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Original Article

Community Health Worker Interventions in Type 2 Diabetes Mellitus Patients: Assessing the Feasibility and Effectiveness in Rural Central India

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ABSTRACT

Background: Globally, across high as well as low-income countries, there is a sub-optimal glycemic control amongst Type 2 diabetes mellitus patients. Community- based programmes with the help of community health workers (CHWs) have been tried to offer culturally appropriate care leading to positive impact on glycemic control. **Methods:** We planned this open-label randomised controlled trial to assess the possibility of CHWs interventions in a rural community in central India. We designed this study to compare glycaemic control, lipid profile, blood pressure and anthropometric measurements between patients in the CHW intervention group and those in the standard therapy group. The intervention group was offered CHW interventions in the form of home visits, health education, patient diary, telephonic reminders etc as compared to standard care group that received usual care. **Results:** We included a total of 299 patients in our study (standard care group n= 146 and intervention group n= 153) and followed them for a period of 6 months (96.98% follow up data) and recorded outcome variables (fasting blood sugar, post-prandial blood sugar, glycosylated haemoglobin, lipid profile, blood pressure) at the start and end of the study. Both the standard care group and intervention group showed improved in their glycemic indices at the end of the study. We established no statistical difference between the intervention and the standard care group at the end of the study. The mean reduction of HbA1c and fasting blood sugar was more in the intervention group as compared to the standard care group. **Conclusion:** Our study demonstrated a trend towards improvement in glycemic indices in the intervention group as compared to the standard care group.
Key words: Type 2 diabetes mellitus, Community health worker interventions, Community-based programmes, Management.

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INTRODUCTION

The latest International Diabetes Federation (IDF) statistics report that more than 415 million patients in the age group of 20-79 years worldwide have diabetes, which amounts to 1 in 11 people afflicted with this non-communicable disease (NCD). These numbers are likely to increase to > 8 million by the year 2040. Approximately 5.0 million deaths are attributable to diabetes out of which about 75% of those with diabetes were living in low- and middle-income countries.[1] The UKPDS has proven beyond doubt that adequate control of blood glucose can minimize vascular complications of diabetes.[2] A metanalysis of four trials (ACCORD, ADVANCE, UKPDS and VADT) done by the collaborators on trials of lowering glucose group (CONTROL) concluded that more intensive glucose control is important for the prevention of long-term microvascular complications in adults with type 2 diabetes.[3] Most recently, the STENO2 study reported an increased survival of 7.9 years, if comprehensive control was instituted, over a follow-up of 22 years.[4] Based on this and other studies, the American diabetes association and other organizations now recommend glycated Hb (HbA1c) levels of 7 or less.

Globally, across both low and high income countries- including India; the glycaemic control in patients with diabetes is usually not optimal in a substantial proportion (typically 40%–60%).Therapeutic inertia from physician to tolerate "mild" hyperglycaemia as well as "low" expectations from patients have been identified as important contributors.[5] Barriers to optimal glycaemic control from an Indian perspective was reviewed and lack of awareness of the disease and its management was identified as a major factor.[6]

Community-based programmes have been found to be effective in increasing awareness about diabetes and complications. Community health workers (CHWs) who share cultural, linguistic economic backgrounds of patients will have a deeper understanding and so form closer relationships with the communities they serve. CHW interventions provide culturally appropriate care and resolution of health disparities. Several randomised controlled trials have demonstrated the positive impact of CHW intervention in knowledge, glycaemic control, low-density lipoprotein level and other risk factor control.[7] However, the feasibility and effectiveness of such a programme have been evaluated in India sparsely,[8] which is a country of diverse communities. Hence this study was planned to assess the possibility of CHWs interventions in a rural community in Central India. The objectives of the study were to compare glycaemic control, lipid profile, blood pressure and anthropometric measurements between patients in the CHW intervention group and those in the standard therapy group.

METHODOLOGY

Ethics statement: Approval was obtained from the institutional ethics committee prior to the commencement of the study and informed consent was taken from all patients.

Study design and settings: The study was open-label randomised controlled trial comparing the intervention with CHWs in T2DM patients as compared to usual care; conducted in a tertiary care teaching institute (Mahatma Gandhi Institute of Medical Sciences) situated in a rural district in Maharashtra. This study was done for a period of 6 months.

Sample size estimation: The conventional methods of sample size calculation for estimating a sufficient sample size in a randomized trial comparing two conditions, the number of participants in each group is

determined based on 3 parameters: type I error, desired statistical power and an anticipated effect size for a relevant test statistic. So with these general conventions we specified a 5% type I error as tolerable and power as 80%.The primary outcome of change in glycosylated haemoglobin (HbA1c) is a continuous variable. The UKPDS concluded that a reduction of 0.5% in HbA1c results in 14% reduction in chronic complications,[9] PPBS. Hence to detect a difference of 0.5 in both the groups from baseline and standard deviation of 1.6 and with a 2-sided test, we estimated a total of 322 participants.

Study participants: The patients were recruited from those attending diabetic clinics as well as inpatients of this institution. We included the entire spectrum of patients with diabetes (recently detected as well as patients with diabetes and on treatment). Patients with terminal or debilitating illness; advanced cancers or disabling stroke, those with dementia and other psychiatric illness – unwilling to cooperate and non-consenting patients were excluded. Community health workers were chosen from the same community catered to by the medical college.

Randomisation: The study participants were randomised into 2 groups – the standard care group and the intervention group using block randomisation by a blinded investigator.

Study procedures

Standard care: Participants in the standard care received usual diabetes care in the hospital setting. They received an evidence-based prescription at enrolment which was based on the guidelines of management by American diabetes association. Their baseline history and physical examination were duly recorded with investigations like HbA1c, lipid profile, serum creatinine. Participants underwent an assessment study at baseline and again at the end of study that is 6 months.

Intervention group

Participants who were randomly assigned to the intervention group received a combination of face to face interaction by CHWs as well as telephonic reminders (Figure 1).

Training of CHWs: The CHWs received extensive training before the start of randomization process. The training program included the study of key concepts in patient-centered communications, epidemiology of diabetes and diabetes-related complications, skills training in behavioural change, evidence-based prescription, evaluation of drug adherence, recognizing the symptoms of hypoglycaemia and other complications related to diabetes and its pharmacotherapy, clinical outcome measurements and the intervention protocol. Training was given to CHWs in accordance with the standardized manual that was prepared. This manual was made from diabetes guidelines such as from American Diabetes Association (in the local vernacular language, Marathi and then translated into English). Manuals were prepared and the workshop comprised 7 days of intensive training

CHW visits: CHWs visited the study participants at their home every 6 weekly (at 6 weeks, 12 weeks, 18 weeks and end of study at 24 weeks).

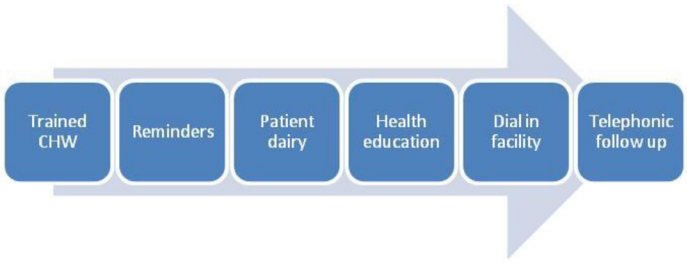

Figure 1: Study procedures in intervention group.

During each visit the CHW did the routine fasting (FBS) and post-prandial blood sugars (PPBS) of the study participant by capillary blood glucose estimation methods using a standard glucometer. Anthropometric measurements were taken and any complaints with regard to diabetes or drugs were documented. The CHW then assessed the adherence to drug therapy by the study participant based on direct interview, patient diary and pill counts. CHW reinforced the evidence-based prescription at every contact particularly stressing on smoking cessation, drug refilling and adherence, physical activity, dietary changes etc.

Telephonic follow-up and reminders: Every 15 days the CHW called the study participants according to a schedule. Any complaints or symptoms were noted and adherence to medications and lifestyle stressed.

Patient diary: Every patient in the intervention group received a diary with all the basic information about patient, the disease and information about treating doctor. The diary had targets to be achieved and advice on achieving those. The anthropometric measurements, blood glucose levels and pills counts were documented in the diary.

Health education: Every patient in the intervention group and the standard group received patient education booklet in the vernacular language highlighting the information about the disease, its symptoms, its complications, various medications and lifestyle measures.

Equipments and measurements: Anthropometric measurements were done by trained CHWs at each contact visit. Weight (in kilograms) was measured by a standardized electronic weighing scale kept on a firm horizontal surface. Weight as recorded in fasting state with a single layer of clothing and was recorded to nearest 0.5 kilograms (kg). Height (in centimetres) was measured by stadiometer attached to a wall. The study participant stood upright, without shoes with his/her back against the vertical board, heels together and eyes directed forward. Body Mass Index (BMI) was calculated using the formula weight in kilograms/height in meters squared. Waist circumference (in centimetres) was measured using a non-stretchable measuring tape. The study participants were asked to stand erect with both feet together. One layer of clothing was accepted. Waist circumference was measured at the smallest horizontal girth between the costal margins and the iliac crest at the end of expiration. Hip circumference (in centimetres) was measured using a non-stretchable measuring tape. The study participants were asked to stand erect with both feet together. One layer of clothing was accepted. Hip circumference was measured at the maximum circumference of the buttocks. Waist-Hip ratio was by taking the ratio of waist circumference to hip circumference.

Blood pressure was recorded in the sitting position in the right arm to the nearest 1 mmHg using the electronic OMRON machine (Omron Corporation, Tokyo, Japan, HEM 7200). The study participants were asked to rest for at least 5 minutes before the measurements. Two readings were taken 5 minutes apart and their mean will be taken as the blood pressure.

Blood sugar estimation, both FBS and PPBS, was done using capillary blood glucose estimation methods of Glucometers (Diachek©). FBS was after at least 8 hours of fasting and PPBS would be done 2 hrs after normal meals. Glycosylated haemoglobin (HbA1c) was measured by an automated analyser. Lipid profile – i.e. total cholesterol, triglyceride and high-density lipoprotein (HDL) was estimated by standard enzymatic methods using automated analyzer. Low-density lipoprotein (LDL) was calculated using Friedwald formula. These were assayed in the laboratory attached to the institution which is NABL accredited.

Statistical analysis

All data was collected on structured clinical record forms by the study investigator and transferred to Microsoft excel. This data was then transferred electronically to statistical software STATA version 13 which was used for analysis. All the parametric quantitative data was expressed in

terms of means± standard deviation (SD); non parametric quantitative variables as median and interquartile ranges (IQRs) and all categorical variables were presented as numbers (percentages). A Mann-Whitney *U* or a Kruskal-Wallis test was used to analyze continuous nonparametric data; continuous parametric data were analyzed using a student's *t* test or analysis of variance when appropriate. Categorical data were analyzed by chi-square test. Descriptive statistics were computed to assess the study sample's characteristics. A paired *t* test was used to compare the baseline and end of study parameters in both the standard care and intervention groups. To assess the effect of intervention at end of the study adjusting for baseline values and drug adherence, analysis of covariance (ANCOVA) was used. The outcomes in the standard care and the intervention group at the end of the study were compared using independent t test. The level of significance was taken as < 0.05.

RESULTS

A total of 302 patients were enrolled in the study. One patient died after enrolment and before randomisation and 2 patients refused to participate in the study after enrolment. Finally, a blinded investigator using block randomisation technique randomised 299 patients. Ultimately, there were 146 patients in the standard care group and 153 patients in the intervention group. We were able to include 299 patients out of estimated 322 patients in our study (92.8%). The study was carried out for a period of 6 months. The outcome variables were recorded at the baseline as well as the end of the study period (6 months). Outcome variables could be collected for 139 patients in the standard care group (n= 146; 1 patient died after baseline visit and 6 patients refused end of study visit). In the intervention group outcome variables were recorded in 151 patients (n=153; 1 patient died after baseline visit and 1 patient died after the 18th week visit). Follow up data and end of study data was obtained for 96.98% of patients in both the groups. Two CHWs were adequately trained for the study. The patients in the intervention group received 4 home visits by CHWs and 12 telephonic reminders by the CHWs.

The patients in the study were in their mid-fifties (56.56 ±10.95), mostly males (56.86%), one-third were current tobacco users and had similar socioeconomic score. The patients were mostly normotensive, marginally overweight (mean BMI 24.14 ± 4.86) with uncontrolled glycaemic status (mean HbA1c 8.16 ± 2.27) and had dyslipidaemia. The patients in both the groups were similar when their baseline characteristics were compared (Table 1).

Patients in standard group (n=146) were seen by CHW at baseline and then at end of study. For the 6 months, in between, standard (usual) care was provided to these patients. At the end of 6 months the patients in the standard care group (Table 2) showed significant reduction in their FBS (172.19 ± 67.80 vs. 153.40 ± 50.85; p = 0.0016), PPBS (260.62 ± 106.19 vs. 236.17 ± 89.37; p =0.01) and HbA1c (8.03 ± 2.13 vs. 7.64 ± 1.79; p = 0.0058). The standard care patients also exhibited significant improvement in their HDL (41.27 ± 11.59 vs. 44.57 ± 13.33; p = 0.0002) and serum creatinine (1.14 ± 0.36 vs. 0.97 ± 0.39; p = 0.000). There was no significant change in systolic or diastolic blood pressure, weight and waist circumference.

The patients in the intervention group received 4 CHWs visits, 12 telephonic reminders apart from the usual care during the 6-month period. The patients in the intervention group showed significant improvement in their glycaemic status (Table 3) as revealed by decrease in FBS (177.14 ± 73.58 vs. 148.33 ± 67.10; p = 0.0000), PPBS (251.25 ± 108.63 vs.226.11 ± 108.09; p = 0.0005) and HbA1c (8.29 ± 2.42 vs.7.63 ± 2.16; p = 0.0000). There was also a significant improvement in the lipid profile of these patients as demonstrated by significant improvement in triglycerides (168.02 ± 113.39 vs. 144.86 ± 101.93; p = 0.0007). The LDL cholesterol showed a mean decrease at end of 6months (107.19 ± 42.79

Table 1: Baseline Characteristics of Study Population.

Characteristics		Standard care (n= 146)	Intervention group (n= 153)	P value
Demographic characteristics				
Age (yrs.) (95% CI)	Mean ±SD	57.42 ± 10.95 (55.63 ,59.22)	55.69 ± 10.94 (53.95, 57.44)	0.17
Female	N (%)	60(41.10)	69 (45.10)	
Currently uses tobacco products	N (%)	50(34.25)	58 (37.91)	
Socio-economic score (95% CI)	Mean± SD	32.08 ± 8.32 (30.72, 33.44)	31.65 ± 8.54 (30.29,33.02)	0.67
Clinical/anthropometric parameters				
SBP (mm of Hg) (95% CI)	Mean± SD	128.34 ± 20.28 (125.02,131.65)	125.14 ± 16.80 (122.46, 127.83)	0.14
DBP (mm of Hg) (95% CI)	Mean± SD	77.34 ± 11.37 (75.48, 79.20)	77.04 ± 9.99 (75.44 ,78.64)	0.81
Height (in cms) (95% CI)	Mean± SD	156.23 ± 10.02 (154.59 ,157.87)	155.75 ± 10.72 (154.04 ,157.46)	0.69
Weight (in kgs) (95% CI)	Mean± SD	59.97 ± 14.41 (57.61 ,62.33)	59.29 ± 16.30 (56.69 ,61.89)	0.70
BMI(kg/m2) (95% CI)	Mean± SD	24.37 ± 5.23 (23.51, 25.22)	23.91± 4.48 (23.19 ,24.63)	0.42
Waist circumference (in cms) (95% CI)	Mean± SD	86.29 ± 14.08 (83.99 ,88.59)	84.71 ± 12.39 (82.73,86.69)	0.30
Hip circumference (in cms) (95% CI)	Mean± SD	94.28 ± 17.02 (91.49 ,97.07)	92.26 ± 8.40 (90.92,93.60)	0.19
W/H ratio (95% CI)	Mean± SD	0.99 ± 0.47 (0.88,1.033)	0.92 ± 0.08 (0.90,0.93)	0.29
FBS(mg/dl) (95% CI)	Mean± SD	172.19 ± 67.81 (161.10,183.28)	177.14 ± 73.58 (165.39 ,188.89)	0.55
PPBS(mg/dl) (95% CI)	Mean± SD	260.62 ± 106.19 (243.25,277.99)	251.25 ± 108.63 (233.90 ,268.61)	0.45
HbA1c (95% CI)	Mean± SD	8.03 ± 2.13 (7.68, 8.37)	8.29 ± 2.41 (7.91015 ,8.68)	0.31
Total cholesterol (95% CI)	Mean± SD	173.50 ± 38.37 (167.23,179.78)	183.81 ± 48.69 (176.03 ,19 1.59)	0.04
LDL (95% CI)	Mean± SD	99.79 ± 32.73 (94.44,105.15)	107.19 ± 42.79 (100.36 ,114.03)	0.01
HDL (95% CI)	Mean± SD	41.27 ± 11.59 (39.37 ,43.17)	41.38 ± 13.83 (39.17 ,43.59)	0.94
TG (95% CI)	Mean± SD	159.33 ± 94.61 (143.8544 ,174.8072)	168.02 ± 113.39 (149.9096, 186.1335)	0.47
VLDL (95% CI)	Mean± SD	32.89 ± 21.37 (29.40, 36.39)	35.11 ± 24.61 (31.18, 39.04)	0.41
Serum creatinine (mg/dl) (95% CI)	Mean± SD	1.14 ± 0.36 (1.08 ,1.19)	1.41 ± 3.21 (0.90 ,1.93)	0.29

Table 2: Baseline and end of study parameters of the standard care group.

Characteristics	Baseline	End of study	P value
SBP (mm of Hg) (95% CI)	128.34 ± 20.28 (125.02,131.65)	128.69 ± 17.53 (125.76,131.64)	0.37
DBP (mm of Hg) (95% CI)	77.34 ± 11.37 (75.48, 79.20)	74.86 ± 19.79 (71.62 ,78.10)	0.16
Weight (in kgs) (95% CI)	59.97 ± 14.41 (57.61 ,62.33)	59.59 ± 12.62 (57.48 ,61.71)	0.57
BMI(kg/m2) (95% CI)	24.37 ± 5.23 (23.51, 25.22)	24.22 ± 4.38 (23.48 ,24.95)	0.41
Waist circumference (in cms) (95% CI)	86.29 ± 14.08 (83.99 ,88.59)	82.32 ± 22.74 (78.59,86.04)	0.02
W/H ratio (95% CI)	0.96 ± 0.47 (0.88,1.03)	0.88 ± 0.21 (0.84,0.91)	0.05
FBS(mg/dl) (95% CI)	172.19 ± 67.80 (161.10,183.28)	153.40 ± 50.85 (144.87 ,161.93)	0.0016
PPBS(mg/dl) (95% CI)	260.62 ± 106.19 (243.25,277.99)	236.17 ± 89.37 (221.18 ,251.15)	0.01
HbA1c (95% CI)	8.03 ± 2.13 (7.68, 8.38)	7.64 ± 1.79 (7.34, 7.94)	0.0058
Total cholesterol (95% CI)	173.51 ± 38.37 (167.23,179.78)	169.08 ± 56.72 (159.79,178.35)	0.32
LDL (95% CI)	99.79 ± 32.73 (94.44,105.15)	99.83 ± 45.43 (92.21 ,107.45)	0.91
HDL (95% CI)	41.27 ± 11.59 (39.37 ,43.17)	44.57 ± 13.33 (42.34 ,46.81)	0.0002
TG (95% CI)	159.33 ± 94.61 (143.85 ,174.81)	163.58 ± 100.46 (146.73, 180.43)	0.65
VLDL (95% CI)	32.89 ± 21.37 (29.40, 36.39)	32.57 ± 19.37 (29.32 ,35.82)	0.75
Serum creatinine (mg/dl) (95% CI)	1.14 ± 0.36 (1.08 ,1.19)	0.97 ± 0.39 (0.90 ,1.03)	0.0000

Table 3: Baseline and end of study parameters of the intervention group.

Characteristics	Baseline – 0 week (n=153)	24 week – end of study (n=151)	P value
SBP (mm of Hg) (95% CI)	125.14 ± 16.80 (122.46, 127.83)	126.04 ± 22.79 (122.39, 129.68)	0.63
DBP (mm of Hg) (95% CI)	77.04 ± 9.99 (75.44, 78.64)	80.23 ± 39.24 (72.78, 85.57)	0.53
Weight (in kgs) (95% CI)	59.29 ± 16.30 (56.69, 61.89)	58.68 ± 13.68 (55.49, 60.33)	0.09
BMI(kg/m2) (95% CI)	23.91 ± 4.48 (23.19, 24.63)	23.84 ± 4.50 (22.69, 24.37)	0.11
Waist circumference (in cms) (95% CI)	84.71 ± 12.39 (82.73, 86.69)	85.72 ± 13.86 (81.89, 87.29)	0.90
W/H ratio (95% CI)	0.92 ± 0.08 (0.90, 0.93)	0.91 ± 0.13 (0.88, 0.93)	0.28
FBS(mg/dl) (95% CI)	177.14 ± 73.58 (165.39, 188.89)	148.33 ± 67.10 (137.62, 159.05)	0.0000
PPBS(mg/dl) (95% CI)	251.25 ± 108.63 (233.90, 268.61)	226.11 ± 108.09 (205.52 240.79)	0.0005
HbA1c (95% CI)	8.29 ± 2.42 (7.91, 8.68)	7.63 ± 2.16 (7.16, 7.89)	0.0000
Total cholesterol (95% CI)	183.81 ± 48.69 (176.03, 191.59)	173.11 ± 48.18 (165.42, 180.81)	0.02
LDL (95% CI)	107.19 ± 42.79 (100.36, 114.03)	98.38 ± 32.42 (91.65, 102.54)	0.01
HDL (95% CI)	41.38 ± 13.83 (39.17, 43.59)	47.39 ± 28.29 (42.19, 51.34)	0.03
TG (95% CI)	168.02 ± 113.39 (149.91, 186.13)	144.86 ± 101.93 (128.58, 161.14)	0.0007
VLDL (95% CI)	35.11 ± 24.61 (31.18 39.04)	29.86 ± 20.49 (26.17, 32.77)	0.0005
Serum creatinine (mg/dl) (95% CI)	1.41 ± 3.22 (0.90, 1.93)	1.01 ± 0.61 (0.91, 1.11)	0.12

vs. 98.38 ± 32.42; p = 0.01) and the HDL cholesterol showed a mean increase by around 6 mg/dl (41.38 ± 13.83 vs. 47.39 ± 28.29). There was no significant change in systolic or diastolic blood pressure, weight and waist circumference. We assessed the effect of intervention at end of the study after adjusting for baseline values and drug adherence (Table 4) and did not find any difference in any outcome variables.

We compared the predefined outcome variables at the end of the study (6 months) between the standard care and the intervention group. No difference was found in the glycaemic status, the blood pressure, any anthropometric measurements or lipid profile between the two groups (Table 5).

DISCUSSION

In the present study, we were able to demonstrate that CHWs interventions could be successfully delivered to the diabetes patients in the intervention group in the form of 4 home visits and 12 telephonic reminders. The patients in both the standard care and the intervention group had similar demographic, anthropometric and glycaemic profile. At the end of 6 months the study, we could establish that patients in both the group showed improvement in their glycaemic indices and their lipid profiles. But at the end of the study there was no statistical difference in the outcome variables between both the groups.

A recently published study[10] investigated the effects of CHWs interventions on poorly controlled diabetic patients (HbA1C> 8) in the Latino population. At the end of 52 weeks; after adjusting for baseline values and covariates, participants in the CHW group had an HbA_{1c} level that was 0.51% lower (95% CI, −0.94% to −0.08%) than that of participants in the enhanced usual care group. The reduction in SBP of 4.62 mm Hg (95% CI, −9.01 to −0.24 mm Hg) was not statistically significant in unadjusted models. No significant differences in LDL levels (mean difference, −8.2 mg/dL; 95% CI, −18.8 to 2.3 mg/dL) or any of the preplanned secondary outcomes were observed. In a study done in rural Australia amongst 213 adults with poorly controlled diabetes (HbA1c > 8.5%) and significant comorbidities. At baseline, mean age of participants was

Table 4: Baseline and end of study parameters of the intervention group adjusting for baseline values and drug adherence.

Characteristics	Baseline – 0 week (n=153)	24 week – end of study (n=151)	P value
SBP (mm of Hg) (95% CI)	125.14 ± 16.80 (122.46, 127.83)	126.04 ± 22.79 (122.39, 129.68)	0.984
DBP (mm of Hg) (95% CI)	77.04 ± 9.99 (75.44, 78.64)	80.23 ± 39.24 (72.78, 85.57)	0.616
Weight (in kgs) (95% CI)	59.29 ± 16.30 (56.69, 61.89)	58.68 ± 13.68 (55.49, 60.33)	0.553
BMI(kg/m2) (95% CI)	23.91 ± 4.48 (23.19, 24.63)	23.84 ± 4.50 (22.69, 24.37)	0.995
Waist circumference (in cms) (95% CI)	84.71 ± 12.39 (82.73, 86.69)	85.72 ± 13.86 (81.89, 87.29)	0.556
W/H ratio (95% CI)	0.92 ± 0.08 (0.90, 0.93)	0.91 ± 0.13 (0.88, 0.93)	0.952
FBS(mg/dl) (95% CI)	177.14 ± 73.58 (165.39, 188.89)	148.33 ± 67.10 (137.62, 159.05)	0.544
PPBS(mg/dl) (95% CI)	251.25 ± 108.63 (233.90, 268.61)	226.11 ± 108.09 (205.52 240.79)	0.674
HbA1c (95% CI)	8.29 ± 2.42 (7.91, 8.68)	7.63 ± 2.16 (7.16, 7.89)	0.48
Total cholesterol (95% CI)	183.81 ± 48.69 (176.03, 191.59)	173.11 ± 48.18 (165.42, 180.81)	0.10
LDL (95% CI)	107.19 ± 42.79 (100.36, 114.03)	98.38 ± 32.42 (91.65, 102.54)	0.30
HDL (95% CI)	41.38 ± 13.83 (39.17, 43.59)	47.39 ± 28.29 (42.19, 51.34)	0.276
TG (95% CI)	168.02 ± 113.39 (149.91, 186.13)	144.86 ± 101.93 (128.58, 161.14)	0.01
VLDL (95% CI)	35.11 ± 24.61 (31.18 39.04)	29.86 ± 20.49 (26.17, 32.77)	0.051
Serum creatinine (mg/dl) (95% CI)	1.41 ± 3.22 (0.90, 1.93)	1.01 ± 0.61 (0.91, 1.11)	0.874

Table 5: Comparison of outcomes in standard care group and intervention group at the end of 6 months.

Characteristics		Standard care (n=139)	Intervention group (n = 151)	P value
SBP (mm of Hg) (95% CI)	Mean± SD	128.69 ± 17.53 (125.76,131.64)	126.03 ± 22.79 (122.39 ,129.68)	0.651
DBP (mm of Hg) (95% CI)	Mean± SD	74.86 ± 19.79 (71.62 ,78.10)	80.23 ± 39.24 (72.78, 85.57)	0.644
Weight (in kgs) (95% CI)	Mean± SD	59.59 ± 12.62 (57.48 ,61.71)	58.68 ± 13.68 (55.49, 60.33)	0.556
BMI(kg/m2) (95% CI)	Mean± SD	24.22 ± 4.38 (23.48 ,24.95)	23.84 ± 4.50 (22.69 ,24.37)	0.474
Waist circumference (in cms) (95% CI)	Mean± SD	82.32 ± 22.74 (78.59,86.04)	85.72 ± 13.86 (81.89 ,87.29)	0.644
W/H ratio (95% CI)	Mean± SD	0.88 ± 0.21 (0.84 ,0.91)	0.91 ± 0.13 (0.88 ,0.93)	0.879
FBS(mg/dl) (95% CI)	Mean± SD	153.40 ± 50.85 (144.87 ,161.93)	148.33 ± 67.10 (137.62, 159.05)	0.654
PPBS(mg/dl) (95% CI)	Mean± SD	236.17 ± 89.37 (221.18 ,251.15)	226.11 ± 108.09 (205.52, 240.79)	0.391
HbA1c (95% CI)	Mean± SD	7.64 ± 1.79 (7.34, 7.94)	7.63 ± 2.16 (7.16 ,7.89)	0.946
Total cholesterol (95% CI)	Mean± SD	169.08 ± 56.72 (159.79,178.35)	173.11 ± 48.18 (165.42,180.81)	0.67
LDL (95% CI)	Mean± SD	99.83 ± 45.43 (92.21 ,107.45)	98.38 ± 32.42 (91.65,102.54)	0.757
HDL (95% CI)	Mean± SD	44.57 ± 13.33 (42.34 ,46.81)	47.39 ± 28.29 (42.19, 51.34)	0.286
TG (95% CI)	Mean± SD	163.58 ± 100.46 (146.73, 180.43)	144.86 ± 101.93 (128.58, 161.14)	0.055
VLDL (95% CI)	Mean± SD	32.57 ± 19.37 (29.32 ,35.82)	29.86 ± 20.49 (26.17 ,32.77)	0.249
Serum creatinine (mg/dl) (95% CI)	Mean± SD	0.97 ± 0.39 (0.90 ,1.03)	1.01 ± 0.61 (0.91 ,1.11)	0.824

47.9 years, mean HbA1c was 10.7% and BMI 32.5.[11] At follow-up, after 18 months, HbA1c reduction was significantly greater in the intervention group (−1.0% vs −0.2%, SE (diff) = 0.2, p = 0.02). There were no significant differences between the groups for blood pressure, lipid profile, BMI or renal function. A community-based participatory research method was used by Balagopal *et al.* in rural Gujarat by engaging trained CHWs as change agents from 1638 rural Indians. In 6 months, CHWs intervention significantly reduced blood glucose levels by 5.7 and 14.9 mg/dL for individuals with prediabetes and diabetes, respectively and systolic and diastolic blood pressure by 8 mm Hg and 4 mm Hg, respectively, in the overall population.[8,12] A study done among the primarily Native Hawaiian and Samoan ethnic minority community T2DM patients with HbA1c more than 10% showed a 2.2 ± 1.8% mean reduction in HbA1C in CHW intervention group as compared to only 0.2 ±1.5% mean reduction in hbA1c in those without CHW intervention.[13]

In a study is to explore the impact and feasibility of a pilot CHW intervention to improve diabetes management among Bangladeshi-American individuals with type 2 diabetes the authors established improvements in diabetes knowledge, exercise and diet to control diabetes, frequency of checking feet, medication compliance and self-efficacy of health and physical activity from baseline to 12 months. Additionally, there were decreases in A1C, weight and body mass index.[14]

In the Mexican American trial of CHWs (MATCH) 144 Mexican Americans were single-blinded, randomised to receive CHW intervention in the form of 36 home visits over 2 years. Intervention participants showed significantly lower HbA1c levels than control participants at both years. There was no effect on blood pressure control, glucose

self-monitoring or adherence to medications or diet. Intervention participants increased physical activity from a mean of 1.63 days per week at baseline to 2.64 days per week after 2 years.[15]

In a randomised controlled trial, Diabetes Care in American Samoa (DCAS) CHW interventions were given to participants for 12 months. After adjustment for confounders, the intervention group was found to have a decrease in HbA1c of 0.28 units per year (95% confidence interval [CI], −0.64 to 0.07) during DCAS (intervention). HbA1c decreased by 0.88 units per year (95% CI, −1.31 to −0.45) during the year after the intervention. HbA1c of the control group did not significantly change during DCAS (usual care) but decreased by 1.31 units per year (95% CI, −1.72 to −0.91) during its intervention.[16]

In our study, there was a mean reduction of approximately 18.79 mg/dl of FBS in standard care group as compared to 28.81 mg/dl mean reduction of FBS in the intervention group. Similarly, the mean reduction in HbA1c was 0.39% in the standard care group as compared to mean reduction of 0.66% in HbA1c in the intervention group. Though there was a reduction in HbA1c in both the groups we anticipate that the results could have been significant if there were 650 participants in each arm as against approximately only 150 participants in each arm. There is a trend towards improvement in the intervention arm, but the change was small for a sample size of about 150.

Most of the randomised trials looking at CHW interventions for improvement in glycaemic profile have been carried out for a longer duration (at least more than 12months). Our study was carried out for a short duration of 6 months. HbA1c levels measure a change over three months. Interventions take time and probably the trend towards HbA1c reduction would have been more evident, had intervention been there for a longer period (more than 12 months) as evident from literature. Longer follow-ups could have helped us better understand and demonstrate these changes.

A systematic review by Seidu *et al.*[17] demonstrated that most of the randomised controlled trials utilizing interventions by community participation were heterogeneous in terms of interventions as well as participants. It validated that the use of telemedicine, clinician reminders and feedback had mixed results, HbA1c showed consistent improvement; but educational interventions did not have any positive impact. One systematic review by Tariana *et al.*[18] aimed to synthesize HbA1c outcomes of CHW delivered interventions for Latinos with T2DM. It concluded that though all the 12 trials were methodologically diverse and inconsistent in reporting key information but most of these trials reported significant improvements in HbA1c.

So, the evidence in the literature is robust that the CHWs interventions in T2DM improve HbA1c.But there are not many studies which look at the acceptability and feasibility of these interventions. A qualitative study done to explore the benefits of CHW delivered peer support for diabetes from the patient's perspectives reported that the patients preferred the CHW to be knowledgeable and have personal experience in managing either their own diabetes or assisting a family member with diabetes. But it also raised concerns of patients regarding confidentiality and privacy.[19]

Our study was one of the few randomised controlled trials done in T2DM patients in India studying the efficacy of CHWs interventions. We had enrolled the entire spectrum of T2DM patients irrespective of their glycaemic status, diabetes-related complications or presence of co-morbidities. The patients suffering from NCDs and hailing from rural areas, like ours, have additional problems of lack of health care facilities and access to the same. Hence our study becomes more pertinent in this context. One major limitation of our study was the time duration for which the study was done and the underpowered study sample.

CONCLUSION

CHW interventions in T2DM may help to improve to HbA1c. Though our study did not show a statistical difference in the standard care and the intervention groups, follow up for a longer duration may have produced better results. CHW interventions have been found to be culturally appropriate and have had a positive impact in glycemic control and should be capitalized as an effective tool in the management of type 2 diabetes mellitus patients.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

ABBREVIATIONS

IDF: International Diabetes Federation; **NCD:** Non-communicable diseases; **UKPDS:** United Kingdom Prospective Diabetes study; **ACCORD:** Action to control cardiovascular risk in diabetes; **ADVANCE:** Action in diabetes and vascular disease; **VADT:** Veterans affairs diabetes trials; **CHW:** Community health worker; **T2DM:** Type 2 diabetes mellitus; **FBS:** Fasting blood sugar; **PPBS:** Post prandial blood sugar; **BMI:** Body Mass Index; **HDL:** High density lipoprotein; **LDL:** Low density lipoprotein; **TG:** Triglycerides; **VLDL:** Very low density lipoprotein; **NABL:** National accreditation bard for testing and calibration laboratories; **SBP:** Systolic blood pressure; **DBP:** Diastolic blood pressure; **W/H ratio:** Waist/hip ratio; **MATCH:** Mexican American trial of CHWs; **DCAS:** Diabetes Care in American Samoa.

SUMMARY

Type 2 diabetes mellitus is managed sub-optimally across the globe and community based interventions with the help of community health workers offer a culturally appropriate care leading to positive impact on glycemic control. Our study assessed the feasibility and effectiveness of CHW interventions in a rural community.in our study both the standard care group and intervention group showed improved in their glycaemic indices at the end of the study. We established no statistical difference between the intervention and the standard care group at the end of the study. The mean reduction of HbA1c and fasting blood sugar was more in the intervention group as compared to the standard care group. Our study demonstrated a trend towards improvement in glycaemic indices in the intervention group a compared to the standard care group.

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