

## Original Research Paper

### Community Medicine

# IMPACT OF HEALTH AWARENESS AMONG DIABETICS TO REDUCE THE PLASMA GLUCOSE LEVEL AND MAINTAIN BETTER HEALTH – A SYSTEMATIC REVIEW.

Dr Rashmi Kundapur	MD, Additional Professor, Department of Community Medicine, All India Institute of Medical Sciences, Bibinagar, Hyderabad, India.
Dr Shreyaswi Sathyanath M	MD, Assistant Professor, Department of Community, A J Institute of Medical Science and Research Centre, Mangalore – 04, Karnataka, India.
Dr Sudip Bhattacharya	MD, Assistant Professor, Department of Community, Himalayan Institute of Medical Sciences, Dehradun, Uttarakhand, India.
Dr Anusha Rashmi*	MD, PGDEPI, Assistant Professor, Department of Community Medicine, KS Hegde Medical Academy, Nitte Deemed to be University, Mangalore – 18, Karnataka, India. *Corresponding Author
Dr Bhavesh V Modi	MD, Associate Professor, Department of Community Medicine, GMERS Medical College, Gandhinagar, Gujarat, India.
Dr Roopa Bhandary	Msc, PhD, Assistant Professor, Department of Biochemistry, K S Hegde Medical Academy, Nitte Deemed to be University, Mangalore – 18, Karnataka, India
Dr Deepak Saxena	MD, PhD, Professor, Indian Institute of Public Health Gandhinagar, Gujarat, 382041, India.

As a chronic communicable disease, diabetes tends to have number of clinical, social along with financial implications. This systematic review attempts to show that health education plays an important role in management of diabetes. Articles were meticulously searched electronic databases and after 3 phases of review 21 articles were selected and scored with Down and Black checklist. 19% studies received a score of more than 25 on Down and Black checklist. 17(80%) studies had good external validity and 12 (57.1%) studies had good internal validity. Majority of the studies were conducted in health facilities with mostly health education to patients especially through counselling and distribution of leaflets. Health outcome indicators studies were diabetes knowledge, attitude and practice and laboratory findings with respect to glycemic control. A significant improvement in KAP scores were noted in most of the studies.

## KEYWORDS: Diabetes, Education, intervention, review, health, awareness, impact

#### INTRODUCTION

Diabetes Mellitus (DM) is a chronic and non-communicable disease characterized by hyperglycemia which may be secondary to an absolute or relative efficiency in insulin signaling Diabetes mellitus (DM) may lead to various clinical, social, financial, and public health issues. The devastating long-term effects of the disease with poor glycemic control affects the quality of life leading to neuropathy, retinopathy, nephropathy, dementia, and cognitive problems. DM prevalence has risen dramatically over the past 2 decades, with India being the major contributor. According to International Diabetic Federation the number of diabetic patients will rise to 642 million by 2040.<sup>12</sup>

"Nothing in life is to be feared, it is only to be understood. Now is the time to understand more, so that we may fear less."-Marie Curie. This is so true about Diabetes Mellitus. The awareness about the disease in majority of diabetic patients is found to be inadequate. Health education plays a very important role in managing the glycemic control in DM subjects. Various studies<sup>7-26</sup> have demonstrated that diabetics with more knowledge and motivated self-care achieve better glycemic control. Health education to DM subjects play a major role to adopt healthy lifestyle practices, remain motivated for regular testing of glycemic status, and be well aware of the complications associated with the diabetic complications. These changes in knowledge, attitude, and practices of diabetic patients are the cardinal points in achieving good glycemic control and also for preventing the micro and macro complications of diabetes.

Studies<sup>7-26</sup> have revealed that adequate knowledge of the disease through health education is associated with good glycemic control leading to prevention of devastating complications associated with diabetes mellitus. In this context, the management of glycemic control in DM subjects becomes a holistic endeavor, by promoting the importance of health education in glycemic control.<sup>3</sup> Hence this systematic review makes an attempt to summarize the data available showing evidences to make health awareness mandatory for maintaining good glycemic among DM subjects.

#### **METHODOLOGY**

The study being a systematic review, articles available as full text over the electronic data bases were only considered for inclusion. The study did not involve any primary data collection and hence did not require ethical approval.

#### **Article Selection**

The electronic databases were comprehensively searched for articles relating to health education in diabetes. The entire process was divided into 3 phases. Phase 1: This consisted of 3 rounds- 1st round-Articles were searched in databases of Google scholar, Pubmed and Proquest and Clinical key by 2 independent reviewers. The MESH terms used were "Health education" to reduce sugar in diabetes", "reduce severity in diabetes" "in India". A total of 68 articles from Pubmed, 20 articles from Clinical key, 72 articles from Proquest and 68 articles from Google Scholar were thus selected. Phase 2: Here 2 independent reviewers further reviewed articles based on title and abstract filtering out non-Indian studies in the 2st

round. This brought down the articles to a total of 29 in the 2<sup>nd</sup> round. Based on study designs as mentioned in the abstract, articles were divided as Cross-sectional, Case control, Interventional studies, Review articles and Systematic reviews. Phase 3: The selected articles were distributed among 2 independent reviewers to be reviewed using CONSORT/STROBE checklists. <sup>4,5</sup> A 3<sup>nd</sup> independent reviewer, reviewed all selected articles independently to look into the scoring, using Down and Black checklists. <sup>5</sup>

#### Inclusion Criteria

The inclusion criteria's looked into were articles published in the past 20 years, were medical articles, English language, intervention solely as health education or as a component of other interventions delivered to study participants who were diabetics, participants >18 year's of age, studies conducted in India

#### Data Extraction

The data's looked into, in each of the articles reviewed were the year of publication, title of the article, study design, study setting, duration of the study, sample size, whether health education was done to groups or just individuals, the method of intervention, outcome variables looked into, main findings from the study and a summary review based on the checklists used. In order to assess the methodological quality of the articles selected for final review the Down and Black checklist was used and scored accordingly. Figure 1 shows the flow chart of the review process. The Down and Black checklist consists of 27 items that are divided under 5 subscales i.e the Reporting of the study, External validity, Internal validity (Study bias/ Blinding), Internal validity (Confounding/ Selection bias) and power of the study. Each of these sub scales are scored as 11, 3,7,6 and 5 respectively. A score of 0 being the lowest and highest being 32. The articles whose results were not consistent with the objectives mentioned for the study were removed in the 3rd round of review. Also those with a score of less than 20 were finally deselected from review presentation in results.

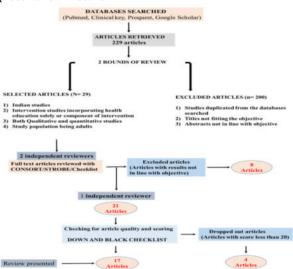


Figure 1. Flow Chart Of Article Selection

Table 2: Description Of Articles With Down And Black Score Of 21

Author &	Title	Study	Study	Sam	Intervention	Outcome variable	Main findings
year of		design	setting	ple	method		
publicati				size			
on							
Ramesh	A Brief but	Pre-	Integral	98	The	The outcome measures	Fasting plasma glucose, serum
L et al.16	Comprehensiv	post	Health		intervention	were fasting plasma	total cholesterol, low-density
	e Lifestyle	Interve	Clinic-An		consisted of	glucose and serum	lipoprotein (LDL) cholesterol,
2002	Education	ntional	OPD		asanas	lipoprotein profile. These	very LDL cholesterol, the ratio of
	Program	study	based		pranayama,	variables were determined	total cholesterol to high density

#### RESULTS

The final 21 articles were reviewed and scored using the Down and Black criteria. Of the 21 articles, in a study by Ambady Ramachandra et al,  $^{7}$  though used health education as a mode of intervention, the study compared 2 different modes of intervention designs and hence did not directly comply to our objectives, hence excluded from the detailed review presented in the tables (Table 2 to Table 5.2).

Table 1 shows the selected articles for detailed review as they scored  $\geq 20$  on Down and Black scoring.

Table 1: Details Of Down And Black Scores Of Articles That Scored  $\geq 20$ 

	Authors	Repo	Extern	Internal	Internal	Powe	Total
		rting (/11)	al validit y (/3)	validity bias (/7)	validity confoun ding (/6)	r (/5)	score (/32)
1.	Jain V et al.8	7	3	6	5	5	26
2.	Khetan A et al. <sup>9</sup>	8	3	6	4	5	26
3.	Kavumpura thu R et al. <sup>10</sup>	9	3	7	4	5	28
4.	Hossein Ali Sadeghian et al <sup>11</sup>	8	2	5	4	5	26
5.	Kumari G et al <sup>12</sup>	7	3	3	5	4	22
6.	D.A. Sutpate et al <sup>14</sup>	6	3	4	3	5	20
7.	Chidambar am Dandapani et al <sup>15</sup>	7	3	3	4	3	20
8.	Ramesh L et al. <sup>16</sup>	8	1	4	3	5	21
9	Javeed Shareef et al <sup>17</sup>	7	1	4	5	4	21
10	Mahyash Imran et al¹8	7	3	4	3	4	21
11	Chopra A et al. 19	7	1	5	4	5	22
	Chawla et al. <sup>20</sup>	7	1	5	5	5	23
	Balagopal et al. <sup>21</sup>	8	3	4	3	5	23
	U Bhojani et al. <sup>22</sup>	7	3	5	4	5	24
	Javalkar K et al. <sup>23</sup>	7	1	5	2	5	20
	Malathy et al <sup>24</sup>	6	2	5	4	4	20
17	Uma Iyer et al <sup>25</sup>	6	3	4	3	4	20

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	Based on Yoga Reduces Risk Factors for Cardiovascula r Disease and Diabetes Mellitus		setting		relaxation techniques, group support, individualized advice, lectures and films on yoga meditation, stress management, nutrition, and knowledge about the illness.	in fasting blood samples, taken on the first and last day of the course.	lipoprotein (HDL) cholesterol, and total triglycerides were significantly reduced, and HDL cholesterol significantly increased, on the last day of the course compared to the first day of the course. The changes were more marked in subjects with hyperglycaemia or hypercholesterolemia.
Javedh Shareef, et al <sup>16</sup>	Evaluating the effect of pharmacist's delivered counselling on	ctive, rando mized	General medicine outpatie nt departm	106	Educational materials (validated patient information	Patient medication adherence behaviour Fasting and post prandial blood glucose values	A statistically significant difference observed between the baseline test and final follow up test level of adherence
2016	medication adherence and glycaemic control in patients with Diabetes Mellitus	ntional study	ent of a tertiary care teaching hospital		leaflets) and medication counselling	Glycosylated haemoglobin (HbÅlc)	Significant decline in fasting blood glucose and the post prandial glucose levels  Significant reduction in the HbAlc level in the intervention group
Mahvash Iram et al <sup>18</sup> 2010	Impact of patient counselling and education of diabetic patients in improving their quality of life	ative interve ntion (concur	Outpatie nt departm ent of St Marth's hospital, Bangalo re 6 months	98	Counselling and Patient Information Leaflet (PIL): education about DM, management, complications, lifestyle modifications, medication	KAP  QOL  Fasting and postprandial blood sugar  Glycosylated haemoglobin	KAP and QOL improved significantly in the intervention group compared to control  Significantly better follow up values (improvement) in FBS and PPBS in intervention group, no improvement in control group  Significant reduction in glycosylated Hb in intervention
					adherence, frequent blood glucose monitoring, diet and physical activity		group

Table 3. Description Of Articles With Down And Black Scores Between 22 To 23

Author & year of publicati on		Study design	Study setting	Sampl e size	Intervention method	Outcome variable	Main findings
Chopra A et al. 19	The impact of free medical supplies and	Cohort + Randomi zed	Diabetes clinic	85	Provision of free Drugs+ free diagnostic strips	level + diαbetes	Significant improvement was seen in HbAlc with provision of free diabetes supplies
2018	regular telephonic contact on glycemic control in Indian children and adolescents with type 1 diabetes	control trial			supplied for 1 year + proactive telephonic advice by a diabetes educator		The knowledge score showed significant improvement in the telephone group during the proactive telephonic advice study compared with the non-telephone group (P = 0.002).
Kumari G et al <sup>12</sup>	Effectiveness of Lifestyle Modification	Quasi- experime ntal	Delhi Diabetes Research		2 phases comprehensive LMC program	Primary outcome measures- blood sugar fasting,	Significant improvement in blood sugar fasting, blood sugar PP. HbAlc % within the LMC
2018	Counselling on Glycaemic Control in Type 2 Diabetes	prospecti ve study	Centre (DDRC), New Delhi,		5 key components of Lifestyle Intervention	blood sugar PP, and HbA1C Secondary	group from baseline to 12 months follow up Significant change observed in
	Mellitus Patients		India 12		Holistic Model (LIH M) used for Lifestyle	outcome measures- weight, BMI, body fat,	blood sugar PP, and HbA1c on comparison between LMC and UC group

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			months		Modification Counselling (LMC)- Balanced diet, physical activity, tobacco & alcohol cessation	systolic and diastolic blood pressure, total cholesterol, triglyceride, LDL and HDL cholesterol, and adherence to counselling	
Chawla et al. <sup>20</sup> 2019	Impact of health education on knowledge, attitude, practices, and glycaemic control in type 2 diabetes mellitus	Interventi onal study	Departm ent of Medicine of a tertiary care teaching hospital in north- west India		Verbal counselling+ patient education leaflet	Difference in KAP (on diabetes management score) and in HbAIc levels in the intervention group	Health education (non-pharmacological management) resulted in improved knowledge, better attitude, and adoption of favourable practices which ultimately lead to better glycaemic control in patients with type 2 DM, thus help to slow progression and prevent complications.
Balagop al et al. <sup>21</sup> 2003	A Community- Based Diabetes Prevention and Management Education Program in a Rural Village in India	Interventi onal study	The village of Alamara thupatti, one of the field sites of Gandhig ram Rural Institute.		Counselling sessions on dietary modification	Difference in FBG and IFG levels. Difference in anthropometrical measurements including waist hip ratio.	Population intervention program successfully reduced some of the obesity and diabetes risk factors, decreased waist hip ratio, improved FBG levels, corrected impaired fasting glucose and improved fibre intake in diet.

Table 4.1 Description Of Articles With Down And Black Scores Between 24 - 28

Author & year of publication	Title	Study design	Study setting	- I	Intervention method	Outcome variable	Main findings
U Bhojani et al. <sup>22</sup> 2015	Intervening in the local health system to improve diabetes care: lessons from a health service experiment in a poor urban neighbourhoo d in India	Quasi experim ental design	Communi ty level (K.G. halli Slum)	317	The intervention included provision of culturally appropriate education to diabetes patients, use of generic medications, and standard treatment guidelines for diabetes management.	Reach, effectiveness, adoption, implementation and maintenance of the interventions. Change on the knowledge, out of- pocket healthcare expenditure, and glycemic control of patients and change in their mean practice score.	This health service intervention did not have statistically or clinically significant impact on the knowledge, out of- pocket healthcare expenditure, or glycemic control of patients with marginal reduction in mean practice score. The doctors, however, perceived that the culturally relevant education delivered in local languages and the videos generated curiosity among patients, who felt more confident in asking questions leading to enhanced knowledge and self-management practices.
Khetan A et al. <sup>9</sup> 2019	Effect of a Community Health Worker- Based Approach to Integrated Cardiovascula r Risk Factor Control in India	ized	Communi ty based (Dalkhola , WB, India)	3785	The intervention group had behavioral change communication through regular home visits from community health workers using flipbooks	Change in FBS, Systolic BP and in Smoking habit	A population-based strategy of integrated risk factor management through community health workers led to improved systolic blood pressure in hypertension, an inconclusive effect on fasting blood glucose in diabetes, and no demonstrable effect on smoking.
Hossein	Effects of a	Interven	Diabetes	314	Intervention as	HbAlc and	Mean reduction in the HbA1C

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Ali et al.11	self-	tional	Clinic of		group	physical activity	was significantly higher in the study
	management	study	the		education on	level (PAL)	group as compared
2016	educational	(RCT)	University		self-		to the control group
	program on		College		management		
	metabolic		of		program:		Mean change in PAL also showed
	control in type		Medical		Planned		an increase in the study group over
	2 diabetes		Sciences		meals,		the control group and the
			and Guru		physical		differences were highly significant
			Teg		activity,		
			Bahadur		management		
			Hospital		of illness and		
					low and high		
					glycemic		
					episodes and		
					management		
					of diabetes		
					during travel		
1			1			1	

Table 4.2 Description Of Articles With Down And Black Scores Between 24 - 28

Author & year of publication	Title	Study design	Study setting		Intervention method	Outcome variable	Main findings
Kavumpur athu R et al. <sup>10</sup> 2017	A peer-support lifestyle intervention for preventing type 2 diabetes in India: A cluster randomized controlled trial of the Kerala Diabetes Prevention Program	ized controlle	nity level		Participants from intervention clusters participated in a 12-month community-based peersupport program comprising 15 group sessions Participants from control clusters received an education booklet with lifestyle change advice.	The primary outcome was the incidence of diabetes at 24 months, diagnosed by an annual OGTT. Secondary outcomes were behavioral, clinical, and biochemical characteristics and health-related quality of life (HRQoL).	After a median follow-up of 24 months, diabetes developed in 17.1% (79/463) of control participants and 14.9% (68/456) of intervention participants (relative risk [RR] 0.88, 95% CI $0.66\pm1.16$ , $p=0.36$ ). At 24 months, compared with the control group, intervention participants had a greater reduction in IDRS score (mean difference: $-1.50$ points, $p=0.022$ ) and alcohol use (RR 0.77, $p=0.018$ ) and a greater increase in fruit and vegetable intake ( $_5$ servings/day) (RR 1.83, $p=0.008$ ) and physical functioning score of the HRQoL scale (mean difference: $3.9$ score, $p=0.016$ ). The cost of delivering the peer-support intervention was US\$22.5 per participant.
Jain V et al. <sup>8</sup> 2018	Community Health Worker Interventions in Type 2 Diabetes Mellitus Patients: Assessing the Feasibility and Effectiveness in Rural Central India	sed controlle d trial	care teaching hospital	322	Face to face counselling by community health workers+ Telephonic reminders+ patient diary+ health education+ dial in facility +telephonic follow up	Change in HbA1c level	The mean reduction of HbA1c and fasting blood sugar was more in the intervention group as compared to the standard care group.  The study demonstrated a trend towards improvement in glycaemic indices in the intervention group as compared to the standard care group. Although no statistical difference was observed between the intervention and the standard care group at the end of the study.

Table 5.1 Description Of Articles With Down And Black Score 20

Author & year of publication	Title	_	-	-	Intervention method	Outcome variable	Main findings
Javalkar K	The	Cross	Cardiology	82	NA	Measuring diabetes	The most used resource
et al.23	association	sectional	OPD			knowledge, self-	was
	between					management, and	books/pamphlets. The
2016	educational					educational	use of television and
	resource					resource utilization.	books/pamphlets as
	utilization					FBS, PPBS, HbAlc	sources of information

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and knowledge/s elf- management among patients with Type 2 Diabetes in Pune, India						was significantly associated with greater knowledge and self-management. Use of books and pamphlets and peers with diabetes was associated with lower fasting and postprandial blood glucose.
patient counselling,	pilot study (before and	Indira Gandhi memorial hospital, North Maharasht ra 12 months	to follow up)	counselling regarding disease, medication, nutrition, exercise, insulin, foot care, eye care, personal hygiene, self-monitoring of glucose and self-care Distribution of information leaf lets At follow up visits (1/ month for 3 months)pharmaci st counselling regarding disease, medication and life style	HbA1c, Fasting and post prandial plasma glucose (FPG and PPG),  Total cholesterol, triglyceride, HDL, LDL and BMI	Significant reductions in FPG, PPG and HbA1C found in all three groups  HbA1c found to be reduced more significantly in group II patients who are on oral hypoglycemic triple combination therapy
Effect of a diabetes counselling programme on knowledge, attitude and practice among diabetic patients in Erode district of South India	trial (test and control)	2 selected multi- speciality hospitals and one diabetic clinic in Erode, Tamil Nadu	207	Pharmacist counselling sessions in the regional language for 20- 25 mins each visit at 1-month intervals over a period of 3 months Printed handouts in the local	KAP score  Glycaemic control (fasting blood glucose level)  Lipid profile (HDL, LDL, triglycerides)	Overall KAP scores of the test group significantly higher Significant reduction in the PPBG levels of the patients in the test group HDL increased and TGL levels reduced significantly in the test group
	and knowledge/s elf-management among patients with Type 2 Diabetes in Pune, India  Assessment of impact of patient with type 2 Diabetes in patients with type 2 Diabetes Mellitus  Effect of a diabetes diabetes counselling programme on knowledge, attitude and practice among diabetic patients in Erode district of South	and knowledge/s elf-management among patients with Type 2 Diabetes in Pune, India  Assessment of impact of patient counselling, nutrition and exercise in patients with type 2 Diabetes Mellitus  Effect of a diabetes counselling programme on knowledge, attitude and practice among diabetic patients in Erode district of South	and knowledge/s elf-management among patients with Type 2 Diabetes in Pune, India  Assessment of impact of patient counselling, nutrition and exercise in patients with type 2 Diabetes Mellitus  Effect of a diabetes counselling programme on knowledge, attitude and practice among diabetic patients in Erode district of South  Randomize d controlled pilot study (before and after)  North Maharasht ra  2 selected multi-speciality and control) hospitals and one diabetic clinic in Erode, Tamil Nadu	and knowledge/s elf-management among patients with Type 2 Diabetes in Pune, India  Assessment of impact of patient counselling, nutrition and exercise in patients with type 2 Diabetes Mellitus  Effect of a diabetes counselling programme on knowledge, attitude and practice among diabetic patients in Erode district of South  End diabetes counselling programme on knowledge, attitude and practice patients in Erode district of South  End diabetes counselling programme on knowledge, attitude and practice patients in Erode district of South  End diabetes counselling programme on knowledge, attitude and practice patients in Erode district of South	and knowledge/s elf- management among patients with Type 2 Diabetes in Pune, India  Assessment of impact of potient counselling, nutrition and exercise in patients with type 2 Diabetes Mellitus  Effect of a diabetes and controlled monthly programme on knowledge, attitude and practice among diabetic patients in Erode district of South India  India  Randomize d controlled Gandhi pilot study (before and hospital, Maharasht ra  Indira  Gandhi memorial hospital, Morth Maharasht ra  Indira  Gandhi memorial hospital, Morth medication, nutrition, exercise, insulin, foot care, eye care, personal hygiene, self-monitoring of glucose and self-care Distribution of information leaf lets  At follow up visits (1/ month for 3 months)pharmaci st counselling regarding disease, medication and life style modification  Pharmacist counselling regarding disease, medication and life style modification  India  Randomize d controlled multi-speciality and controlled strial (test among diabetic clinic in Erode, among diabetic patients in Erode district of South India  India  Randomize d controlled formation on indirection and life style modification  Pharmacist counselling regarding disease, medication, nutrition, exercise, insulin, foot care, eye care, personal hygiene, self-monitoring of glucose and self-care Distribution of information leaf lets  At follow up visits (1/ month for 3 months)pharmaci st counselling regarding disease, medication and life style modification  Pharmacist counselling regarding disease, medication, nutrition, exercise, insulin, foot care, eye care, personal hygiene, self-monitoring of glucose and self-care  Distribution of information of information leaf lets  At follow up visits (1/ month for 3 months) pharmaci st counselling regarding disease, medication, nutrition, exercise, insulin, foot care, eye care	knowledge/s elf- management among patients with Type 2 Diabetes in Pune, India  Assessment of impact of potition and exercise in patients with type 2 Diabetes Mellitus  Effect of a diabetes counselling programme on knowledge, attitude and practice among diabetic potients of South India  Effect of south India  Effect of a management among patients with type 2 Diabetes  Effect of a diabetes counselling programme on knowledge, attitude and practice among diabetic potients in Datients in Pune, India  Effect of a management among patients with Type 2 Diabetes  Effect of a diabetes counselling programme on knowledge, attitude and practice among diabetic potients in Datients in Datients in Pune, India Pune, Indi

Table 5.2 Description Of Articles With Down And Black Score 20

Author & year of publication	Title	Study design	Study setting	Sampl e size	Intervention method	Outcome variable	Main findings
Chidambaram Dhandapani, et al <sup>15</sup> 2014		interventiona l study	Kovai Medical Centre and Hospital, Coimbatore	s	of various supportive materials for patient education.	KAP and diabetic foot care knowledge Changes in parameters like FBS, PPBS and HbA1C	Significant improvement in mean foot care knowledge scores  No significant improvement in control group  Mean FBS and PPBS showed a trend of continuous improvement in the intervention group  Statistically significant reduction in FBS and

			VOLUME - 10, I	SSUE - 03	3, MARCH - 2021	• PRINT ISSN No. 2277	- 8160 • DOI : 10.36106/gjra
							PPBS for intervention group. Mean HbA1C value in the test group at the end of the study shows tendency toward lower value than the first visit, but, not statistically significant
Uma Iyer et al 2010	Impact of interpersonal counselling on the blood sugar and lipid profile of type 2 diabetes mellitus subjects (nutrition health education and diabetes mellitus)	Intervention study	Subjects enrolled from biochemistry laboratories of the city; counselling at the subjects' residence	60	by the investigator on the knowledge and lifestyle-related risk factors and its	cholesterol (HDL-C) and triglycerides (TG);	In the test group, slight improvements seen with regard to protein and fat intake; 4% decrease in fat intake after intervention primarily due to the decrease in the saturated fat intake After an intervention period of 2 and 4 months, a 6.4 and 14.2% decrease in the FBG noted in the test group, accompanied by a significant fall in the HbA1c levels Highly significant lowering of TC, LDL-C, and non-HDL-C noted in the experimental group; increase in the HDL-C levels- both at the end of 2 months of IPC as well as long-term intervention for 4 months

#### Quasi Experimental/Non Randomized Trials

Of the 21 studies assessed using the Down and Black checklist, only 4, 19% studies ( $Jain\ V$  et  $al.^{\circ}\ Khetan\ A$  et  $al.^{\circ}\ Kavumpurathu\ R$  et  $al.^{\circ}\ and\ Hossein\ Ali\ Sadeghian\ et\ <math>al.^{11}$ ) received an overall score of above 25 out of 32 with consistently high scores in all subscales including reporting, external validity, internal validity and power; while addressing both measurement and confounding bias. Most of the studies (14 out of 21 = 66.7%) scored between 20 to 25 and 3 (14.3%) studies scored very low (less than 20).

Most of the studies (17 of 21= 81%) scored high on power except for 4 studies (which scored 3 or less). External validity was high (2 or above) in 17 of 21 (81%) studies and it was less than 2 in only 4 studies. Internal validity (addressed biases in the measurement of the intervention and the outcome) was high (4 or more) in 12 of 21 studies (57.1%). Scores in the confounding sub scale (which addressed bias in the selection of study subjects) were high (4 or more) in 11 out of 21 studies (52.4%). The conclusions on the objectives of our systematic review were drawn from the review of the quasi-experimental studies while keeping in mind the overall scores as well as the scores in the individual sub scales in the Down and Black checklist. The studies that scored high were given more weightage while drawing overall conclusions for our systematic review.

#### Randomized Trials

Among the randomized trials reviewed using the CONSORT checklist, only 2 studies (Kumari G et  $al^{12}$  and Aswathy Sreedevi et  $al^{13}$ ) clearly mentioned how the sample size was calculated. Only 1 study mentioned the details of randomization (Aswathy Sreedevi et  $al^{13}$ ) including the method used to generate the random allocation sequence, mechanism used to implement the random allocation sequence and the details on who generated the random allocation sequence, enrolled participants, and assigned participants to interventions while all the remaining studies gave incomplete details on randomization.

In the study by DA Satpute et al, <sup>14</sup> although the participants were randomized into 3 groups, all 3 groups received the same health education intervention. Hence, the differences in glycemic control achieved was due to the different medication combinations and not due to the education intervention. The details on blinding was missing in most of the studies except one, Aswathy Sreedevi et  $al^{13}$  in which the assessment of the primary outcome, QOL was done by staff who were not directly associated with the study).

All the studies reported the eligibility criteria, settings and locations where the data were collected as well as the interventions for each group with sufficient details except the study by Chidambaram Dhandapani et  $al^{15}$  which did not give enough details on the counselling session in the test group. Participant flow details were limited or the diagram was missing in 8 studies and sufficient focus on discussion with respect to address on the limitations, generalizability and sources of bias was lacking in most of the studies except the one reported by Kumari Get al.

The above considerations on the methodology and reporting of the individual studies based on the CONSORT criteria have been kept in mind while interpreting the primary and secondary outcome of the studies for the purpose of our systematic review.

#### DISCUSSION

# Assessment of quality and risk of bias for individual studies:

During the process of conducting the review of the individual studies, we initially had planned to employ the CONSORT checklist for randomized controlled trials. However, as we reviewed the articles, it was evident that several studies were not randomized and many of them were not executed well enough for us to be able to review using several items in the CONSORT checklist. Thus, we had to broaden the scope to a quality assessment tool which was valid and reliable for both

randomized and non-randomized trials which led us to use the checklist developed by Down and Black. By using the Down and Black checklist for the individual studies included in our review, we were able to provide and overall score for the quality of each study as well as in addition, profile each study with respect to quality of reporting, internal validity (bias and confounding) and power and the external validity as well.

We believe that our systematic review provides summary evidence of impact of health education on diabetes mellitus with respect to glycemic control in the Indian setting, which has not been done before and the use of such a checklist has allowed us to include a broader range of studies while also providing us with numerical representation for quality of individual studies- both overall as well as sub scales on how well reporting was done, how well the findings from each of the study may be generalized, what is the probability of the results influenced by any biases in measurement or bias due to confounding, as well as make an interpretation on the estimate of each study based on the power of the study.

#### Demography-

The age varied across the different studies from an average of 13 years to 56 years. Inclusion of males and females was almost equal across studies. A common aspect noted was regarding education wherein on an average 30-40% of the participants had completed secondary school. 28%-30% of participants across the studies belonged to middle class. A few studies gathered data on caste showed that the participants belonged to upper class majorly. However, we did not find these findings of any added value to the objective of our study.

#### Settings And Study Design-

In this systematic review of educational interventions for adults with type 2 diabetes living in urban and rural areas, we found that most of the studies were conducted in health care facilities either in out-patient department of Medicine or in Diabetic clinic or in the laboratory setting. Only one study was a community based study

The duration of the studies ranged from 3 months to 12 months. Among all studies, only three were randomized control trials and the remaining were prospective interventional studies. Sample size varied from 35 to 314. It was observed from most of the studies, that there were two groups in each arm, one was interventional and another was control. The ratio of intervention and control groups were kept to 1:1 ratio. It was also observed that none of the studies had any mechanism for blinding of the participants to avoid the bigs

#### Intervention Design And Delivery-

The mode of intervention in almost all studies were patient education through counselling and distribution of educational leaflets. The duration of counselling/intervention ranged from 1-3 months. The study conducted by Shareef J et al. 26 (2016) revealed that their counselling program included knowledge on diabetes, self-monitoring of blood glucose, diet, exercise therapy, importance of medication adherence, tips to carry medicines while travelling, early recognition of the symptoms of hypoglycemia and its management. Patients in the intervention group were also educated on diabetic complications such as micro vascular, macro vascular and diabetic foot ulcers.

A similar intervention was observed in a study conducted by Singh et al. which included comprehensive LMC program. The 5 key components of Lifestyle Intervention Holistic Model (LIH M) used for Lifestyle Modification Counselling (LMC)-consisted of balanced diet, physical activity, tobacco & alcohol cessation, it was repeated at every month for 6 months

and follow up; the educational materials were made in the local language, supported by pictures, videos and face to face interviews and discussions with individual or group of individuals.

#### Health Outcome Indicators-

The studies reviewed majorly showed 2 outcomes in terms of 1) knowledge attitude and practice regarding diabetes and its management and 2) laboratory indicators on improvement of diabetic control.

#### 1)Diabetes knowledge, attitude, and practice-

The assessments concentrated on KAP scores regarding Knowledge about diabetes that framed the basis for their informed decisions on , diet, exercise, weight-control, blood glucose monitoring, use of medications, foot and eye care, and control of macrovascular risk factors. etc

In all studies, diabetes related knowledge, attitude and practice data were collected by various different questionnaire. No uniformity/standardization was maintained regarding the questionnaire administrated. Majority of the reviewed studies showed a significant improvement (p<0.01) in KAP score.

A study by Kumari G et al  $^{12}(2018)$  showed good adherence to balanced diet, physical activity, and tobacco and alcohol cessation, however a reduced adherence was observed towards meditation for stress management, regular checkups, and medication. In a study conducted by Malathy et al  $^{24}$  showed that the practice domain did not show any improvement (P<0.06), since the scores at the first visit itself was remarkably high. So, we must interpret this finding very cautiously that why some peoples' attitude did not change despite of educational intervention who initially came with high baseline score.

In all KAP studies it was found that literacy and socioeconomic status had a definite role in KAP score. Most of the studies revealed that people from a higher socioeconomic status background had higher KAP scores than those who were illiterate and who belonged to low socioeconomic status.

# 2) Laboratory Indicators On Improvement Of Diabetic Control-

The observations made in most of the studies with regards to the outcome indicators were-changes in HbAlc, fasting blood sugar(FBS), post-prandial blood sugar(PPBS), total cholesterol, triglyceride(TG), high density lipoprotein(HDL), low density lipoprotein(LDL) and body mass index(BMI).

A study conducted by Satpute D A.et al. (2009) at north Maharashtra showed a reduction of HbA1c in Group-I by 1.0  $\pm$ 0.2%, in Group-II by 1.3  $\pm$ 1.71% and in Group-III by 1.2  $\pm$ 0.13% after educational interventions at repeated intervals. In another study by Kumari G et al. (2018) at new New Delhi revealed that reduction in HbA1c% occurred (9.3 $\pm$ 1.5 to 8.4 $\pm$ 1.3) within the intervention group from baseline to 12 months follow up. Most of the studies reflected that the reduction in mean HbA1c occurred and all changes were statistically significant (<0.01). In a study conducted by Shareef J et al. (2016) revealed that there was a significant improvement in blood sugar fasting (175.5 $\pm$ 32.3 to 144.7 $\pm$ 17.6), blood sugar PP (275.5 $\pm$ 61.3 to 199.0 $\pm$ 48.3), within the intervention group from baseline to 12 months followup.

In another study conducted by Iyer U aet al.  $^{25}$ (2018) at Gujarat showed that four months of nutrition health education led to a significant reduction in the fasting blood glucose (FBG; 14.2%). A study conducted in Tamil Nadu by Malathi R et al.  $^{24}$  revealed that after educational intervention, PPBS levels between control and test groups got reduced (in control group

229.17-211.14mg/dl and in test group 237-204.47 mg/dl). One of the cardinal observation seen in all studies was a significant reduction (p<0.001) in PPBS as well as RBS by educational and lifestyle interventions.

Most of the studies showed reduction in serum TG, HDL and in LDL after intervention.

Regarding BMI and vitals, the study conducted by Kumari G et al  $^{12}$  (2018) revealed that there was a significant improvement being observed in Weight (74.4 $\pm$ 14.5 to 72.6 $\pm$ 12.3) Body fat %( 30.7 $\pm$ 5.5 to 29.2 $\pm$ 3.8), Systolic B.P mmHg (134.9 $\pm$ 16.0 to 124.7 $\pm$ 9.5), Diastolic B.P (82.6 $\pm$ 7.0 to 79.4 $\pm$ 6.1), Pulse (76.6 $\pm$ 3.7 to 74.9 $\pm$ 2.5) from the baseline to 12th months follow-up. Most of the study revealed that there was improvement in BMI after educational inventions although it was not statistically significant (<0.01)

#### CONCLUSIONS

It was observed through the systematic review that majority of the studies were OPD or clinic based studies. Duration of study period across studies varied greatly and hence interpreting the impact of health education based on this becomes difficult. Blinding was not followed in any of the studies and hence bias arising out of this serves as limitation. Demographic background of participants did not provide any added value to the objective of our study. The KAP assessed across studies revolved around similar themes. Majority of the studies showed a significant improvement in KAP scores assessed.

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