

Application of Transtheoretical Model of Change on Foot Care Management among Diabetic Patients: Prevention Better than Cure

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Abstract

Diabetic foot ulcer is one of the most common consequences of uncontrolled blood glucose level which takes place in 15% of people with diabetes, and precedes 84% of all diabetes-related lower-leg amputations that have the adverse effect on the diabetic patients causing physical, psychosocial, and financial burden as well as an economic burden on health care system. **The aim** of the study is to improve foot care management among diabetic patients by applying the Transtheoretical Model of Change. **Design:** A quasi-experimental design was conducted with a systematic random sample. **Study sample:** 154 patients who were selected from the registration system were divided equally into (77 study group) and (77 control group). **Setting:** the study was conducted at the outpatient diabetic clinic affiliated to Tanta University Hospital and Segar primary health care center affiliated to ministry of health, Tanat Governorate, Egypt. **Tools:** three tools were used for the purpose of data collection (I) Bio-socio-demographic characteristics questionnaire;(II)Trans-theoretical Model scale and (III) Diabetes Management Self-Efficacy Scale (DMSES). A survey was conducted by using Arabic version of self-reporting questionnaire to assess the stages of change and self efficacy among the studied groups as a baseline and during the implementation of foot care intervention program. **Results** revealed that, there was a statistical significant difference in the stages of change of the Transtheoretical Model for diabetic foot care management of the study group compared to the control group at 2, 4, and 6 months after implementation of intervention program. In addition, there was a statistical significant difference in Diabetes Management Self-Efficacy Levels between study group who received program intervention compared to control group 6 months after intervention. **Recommendation:** encouraging nurses who are dealing with diabetic patients to use the Transtheoretical Model of change or other health promotion models to enhance diabetic patient for foot care management, and adoption of healthy behavior.

Keywords: Transtheoretical model of change, diabetic foot care management.

Introduction:

Diabetes mellitus is one of metabolic disorder that inhibits the typical steps of the wound healing process. Several studies show a chronic inflammatory stage in diabetic wounds, which ends up in a delay in the formation of mature connective tissue and a parallel reduction in wound curing and repair which result in diabetic foot ulcer.⁽¹⁻⁵⁾ Where diabetic foot is defined by World Health Organization as “the foot of a diabetic patient that has the potential risk of pathologic consequences, including infection, ulceration, and destruction of deep tissues associated with neurologic abnormalities, various degrees of peripheral vascular disease, and metabolic complications of diabetes in the lower limb.”⁽⁶⁾

According to the report of the World Health Organization (WHO, 2015), the prevalence of diabetes all over the world are expected to increase to 380 million by 2025. ⁽⁶⁾ Hence, the morbidity and mortality rates are expected to increase because of diabetes complications, particularly diabetic foot ulcers that have the adverse effect on the diabetic patients, causing physical, psychosocial, and financial burden as well as an economic burden on health care system. ⁽⁷⁻⁹⁾

Diabetic foot disease is the leading cause of non-traumatic lower limb amputations. There are many risk factors involved within the development of diabetic foot ulceration such as old age ; presence of infection; existing of other chronic illness as cardiovascular diseases, and peripheral vascular neuropathy; poor behaviors life style such as smoking and poor eating pattern which leads to overweight and obesity that have adverse effects on the level of blood sugar and HbAc1, in addition to previous foot ulceration or amputation , and ischemia of small or large blood vessels.⁽¹⁰⁾ Also previous history of foot ulcer or lesion, foot deformities that create abnormal high forces of pressure, renal failure, edema, inability to perform the personal hygiene are further risk factors for diabetic foot lesion or ulcer. Furthermore, occurrence of pressure or injury on distressed areas of the feet and legs, such as metatarsal-phalangeal joints, heel area among diabetic patients results in the development of sores or lesion and blisters, which become a port of microorganism invasion and contribute to infection. ^(11, 12)

Diabetes causes vast changes in the skin and circulation of the foot where the skin of the foot may become very dry, and fragile. Moreover, people with diabetes will develop neurovascularopathy which results in reducing blood flow and decrease sensation in the toes, legs, arms and feet, which make it easier to get undetectable ulcers and infections that may contribute to gangrene and subsequent amputation.^(13, 14)

Amputation is one of the severe consequence complications of diabetes, which is preceded by a diabetic foot ulcer. According to the findings of several studies, the prevalence of foot ulcers ranges from 4% to 10% among persons diagnosed with diabetes mellitus. Out of all amputations in diabetic patients, up to 85% are preceded by a diabetic foot ulcer, which deteriorated into poor progress leading to a severe infection or gangrene.⁽¹⁵⁾

Other many studies show that both foot ulcers and amputations have associated with a lower quality of life, which affects both physical and mental health, they are also associated with a substantial economic burden, in which hospitalization and amputation are responsible for 50% of the costs.^(16,17) Meanwhile, half of the patient with amputation surviving for more than 2 years, while fifty six of diabetic patients who have a history of foot ulcer without amputations survive for almost 5 years. In addition, the rate of hospital admission of the diabetic patients due to foot related problems were estimated by 8.8 %, while hospital admission without foot related problems was 13%. Regarding the healing process, about 35-40 % of diabetic foot ulcer recur within 3 years and more than 70 % of the recur within 5 years.⁽¹⁸⁾

Diabetic patients cannot detect the signs of infection easily in the beginning of its occurrence due to poor sensation and loss of pain which usually alert the patient to seek medical attention. While, they can detect the first sign of the active infection when inflammation and suppuration and abnormal discharge are appearing in the foot .Therefore , preventive measures of the diabetic foot are a prophylactic methods in the health care setting which have been supported to decrease patient morbidity and mortality rate among diabetic patients , increase health utilization services that reflect a positive influence on the patient 's quality of life and minimize the risk factors for amputations.⁽¹⁹⁾ These preventive measures are the primary level of prevention include the identification of risk factors, intensive podiatric care , and patient education along with their family members or caregivers to increase awareness regarding the diabetic foot care and provide proper foot care management , which have direct impact on improving clinical outcomes and quality of life of diabetic patients and their family as well as reduce the economic and financial burden on the health care system .^(12,15,17,20,21)

With respect to improving health outcomes, health care professional has been spending much effort on developing diabetes care guidelines for diabetic foot care and inform diabetic patients and their family caregivers regarding their health problems and teach them psychomotor skills for management process that make the necessary lifestyle changes behaviors to minimize diabetic foot complications.⁽²¹⁻²³⁾ Therefore, the professional nurses who is dealing with diabetic patients in the primary health care setting or other institutional health care agencies have a crucial role after the diagnosis of diabetes, where the nurses are most concerned with specific measures such as blood pressure monitoring, fasting blood sugar testing, routine eye and foot examinations, micro-albumin levels, lipid profiles and measuring glycated hemoglobin (HbA1c) to get an overall idea of average blood sugar levels over a period of weeks/months which is important indicators of developing diabetes-related complications and being at risk group. In addition, these measures are related to the development of proteinuria, retinopathy, dyslipidemia and foot ulcers.^(24, 25)

Because of diabetes is a costly disease, there are an evidences that improved care can lead to better quality of life as well as reductions in health care resource utilization. Therefore, intervention program for the diabetic patients and other various diabetes management programs provide the community with the initial database, which indicate that establishing standardized care may lead to cost savings, and improved health outcome.⁽²⁶⁻²⁹⁾ Therefore, the outcomes of the current research will have a key role in supporting Transtheoretical Model (TTM) of behavior change of diabetes foot care.

Theoretical framework

The Transtheoretical Model (TTM) of behavior change was developed by Prochaska, et al (1992) and was first applied to diabetes management in 1993.⁽³⁰⁾ It has become one of the most common, constant and enduring theories in the field of health promotion and education. The Transtheoretical Model (TTM) of behavior change has been beneficial to those interested in enhancing motivation for self-care. It has become one of the most influential theoretical models within health human psychology characterized by focusing in behavior change as a dynamic process. In addition, the Transtheoretical Model (TTM) of behavior change has recently been applied to diabetes mellitus patients and it is proved as a useful model for helping people with diabetes change their behavior for better sequences of health promotion.

Many studies, have applied the Trans-theoretical model to the care of patients with diabetes in various health settings. It is a behavioral theory that describes behavior change as occurring in six stages, starting from pre-contemplation to relapse. The central concept of the theory is that the behavior change is most likely to happen when individuals involved in the right activities or processes of change, at the right time, or right stage.

(31, 32)

According to the theory, individuals are more likely to experience success in changing behavior when they participate in strategies that are suitable to their stage of readiness to make the required change. The discrete motivational stages of change model assume behavioral change as a process of five stages through which individual passes across pre-contemplation, contemplation, preparation, action, maintenance and relapse. The model demonstrated that for most individuals; a change in behavior occurs gradually with the person moving from being unwilling, unaware and not intending to change in the foreseeable future usually measured as the next 6 months (pre-contemplation), to considering a change or intending to take an active action within the next coming 6 months (contemplation), then deciding, determine, preparing and actively considering making a change within the next month (preparation); followed by actual, determined action is then taken and over time individual has made an obvious behavior change in the recent past, the changes are well established for less than 6 months (action), finally the individual will change behavior for more than 6 months and is working to maintain the obvious change of the new behavior and are functioning to prevent relapse(maintenance). This model allows for applying a temporal dimension to the Stages of Change. Within the model, (relapse) is almost possible and predictable and become part of the process of working toward lifelong change.

Individuals in the first three stages; pre-contemplation, contemplation, and preparation are considered to be in the pre-action stages, whereas those in the last three stages; action, maintenance and relapse are considered to be in the action stages. Stages are specific to different behaviors and change is often periodic and repeated; that is, behaviors can move from one stage back to a previous one.^(31, 32)

The integrated application of all stages of the TTM can help health care providers adjust behavior change interventions to maintain compliance and improve required outcomes for individuals with diabetes mellitus.⁽³²⁾ Because of diabetes is a serious and prevalent disease, so managing diabetes requires a motivated client and skilled nurse as a health care provider who is responsible to inform diabetic patients about the behavior change stage specific interventions as well as application of stage-matched strategies may be useful in motivating clients with diabetes to adhere to health instructions.^(24,25)

Nurses being an irreplaceable health care professional. They play a crucial role of the health care system that is associated actively in different aspects of health particularly in disease prevention and health protection. Moreover, nurses work directly with patients and considered as primary care providers. They are a caregiver, communicator, educator, and consultant and most important, they are a teacher. They help patients to manage all the challenges during and after their illness by providing education and health teaching about their disease, medications and treatments.^(24, 25)

Materials and Method

Aim: was to improve foot care management among diabetic patients through the application of the trans-theoretical model of behavior change.

Research hypotheses

H1. The study group of the diabetic patients who received the intervention program of foot care management may exhibit a significant difference in the progression of the stages of Transtheoretical Model of Change (TTM) compared to the control group.

H2. The study group of the diabetic patients who received the intervention program of foot care management may exhibit a significant improvement of their clinical outcomes compared to control group.

H3. The study group who received the intervention program of foot care management may exhibit a significant improvement of their self-efficacy sub-items compared to control group.

H4. The study group of the diabetic patients who demonstrate foot care measures which included in the intervention program may exhibit a significant improvement of their total level of self-efficacy compared to the control group.

Design: A quasi-experimental design through pre-post intervention to investigate the study hypotheses.

Setting: This study was conducted at two different health setting ; Segar Primary Health Care Center, Ministry of Health and in the outpatient Diabetic Clinic affiliated to Tanta University Hospital, Tanta Governorate, Egypt.

Sample: A systematic random sampling method was used to select the study sample from the sampling frame of the patients' registration documents. Participants were invited to participate in the research study and answer the research questionnaire. The sample size was 154 diabetic patients presented at the outpatient diabetic clinic of the above-mentioned settings for regular medical follow up.

The inclusion criteria: non-insulin dependent patients, both gender, can read and write Arabic language, did not attend any diabetic educational program before the study.

The exclusion criteria: patients with a history of diabetic foot, who have a foot amputation, those who have cognitive and psychological problems, and those who are not willing to participate in the study.

Sample Size : According to Yamane (1967), a sampling size formula was used to determine sample size of the diabetic patients who are concrete recruited at the outpatient diabetic clinic, considering the confidence level

95% and confidence interval 5%, the calculated sample size is 154 diabetic patients. ⁽³³⁾

$$n = \frac{N}{1 + N(e)^2}$$

tn = sample size / N= Population size / e = level of precision = 0.05

$$n = \frac{250}{1 + 250(0.05)^2} = 154$$

Tools of the study

Three tools were used for the purpose of the study:

Tool I: Bio-socio-demographic characteristics questionnaire: Were composed of age, gender, education, and employment status; while biological data was consisted of duration of diabetes, HbA1c, cholesterol level, BP, BMI, and co- morbidity.

Tool II: Trans-theoretical Model scale: This scale was developed by Prochaska J., et al .,(1992) to assess the diabetic patients' stage of change toward diabetic foot care measures. It include 6 stages of change as follow: **1. Pre-contemplation (PC):** Patient has no intention to adopt his change within the next 6 months, ignorant of their issues, and is not serious about change; **2. Contemplation(C):** Patient admits there is a problem, thinking about making a change and plan to make changes within the next six months .The goal in this stage is to improve self-efficacy and reduce obstacles to change; **3. Preparation (P):** In this stage, the patient is planning to make change of his behavior within the next month, is not certain how to perform the changes and may distrust his ability of change, may begin a plan of action with the caregiver who starts to develop a strategy to find out the barriers for each individual patient and overcome it; **4. Action (A):** At this stage, the patient is really making the changes to modify specific lifestyle behavior on a constant daily basis; changes have occurred already for six months and is goal achieved; **5. Maintenance (M):** At this stage, patient have changed this lifestyle behavior for more than 6 months and are working to prevent deterioration;**6. Relapse (R):** Some patient may feel failure, return back old behaviors, feel they are bad and experience frustration ,and there is an opportunity to regroup and continue to learn and grow from the experience. ⁽³⁰⁾

Tool III Diabetes Management Self-Efficacy Scale (DMSES): Is a self-administered scale containing 20 items. ⁽³⁴⁾ It is used to assess the extent to which diabetic patients are confident to perform their diabetic management related to; nutrition ; blood glucose control ; physical activity and weight control ; medication intake and foot care management. The participants responses were rated on a 5 point Likert scale ranging from 1 to 5 whereas (1) can't do at all; (2) can do somewhat;(3) can do much;(4) can do most;(5) certain can do. Patient responses were added, the possible obtained score ranged from 20-100 where the higher scores indicate higher self-efficacy and low scores refer to lower self-efficacy. The tool was translated into Arabic language for the convenience of the patient.

Method

1. An official Permission to carry out the study was obtained from the responsible authorities.
2. **Ethical consideration:** Patient's written consent to participate in the study was obtained, patient's confidentiality was ascertained, the researchers was clarified that there are no potential risks associated with the participation and patients have the right to withdraw from the research without penalty at any time of the study period. Privacy and confidentiality were completely protected, no identifiers or personal information was collected or stored, including participant's name IDs and others.
3. Tools II and III of the study were adopted, translated into Arabic language for convenience of the patient.
4. **Content validity:** Study tools were tested for content validity by 6 experts in the field of medical-surgical, community nursing, and health education accordingly some modifications were done.
5. **Reliability:** Study tool was tested for reliability, Cronbach alpha was used based on standardized items, and it was 0.837 and 0.93 for tool II and III respectively.
6. **Pilot study:** The questionnaire was piloted among (15) diabetic patients to evaluate feasibility and reliability of the questionnaire as well as to assess time frame that was required to fulfill the questionnaire. This pilot sample was not included within study sample.
7. Data was collected from the end of March 2016 to the end of November 2017.
8. A self-reported questionnaire was administered to all diabetic patients included in the study during their follow up visits four times; pre,2,4, and 6 month post the intervention
9. The participants were interviewed individually in a separate room of the diabetic clinic to keep the privacy and confidentiality of the information when answering the questionnaire.

10. Phases of the study: The present study was conducted on four phases.

I. Assessment phase: All patient in the study and control group were assessed for the base line data using tool I,II &II, patients were required to select one of the 6 stages of change model " 1 = pre-contemplation; 2 = contemplation; 3= preparation; 4= action; 5 = maintenance; and 6 = relapse".

II. Planning Phase: This phase was formulated based on assessment phase and literature review. Intervention program was planned to be given to all participant in the study group according their stage of the Trans-theoretical Model for enhancing their care management towards diabetic foot care measures.

III. Intervention Phase: Based on the patient's obtained baseline data, the intervention material of the program was given to all patients in the study group according to their stage of behavior changes. The program includes health teaching, distribution of material handouts and demonstration by the researcher and re-demonstration by the patients of foot care hygiene measures. Health teaching, material handouts and demonstration of foot care focuses on foot care management which include, foot inspection, hygiene, washing and drying, applying of moister cream, wearing suitable socks and shoes, appropriate nail cutting, and care of corn, laceration and abrasion of foot.

VI. Evaluation phase: To obtain the aim of the study, all patients were reassessed three times 2,4 and 6 month after program intervention. The researchers scheduled with each patient to be met every two months for a period of six months according to the upcoming follow up visit schedule to assess the diabetic patients' stage of change toward diabetic foot care measures and self-efficacy of diabetic management using tool I,II &II.

Data analysis: The collected data were coded and analyzed using Statistical Package for Social Sciences (SPSS) version 20. Descriptive statistical analysis represents the calculated frequency count, percentage, mean, median, standard deviation, figures, and charts will be used for describing data. Bi-variate analyses between dependent and independent variables were performed using chi-square test to determine if there is a significant relationship between two variables. **Paired-samples t test (dependent t test)** is used to compare the means of two variables for a single group⁽³⁵⁾.

Results

The demographic Characteristics of the participants

The sample consisted of 154 type 2diabetic patients, which is divided into 77-study and 77-control group. The age of the studied sample ranged from20 to 60+ years (Table 1). In the study group, the mean age of the sample was 51.6 years (S.D. = 1.13), while for the control group, the mean age was 52.41 years (S.D. = 7.0). The majority of the study group was aged 60 years and above (45.5%), while the majority of the control group was represented 66.2%, betweenage40-59.5 years. The study group was represented a higher percent for females (62.3%) and less distribution of males (37.7%); meanwhile among control group the higher percent was for males (53.2 %) and lower percent was for females (46.8%). More than half for both study and control groups (58.4%& 65%) respectively were married. About 66.2% of the study group had a secondary school/ technical diploma, and only (11.7%) had university degree also, the control group (26%) had a secondary school or technical diploma, while less percent (16.9%) had a university degree. The majority of the study group (62.3%) was employed and (15.6%) was retired. In the study group (36.4%) was employed and almost forty percent was retired. In the study group, more than half (55.8%) reported that they have diabetes since 10 years; meanwhile a slightly higher percentage of the control group (41.5%) stated that they have diabetes for 5years. The study group represented, the majority of the patients have dyslipidemia and hypertension (26 % & 22.1 %) respectively; while in the control group have a greater percent of hypertension (23.4%) and neurological disorders (19.5%).

As shown in Table 2, the result was supported the first hypothesis which stated, "A study group may exhibit a significant difference in the stages of change of the Transtheoretical Model for foot care management compared to the control group".

Table 2 revealed the comparison of transtheoretical model of change stages among study and control groups in pre and post intervention program of foot care management. The results proved that there was no significant differences between the study and control group in pre-intervention, (as baseline data at the beginning of the program) where PC & C stages among study and control group were represented a higher percent (15.6 % & 57.1%) and (38.9 % & 44.1%) respectively. For (A) stage, it was counted the lowest percent in, both study and control groups (14.3 % & 6.5%) respectively. Meanwhile, after 2 months of intervention, there was a significant difference between study and control groups at $P = .022$ There was also, a slight increase patients percent in the stages of change of (P & A) among the study compared to the control group which displayed (P = 49.4% & 10.5%) and (A = 18.1% & 6.5%) respectively.

In addition , there was a significant difference between study and control groups at $P = .012$ four months after intervention , where the results show there was increased patients percent in the stages of changes of (A=48.0% & M=44.2%) among the study group compared to control group (A=7.8% & M= 0.0%).Moreover, after 6 months of intervention, the finding of the current study revealed that there was a significant difference between study and control groups at $P = .002$ where the results show that there was increased patients percent in

the stages of change of (M = 59.7 %) among the study group compared to control group (M= 0.0%).

As shown in table (3), the result supported the second hypothesis that stated, "A study group who received the intervention program for foot care management may exhibit a significant improvement of the clinical outcomes compared to the control group".

In table (3), (t- values = 2.43; 4.42; 3.23) which indicated that there is a significant difference in the clinical outcomes of "HbA1c, fasting blood sugar, and blood pressure" respectively for the study and control groups in pre and 6 month post intervention of the program. Meanwhile (t- values =0.514 ; 0.021) pointed out that, there is no a significant difference in the clinical outcomes of total cholesterol level and body mass index of study compared to control groups in pre and 6 month post intervention of the program.

In table 4, the result supported the third hypothesis that stated, "A study group who received the intervention program for diabetes management may exhibit a significant improvement of their self-efficacy items compared to control group".

As demonstrated in table (4), the findings showed the comparison of the total mean score of diabetic management self-efficacy items among study and control groups pre and 6 months after program intervention. The results displayed that there was a highly significant difference between the study and control group in their ability to perform proper management of the diet intake, control of blood pressure and medication intake & foot care where (P = 0.02; 0.09, 0.00 respectively), while there is no a significant difference in their ability to maintain physical activity and weight control since P = 0.83.

In table 5, the result supported the fourth hypothesis that stated, "A study group of the diabetic patients who demonstrate foot care management included in the intervention program may exhibit a significant improvement of their self-efficacy levels compared to the control group".

As the results revealed in table (5), the findings showed that the comparison of the total mean score of the diabetic management self-efficacy levels among study and control groups 6 months after intervention. The result indicated that there was a high significant difference between the study and control group for all self- efficacy levels since P value < 0.000 each.

Figure 1 showed a longitudinal comparison of diabetic management self-efficacy levels in pre and post-intervention program among study group. At baseline data, i.e., pre-intervention, the finding indicated the greater percentage (62.5%) of the diabetic patients had low management self efficacy level and only few percentage (5.2%) had a strong management self efficacy level. Meanwhile, after two months post intervention the low management self efficacy level was lowered to (52.2%) and strong management self –efficacy level was increased to (18.3%). In addition, strong management self –efficacy level was increased after fourth and sixth months post intervention to (38.7% and 45.8%) respectively.

In Figure (2), the results showed a longitudinal comparison of diabetic management self-efficacy levels in pre and post-intervention program among control group. The figure showed, low management self efficacy level among the control group was represented the highest percent (73.5%) in the pre-intervention program, and the percent of low management self efficacy level was continuously with a high percent (72.2 %; 71.5%; 71.5%) at 2, 4, and 6 month post intervention respectively.

Discussion

Diabetes mellitus is a chronic disease that accompanied with complication and requires lifelong treatment, care and self-management. The present study aimed to assess the change in behavior post application of transtheoretical model on foot care management, clinical outcomes and self-efficacy of type 2 diabetic patients. The result of the present study presented that majority of the studied groups were between age of 40-< 60 while more than half was female and married, and employed with secondary school certificate, in addition they diagnosed with diabetes from 6-10 years ago which is supported by Michael, M. et al., (2013)⁽³⁶⁾ who found in the study that the mean age was 53 years and 52% were female, also Heidi, H. et al., (2017)⁽³⁷⁾ was in congruence and stated that participants were middle-aged with a median age of 58 years, less than half were male, had higher education and more than half were currently working and the median duration of type 2 diabetes was 9 years. Dyslipidemia and hypertension was the co-morbidity of about third of participant of the present study, which is the same as the result of Michael, M. et al., (2013)⁽³⁶⁾

The transtheoretical model of behavior change has become one of the most influential theoretical models within health psychology⁽³⁾, the clinical outcomes of the study group of the present study have been improved foot care management post than pre the intervention program, in addition, there was a significant differences post than pre intervention in the study group regarding to; HbA1c, Fasting Blood Sugar, and Blood Pressure, this result was agreed by Partapsingh, V. et al., (2011)⁽³⁸⁾ who stated that after TTM intervention, blood samples indicated a reduction in HbA1c, and individuals in the intervention group self-reported an improvement in diet and exercise, moreover Thompson, J. et al., (2007)⁽³⁹⁾ was in congruence and added that post the TTM intervention, blood specimens collected indicated a significant reduction in HbA1c from baseline to 1 year (P < 0.004), with a more prominent reduction in women than men.

The Transtheoretical Model (TTM) offers guidance for people at all stages of readiness for change; the integrated application of all of the components of the TTM can help health care providers tailor behavior change interventions to maximize successful outcomes for individuals with diabetes. The ideal reason for a determination of a person's stage of readiness to change a behavior is for the intervention to facilitate a move from the current stage to a healthier stage.⁽³⁰⁾

On applying the stage of change model to the studied sample, it was found that the majority of participants of study and control group were either in the pre contemplation or contemplation stages pre the intervention, pre contemplation is the stage where people have no intention to change a specific, unhealthy behavior while only small percent were in preparation, action or in maintenance stages as regard; foot care, proper intake of diabetic medication and dietary intake management, on contrast in the post intervention majority of the participant in study group were in the action and maintenance stage while only small percent were in preparation or relapse stage, in addition the result of the present study also presented that there was a significant difference between the study and control group in the three aspect of diabetic management pre and post the intervention program. Heidi, H. et al., (2017)⁽³⁷⁾, confirmed the present study result and mentioned that most of the participants placed themselves in the pre action stage for behavior change. In addition, Jones, H, et al., (2003)⁽⁴⁰⁾ and Natarajan, S et Al., (2002)⁽⁴¹⁾ supported the present study and reported that there is an evidence of increased frequency of self-monitoring of blood glucose levels in patients who receive trans-theoretical model-based interventions. Moreover, Kirk, A. et al.,(2010)⁽⁴²⁾ agreed with the result of the current study and stated that post a TTM intervention which addressed the pros and cons of physical activity, the results of a questionnaire to assess exercise behavior change indicated an improvement in physical activity; and Highstein, G. et al., (2009)⁽⁴³⁾ added combining the TTM and the Resources and Supports for Self-management models together could develop a successful diabetes self-management program which approaches diabetes care in a comprehensive manner; Yara, A. et al., (2016)⁽⁴⁴⁾ supported the result and mentioned in systematic review study that the narrative findings provide evidence that TTM interventions are effective in promoting exercise, encouraging participants to pursue a healthier diet and lowering HbA1c levels.

On the other hand, Wiegand, P. et al., (2008)⁽⁴⁵⁾ contradicted the result of the present study and mentioned that none of the literature review studies performed proved that using the TTM would enhance the medication adherence levels of patients with type 2 diabetes, although one study suggests that applying TTM interventions to improve medication adherence would result in cost savings.

During the maintenance of behavior change stage, individuals are working to prevent relapse, diabetic patients consolidate the gains attained during action stage, stabilizing behavior change, and avoiding relapse are the hallmarks of this stage. The present study illustrated that a high percent of the study group were in the maintenance stage compared to control group. Magda, M.et al., (2014)⁽⁴⁶⁾ agreed with the result of the present study and stated that for the experimental group, there was statistical significant forward stages progression at all three time points while, in the control group, at the baseline, of the first and the second intervention, there was no statistical significant forward stages progression at all three time points. Additionally, the present study proved that there was a statistical significant difference between study and control groups at all three time points regarding stages of change for dietary management behavior, in addition Johnson, S. et al (2006)⁽⁴⁷⁾ support this result and added that intervention group was more likely than the control group to move into action or maintenance stage and remain there for the duration of the study, regardless of their stage at baseline. Moreover, Armitage, C. (2006)⁽⁴⁸⁾ supported the result of the present study and reported that those participants in the intervention group were significantly more likely to progress forward in stage; and the relapse rates were similar for both control and intervention groups

Being in the action and maintenance stage was associated with higher scores of self-efficacy management, which is an essential and important aspect for type 2 diabetic patients. The result of the present study demonstrated that the total level of self-efficacy management has been increased post than pre intervention program and there was a significant difference between the study and control group of the total level of self-efficacy management in the post intervention program. Velicer, et al., (1999)⁽⁴⁹⁾ agreed with the present study and shown a specific pattern of changes in self-confidence and temptations across the stages of change. Specifically, people report greater temptations and less confidence in the early stages, and this pattern reverses itself in the later stages where people feel less temptation and more confidence, Magda, M. (2014)⁽⁴⁶⁾ supported the present study and stated that the implementation of the Transtheoretical Model of change-based behavioral intervention improved the self-management practices and well-being of children with type I diabetes in addition, the present study is supported by Crowley, R. et al.,(2011)⁽⁵⁰⁾ who indicated a significant increase in self-efficacy in the intervention group compared to the control group, also this finding comes in agreement with Majaliwa, E. et al. (2007)⁽⁵¹⁾ who mentioned that their intervention had significant improvement in self efficacy of diabetic patients.

Limitation of the study:

There were some difficulties which encountered the researchers when collecting the data since some patients missed their appointment and did not show in the assigned time, so they were needed to be rescheduled again for the completion of the data. Due to overcrowdings of the outpatient clinic all times specially morning, provision of quiet environment was not easy for completion of the study tools.

Conclusion

The application of the Trans-theoretical Model of change- based intervention program brought a positive change in stages of diabetic patient’ behaviors change related to dietary management, proper medication intake, foot care and self-efficacy management.

Recommendation:

Based on the result of the present study, it can be recommended that:

1. Encourage primary care nurse practitioner to use the Transtheoretical Model of change to enhance patient care, and adoption of healthy behavior.
2. Appropriately, staging individuals are the cornerstone of all TTM applications.
3. Handout of stage-matched intervention materials should be distributed to diabetic patients.
4. The application of the entire TTM is important in designing and evaluating interventions, rather than just the stage-of-change construct.
5. Understanding how situational fascination and self-efficacy affect stage progression would also be helpful in designing effective interventions related to diabetic care management.

Table 1: Bio-sociodemographic Characteristics of the Studied Groups

Variables	Study Group	Control Group	Total
	n=77 (n) %	n=77 (n) %	n=157 (n) %
Age (Year)			
20-	15 (19.5)	2(2.6)	17(11.0)
40-	27 (35.0)	51(66.2)	78(51.0)
60+ above	35(45.5)	24(31.2)	59(38.0)
Mean ± SD	51.6±1.13	52.4±7.00	52.0 ± 4.07
Gender			
Male	29(37.7)	41(53.2)	70(45.5)
Female	48(62.3)	36(46.8)	84(54.5)
Marital status			
Single	20(26.0)	16(20.8)	36(23.4)
Married	45(58.4)	50(65.0)	94(61.0)
Divorcee	0 (0.00)	0(0.00)	0(0.00)
Widow	12(15.6)	11(14.2)	33(21.4)
Level of Education			
Read and write		12(15)	16(10.4)
Primary school	4(5.2)	20(41.5)	33(21.4)
Secondary school/ Technical	13(16.9)	32(26.0)	83(53.9)
Diploma	51(66.2)	13(16.9)	22(14.3)
University degree	9(11.7)		
Employment status			
Employed	48(62.3)	28(36.4)	76(49.1)
Not employed	17(22.1)	18(23.3)	35(22.7)
Retired	12(15.6)	31(40.3)	43(28.0)
Duration of Diabetes (years)			
5-	12(15.6)	32(41.5)	44(28.5)
10-	43(55.8)	20(26.0)	63(41.0)
>10+	22(28.6)	25(32.5)	47(30.5)
Co-morbidity Conditions			
Dyslipidemia	20(26.0)	12(15.6)	32(20.8)
Hypertension	17(22.1)	18(23.4)	35(22.7)
Neuro disorders	13(16.9)	15(19.50)	23(15.0)
Renal disorders	12(15.6)	11(14.2)	23(15.0)
Ischemic heart disease	6 (7.8)	5 (6.50)	11(7.10)
Asthma	5 (6.5)	6 (7.80)	11(7.10)
None	4 (5.2)	10(13.0)	19(12.30)

Table 2: Comparison of Transtheoretical Model of Change stages among Study and Control Groups Pre and Post Intervention Program of Foot Care Management

TTM Stages	Study Group n=77 (n) %	Control Group n=77 (n) %	X² P-Value
<i>Baseline data</i>			
Pre-contemplation	12(15.6)	30(38.9)	
Contemplation	44(57.1)	34(44.1)	.110
Preparation	10(13.0)	8(10.5)	.480
Action	11(14.3)	5(6.5)	
<i>2 months After intervention</i>			
Pre-contemplation	0(0.0)	30(38.9)	
Contemplation	20(26.0)	34(44.1)	
Preparation	38(49.4)	8(10.5)	5.04
Action	14(18.1)	5(6.5)	.022*
Maintainence	5(6.5)	0(0.0)	
<i>4 months After intervention</i>			
Pre-contemplation	0(0.0)	30(38.9)	
Contemplation	0(0.0)	33(42.8)	
Preparation	6(7.8)	8(10.5)	6.27
Action	37(48.0)	6(7.8)	.012*
Maintainence	34 (44.2)	0(0.00)	
<i>6 months After intervention</i>			
Pre-contemplation	0(0.0)	30(38.9)	
Contemplation	0(0.0)	33(42.8)	
Preparation	0(0.0)	8(10.5)	9.98
Action	26(33.8)	6(7.8)	.002*
Maintainence	46 (59.7)	0(0.00)	
Relapse	5(6.5)	0(0.00)	

*P < 0.05 level of significance

Table 3: Comparison of Total mean Score of Clinical Outcomes between Study and Control Groups Pre and 6 months after Program Intervention

<i>Clinical Outcomes</i>	<i>Study Period</i>	Study Group (Mean \pm SD)	Control Group (Mean \pm SD)	t-test P-value
HbA1c	Pre- Intervention	12.9 \pm 1.7	13.2 \pm 3.4	2.43 0.02*
	<i>6 months after intervention</i>	9.2 \pm 2.5	13.8 \pm 4.2	
Fasting Blood Sugar	Pre-Intervention	210 \pm 8.7	236 \pm 10.1	4.42 0.05*
	<i>6 months after intervention</i>	149.9 \pm 5.2	233.7 \pm 4.6	
Blood Pressure	Pre-Intervention	155 /95	145/95	3.23 0.04*
	<i>6 months after intervention</i>	130 /85	145/94	
Fasting Total Cholesterol	Pre-Intervention	340 \pm 1.4	426 \pm 2.2	.514 0.83
	<i>6 months after intervention</i>	345 \pm 2.2	429 \pm 3.1	
Body Mass Index	Pre-Intervention	35.4 \pm 2.6	31.7 \pm 2.3	0.02 0.66
	<i>6 months after intervention</i>	33.8 \pm 3.2	31.9 \pm 3.1	

*P < 0.05 level of significance

Table 4: Comparison of Total Mean Score of Diabetic Management Self-Efficacy Items among Study and Control Groups Pre and 6 Months after Program Intervention

Items	Study Period	Study Group (Mean \pm SD)	Control Group (Mean \pm SD)	t-test P-value
Proper Management of the Diet Intake	Pre- Intervention	55.3 \pm 5.7	45.3 \pm 5.7	5.43 0.02*
	<i>6 months after intervention</i>	86.3 \pm 3.7	46.3 \pm 3.7	
Blood Pressure Control	Pre-Intervention	75.4 \pm 5.6	55.4 \pm 5.6	6.42 0.09*
	<i>6 months after intervention</i>	77.6 \pm 2.4	57.5 \pm 3.5	
Physical Activity and Weight Control	Pre-Intervention	55.1 \pm 1.9	45.2 \pm 2.8	.514 0.83
	<i>6 months after intervention</i>	53.5 \pm 2.5	47.3 \pm 2.7	
Medical Control (Medication Intake and Foot Care Measures)	Pre-Intervention	78.2 \pm 1.8	66.32 \pm 3.7	4.23 0.000*
	<i>6 months after intervention</i>	87.1 \pm 4.9	64.1 \pm 2.9	

*P < 0.05 level of significance

Table 5: Comparison of Total mean Score of Diabetic Management Self-Efficacy Levels among Study and Control Groups (6 months after Intervention)

<i>Self-Efficacy</i>	<i>Studied Groups (6 month after intervention)</i>	<i>Mean ± SD</i>	<i>t-value</i>	<i>P-value</i>
Low Management Self-Efficacy	Study Group	34.96±23.67	4.42	0.000*
	Control Group	22.85±2.19		
Mild Management Self-Efficacy	Study Group	42.81±12.93	11.86	0.000*
	Control Group	23.77±3.50		
Moderate Management Self-Efficacy	Study Group	51.88±10.52	21.36	0.000*
	Control Group	25.42±4.68		
Strong Management Self-Efficacy	Study Group	77.09±15.85	24.33	0.000*
	Control Group	27.38±5.24		

*P < 0.05 level of significance

Figure 1- Longitudinal Comparison of Diabetic Management Self-Efficacy Levels in Pre and Post-Intervention Program among Study Group

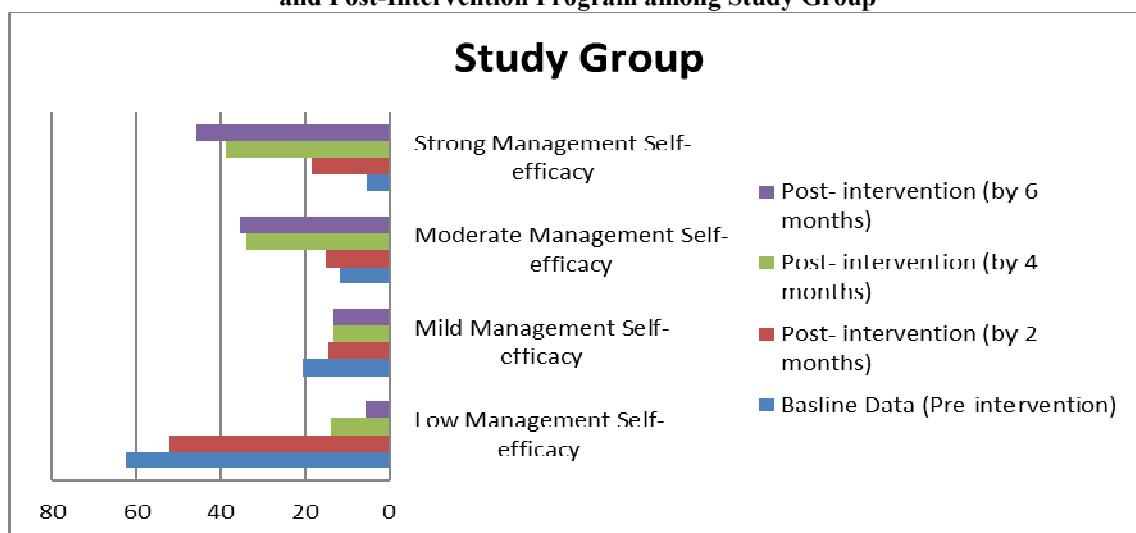
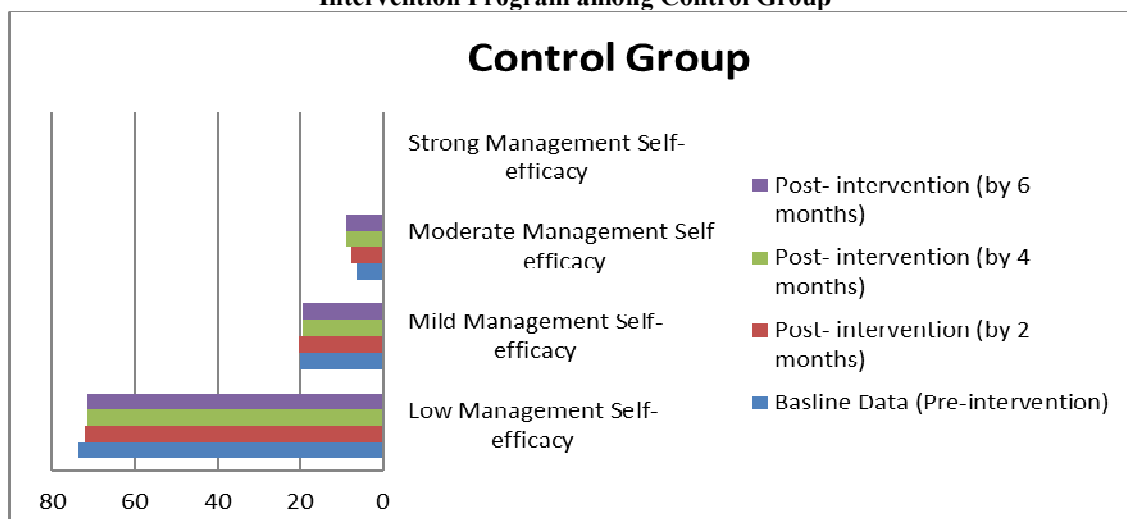


Figure 2: Longitudinal Comparison of Diabetic Management Self-Efficacy Levels in Pre and Post-Intervention Program among Control Group



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