

COMMUNITY INTERVENTIONAL TRIAL FOR CONTROL OF DIABETES AMONG RURAL POPULATION OF MAHARASHTRA

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Received : 10/03/2023
Received in revised form : 09/04/2023
Accepted : 20/04/2023

Keywords:

Diabetes Mellitus, Community Based Intervention, NCD, Rural.

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DOI:10.47009/jamp.2023.5.3.102

Source of Support: Nil,
Conflict of Interest: None declared

Int J Acad Med Pharm
2023; 5(3); 477-482



Abstract

Background: The transition from communicable to non-communicable diseases has occurred in India, with non-communicable diseases (NCDs) causing high morbidity and mortality. The majority of India's population lives in rural areas, resulting in a greater burden of undiagnosed diabetes. Early diagnosis and management of type 2 diabetes in rural areas can help prevent complications. Comprehensive Primary Health Care plays a crucial role in the prevention of these diseases, reducing morbidity, disability, and mortality at much lower costs. The objectives are to determine if community-based intervention delivered to community and healthcare workers in a rural area can be effective in controlling diabetes and if any beneficial effects can be sustained in the long term. **Materials and Methods:** The study was conducted in the Coverage area of two Primary Health Centers in Palghar District of Maharashtra from Jan 2018 to Dec 2022. It was a Cluster randomized controlled trial with 1850 people in each Sub-Center. Comprehensive community-based intervention was implemented in one Subcenter under Primary Health Centre of Kaman and second in the Primary Health Centre of Satpati in rural area of Maharashtra and its effect was assessed. **Result:** The baseline characteristics of the study population were similar in both sub-centers. The recommended Physical activity was less in both subcenters, Overweight was higher in Kaman, while central obesity was higher in both PHCs. The prevalence of Ischaemic Heart Disease was lower in Kaman. The prevalence of known cases of both Diabetes Mellitus and Hypertension was 3.4% in Kaman, 6 % in Satpati, while Suspected Diabetes Mellitus cases was higher in Kaman (37.9%) than in Satpati (31.4%). In Kaman there were 18.3% of confirmed cases of diabetes mellitus and after intervention it has reduced to 11.8%. There was a decrease of 6.5%. In Satpati there were 16.6% of confirmed cases of diabetes mellitus and after intervention it has reduced to 14.4%. There was a decrease of 2.2%. **Conclusion:** A high number of Diabetes Mellitus is found in rural population. 18.3% of the participants were newly diagnosed with Diabetes. Screening and early detection and treatment of Diabetes is highly needed in rural areas. Community-based intervention is equally important to focus on prevention, promotion, and enable lifestyle changes to prevent and control Diabetes and avoid risk factors.

INTRODUCTION

Epidemiological transition from communicable to non-communicable diseases has occurred in India.^[1]Non-Communicable Diseases (NCDs) are increasingly posing a significant public health concern due to the high morbidity and mortality associated with these diseases in India. Comprehensive Primary Health Care plays a crucial role in the primary and secondary prevention of several disease conditions, including non-

communicable diseases which currently contribute to over 60% of the mortality in India. Comprehensive primary health care reduces morbidity, disability, and mortality at much lower costs, and reduces the need for secondary and tertiary care by a substantial amount. It is estimated that 52% of all conditions can be managed at the primary care level.^[2]Cardiovascular diseases and diabetes represent a set of conditions that share common risk factors and for which there are a set of similar public health strategies related to health

promotion, prevention, and management. Tobacco use and exposure, unhealthy diet, physical inactivity, alcohol abuse, indoor and outdoor air pollution, stress, poverty (as a cause and a consequence), poor health-seeking behaviours, and limited access to health-care services are key factors associated with the onset and progression of NCDs. According to world diabetes atlas nearly one-fifth of all adults with diabetes in the world live in the South-East Asia Region. Current estimates indicate that 10.5% of the adult population, or 536.6 million people, have diabetes, of which 74.2 million reside in India. By 2045, 123 million individuals India's adult population will have diabetes. A further 46.9 million people have IGT, and this will increase to 76.6 million by 2045. India accounts for 1 in 12 of all adults living with diabetes worldwide. India has the second highest prevalence of diabetes among adults at 9.1% in the southeast Asian region. In the SEA Region, only 6.9% of total deaths under the age of 60 are associated with diabetes. About 1.1 million people die from diabetes related illnesses in India every year. It has been estimated by IDF that in India as many as more than half (53.1%) of all people with diabetes, are unaware of their disease.^[3] Unfortunately, the vast majority of India's population (70%) lives in rural areas.^[4] Screening for diabetes is seldom done in rural areas, resulting in a much greater burden of undiagnosed diabetes in rural areas.^[5] Most of these cases are type 2 diabetes. The earlier a person is diagnosed, and management initiated, the better the chances of preventing harmful and costly complications. There is an urgent need to screen, diagnose and provide appropriate care to people with diabetes. Diabetes is traditionally known as a "silent disease," exhibiting no symptoms until it progresses to severe target organ damage.

There were several studies done for the prevalence of Type 2 diabetes mellitus but most of them were conducted in urban setting. Present study was therefore undertaken as Community Interventional Trial for Control of Diabetes among rural population of Maharashtra, India.

The main purpose of the study is to know whether community-based intervention delivered to community and healthcare workers in a rural area can be effective in the control of Diabetes and whether any beneficial effects can be sustained in the long term.

Objectives

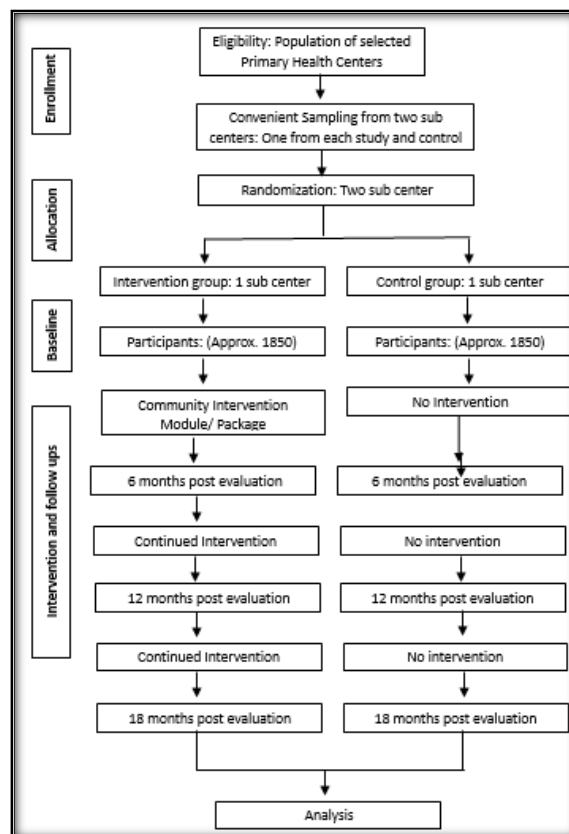
1. To find out the current status of Diabetes in the study area.
2. To implement comprehensive community-based intervention among the study group.
3. To assess the effect of comprehensive community-based intervention.
4. To recommend and implement comprehensive community-based intervention through Primary Health Care services.

MATERIALS AND METHODS

Study Location and Duration:

The study was conducted in the Coverage area of two Primary Health Centers of Palghar District of Maharashtra from Jan 2018 to Dec 2022.

Study design and participant flow:



Study Design

It is a community based on Cluster randomized controlled trial.

Inclusion and Exclusion Criteria

The study was conducted among residents of the study area with their consent including people with the age of more than 30 years irrespective of sex with any underlying conditions and excluding people with whom it was difficult to establish communication.

Sampling Technique and Randomisation

Sampling was done among two neighborhoods of Primary Health Centers (PHCs) and matched by similar demographic and socioeconomic characteristics. One community (Subcenter) within each Primary Health Center was selected randomly (Study area and Control area in the ratio of 1:1).

Participants

In a population of 1000, the proportion of people in the age group over 30 years is about 37%, implying about 370 people. Considering the normative sub-centre population of 5000, 1850 people (Clusters of 1850 people aged more than 30 Years) were selected for the baseline survey. Participants were classified

as Diabetic or non-diabetic following the WHO guidelines.

Intervention

A Comprehensive community-based intervention was implemented in the study area and its effect was assessed. Participants were assessed at baseline, 6 months, and 12 months and 18 Months. Subcenter 1 is the Primary Health Centre of Kaman and subcenter 2 is the Primary Health Centre of Satpati in rural area of Maharashtra. The intervention was designed in such way considering the risk factors, ongoing treatment, Healthcare delivery, Referral Linkage for Diabetes Mellitus given in study area. The intervention includes Group Counselling, Social awareness through local leaders, ZP members and DHO office, Healthcare workers training, Intense and Ongoing Screening, Early Diagnosis and Treatment, Referral linkage developed. Association with Public health authorities of the Palghar district for Health and Wellness centers at respective subcenters including its evaluation.

Outcomes

The outcome measured was the confirmed cases of diabetes at baseline, 6, 12, 18 months, diagnosed according to WHO Guidelines. Comparison of confirmed cases of Diabetes Mellitus across both the groups and the impact of Community Intervention trial on the status of Diabetes mellitus in the of study and control group of two PHCs.

Statistical Analysis

The data was stored in the MS Excel and data was analysed in IBM SPSS 22.0. Baseline characteristics of clusters and participants are summarized using Proportions. The Chi-square test was applied to find out the association between the risk factors and Diabetes. The logistic regression was applied to find out the predictors of Diabetes in Both the Subcenters.

RESULTS

Demographic characteristics of study population are presented in table 1. The baseline characteristics was almost similar in both the groups. Majority of the participants in both the sub-centres were between 31 to 40 years of age. This age group included 54.0% in PHC Kaman and 31.6% in Satpati PHC. The proportion of participants above 70-years age there were 3.2% and 9.4% participants respectively. The proportion of male was higher in Kaman (51.4%) and the Proportion of female is slightly higher in Satpati (50.2%). Majority of them educated upto 9th standard in Kaman (40.7%) and in Satpati (53.4%), only few people have completed graduation i.e. 5% in Kaman and 6.6% in Satpati. Almost most of them are housewife in both the centers and among the others majority of them are unskilled workers 17.8% in Kaman and 17.2% in Satpati. The proportion of Professional and skilled workers are more in Kaman

compared to the Satpati. The majority of participants were living in nuclear type of family in both the PHCs Kaman (70.1%) and Satpati (53.8%). The proportion of joint family is seen higher in the Satpati (39.9%) than kaman (26.1%). The maximum proportions of per capita income fall under 6000 in both the groups, kaman (75.1%), Satpati (76%).

Majority of the study participants doesn't have the history of Addiction; the proportion is higher among people in Kaman (89.3%) than Satpati (85.5%). The prevalence of Alcohol consumption is 2.8% in Kaman, and it is lesser compared to the prevalence in Satpati (8.1%) whereas the prevalence of Tobacco consumption is higher in Kaman (7%) compared to Satpati (5.1%). The prevalence of addiction in the family was higher in Satpati (14.5%) than the Kaman (10.7%). The prevalence of Recommended Physical activity (Daily Exercise) was less in both the subcentre, and the prevalence is lesser in Kaman (5.2%) compared to the Satpati (12.8%). Most of the participants consumes 2000 to 2499 Kcal/Day in both groups. Few participants were consuming < 1500 kcal and >2500 kcal in both groups. Majority of the people consume almost the daily required protein per day (60 to 89 gms) in both Kaman (47.7%) and Satpati (68.6%). Very a smaller number of participants consume very less proteins per day than the daily requirements in both Kaman (8.5%) and Satpati (5.9%).

In this study majority of the study participants was having their BMI under Normal Range which is 50.8% in Kaman and 55.6% in Satpati. The prevalence of obesity was normal in both (8.8%), but the Prevalence of Overweight is higher in the Kaman (36.7%). The prevalence of central obesity was higher among participants belonging to both the Primary subcentres and it is almost similar in both the PHCs Kaman (41.5%) and in Satpati (41.1%). One of the determinants of Diabetes Mellitus was family issues and stress, the prevalence of which is 1.7% in Satpati and 0.6% in Kaman. The Diabetes Mellitus runs in the family, in this study the prevalence of Diabetes Mellitus in any of their family member was 3% in Kaman and it is slightly higher than Satpati where the prevalence was only 1.7%. But, the prevalence of Ischaemic Heart Disease in any of their family member was 0.8% in Kaman and it is slightly lower than Satpati where the prevalence was only 1.1%.

The Prevalence of known case of both Diabetes Mellitus and Hypertension was 3.4% in Kaman that is lesser than the Prevalence in Satpati (6%). The number of Suspected cases of Diabetes Mellitus is higher in Kaman (37.9%) whereas in the Satpati it is 31.4%. The number of confirmed cases of Diabetes Mellitus in community of Kaman was 18.3% and it is little higher than the Satpati where it was 16.6%.

Table 1: Baseline characteristics of clusters and participants by study group.

Socio Demographic Characteristics	Subcentre 1n (%)	Subcentre 2n (%)
Age (in Years)		
31 to 40	999 (54%)	584 (31.6%)
41 to 50	365 (19.7%)	384 (20.8%)
51 to 60	263 (14.2%)	382 (20.6%)
61 to 70	164 (8.9%)	327 (17.7%)
> 70 Years	59 (3.2%)	173 (9.4%)
Gender		
Male	950 (51.4%)	921 (49.8%)
Female	900 (48.6%)	929 (50.2%)
Education		
Illiterate	264 (14.3%)	199 (10.8%)
1st to 9th std	753 (40.7%)	987 (53.4%)
SSC	485 (26.2%)	369 (19.9%)
HSC	249 (13.5%)	167 (9.0%)
Graduation	93 (5%)	122 (6.6%)
Post Graduation	6 (0.3%)	6 (0.3%)
Occupation		
Unemployed	93 (5%)	260 (14.1%)
Housewife	729 (39.4%)	755 (40.8%)
Professional	102 (5.5%)	34 (1.8%)
Skilled	290 (15.7%)	232 (12.5%)
Unskilled	329 (17.8%)	319 (17.2%)
Business	307 (16.6%)	250 (13.5%)
Type of Family		
Nuclear	1296 (70.1%)	995 (53.8%)
Joint	483 (26.1%)	739 (39.9%)
Three Generation	71 (3.8%)	116 (6.3%)
Per Capita Income		
< Rs 1500	129 (7%)	128 (6.9%)
Rs 1500 to 2999	438 (23.7%)	417 (22.5%)
Rs 3000 to 4499	530 (28.6%)	518 (28%)
Rs 4500 to 5999	293 (15.8%)	345 (18.6%)
Rs 6000 to 7499	184 (9.9%)	158 (8.5%)
Rs 7500 to 8999	106 (5.7%)	110 (5.9%)
> Rs 9000	170 (9.2%)	166 (9%)

Table 2: Prevalence of Addiction

Characteristics	Subcenter 1	Subcenter 2
Addiction		
Absent	1652 (89.3%)	1582 (85.5%)
Alcohol	51 (2.8%)	150 (8.1%)
Tobacco	129 (7%)	94 (5.1%)
Multiple	18 (1%)	24 (1.3%)
Addiction in Family Members		
Present	198 (10.7%)	268 (14.5%)
Absent	1652 (89.3%)	1582 (85.5%)

Table 3: Prevalence of Recommended Physical Activity

Physical Activity (Daily Exercise)	Subcenter 1	Subcenter 2
Present	96 (5.2%)	236 (12.8%)
Absent	1754 (94.8%)	1614 (87.2%)

Table 4: Per Day Calories and Protein consumption

Characteristics	Subcenter 1	Subcenter 2
Per Day calories consumption		
>1500 Kcal	73 (3.9%)	43 (2.3%)
1500 to 1999 Kcal	570 (30.8%)	496 (26.8%)
2000 to 2499 Kcal	1057 (57.1%)	1269 (68.6%)
>2500 Kcal	150 (8.1%)	42 (2.3%)
Per Day Proteins Consumption		
<30 gms	157 (8.5%)	109 (5.9%)
30 to 59 gms	480 (25.9%)	366 (19.8%)
60 to 89 gms	882 (47.7%)	1321 (71.4%)
>90 gms	331 (17.9%)	54 (2.9%)

Table 5: Prevalence of Obesity

Characteristics	Subcenter 1	Subcenter 2
BMI		
18.4 and less	69 (3.7%)	58 (3.1%)
18.5 to 24.9	939 (50.8%)	1028 (55.6%)
25 to 29.9	679 (36.7%)	601 (32.5%)

30 and more	163 (8.8%)	163 (8.8%)
Central Obesity		
Present	768 (41.5%)	760 (41.1%)
Absent	1082 (58.5%)	1090 (58.9%)

Table 6: Prevalence of Comorbidities

Characteristics	Subcenter 1	Subcenter 2
Family History of Issues and Stress		
Present	11 (0.6%)	31 (1.7%)
Absent	1839 (99.4%)	1819 (98.3%)
Past History of DM HTN		
Present	63 (3.4%)	111 (6%)
Absent	1787 (96.6%)	1739 (94%)
Family History of DM		
Present	56 (3%)	32 (1.7%)
Absent	1794 (97%)	1818 (98.3%)
Family History of IHD		
Present	14 (0.8%)	21 (1.1%)
Absent	1836 (99.2%)	1829 (98.9%)

Table 7: Suspected and Confirmed cases of Diabetes Mellitus

Characteristics	Subcenter 1	Subcenter 2
Suspected Diabetes Mellitus		
Present	702 (37.9%)	581 (31.4%)
Absent	1148 (62.1%)	1269 (68.6%)
Confirmed Diabetes Mellitus (DM)		
Present	338 (18.3%)	307 (16.6%)
Absent	1512 (81.7%)	1543 (83.4%)

Post Intervention Results:

Table 8: Number of confirmed cases of Diabetes before and after Intervention

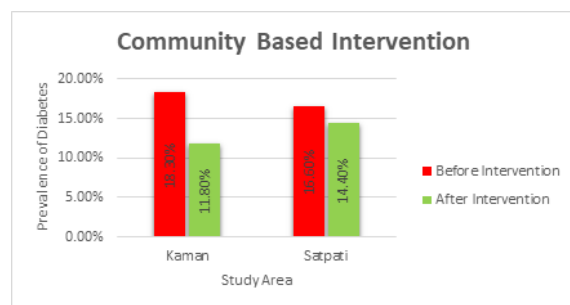
Confirmed case of Diabetes Mellitus	Subcenter 1	Subcenter 2
Before Intervention	218 (11.8%)	266 (14.4%)
After Intervention	1632 (88.2%)	1584 (85.6%)

There is statistically significant difference in number of confirmed cases of Diabetes Mellitus across different risk factors in both the groups. In Kaman there is significant difference in number of cases of Diabetes Mellitus across the following factors such as Age, Gender, Education, Family Types, Total Family Members, Per capita Income, Addictions, Addictions in family, Daily Exercise, Per Capita Calories Intake, Body Mass Index, Central Obesity, Family History of Diabetes Mellitus, Hypertension, Ischaemic Heart Disease.

In Satpati there is significant difference in number of confirmed cases of Diabetes Mellitus across the following factors such as Age, Education, Occupation, Family Types, Total Family Members, Per capita Income, Addictions, Addictions in family, Daily Exercise, Per Capita Calories Intake, Body Mass Index, Central Obesity, Family History of Diabetes Mellitus, Hypertension, Ischaemic Heart Disease. Risk factors association *P- value <0.05 is statistically significant.

Post Intervention Results

In Kaman there were 18.3% of confirmed cases of diabetes mellitus and after intervention it has reduced to 11.8%. There was a decrease of 6.5%. In Satpati there were 16.6% of confirmed cases of diabetes mellitus and after intervention it has reduced to 14.4%. There was a decrease of 2.2%.



DISCUSSION

In India, Hypertension and Diabetes Mellitus are one of the major causes of morbidity and mortality and are the risk factors of many other diseases including heart attack, stroke, kidney failure, leg amputation, vision loss, blood vessels, and peripheral nerve damage. In the current study, 37.9% (702 out 1850) study participants in one PHC area and 31.4% (581 out 1850) in another PHC area were suspected of Diabetes Mellitus and 338 (18.3%) and 307(16.6%) respectively were confirmed and put on medication. The number of confirmed cases of Diabetes Mellitus in Kaman and Satpati was higher than NFHS-5 Data for Rural Maharashtra (10.7%),^[6] Rural Uttarakhand (14.6%) but lesser than Uttar Pradesh (35.8%).^[7,8] Risk factors associated with Diabetes Mellitus were analyzed separately for two different PHC areas. Higher age group, lower

education, sedentary life, addictions, higher body mass index, central obesity and family history of these diseases were significantly associated with the newly diagnosed cases. Above mentioned risk factors, especially Higher BMI, have been found to be an important predictor of the disease as found by other researchers.^[7,9-14] After the community intervention in the study area, the newly diagnosed cases of Diabetes Mellitus have been reduced by 10% and 6.5%. A similar effect of community intervention was found in a study done at Norway,^[15] DanishChinaand in Systematic review from Japan and other east and Southeast Asian Countries,^[16-18] COMMIT study where it was found that the cardiovascular events and mortality has been decreased through health Promotion.^[19] In India the similar effects have been found in the studies done in Kerala.^[20,21] The community Intervention trial is found to be important Public health Strategy to cut down the Risk factors, Diseases.

CONCLUSION

A high number of Diabetes Mellitus is found in rural population. 18.3% of the participants were newly diagnosed with Diabetes. Screening and early detection and treatment of Diabetes is highly needed in rural areas. Community-based intervention is equally important to focus on prevention, promotion, and enable lifestyle changes to prevent and control Diabetes and avoid risk factors.

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