control group sample because there were no modifications found.

Field Work:

The actual field work for data collection process had consumed eleven months; started at the beginning of February 2017 and was completed by the end of November 2017. Data were collected 2 days/week (Saturday–Wednesday).

First step

Data was collected from the control group who did not obtain the intervention program. The researcher introduced herself to the patient and explained the aim of the study in order to obtain patient's oral agreement to participate in the study. Confidentiality of any obtained information was assured. The subjects were informed about their right to participate or not in the study and to withdraw at any time without giving any reason. The participants were also assured

about anonymity, and that data will only be used for the purpose of the study.

The study tools were filled in by the researcher and took about 40-45 minutes for each case. The researcher took the patients' telephone number at the first interview (pre assessment) to determine the second appointment (post assessment).

Second step

Researcher started the intervention program's sessions with study group. Patients' telephone number was obtained to determine the next appointments. The intervention program was implemented for each patient separately.

Contents of intervention program:

1-The theoretical part dealt with overview about diabetic foot problems, overview about prosthesis, avoiding diabetic complications, and Overview about post traumatic stress disorder.

2-The practical part dealt with caring of residual limb, caring of prosthesis , diabetes self care, dealing with grief reaction, improving self esteem and body image, managing post traumatic stress, improving sleep quality, managing anger, practicing problem solving techniques and performing different relaxation techniques.

Administrative Design:

An official letter was issued from the Faculty of Nursing, Ain Shams University to the director of Agouza Rehabilitation & Rheumatology Center of The Army to conduct the study. An informed and oral

consent were obtained from every participant who agreed to share in the study.

Ethical Considerations:

The ethical research considerations in this study included the following:

- The research approval of each participant to share in the study was taken.
- The researcher clarified the aim and objectives of the study to subjects.
- The researcher maintained anonymity and confidentiality of subjects's data.

- Subjects participation was voluntary as they had the right to participate or not, and they had the right to withdraw from the study at any time without penalty.

Statistical Design:

The collected data were organized, analyzed using appropriate statistical significant tests. Chi square test was used to compare the frequencies of study and control groups regarding socio-demographic characteristics and clinical data. Independent T test is used to compare means of study and control groups pre- and post-intervention. Pearson Chi square test was used to test relation between study and control group variables.

Results

Table(1):Comparison between study and control groups regarding socio-demographic characteristics (n=60).

Items		Study group (n=30)		Control group (n=30)		X2	P value
		No.	(%)	No.	(%)		
Age	Less than 40 years old	2	6.7	2	6.7	5.33	.255
	40-60 years old	24	80	19	63.3		
	More than 60 years old	4	13.3	9	30		
	Mean± SD	51.1±14		53.5± 15.8			
Gender	Male	19	63.3	20	66.7	.287	.592
	Female	11	37.3	10	33.3		
	Not read or write	7	23.3	6	20		
Educational Level	Primary education	8	26.7	10	33.3	7.00	.637
	Secondary education	10	33.3	12	40		
	High education	5	16.7	2	6.7		
Marital status	Married	17	56.7	19	63.3	3.7	.929
	Widow	9	30	4	13.3		
	Divorced	3	10	6	20		
	Single	1	3.3	1	3.3		
	Not employed	13	43.3	14	46.7		
Occupation	House worker	7	23.3	4	13.3	1.59	.811
	Employed	10	33.3	12	40		
Nature of work	Muscular	12	40	9	30	1.33	.248
	Mental	5	16.7	7	23.3		
Income	Monthly	21	70	22	73.3	1.591	.207
	Daily	9	30	8	26.7		

Table (1): Clarifies that, the mean age of the study group was 51.1±14, while the mean age of the control group was 53.5±15.8, majority of study group (80%) and less than two thirds of control group (63%) aged between 40-60 years. Regarding gender, less than two thirds of study group (63.3%) and two thirds of control group (66.7%) were males. Regarding level of education, third of study group (33.3%)

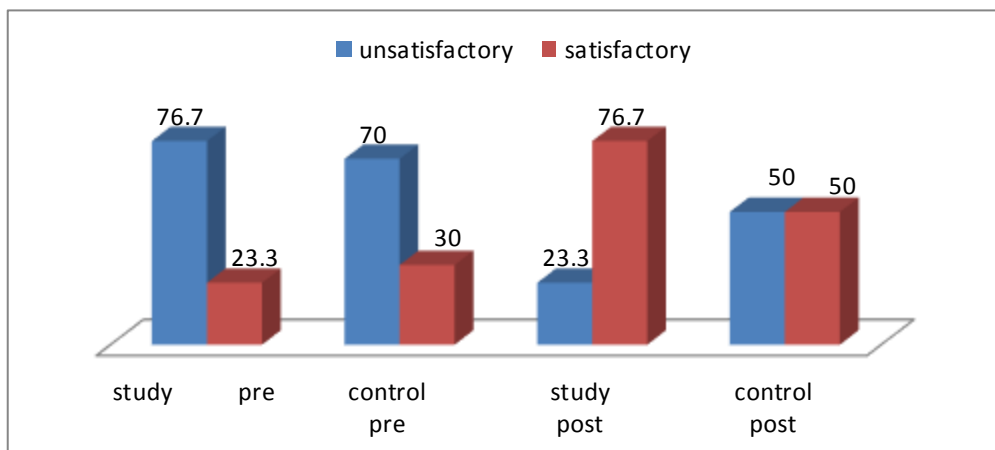
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and two fifths of control group (40%) had secondary education. Concerning marital status, more than half of study group (56.7%) and less than two thirds of control group (63.3%) were married. As regards their occupation, third of study group (33.3%) and two fifths of (40%) of control group were employees. Regarding income, less than two thirds of study group (63.3%) and three fifths of control group had insufficient income.

Table (2): Comparison between study and control groups of physical assessment (n=60).

Items	Study group (n=30)		Control group (n=30)		X2	P value	
	No.	(%)	No.	(%)			
Level of amputation	■ below knee	22	73.3	21	70	2.07	.149
	■ Above knee	8	26.7	9	30		
Side of amputation	■ Right	20	66.7	19	63.3	1.79	.180
	■ Left	10	33.3	11	36.7		
Diabetic treatment	■ Insulin	16	53.3	19	63.3	2.60	.627
	■ Pills	9	30	4	13.4		
	■ Both	5	16.7	7	23.3		

Table (2) reveals that, slightly less than four quarters of study group (73.3%) and more than two thirds of control group (70%) had below knee amputation. Insulin is the most frequent number among study and control groups, which represent 53.3 % 63.3% and respectively. There were statistically no significant differences between study and control groups regarding level and side of amputation, and diabetes treatment, which represent ($p>0.05$).



Figure(1): Comparison between pre- and post-intervention regarding satisfactory level of total knowledge among study and control groups (n=60).

Figure(1):reveals that, non of patients in the study and control group had satisfactory level of total knowledge pre intervention, while more than three quarters of study group (76.7%) had satisfactory level of knowledge post intervention.

Table (3):Comparison between pre-and post- intervention regarding dimensions of quality of life among study and control groups (n=60).

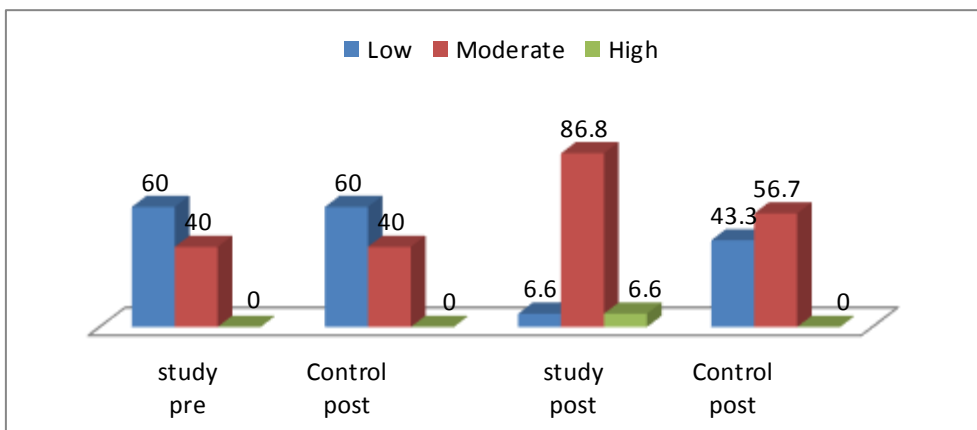
Statement	Pre-intervention		T	P value	Post-intervention		T	P value
	Study mean±SD	Control mean±SD			Study mean±SD	Control mean±SD		
Physical	132±20	131±23	.160	.873	154±16	131± 26	-3.92	.000 (HS)
Psychological	56 ±17	53 ±15	-.675	.502	76 ±7	57±16	-6.04	.000 (HS)
Social	26 ± 8	25.8±7	-.550	.584	32.7± 4	28.7± 7	-1.92	0.05 (S)
Environmental	14 ± 3	14.3±4	.251	.803	17± 4	14± 3	-2.75	.008 (HS)
Overall quality of life	3 ±.83	3 ±.85	.154	.878	4.03±.96	2.96±.85	-4.54	.000 (HS)
Total	232± 34.4	228±39.8	-.478	.634	284±25.5	234.4± 47	-	.000 (HS)
							5.04	(HS)

HS= Statistically highly significant at $p \leq 0.001$

S= Statistically significant at $p \leq 0.05$

NS= Statistically not significant at $p > 0.05$

Table (3): shows that there was no statistical significant difference between study and control groups regarding total dimensions of quality of life pre intervention, in which ($p > 0.05$). There was highly statistical significant difference between study and control groups regarding total dimensions of quality of life post intervention, in which ($p < 0.001$).



Figure(2):Comparison between pre-and post- intervention regarding total dimensions of quality of life among study and control groups (n=60).

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Figure(2): reveals that, majority of study group (86.7%) had moderate quality of life and 6.6 % of them had high quality of life post intervention while, more than half of control group (56.7%) had moderate quality of life post- intervention.

Table (4): Relation between socio-demographic characteristics and total quality of life pre-and post- intervention among study and control groups (n=60).

Items	Total quality of life Study group				Control group			
	Pre		Post		Pre		Post	
	X2	P value	X2	P value	X2	P value	X2	P value
Age	48.75	.524	43.2	.335	49.25	.503	55.0	.433
Gender	23.54	.546	17.4	.624	23.2	.563	30.0	.314
Educational Level	74.4	.061	70.2	.020	70.75	.618	90.0	.231
Marital status	64.1	.811	76.8	.070	63.0	.835	90.1	.232
Occupation	40.7	.352	46.48	.047	45.5	.653	60.0	.267
Income	50.75	.444	36.12	.646	24.8	.469	30.0	.314

HS= Statistically highly significant at $p \leq 0.001$ S= Statistically significant at $p \leq 0.05$
NS= Statistically not significant at $p > 0.05$

Table(4): reveals that, there was statistical significant difference between level of education and occupation and total quality of life among study group post intervention, in which ($p < 0.05$).

Table (5): Relation between total knowledge and total quality of life pre-and post-intervention among study and control groups (n=60).

Items	Total quality of life Study group				Control group			
	Pre		Post		Pre		Post	
	X2	P value	X2	P value	X2	P value	X2	P value
Total knowledge	263.3	.431	447.8	.056	472.5	.524	450.0	.265

HS= Statistically highly significant at $p \leq 0.001$ S= Statistically significant at $p \leq 0.05$
NS= Statistically not significant at $p > 0.05$

Table (5): reveals that, there was statistical significant differences between total knowledge and total quality of life among study group post intervention, in which ($p > 0.05$).

Discussion

Association between diabetics and amputation made a significantly poorer psychosocial adjustment to patients disability (Desmond et al., 2012). However, amputation is both a life-saving procedure, it is a life-changing event that is likely to pose considerable challenges in terms of physical, psychological, social adjustment. It is important for patient to adjust to their amputation and prosthetic limb in order to achieve their goals of mobility, functioning and improved QoL (Anwar, and Alkhayer, 2016).

Regarding age and gender, the results of present study revealed that male patients, and age ranged from 40 to 60 years constitute the highest percentage among both study and control groups with no statistically significant differences between them. This result is supported by Ewees (2014), who assessed stressors and coping strategies among patients with limb amputation and revealed that majority of the study sample's age between 41-60 years and more than half were males.

In the current study the result showed that third of study group and two fifths of control group were secondary educated with no statistically significant difference between them. This result is in contradiction with Soomro et al. (2013), who assessed determinants of lower extremity amputations and found that low educational level was a major significant predictor for limb amputation among both diabetic related and non-diabetic amputees.

Regarding to marital status, this study result revealed that more than half of study group and near two thirds of control group were married with no statistically

significant difference between them. This result is supported by El Sebaee and Mohamed (2011), who assessed stressors and positive coping strategies among patients with new limb amputation and reported that about three quarters of study sample were married.

Concerning working status, this study finding revealed that near half of patients in both groups were unemployed with no statistically significant difference between them. This result may be due to most of patients became retired after being amputees especially disabled veterans. This result is consistent with Sinha et al. (2011), who assessed factors affecting quality of life in lower limb amputees and revealed that more than half of study sample were un employed.

As regards nature of work, this study findings showed that two fifths of study group and near third of control group had muscular nature of work with no statistically significant difference between them. This result may be due near quarter of study and control groups are home maker with household responsibilities. This result is in consistent with Dajpratham, Tantiniramai and Lukkanapichonchut (2011), who assessed health related quality of life (HRQOL) among Thai unilateral lower limb amputees and determine the factors associated with a good Health Related Quality of life (HRQOL) and found that more than three quarters of study sample return to work after using prosthesis with high QoL.

As regards income, the current study result revealed that near two thirds of study group and three fifths of control group had insufficient income with no statistically significant difference between them. This could be due to the poor socioeconomic class of most of Egyptian

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people. These results are correspondent with **Ewees (2014)**, who revealed that two thirds of study sample had insufficient income.

Finding of present study showed that more than two thirds of study group and near four quarters of control group had below knee amputation with no statistically significant difference between them. This result is in agreement with **Sinha (2013)**, who assessed adjustments to amputation and artificial limb, and QoL in lower limb amputees stated that more than three quarter of study sample had below knee amputation.

Concerning side of amputation, the finding of this study showed that two thirds of study group and slightly less than two thirds of control group experienced amputation in right leg with no statistically significant difference between them. This result may be due to the right limb is the most common dominant side that might be more susceptible for mechanical stresses. This result is consistent with **Sinha (2013)**, who stated that more than half of study sample had right limb amputation.

Concerning patient's knowledge regarding diabetes, current study clarified that the level of knowledge among study group regarding diabetes had increased post intervention; three quarters of them had accurate responses regarding diabetes and most of them had satisfactory level of knowledge post intervention with statistically significant difference with control group who did not have any satisfactory level of knowledge pre or post intervention.

This result is consistent with **Rashed (2012)**, who measured the effect of diabetes educational program for type 2

diabetic patients attending the Diabetic clinic in Tulkarm Directorate of Health and stated that a significant increase in knowledge evaluation test scores were shown after educational intervention ($p = 0.000$). The mean score of knowledge questionnaire before educational intervention was 60.6 ± 20.65 increased to 78.1 ± 13.4 after conducting educational intervention.

As regards, total dimensions of QoL, current study showed that majority of study group had moderate QoL post intervention. this result may be due to QoL and satisfaction with prosthesis are increased in parallel with the use of well-fitting prosthesis and study sample were at early stage of using prosthesis. Other explanation that majority of study group had moderate physical and social QoL. This results is consistent with **Sinha et al. (2013)**, who stated that amputees were on average satisfied with the way they could function with the prosthesis and were moderately psychosocially adjusted.

There was statistical significant difference between study and control groups regarding total dimensions of quality of life post intervention, in which ($p < 0.001$). This result may be due to significant relationship between study and control group post intervention regarding physical, psychological, social, environmental and overall QoL. Regarding relation between patient's socio-demographic characteristics and total QoL.

Current study revealed that there were statistical significant differences between occupation and total QoL among study group post intervention. This result is consistent with **Sinha et al. (2013)**, who found that, employment was one of the

most important factors associated with adjustment to amputation and prosthesis.

Conclusion

The results of this study concluded that:

The implementation of the intervention had statistically positive effect on quality of life dimensions of diabetic patients with lower limb prosthesis.

1) Clinically

- Comprehensive nursing management protocol focusing on liaison role of psychiatric nurse to facilitate psychosocial adjustment among diabetic patients with lower limb prosthesis through providing care, guidance and support during prosthetic training.

2) For patients and their families

- Development of preparatory psycho-educational program for diabetic patients with limb amputation prior to using prosthetic limb to enhance psychosocial adjustment after using prosthesis.

3) For research

- Follow-up study is recommended to determine effect of compliance to the intervention program for six months and one year after completion of the program.

Replication of the study is required to compare QoL among patients with lower versus upper limb prosthesis, and unilateral versus bilateral prosthesis.

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