2. REVIEW OF LITERATURE

It is desirable to have a brief survey of the work done in the field of patient education. This provides knowledge regarding the type of work done in this field. Unfortunately most of the research on the impact of Diabetes Patient Education is directed towards several outcomes including knowledge, quality of life, self-management, behavior, psychosocial outcomes, adherence to medication and medical care, glycemic and metabolic control, long-term complications, and controlling the level of blood sugar. Very few research studies on impact of Patient Education are directed towards psychological problems like Anxiety, Depression and Stress.

Studies have been conducted to understand the phenomenon better so that the ill effect can be minimized. The following studies provide a partial basis for the present study and help our views into a proper perspective.

2.1. Effect of diabetes patient education on Depression, Anxiety and Stress

Diabetes is often perceived as a burden. It can be hard to accept, and feelings of depression (feeling overwhelmed), anxiety (fear of complications or hypoglycemia) and frustration (with the demands of self-care, or the medical system) are common (Suresh, 2006). Psychological stress can also affect diabetes control where the release of counter regulatory hormones often results in elevated glucose levels. In addition stress can disrupt diabetes control indirectly through its impact on diet, exercise and other self-care behaviors (Surwit, 2002).

Rubin et al. (1993) in their study evaluated the effect of a Diabetes Education Program and incorporating coping skills training on emotional well-being and diabetes self-efficacy. Ninety-one adults who participated in the diabetes education program completed the entire research protocol and also follow-ups at 6-months and
12-months. The study assessed depression, anxiety, self-esteem, diabetes-specific knowledge and self-efficacy. Participants improved initially on all measures and maintained the improvements at 1-year follow-up on measures of anxiety, self-esteem, and diabetes-specific knowledge and self-efficacy. Subjects in intervention group learned about the nature of diabetes as well as diabetes self-management techniques which included nutrition management, increasing physical activity and exercise, daily control, self-monitoring of glucose, knowledge of HbA1c and initiating treatment. Those in the intervention group also learned about making appropriate lifestyle changes, dealing adequately with stress, the psychological aspects of diabetes and awareness, prevention, detection, treatment of acute/chronic complications of diabetes to reduce their Anxiety, Depression and to increase their self-esteem, diabetes-specific knowledge and self-efficacy.

Tankova et al. (2004) in their randomized, controlled study examined the effect of a 5-day teaching program for diabetic patients on their quality of life 1 and 2 years afterwards. Three hundred and nineteen insulin-treated patients were followed up at re-education sessions 1 and 2 years after the program. A group of 241 insulin-treated patients were also followed up and served as a control group. At baseline and 1 and 2 years later, patients’ well-being was assessed using a standard 22-item questionnaire. There was a significant increase in overall well-being of patients at 1 year (P<0.0001) and 2 years (P<0.001) after the program due to a reduction in depression and anxiety and an increase in positive well-being after 1 year and to a decrease in depression and increase in positive well-being after 2 years as compared to the control group. There was an improvement in glycemic control of the educated patients as compared to the control group (P<0.01). The results from the study also demonstrated that structured Patient Education improved patients’ well-being 1 and 2 years after the teaching program and reduce their Anxiety and Depression.
Scott et al. (1984) investigated the effectiveness of Diabetes Education for non-insulin-dependent diabetic persons. Individuals with noninsulin dependent diabetes who were referred to a diabetes education program were randomly assigned to treatment (n = 32) or non-treatment (n = 28) groups in order to assess the effectiveness of this program. The education course lasted four weeks, and at the end, the participants in the treatment group showed reductions of HbA1c and post-prandial glucose levels. They also showed an improvement in knowledge and less anxiety because they learned about the nature of diabetes and diabetes self management techniques which included nutrition management, increasing physical activity and exercise, daily control, self monitoring of glucose-knowledge of HbA1c, initiating treatment, and making appropriate lifestyle changes. Treatment group subjects also learned how to deal adequately with stress and the psychological aspects of diabetes.

A cluster randomized controlled trial by Davies et al. (2008) on the effectiveness of the Diabetes Education and Self Management for Ongoing and Newly Diagnosed (DESMOND) program for people with recent diagnosis of Type 2 diabetes, found that the intervention group had a significantly lower depression score at 12 months compared to the control group. Participants in intervention group learned about the nature of diabetes and diabetes self-management techniques to reduce their Depression, and adjust with diabetes.

Izquierdo et al. (2003) in their study on a comparison of Diabetes Education administered through telemedicine versus in person found that Diabetes Education by telemedicine was equally as effective as providing education in person. Both groups were equally effective in improving glycemic control and reducing diabetes-related stress. They concluded that the Diabetes Patient Education was successful in psychological problems such as stress.
In similar study by Surwit et al. (2002), stress management improved long-term glycemic control in Type 2 diabetes. Patients with Type 2 diabetes were randomized to undergo a five-session group diabetes education program with or without stress management training. They found that a cost-effective, group stress management program in a “real-world” setting can result in clinically significant benefits for patients with Type 2 diabetes because participants in the intervention group learned about the nature of diabetes and making appropriate lifestyle changes and dealing adequately with stress and psychological aspects of diabetes and awareness, prevention, detection, treatment of acute/chronic complications of diabetes to reduce their Stress and adjust with diabetes.

Higher Perceived Stress scores were associated with failure among diabetics to control blood sugar levels; failure to quit smoking; greater vulnerability to stressful life events elicited depressive symptoms and more colds (Cohen et al., 1983).

2.2. Empirical studies related to effectiveness of Diabetes Patient Education

2.2.1. Effect of Diabetes Patient Education on Quality of Life

The development of complications can result in sickness, absence, disability, premature retirement or premature mortality with loss in earnings and negative impact on quality of life of the person with diabetes and his or her family (Suresh, 2006). Some research studies are given below.

A systematic review by Norris and colleagues (2001) the effectiveness of Diabetes Self-Management Training in Type 2 diabetes. Three studies were included which assessed Quality of Life (QOL). One study noted an increase in QOL at 18
months for an intervention subgroup that received intensive counseling on both diet and physical activity. Two studies of brief interventions did not find an improvement in QOL.

A systematic review by Zhang et al. (2007) assessed the effect of interventions for adults with diabetes on Health-Related Quality of Life (HRQL), as measured by the SF-36 questionnaire. The mean changes and standardized mean differences between pre- and post-intervention were reported as outcome measures. Pooled estimates were obtained using random effects models. A total of 33 studies examining a wide range of interventions, including diabetes education and behavioral modifications (15 studies), pharmacotherapy (11 studies), and surgery (seven studies), were identified. Pooled effects from five RCTs of educational interventions demonstrated significantly improved physical function 3.4 (95%CI 0.1 to 6.6) and mental health 4.2 (95%CI 1.8 to 6.6), and a decrease in bodily pain 3.6 (95%CI 0.6 to 6.7). A pooled effect for five pre- vs. post-educational interventions also showed significantly improved social function 5.8 (95%CI 2.0 to 9.6), vitality 3.0 (95%CI 1.6 to 4.4), and mental health 2.5 (95%CI 0.6 to 4.4), and a decrease in role limitations due to physical problems 4.3 (95%CI 0.1 to 8.4). It was concluded that a variety of interventions can improve HRQL among adults with diabetes, but the magnitude of effects varied with the interventions.

Davies et al. (2008) evaluated the effectiveness of a structured group education program on biomedical, psychosocial, and lifestyle measures. Adjusted analyses show that the groups did not differ significantly in any of the scores for six dimensions of QOL (two overall scores and four subscale scores for physical,
psychological, social, and environmental). In addition, the groups did not differ significantly for emotional impact of diabetes at 8 and 12 months (p=0.97 and p=0.91, respectively).

A systematic review by Loveman et al. (2008) summarized the clinical effectiveness of Patient Education models for adults with Type 2 diabetes (two published trials were found that reported on QOL using a validated scale). In the first trial the Diabetes Quality of Life (DQOL) scale was used. This study reported results from a 2-year follow-up from inception; however, educational sessions were conducted every 3 months throughout the 2-year period. At 2 years the intervention group (treatment using group sessions) had significantly improved QOL compared with baseline (DQOL/Mod score 55.6 ± 15.9 vs 67.6 ± 19.0, p<0.001), whereas deterioration was seen in the control group (treatment using individual sessions) (80.8 ± 31.5 vs 66.7 ± 25.0). This difference was statistically significant between intervention and control groups (p<0.01). In a follow-up study at 5 years, this trend continued. The mean change in DQOL was –23.7 (95%CI -30.0 to -17.3) in the intervention group compared with 19.2 (8.4 to 29.9) in the control group (p<0.001). In the other trial, no statistically significant difference in QOL as measured by the Audit of Diabetes-Dependent Quality of life (ADDQOL) was observed between the treatment group and control group after 14 months although it appeared that the change in mean scores was greater in the treatment group than the control group. In this study, the intervention–evaluation interval was much larger as participants had a 6 week intervention and then were followed up at 14 months.
2.2.2. Effect of Diabetes Patient Education on Self-efficacy/ Empowerment /Attitudes and Beliefs

Empirical evidence supports the following factors to improve the education outcomes for adults with diabetes: involve people with diabetes in their self-care, guide them in actively learning about the disease, explore their feelings about having the disease, and teach them the skills necessary to adjust their behavior to control their own health outcomes. Thus, the goal for educating people with diabetes is to improve their individual self-efficacy, change their attitudes and beliefs about diabetes and accordingly, and improve their self-management ability (Krichbaum, Aarestad & Buethe, 2003). Some research studies are given below.

Deakin and colleagues (2005) located two studies which assessed the effect of diabetes education on empowerment/self-efficacy. Validated questionnaires were used in both studies to assess outcome variables. The first study indicated that at 4 months there was a significant difference in total empowerment score between the two groups in favor of the group education program (difference 0.3; 95%CI 0 to 0.6; p<0.001). That was also the case for the three sub scales: psychosocial adjustment to diabetes (difference 0.3; 95%CI 0 to 0.6; p=0.002); readiness to change (difference 0.4; 95%CI 0.2 to 0.5; p<0.001); and setting and achieving goals (difference 0.3; 95%CI 0.2 to 0.5; p<0.001). At 14 months, empowerment scores were still significantly higher among subjects allocated to the group education program: the total empowerment score was 3.5 for the group education program participants as opposed to 3.2 for the control group (difference 0.3; 95%CI 0.04 to 0.6; p=0.006); psychosocial adjustment to diabetes (difference 0.3; 95%CI 0.02 to 0.7; p=0.005); readiness to change (difference 0.3; 95%CI 0.1 to 0.5; p=0.001); and setting and achieving goals (difference 0.2; 95%CI 0.05 to 0.4; p=0.02). The second study found that at 6 months,
both the intervention and control groups significantly improved their psychological adjustment to diabetes (p<0.01), but there was no statistical significance between the two groups (p=0.64). It was concluded that there is some evidence that group-based education programs improve empowerment/self-efficacy; however, due to the limited number of studies further research is required.

Adolfsson et al. (2007) conducted an RCT aimed to evaluate the impact of empowerment group education on the confidence of people with Type 2 diabetes in terms of their self-efficacy and satisfaction with daily life compared to the impact of routine diabetes care. At 1-year follow-up, no significant differences were found in self-efficacy (p=0.272) and satisfaction with daily life (p=0.588) between the intervention and control group.

Davies et al. (2008) showed that compared with the control group, the intervention group had significantly greater changes in four illness belief scores (coherence, timeline, personal responsibility, and seriousness) (p=0.001), and the directions of change were positive indicating greater understanding of diabetes and its seriousness.

2.2.3. Effect of Diabetes Patient Education on Knowledge

Improvement of diabetes knowledge is one of the most important aims of Diabetes Patient Education (IDF, 2010). Some research studies are given below.

A systematic review by Norris et al. (2001) of 72 studies (describing 84 articles) of Diabetes Self-Management Training (DSMT) with follow-up of 6-12 months reported positive effects of patient education on knowledge. However, only
seven studies showed improved knowledge for both the intervention and control groups, suggesting possible contamination due to the lack of feasibility in blinding participants. Several studies showed that regular reinforcement of the intervention seemed to improve knowledge levels at variable length of follow-up.

A systematic review conducted by Valk and colleagues (2002) to assess the effectiveness of patient education in preventing diabetic foot ulcers reported conflicting outcomes. Two out of eight RCTs that evaluated intensive vs. brief education interventions demonstrated significantly superior foot care knowledge at six months in one study (p<0.001) and at one year in another study (I: 26.7 ≥ 32.1 vs. C: 26.1 ≥ 29.2; p=0.004). In the latter, knowledge was measured on a 19 item, three-choice questionnaire with total score ranging from 0-57. In a third study with a small sample size and high dropout rate, knowledge test scores were significantly worse in the intervention group compared with the control group at 6 months follow-up (I: 9.1 ≥ 10.0 vs C: 8.66 ≥ 9.86; p=0.02). While the authors identified one study reporting a statistically significant improvement in foot care knowledge at 6 months (I: 62.2 ± 1.7 vs. C: 53.1 ± 1.8; p=0.001), a study with longer follow-up showed that positive knowledge effect disappeared at 7 years. Studies assessing intensive, tailored patient education vs. usual care, also showed no effect at 1 year follow-up, although foot care behavior improved significantly. The authors concluded that the evidence, while limited by poor methodological quality and conflicting results, suggests that patient education may have positive but short-lived effects on foot care knowledge and behavior. Findings from a recent RCT assessing the effectiveness of the Diabetes Education and Self-Management for Ongoing and Newly Diagnosed (DESMOND) program highlighted the impact of patient education in increasing patient’s knowledge.
and understanding of diabetes (Davies et al., 2008). This study assessed the extent to which participants believe they understand their diabetes and their agreement with diabetes being a chronic condition and revealed that a structured group education program can positively affect participants understanding of their illness and its seriousness. Adjusted analysis showed that differences between intervention and control groups in four illness beliefs (coherence, timeline, personal responsibility and seriousness) were all highly significant (p<0.001).

Deakin et al. (2006) in a patient-centered group-based education program (X-PERT) conducted in the UK showed that at 14-month follow-up, structured patient education significantly improved diabetes knowledge scores in participants randomized to the patient-centered group-based self-management program (+1.8) compared with participants in the control group (+0.8) p<0.001.

Kulzer et al. (2007) tested the efficacy of three education programs: (A) didactic-orientated intervention focusing on the acquisition of knowledge, skills and information about the correct treatment of diabetes; (B) self-management/empowerment approach focused on emotional, cognitive, and motivational processes of behavior change; and (C) lessons in an individual and group setting with the same approach as (B). No significant differences in diabetes-related knowledge were found between any of the three groups.

Adolfsson et al. (2007) demonstrated a significantly higher level of confidence in diabetes knowledge in participants attending an empowerment group education program compared with participants in the usual care group after 1-year follow-up (p<0.012).
2.2.4. Effect of Diabetes Patient Education on Dietary habits

Before the discovery of insulin in 1921, the only treatment available for diabetics was diet therapy. This meant starvation and no carbohydrates. Over the past few decades, diet education has been revolutionized. Diabetes Education concept holds that a diabetic person can have a normal diet and choose a variety of foods available, provided that the quality and quantity are balanced in micro and macronutrients and that the total calories are proportionate to one’s ideal body weight (Pendsey, 2004). Diet management is one of the basics diabetes treatment (IDS, 2010). Some research studies are given below.

Deakin et al. (2005) reviewed the evidence of the effect of group education programs on self-management skills. Six of the 11 included studies which measured some aspect of self-management. Of these six, one RCT measured food intake with a validated food frequency questionnaire. At 4-month follow-up, participants allocated to group education had increased energy intake from carbohydrate (difference 4.1%; 95%CI 0.4 to 7.9; p=0.03), total sugars (difference 5.1%; 95%CI 2.4 to 7.9; p<0.001) and more fruit and vegetable portions per day (difference 1 portion; 95%CI 0.2 to 1.8; p=0.01) compared with those in the control group. At 14-month follow-up, trends suggested that participants in the group education were consuming more percentage energy from carbohydrate (difference 3.3%; 95%CI 0.3 to 6.9; p=0.07), more energy from total sugars (difference 6.6%; 95%CI 3.4 to 9.9; p<0.001), less energy from total fat (difference 2.7%; 95%CI 0.3 to 5.6; p=0.08), less energy from saturated fat (difference 1.1%; 95%CI 0.0 to 2.3; p=0.05) and an extra two portions of fruit and vegetables per day (difference 2.2 portions; 95%CI 1.1 to 3.2; p<0.001) compared with those in the control group. Deakin’s review also identified similar findings from
another study that showed positive improvement in stages of change with regards to: reduction of high fat foods ($p=0.008$); consumption of five portions of fruit and vegetables ($p<0.0001$); consumption of three meals daily ($p=0.9$); and limitation of refined sugar intake to one product per day or less ($p=0.001$). This confirms earlier findings from the systematic review by Norris and colleagues (2001) that also reported positive effects of self-management training on self-reported dietary habits, including improvements in dietary carbohydrate or fat intake, decreased caloric intake and increased consumption of low glycemic index food.

Norris et al. (2002b) in their systematic review could not demonstrate statistically significant changes in dietary intake, measured as kcal/day, in both men and women from one study. However, they concluded that there is insufficient evidence of effectiveness of DSME in community settings on the outcome of dietary intake due to the small number of studies.

In another study by Ko and colleagues (2007) showed that at 1-, 2-, 3- and 4-year follow-up, participants who had attended an intensive diabetes education program had a statistically significant improvement in dietary habits (measured by self-reported questionnaire) compared with conventional education.

### 2.2.5. Effect of Diabetes Patient Education on Physical activity

Increased physical activity is beneficial to normal weight patient with diabetes. In addition to helping them maintain normal body weight, insulin sensitivity and glycemic control will improve if the level of activity is significantly increased (Reaven & Storm, 2003). Some research studies are given below.
One study by Corabian and Harstall (2001) demonstrated a significant increase in physical activity in the intervention group compared with the control group (p<0.001). The authors concluded that diabetes patient education did increase physical activity of participants in the intervention group.

In another study, Deakin and colleagues (2005) reviewed measured self-management scores for physical activity using a validated questionnaire and found a positive effect at both 4 (p<0.001) and 14 months (p=0.02), whereas another study found no effect. The Norris et al (2001) review also showed improvement in physical activity in four studies, whereas five other studies found no change.

A Korean study by Ko et al. (2007) showed a statistically significant improvement in frequency of physical activity per week at 1-, 2-, 3- and 4-year follow-up (p<0.001 for all time points) in the intervention group compared with the control. The authors reported that 59.4% of people in the intervention group performed physical activity 3-4 times/week compared with 30.6% in control group.

Kulzer et al. (2007) compared the efficacy of three education programs: (A) a didactic-orientated intervention focusing on the acquisition of knowledge, skills and information about the correct treatment of diabetes; (B) self-management/ empowerment approach focused on emotional, cognitive and motivational processes of behavior change; and (C) a combination of individual and group settings using the same approach as (B). This study showed that regular exercise was significantly increased among treatment B and C subjects compared with treatment A subjects (both p<0.0001). Treatment C had a poorer effect on exercise than treatment B.
Davies et al. (2008) measured physical activity using the international physical activity questionnaire. Participants in the intervention group showed a greater increase in physical activity (reported in the previous week) at 4-, 8- and 12-month follow-up time points, with a significant increase at 4 months (p=0.046).

2.2.6. Effect of Diabetes Patient Education on self monitoring of blood glucose

Self-Monitoring of Blood Glucose (SMBG) is an important component of modern therapy for diabetes. SMBG has been recommended for people with diabetes and their health care professionals in order to achieve a specific level of glycemic control and to prevent hypoglycemia. The goal of SMBG is to collect detailed information about blood glucose levels at many time points to enable maintenance of a more constant glucose level by more precise regimens. It can be used to aid in the adjustment of a therapeutic regimen in response to blood glucose values and to help individuals adjust their dietary intake, physical activity, and insulin doses to improve glycemic control on a day-to-day basis (Benjamin, 2002). Some research studies are given below.

A systematic review by Norris et al. (2001) found positive effects of DSMT on frequency and accuracy of SMBG, demonstrated by decreased discrepancy between measurements by education provider and patient. They concluded that education interventions had a short-term (<6 months) positive effect on SMBG skills.

Deakin et al. (2005) in their systematic review include two RCTs that assessed the impact of group education on SMBG. The first Randomised Controlled Trial (RCT) demonstrated that self-management scores for SMBG levels increased at 4-
months follow-up (p=0.009) in participants allocated to a group education program, but there was no significant difference between the groups at 14 months (p=0.17). The second study showed that the percentage of participants who carried out SMBG was significantly higher in the group allocated to education program at both 1 and 2 years (p<0.005).

Ko and colleagues (2007) showed a statistically significant improvement in SMBG (measured by self-reported questionnaire) at all time points in their 1-, 2-, 3- and 4-year follow-up in the intervention compared with control group (p<0.001 for all).

2.2.7. Effect of Diabetes Patient Education on Glycemic control - HbA1c

Glycemic control is a medical term referring to the typical levels of blood sugar (glucose) in a person with diabetes mellitus, and HbA1c is a form of hemoglobin which is measured primarily to identify the average plasma glucose concentration over prolonged periods of time. Much evidence suggests that many of the long-term complications of diabetes, especially the microvascular complications, result from many years of hyperglycemia (elevated levels of glucose in the blood). Good glycemic control, in the sense of a "target" for treatment, has become an important goal of diabetes care, although recent research suggests that the complications of diabetes may be caused by genetic factors (Tarnow et al., 2008) or, in type 1 diabetics, by the continuing effects of the autoimmune disease which first caused the pancreas to lose its insulin-producing ability (Adams, 2008). Some research studies are given below.
Deakin et al. (2005) reported results of meta-analyses of: three studies that assessed HbA$_{1c}$ at 4-6 months (heterogeneity of $I^2 = 36.7\%$); seven studies at 12-14 months ($I^2 = 18\%$); and two studies at 2 years ($I^2 = 0\%$), respectively. The results of these meta-analyses showed statistically significant reduced HbA$_{1c}$ levels in favor of group-based diabetes education compared with control groups. Of the four studies not included in the meta-analyses due to high heterogeneity, two studies also showed significant improvements at 4- and 6-months follow-up while two other studies showed no significant difference. However, this was reflecting the baseline HbA$_{1c}$ which differed substantially between intervention and control groups. Deakin and colleagues concluded that group-based patient education in people with Type 2 diabetes is effective in improving HbA$_{1c}$.

A systematic review by (Sigurdardottir et al., 2007) demonstrated that initial HbA$_{1c}$ level is the single most important factor affecting improvement in glycemic control in response to patient education. When initial HbA$_{1c}$ levels were ≥ 8%, the reduction was 0.8 to 2.5%, and if initial HbA$_{1c}$ level was ≤ 7.9%, the change ranged from +0.1 to -0.7%. The differences between intervention and control groups in HbA$_{1c}$ mean reduction according to high or low initial HbA$_{1c}$ level was statistically significant ($t(33) = -2.82$, p=0.008) despite the control groups receiving more than standard care in at least seven studies. Seven of 18 RCTs achieved more than 10% reduction in HbA$_{1c}$ level, and four of these achieved post intervention HbA$_{1c}$ levels of ≤7.0%. For the intervention groups, the relative HbA$_{1c}$ level reduction was on average 6 to 7% compared with the control groups.
Davies et al. (2008) in their finding did not show a statistically significant difference in glycemic control between the intervention and the control group at 1-year follow-up. The HbA1c baseline level was higher in the intervention group compared with the control group (8.3% vs. 7.9%). Despite a decrease in HbA1c levels at 12 months by 1.49% in the intervention group compared with 1.21% in the control group, after adjusting for baseline and cluster, the difference was not significant: (95%CI −0.10% to 0.20%; p=0.52). Similar findings were also reported by an earlier RCT from Sweden (Adolfsson et al., 2007). The between-group difference in HbA1c was -0.3% (95%CI: -0.7 to 0.2) with a mean HbA1c level of 7.3% (SD 1.3) in the intervention group and 7.4% (SD 1.1) in the control group at 1-year follow-up. Structured education for people with Type 2 diabetes resulted in a small but non-significant reduction in HbA1c levels.

Duke et al. (2009) in a systematic review and meta-analysis of RCTs and Control Clinical Trial (CCTs) evaluated the effectiveness of individual patient education on metabolic control. This review included nine studies involving 1,359 participants that met the review pre-specified inclusion criteria. Six studies compared individual education to usual care and three compared individual education to group education (361 participants). In the six studies comparing individual face-to-face education to usual care, individual education did not significantly improve glycemic control in terms of a Weighted Mean Difference (WMD) in HbA1c of -0.1% (95% CI -0.3 to 0.1, p = 0.33) over a 12 to 18 month period. However, there did appear to be a significant benefit of individual education on glycemic control in a subgroup analysis of three studies involving participants with a higher mean baseline HbA1c greater than 8% WMD, -0.3% (95% CI -0.5 to -0.1, p = 0.007). In the studies that compared
individual with group education, there was no significant difference in glycemic control between individual or group education at 12 to 18 months with a WMD in HbA1c of 0.03% (95% CI -0.02 to 0.1, P = 0.22).

2.2.8. Effect of Diabetes Patient Education on Blood Pressure

Blood pressure plays an important part in the management of diabetes. High blood pressure (hypertension) adds to the workload of the heart, arteries and kidneys. Damage to kidneys, eyes and feet are long-term complications that can go along with a diagnosis of diabetes, but patients need to be aware of other health risks, including heart disease and strokes (Manzella, 2006).

Earlier systematic reviews showed mixed results (Norris et al., 2001; Norris et al., 2002b). In the 2001 review, one study demonstrated a decrease in systolic BP (-4 mmHg) and four studies in diastolic BP (-3 to –8 mmHg), respectively, whereas four studies showed no significant changes. Two studies included in the 2002 review demonstrated an improvement in systolic BP (mmHg) (-12.3 and -8.6) and diastolic BP (- 5.2 and -1.0). These two reviews did not provide sufficient evidence of an effect of Diabetes Education on blood pressure.

A review by Deakin et al. (2005) demonstrated evidence of short-term significant reductions in systolic blood pressure (BP). Two studies that measured systolic and diastolic BP at 4-6 months follow-up (n=399 participants) with no heterogeneity between the studies for systolic BP ($I^2 = 0\%$) and low heterogeneity for diastolic BP ($I^2 = 28.3\%$) were identified. A meta-analysis showed that systolic BP was significantly reduced in patients allocated to group education programs (5
mmHg: 95%CI 1 to 10; Z = 2.53; p=0.01) and there was a trend towards reduced diastolic BP (3 mmHg; 95%CI -6 to 0; Z = 0.38; p=0.08). At 12-14 months follow-up, two studies measured BP (I² = 0%), and a meta-analysis showed that there was a small non-significant reduction in systolic BP (3 mmHg; 95%CI -7 to 2; Z = 1.24; p=0.22). A meta-analysis could not be performed for diastolic BP due to substantial heterogeneity between the two studies (I² = 67.9%). However, neither of the two studies reported significant differences between the intervention and control group for diastolic BP.

Recent RCTs did not demonstrate effectiveness of patient education on BP levels in patients with Type 2 diabetes (Horsten et al., 2005; Davies et al., 2008). The most recent RCT measured systolic and diastolic BP in people with newly diagnosed Type 2 diabetes at 4, 8 and 12 months (Davies et al., 2008) found clinical significant improvements in both the intervention and control groups. However, after adjusting for baseline and cluster values, the authors found no statistically significant difference between the groups in systolic or diastolic BP.

2.2.9. Effect of Diabetes Patient Education on Body Mass Index/Weight

A systematic review by Norris et al. (2001) found 13 studies that demonstrated positive effects of patient education on weight loss. The average weight loss for these studies was 2 kg (range 1.3–3.1). Most studies with positive weight loss results involved regular contacts or reinforcement sessions (six studies) or very short follow-up periods (two studies), although four studies had follow-up periods of 5 months. All studies with follow-up of 6 months (from the end of the intervention) failed to demonstrate significant differences in weight loss between control and intervention
Only one of three studies involving didactic interventions showed a decrease in weight. A subsequent review and meta-analysis of six of eight studies by Norris et al. (2002b) reported differences in weight in participants attending for self-management education in community settings. Median absolute effect size was -2.4kg, with a range of -4.1kg to +0.7kg. The authors, however, conclude from both reviews that this evidence of effectiveness was insufficient due to the few studies and inconsistent results.

Deakin et al. (2005) in their review highlighted that there is no evidence that group-based diabetes education programs had an impact on body weight or Body Mass Index (BMI) at 4 to 6 months follow-up. A meta-analysis of four studies (n = 566), with low heterogeneity ($I^2 = 31.3\%$) showed an overall non-significant reduction in bodyweight in the intervention group compared with the control group (2.1 kg, 95%CI -0.5 to 4.7; $Z = 1.62; p=0.11$). Four studies (n=718) that assessed BMI ($I^2 = 0\%$) also showed a non-significant difference between groups of 0.2 kg/m$^2$ in favor of group education (95%CI -0.7 to 1.0; $Z = 0.37; p=0.71$). However, at 12-14 months follow-up, Deakin’s review suggested that there was some evidence in favor of the group education programs improving body weight but not BMI. This has been demonstrated in a meta-analysis of five studies, (n=591) of assessed body weight ($I^2 = 0\%$) in which there was an overall difference between the group education and control group of 1.6 kg (95%CI 0.3 to 3.0; $Z = 2.32; p=0.02$). Nonetheless, another meta-analysis of four studies (n=751) which assessed BMI at 12-14 months ($I^2 = 0\%$) showed no effect (difference 0.45 kg/m$^2$; 95%CI -0.2 to 1.2; $Z = 1.15; p=0.25$). Only one study measured waist circumference, and results indicated that at both 4 and 14 months there was no significant difference between
the two groups at 4 months (difference 1.3 cm; 95% CI -1.8 to 4.1; p=0.44) but a favorable effect of the group education program at 14 months (difference 2.8 cm; 95% CI -0.3 to 5.6; p=0.06) was noted.

In the DESMOND trial, participants with newly diagnosed type 2 diabetes attending a structured group education program (intervention) showed a greater weight loss: -2.98 kg (95% CI -3.54 to -2.41) compared with 1.86 kg (95% CI -2.44 to -1.28; p=0.027) in the control group at 12 months (Davies et al., 2008).

Adolfsson and colleagues (2007) reported no significant difference in BMI between the intervention and the control group at 1 year follow-up. Participants in the intervention group did not improve their BMI, and the between-group difference in BMI was only 0.8%. In contrast, Hornsten and colleagues (2005) found improved BMI within the intervention group when looking within the groups. The BMI decreased after 12 months from 29.4 to 28.7 (S.D. ± 4.6) in the intervention group, while the control group remained stable. However, there were no significant differences in BMI between the groups (p=0.08) at 1 and 5 years follow-up (Hornsten et al., 2005; Hornsten et al., 2008).

2.2.10. Effect of Diabetes Patient Education on Complications

Diabetes is a chronic, life-long condition that requires careful control. Without proper management it can lead to various complications such as cardiovascular disease, kidney failure, blindness and nerve damage (IDF, 2010). Both long-term and short-term complications can negatively affect physical functioning. The development of complications can result in sickness absence, disability, premature retirement or
premature mortality with loss in earnings and negative impact on quality of life of the person with diabetes and his or her family. Diabetes Patient Education can prevent from diabetes complications (Suresh, 2006). Some research studies are given blow.

Only one study included in the systematic review by Norris and colleagues (2001) examined cardiovascular disease (CVD) events. This study assessed the effects of a diabetes education intervention where people were followed-up every 3 months over 5 years. No significant differences in CVD events were found after 5 years follow-up. Similarly, a Health Technology Assessment (HTA) report (Corabian & Harstall, 2001) concluded that the published literature showed mixed inconclusive results in terms of diabetes education reducing the risk of diabetes associated long-term complications including CVD when using standard consultation (SC) or patient participation (PP). This study documented 72 CVD events in 45 patients of the SC group vs. 47 in 31 patients in the PP group. The total number of CVD events was 80 vs. 52, respectively (p=0.001). The relative risk (RR) over 8 years for a cardiovascular event in the intervention (PP) vs. the control (SC) group was 0.65 (95%CI 0.89 to 0.41; p=0.001). There were 17 cases of stroke (fatal and non-fatal) in the SC vs. 8 cases in the PP group (p=0.01). The RR for stroke was 0.47 (95%CI 0.85 to 0.32). There were also fewer coronary events and interventions in the PP than in the SC patients, 56 vs. 41 (fatal/nonfatal myocardial infarction [MI]/coronary artery bypass graft/percutaneous coronary intervention [PCI]), respectively (p=0.005). Also, the participants of the PP program had fewer bypass surgeries than their SC counterparts (3 vs. 7). A Kaplan-Meier estimation of combined cardiovascular event-free survival in the SC vs. PP group was statistically significant (p=0.004). It needs to be noted that although there was no direct pharmaceutical intervention and no prescriptions were
issued by the consultation team in this study, patients in the intervention group were more likely to receive angiotensin-converting enzyme inhibitors or angiotensin II antagonists than those in the control group at both 4- and 8-year follow-up (p<0.05 for both time intervals). Also, at 4 and 8 years, 81% and 96% of PP patients were prescribed lipid-lowering medication vs. 34% and 59% of the SC patients, respectively (p<0.05 for both time intervals). The prescribed daily doses of most of the antihypertensive agents and those of statins were higher in the PP than in the SC group. Glucose-lowering medications were not different in the two groups.

One study reviewed by Deakin et al. (2005) monitored the presence of diabetes complications. The study reported that at 2 years no significant differences between the group education participants and controls were seen with regard to diabetes retinopathy. However, at 4 years diabetes retinopathy had progressed more slowly amongst participants that had attended the group education program (p<0.009).

Retinopathy was assessed in one RCT that was included in the systematic review by Loveman et al. (2008), but it showed no significant difference between intervention and control groups at 2 years follow-up.

The RCT by Rachmani et al. (2005) showed a greater average annual decline in Estimated Glomerular Filtration Rate (EGFR) in the control (SC) vs. intervention (PP) groups (4.6 ± 2.1 vs. 3.0 ± 1.8 ml/min per 1.73 m^2, respectively) (p<0.01). Overt nephropathy (albumin/creatinine ratio >300 mg/g) developed in 14 (22%) patients in the control group vs. 7 (12.5%) in the intervention group (p=0.01). Four subjects in
the intervention group and one in the control group developed end stage renal disease. No standard method was used to assess neuropathy. This study found that the relative risk reduction of microvascular complications in the intervention vs. the control group was 0.57 (95% CI 0.91 to 0.28). However the authors noted that subjects in the intervention group were more likely to receive angiotensin-converting enzyme inhibitors or angiotensin II antagonists than those in the control group.

In their HTA report, Loveman et al. (2008) acknowledge the difficulty of performing long-term studies to specifically assess the effect of education on long-term end-points. Their review identified very few studies that included complications as outcomes, usually because the follow-up in the included studies was too short. One RCT evaluated the effect of patient education intervention on incidence of foot ulcers and reported that after 2 years follow-up there was no statistical difference between the two groups.

Two of four RCTs which measured clinical endpoints suggested that patient education reduces incidence of foot ulceration (Bazian Ltd, 2005). The first study involved an intensive, foot-specific education program delivered by nurse clinicians. The intervention did reduce the incidence of serious foot lesions (p<0.05), but there was no significant effect on amputations (OR 0.32, 95% CI 0.05 to 1.86). The second study involved one hour foot care education, as part of a broader education for people at very high risk of foot problems. The intervention significantly reduced the incidence of foot ulcers (15% vs 5%; p≤0.005) and foot and limb amputations (12% vs 4%; p≤0.025) at 26 months.
A previous review (Valk et al., 2002) reported similar findings from eight RCTs, six of which also later had been reviewed by Bazian Ltd (2005). Authors of both reviews concluded that due to poor methodology of all RCTs and conflicting findings, results need to be viewed with caution and that good quality RCTs are warranted to establish the efficacy of patient education in preventing foot ulcerations.