

Scale-up of the Kerala Diabetes Prevention Program (K-DPP) in Kerala, India: implementation evaluation findings

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Cite this as: *TBM* 2020;10:5–12
doi: 10.1093/tbm/ibz197

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Abstract

The cluster-randomized controlled trial of the Kerala Diabetes Prevention Program (K-DPP) demonstrated some significant improvements in cardiometabolic risk factors and other outcomes. We aimed to refine and improve K-DPP for wider implementation in the Kerala state of India. The specific objectives of the scale-up program were (a) to develop a scalable program delivery model and related capacity building in Kerala and (b) to achieve significant improvements in cardiometabolic risk factors in the target population. A total of 118 key trainers of a large women's organization trained 15,000 peer leaders in three districts of Kerala. Each of these peer leaders was required to deliver 12 monthly sessions to ~25 people, reaching an estimated total of 375,000 adults over 12 months. We evaluated the number of sessions conducted, the participation of men, and program reach. We also assessed the effectiveness of the program in a random sample of 1,200 adults before and after the intervention and performed a biochemical evaluation on a subsample of 321. Of the 15,222 peer leaders who were trained, 1,475 (9.7%) returned their evaluation forms, of which, 98% reported conducting at least 1 session, 88% ≥6 sessions, and 74% all 12 sessions. Tobacco use among men reduced from 30% to 25% ($p = .02$) and alcohol use from 40% to 32% ($p = .001$). Overall, mean waist circumference reduced from 89.5 to 87.5 cm ($p < .001$). Although there were some study shortcomings, the approach to scale-up and its implementation was quite effective in reaching a large population in Kerala and there were also some significant improvements in key cardiometabolic risk factors following the 1 year intervention.

Keywords

K-DPP, Scale-up, Kerala, Diabetes, India

INTRODUCTION

Type 2 diabetes is the most common type of diabetes accounting for the majority (90%) of diabetes cases [1]. Globally, 1 in 10 people is living with diabetes. The prevalence of diabetes is increasing worldwide and a large proportion (79%) of diabetes is living in low- and middle-income countries (LMICs). Currently, India has the second-largest number of adults with diabetes in the world (72.9 million) after China (114.4 million) and this number is expected to rise to nearly 134.3 million by 2045, placing India at the top with the highest number of people with diabetes [1]. India has nearly 1 million estimated deaths attributable to diabetes [1]. There are wide

Implications

Researchers: This study provides an evidence base for further adaptation of the community-based diabetes prevention interventions for further scale-up.

Practitioners: The study will help to better inform the professional practice in the management of diabetes by linking community-based diabetes prevention initiatives with curative care.

Policymakers: This project was implemented in partnership with the government-run Kudumbashree State Mission of Kerala, which helped to refine and adapt the interventions for wider implementation in new communities in Kerala in future.

variations in diabetes prevalence among the states in India. The Indian state of Kerala is the most advanced Indian state in terms of epidemiological and demographic transitions. For example, the state has the highest prevalence of Type 2 diabetes (19.2%) [2], among all the Indian states. The state also has among the best health indicators in India. For example, the most recent infant mortality rate was 10 per 1,000 live births compared to 44 for India as a whole, and life expectancy at birth was 79 for women and 74 for men [3]. Kerala also had the highest literacy level of 94% as per the 2011 census in India, another enabling factor that we considered for the scale-up plan in the state.

The efficacy of lifestyle interventions in delaying and preventing the onset of diabetes is well established in different parts of the world [4–6]. Large randomized controlled trials of lifestyle interventions in India [6], Finland [7], USA [5], and China [8,9] have demonstrated a reduction in diabetes incidence between 28.5% and 58%, with generally good maintenance for up to 30 years [10]. Indeed, the nonpharmacologic and behavioral intervention methods used in these trials have been shown to be even more cost effective than pharmacologic

treatments [11,12]. The prevention of diabetes has progressed from efficacy trials to real-world translational studies and practical implementation in recent years [13]. In addition to the management of those with diabetes, identifying those at high risk for developing diabetes is also an urgent need especially in LMICs [14,15]. However, attempts to adapt community-based and scalable approaches and models to LMICs have been limited, so far. The Kerala Diabetes Prevention Program (K-DPP) is an example of a program, which has been carefully adapted from the Good Ageing in Lahti (GOAL) Lifestyle Implementation Trial in Finland [16], the U.S. Diabetes Prevention Program [5], and the Greater Green Triangle Diabetes Prevention Program in Australia [17]. The K-DPP study design details have been previously published [18–20], and the study protocol is available from <https://www.ncbi.nlm.nih.gov/pubmed/24180316>. Briefly, K-DPP was a cluster-randomized controlled trial evaluation of a peer-support lifestyle intervention for the prevention of Type 2 diabetes in India. The trial was undertaken in 60 polling areas (electoral divisions), which were selected randomly from the *Neyyattinkara* taluk (sub-district) in Trivandrum district of Kerala state. These polling areas were randomized equally into a lifestyle intervention arm or a control arm by an independent person using a computer-generated randomization sequence. Individuals aged 30–60 years were identified from the electoral roll of the selected polling areas and were approached at their households by trained field staff. A total of 3,421 potential participants were screened for eligibility and those with a history of diabetes or other major chronic illnesses, taking medications that influence glucose tolerance (e.g., corticosteroids), or who were illiterate in the local language and pregnant women were excluded. Those satisfying the eligibility criteria ($n = 2,586$) underwent a two-step screening procedure involving a diabetes risk score and a 2 hr 75 gm oral glucose tolerance test (OGTT) [20]. The Indian Diabetes Risk Score (IDRS), which is comprised of age, family history of diabetes, physical activity, and waist circumference [21], was administered by trained staff. Those with an IDRS score ≥ 60 ($n = 1,529$) were invited to attend clinics organized in local neighborhoods to undergo an OGTT. Of 1,209 participants who attended the clinics, those diagnosed with diabetes on the OGTT were excluded ($n = 202$) and referred to health care facilities for further management. Diabetes was diagnosed based on the American Diabetes Association criteria (fasting plasma glucose ≥ 126 mg/dL and/or 2 hr plasma glucose ≥ 200 mg/dL) [22]. The remaining 1,007 individuals were recruited to the trial (control group: 507; intervention group: 500). Baseline survey was conducted among participants in both the study arms to collect data on demographic, lifestyle, clinical, and biochemical

characteristics using standardized tools and protocols [21,23]. Tobacco use and alcohol use were collected using the WHO STEPs questionnaire. Current tobacco use was defined as the use of any tobacco products in the previous month. Similarly, current use of alcohol use was defined as the use of any alcoholic products in the previous month. The control arm received a health education booklet on lifestyle change. Detailed description of the development, theoretical background, cultural adaptation, and implementation fidelity of the K-DPP intervention have been reported previously [18–20,24,25]. Briefly, the K-DPP intervention was a culturally adapted program derived from earlier implementation trials conducted in the USA, Finland, and Australia [17]. The intervention arm received behavioral educational sessions via peer groups from lay-trained peer leaders, diabetes prevention education sessions led by experts, a participant handbook on lifestyle modification, a participant workbook to guide self-monitoring of lifestyle behaviors and goal setting, and a health education booklet on lifestyle change advice. This community-based intervention was delivered over a period of 12 months. The peer groups were also encouraged to undertake other chronic disease prevention and health promotion activities in their communities, including kitchen gardening, yoga sessions, and walking groups. The health education booklet was given to the control arm participants. Follow-up assessments were conducted at 12 and 24 months [25]. Findings from the 24 month evaluation of the K-DPP showed that the program was effective in promoting health behavior changes and led to significant improvements in cardiometabolic behavioral and clinical risk factors in intervention participants [25].

With this strong evidence base from the original trial of K-DPP, funding became available from the World Diabetes Foundation to implement the program more widely in Kerala. Globally, scaling up is now of significant interest to global agencies, policymakers, and others because of the urgent need for countries to more effectively implement strategies and programs to their noncommunicable disease and related goals and targets [26]. While it is important that public health and community-based programs that have been proven to be effective in controlled research settings or conducted as pilots should be scaled up to achieve population-wide health improvements, there is still only a small evidence base about how to do this [26]. Research on scaling up of interventions to prevent or delay diabetes in LMICs is still very limited. Evidence from high-income countries indicates that, in order to achieve the prevention of Type 2 diabetes, there is a need to scale up national efforts in order to create a sustained prevention system [27]. Therefore, with support from the World Diabetes Foundation, it was agreed to evaluate the wider implementation of

K-DPP in partnership with the Kudumbasree State Mission (KSM), one of the largest women's networks in the world, which was originally established in 1997 for poverty alleviation [28]. Selection of Kerala KSM as our implementation partner was considered to be essential in order to be able to implement the program at scale. KSM has a large network of women's groups spread all over the state, including the three selected districts. KSM has a reach of more than 4.1 million households out of around 10 million households in the State. Although the historical focus of KSM has been women and their families, they have neighborhood groups (NGs) of 20–25 women, and their family members typically meet monthly. KSM was keen to partner with the K-DPP program in order to see whether their network and approach could be appropriately adapted to train the required number of peer group leaders to deliver 12 monthly sessions focused on the prevention and control of diabetes. In this manuscript, we discuss the details of the scale-up of this effective intervention program to three additional districts in Kerala with a total population of about 10 million. The specific objectives of the scale-up program were [1]: to develop and implement a program delivery model for diabetes prevention and related capacity building in the Indian state of Kerala that can be scaled up to the whole of India in the future and [2] to achieve significant improvements in cardiometabolic risk factors in the target population.

METHODOLOGY

Strategy for the scale-up of K-DPP

As a first step to scale up K-DPP, a state-level steering committee was established, comprising stakeholders from KSM, Directorate of Medical Education, Social Security Mission, Indian Medical Association, Indian Institute of Diabetes, and District Panchayat Offices of the Government of Kerala to offer guidance, advice, directions, and insights on concerns, if any, and for prioritizing goals. The committee conducted meetings every 6 months for a period of 2 years.

For selection purpose, the Kerala state was divided into three regions based on the geographic boundaries, South, Center, and North. There are 14 revenue districts in Kerala. From each region, one district was randomly selected; Kollam in the South, Ernakulam in the Center, and Kannur in the North regions of Kerala. Four community development blocks (CDBs; subdivisions of district) from each of these three districts were selected, representing coastal, midland, and hilly areas (Kannur 4 out of 9, Ernakulam 4 out of 14, and Kollam 4 out of 12). In each of the three selected districts, we aimed to train 40 KSM trainers, making a total of 120 trainers from all the three districts. In turn, they were required to train 5,000 KSM members (peer leaders) in each district, making a total of 15,000 peer leaders. Each of

these peer leaders was trained to deliver 12 monthly sessions to their regular NGs. An NG consists of nearly 20–25 women and their family members. Thus, the plan was to reach to around 375,000 women and their family members, including men over a period of 1 year. Although KSM is a women's organization and the NG focuses on women, for this project, we purposely wanted to invite men also into their group meetings. A District Implementation Committee was established in all the three study districts comprising of stakeholders from KSM and District *Panchayat* offices (local administrative unit of governance) to oversee the implementation process and address any concerns.

Development and distribution of resources

The resource materials initially adapted K-DPP [24,29] and, then, further modified after seeking expert opinion from the state-level and district-level committees and a subsample of trainers. KSM trainers received a training manual, a flip chart, and measuring tapes for measuring waist circumference. The peer leader trainers additionally received a report form for 12 monthly sessions. The heavy load of resource materials (about 4 kg for each peer leader, making a total of 60,000 kilograms) were sent through Roadways Parcel Service to the KSM District Office of the selected districts. From there, the trainers collected and distributed resources to four selected CDBs of respective districts. The resources were then distributed by the community development society (CDS) chairpersons (elected representatives of KSM in the community) to the peer leaders of NGs.

KSM delivers its programs through a three-tier organizational structure. Tier 1 is at the community-level NGs consisting of approximately 20–25 women. Each NG also includes a health convener responsible for organizing and carrying out health-related activities at the neighborhood level. Tier 2 consists of area development societies (ADSs), formed at the ward level (*smallest geographical unit of the decentralized government in Kerala*) by federating all the NGs in the ward. The third tier consists of CDSs at the *Panchayat* level, which are formed by federating all the ADSs within the *Panchayat*. There is an elected chairperson co-coordinating KSM activities at each level. Capacity building of the individuals and families within these networks is undertaken by the 19 state-level training groups, who are supported by local resource persons at each tier. It was estimated that, through this structure, KSM currently reaches 4.1 million households in Kerala.

Training

Training took place at three levels: KSM trainers, peer leaders, and data collectors

KSM has 19 training groups catering to different training purposes of the KSM network. Among the

accredited 530 KSM trainers in three districts (150 in Kollam, 200 in Ernakulam, and 180 in Kannur), 120 (Kollam 40, Ernakulam 40, and Kannur 40) were selected by the KSM District team based on their previous experience and were invited to participate in the training of trainer's program. In order to elicit the feasibility, comprehensibility, and appropriateness of the sessions and resource materials, a state-level pilot training was conducted for the 12 trainers selected randomly from all the three districts, who, in turn, trained 36 peer leaders from 36 NGs at the CDB level. From each district, we selected four CDBs (planning unit below the district) out of around 10 CDBs. Each trainer was to train 125 peer leaders. Pilot training sessions provided insight on the requirement of flip charts for assisting in training as most centers lacked the facility for power-point presentation. Flipcharts were then developed by the research team members with guidance from the experts at state- and district-level committees. Two day training sessions were conducted at district level by the K-DPP state-level research team with 1 month interval. First-round training was conducted at Kollam, in which 39 trainers participated. In the subsequent month, the second-round training was held at Ernakulam where 39 trainers participated. The third 2 day training was conducted in Kannur district, with the participation of 40 trainers. The training materials were distributed at the end of the sessions. Thus, a total of 118 trainers participated in the training of trainers in the selected three districts.

These 118 KSM trainers trained at least 15,000 women peer leaders (5,000 each from Kannur, Ernakulam, and Kollam). The training manual, flip chart, and the measuring tapes were used for training the peer leaders. The training manual contained details of all the 12 monthly sessions, and these sessions were discussed in detail and doubts, if any, were clarified during the sessions. As a part of monitoring weight, a measuring tape was distributed and the standard procedure for measuring the waist circumference was demonstrated in the training session. Each peer leader was requested to measure the waist circumference of another peer leader in the session in order to understand the measurement procedure.

Training of data collectors was done for the evaluation of the effectiveness of this scale-up program. After consultation with the accredited KSM trainers of each district, we selected 11 data collectors from Kollam, 9 from Ernakulam, and 11 from Kannur for data collection. Two day training for these data collectors was conducted at the district level by the K-DPP state research team members. For participating in the training sessions, data collectors were given an amount of INR 100 (USD 1.4) to cover food and travel expenses. An incentive of INR 100 (USD 1.4) was given to data collectors for the successful completion of each questionnaire.

Each CDB consists of 1,250 NGs [28]. We planned to collect data concurrently for all 60 NGs (20 NGs from each block \times 3 districts) at the beginning and at the end of the program implementation, that is, the completion of the 12 sessions. All the participants (women and their family members) from each of these selected 20 NGs were contacted to participate in the behavioral outcome evaluation. Participants who were not willing to provide consent and could not be contacted after three house visits were considered unavailable to participate in the study. A feedback form was included with each educational booklet in order to get an idea about the conduct of the program and participation of men.

The evaluation of clinical effectiveness of the program was conducted among 1,200 (400 from each district) adults selected using a systematic random sampling technique (see Fig. 1). Clinical and biochemical measurements were conducted in a subsample of 312 participants based on the selection criteria detailed in Fig. 1. All the measurements were done free of cost at clinics conducted in the local community using community buildings (e.g., schools and community halls). The results of these evaluations were provided to the participants.

We used a structured questionnaire for data collection. This was done before and after the 12 month intervention. Trained data collectors administered the questionnaire. For the baseline data collection, details on sociodemographic characteristics, knowledge about diabetes, history of diabetes, and current tobacco and alcohol use were collected. Tobacco use and alcohol use were captured using the WHO STEPs questions, which were modified to reduce the number of questions on each of these. Current tobacco use was defined as the use of any tobacco products in the last 1 month. Current alcohol use was defined as the use of any alcoholic products in the last 1 month.

Following the 12 month intervention period, data were collected using the same questionnaire. During each assessment, anthropometric measurements, such as weight and waist circumference, were taken using standard tools and protocols [23].

From a subsample population, blood samples were taken for fasting glucose and lipids according to standard protocols [23]. Individuals who were diagnosed with diabetes as per the American Diabetes Association (ADA) criteria [22] on the OGTT at baseline and at 12 month follow-up were referred to health care facilities for confirmation of diagnosis and management. Blood samples were centrifuged within 30 min of collection and transported in boxes with dry ice to a nationally accredited laboratory. Blood glucose was measured using the hexokinase method on a COBAS 6000 analyzer, with kits supplied from Roche Diagnostics, Switzerland, and lipids by enzymatic methods on a COBAS 6000 analyzer, using kits supplied by Roche Diagnostics,

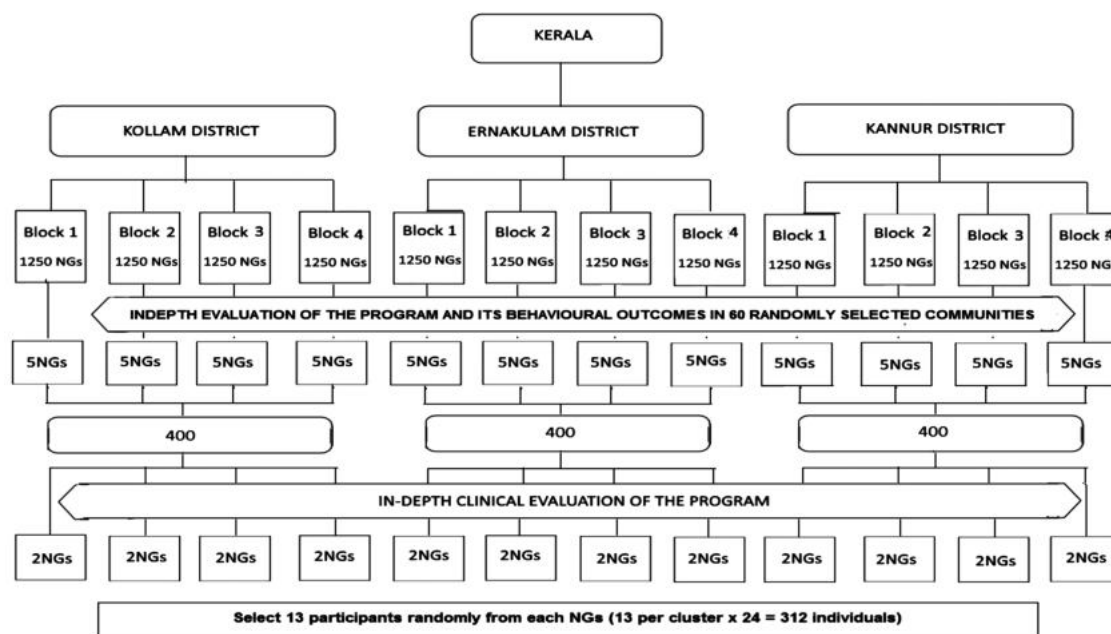


Fig. 1 | Sample selection procedure for the evaluation.

Switzerland. Low-density lipoprotein (LDL) cholesterol was estimated using the Friedewald equation for those with triglycerides ≤ 400 mg/dL and, for the remaining individuals, estimates from the direct method were used [30].

Statistical analysis

Data from each district were pooled and analyzed using SPSS (version 17.0; SPSS Inc., Chicago, IL). Descriptive statistical analyses were performed, and percentages, medians, and range were calculated for all relevant variables. For comparing the presurvey and postsurvey results, McNemar test was used for categorical variables and paired *t*-test for continuous variables. A *p*-value of $< .05$ was considered statistically significant.

Ethical clearance

The study was approved by the Institute Ethics Committee of Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum, Kerala, and the Health Ministry Screening Committee of the Government of India. Written informed consent was obtained from all the study participants.

RESULTS

For the first objective, the feedback form was provided to all trainers and peer leaders. A total of 15,222 peer leaders (5,143 in the northern district, 5,083 in the central district, and 5,000 in the southern district) were trained and evaluation forms were collected from 1,475 (9.7%) peer leaders for analysis. From them, almost all (98%) of the peer leaders conducted at least 1 session, 88% conducted

Table 1 | Baseline characteristics of study participants ($N = 1,208$)

Characteristics	<i>n</i> (%)
Sex	
Men	548 (45.4)
Women	660 (54.6)
Education	
Illiterates	25 (2.1)
Below 10 years of schooling	516 (42.7)
10th class completed	385 (31.9)
Above 10th class	282 (23.3)
Occupation	
Employed	470 (38.9)
Unemployed	738 (61.1)
Marital status	
Currently married	1,104 (91.4)
Others	104 (8.6)

at least 6 sessions, and 74% conducted all the 12 sessions. Participation of men was only 9.3%.

For the second objective, behavioral risk factors were evaluated in 1,208 adults for the baseline survey (women 55%). Mean age of the sample population was 47.8 years (standard deviation [*SD*]: 11.3). The average monthly household income was INR 8,000 (USD 112). Other baseline characteristics are presented in Table 1. The majority (94%) were followed up at 12 months. Biochemical measurements were also done among a subsample of these individuals, 386 at baseline and 324 at follow-up. We analyzed behavioral risk factors of 1,107 individuals and clinical and biochemical characteristics of 321 individuals who participated in both the baseline and end-line surveys and had complete data.

The changes in behavioral, clinical, and biochemical measurements from baseline to postintervention survey are summarized in Table 2. Among men, current tobacco use significantly decreased from 30% to 25% and current alcohol use significantly decreased from 40% to 32% after 12 months of intervention. The mean waist circumference decreased significantly in the postintervention survey.

In the postintervention survey, the mean fasting plasma glucose, total cholesterol, and LDL cholesterol did not show any significant change. However, there was a significant decrease in high-density lipoprotein (HDL) cholesterol.

DISCUSSION

A total of more than 15,000 peer leaders were trained in the three selected districts of the Kerala state. Each of these trained peer leaders was required to provide 12 sessions on diabetes prevention to the members of their NGs consisting of 20–25 women and their family members. From the feedback forms collected from the peer leaders, it was reported that 98% of the peer leaders conducted at least 1 session, 88% conducted at least 6 sessions, and 74% conducted all the 12 sessions. It was not feasible to collect feedback forms from all 15,000 peer leaders due to logistic reasons.

One of the major achievements of this scale-up program was to reach such a large number of peer leaders (KSM women) in three districts of the Kerala state. We have demonstrated that the KSM network was able to reach more than the targeted number of peer group leaders and they were all trained with printed modules in a standardized manner on prevention and control of diabetes. The training materials not only proved to be a very good resource for this program, but they could also be adapted to some other KSM programs. As a result of their involvement in this program, many of the peer leaders were subsequently identified as

local experts on prevention and management of diabetes, which is a very common condition in the population all over the state. Indeed, subsequent community education program on diabetes utilized many of these trained peer leaders as resource persons.

It is possible that 10% of the peer group leaders who returned their feedback forms reported more favorable outcomes than those who did not return their feedback forms. However, this has not been the case with other similar large-scale programs delivered by KSM over many years because of their very deep reach into so many households and communities throughout Kerala State. Therefore, if we extrapolate from these findings, it does seem very likely that the majority of the estimated 375,000 people to be reached by the program, attended at least one session on diabetes prevention. Although KSM is a women's group, we wanted to involve and engage men in the program. Although the participation of men was less than 10% in the face-to-face sessions, this provides some further evidence that the feedback forms were likely to be reasonably accurate. Although, not surprisingly, the KSM groups were predominantly women, the program trained the peer leaders to present and discuss diabetes prevention as a family, household, and community issue that should involve everybody and particularly men. In addition to the proposed group sessions, many of the peer leaders reported spinoff activities from this program in their local community. Some of the peer leaders were invited by other organizations, such as the residents' association to conduct other classes on diabetes prevention. As a result of this scale-up program, diabetes prevention programs were also incorporated in other education programs developed by KSM in other places. Other voluntary activities, such as *Kolkali* (a form of dance in northern Kerala), were initiated in order to promote physical activity after the classes. Kitchen gardens were started by some groups to promote vegetable cultivation.

Table 2 | Preintervention and postintervention changes in behavioral, clinical, and biochemical characteristics of the study participants

	Baseline	Postintervention	<i>p</i> value
Behavioral characteristics (<i>n</i>, %)			
Current tobacco use (men only, <i>n</i> = 488)	146 (29.9)	122 (25.0)	.020
Current alcohol consumption (men only, <i>n</i> = 488)	194 (39.8)	158 (32.4)	.001
Physical activity (regular exercise), <i>n</i> = 1,107	357 (32.3)	366 (33.1)	.667
Anthropometric measurements (mean ± <i>SD</i>)			
Weight (kg), <i>n</i> = 1,098	62.1 ± 12.1	61.1 ± 12.3	.892
Waist circumference (cm), <i>n</i> = 1,079	89.5 ± 12.7	87.5 ± 13.2	<.001
Biochemical characteristics (mean ± <i>SD</i>)			
Fasting plasma glucose (mg/dL), <i>n</i> = 321	116.2 ± 42.1	114.0 ± 41.6	.152
Total cholesterol (mg/dL), mean (<i>SD</i>), <i>n</i> = 321	210.1 ± 40.8	206.9 ± 38.3	.055
HDL cholesterol (mg/dL), mean (<i>SD</i>), <i>n</i> = 320	50.9 ± 12.7	46.8 ± 11.1	<.001
LDL cholesterol (mg/dL), mean (<i>SD</i>), <i>n</i> = 320	143.8 ± 38.5	141.9 ± 37.5	.211

HDL high-density lipoprotein; LDL low-density lipoprotein; *SD* standard deviation.

These “spinoff” activities provide some evidence of the wider adoption and spread of the program elsewhere in Kerala.

The effectiveness of this program in reducing tobacco use was similar to that reported in the original K-DPP trial at 1 year [26] and from a previous study among diabetes patients in Kerala [31]. The effects of the program on alcohol use were also similar to that reported in the K-DPP trial at 1 year [26] and found to be similar to other studies [31]. Alcohol consumption, with all its direct and indirect complications, is a major public health problem in Kerala. There was significant reduction in the proportion of men who reported alcohol consumption in the postintervention survey, even among those males who did not attend any or most of the group sessions. This could be due to the influence of women who attended the sessions on alcohol. A 2 cm significant reduction in waist circumference at 1 year was similar to that reported from Finland [32]. The study’s methodological shortcomings notwithstanding, the likely successful impact of our intervention program on at least some behavioral and clinical risk factors suggests that the active leadership of the KSM organization through the training and the program implementation through their statewide network in Kerala was an effective strategy for lifestyle change and some reductions of chronic diseases risk factors. In LMICs, despite the evidence on program effectiveness, when programs have been well adapted for context, one of the key factors that affect the further adaptation and scale-up of diabetes prevention and management interventions are the resource constraints and lack of evidence about how to take to scale. Therefore, evidence on the cost and cost effectiveness of diabetes prevention and management interventions using networks like KSM could help better inform policy decisions on further adaptation and scaling up of interventions population wide. However, this was beyond the scope of this current study. The State of Kerala has the KSM with a mature program delivery network. This facilitated the implementation of the interventions. However, for further scale-up and sustainability, identifying strategies to better link diabetes prevention and control interventions to the health care delivery system in order to maximize synergy and efficiency of the health system will be important.

Limitations

One of the limitations of this scale-up program was that feedback forms were only collected from 10% of the peer leaders, which might be biased toward the reporting of more positive outcomes. Another limitation is the reliance on self-reports. We compared the cardiometabolic risk factors at baseline and at postintervention for the same group of people without any control population.

Lessons learned

The major lesson learned from this program is that through a partnership with a large and very well-established community-based organization in Kerala, it was possible to train a large number of women peer leaders to deliver a peer-led community-based diabetes prevention program in three geographically different regions of the state. They were able to provide at least some diabetes prevention sessions to approximately 375,000 people. There were also some indications of the program spreading more widely both within and between communities. There were also some encouraging improvements in key behavioral and clinical risk factors that were comparable to the original K-DPP trial. On the basis of these encouraging findings, the State Governments of Kerala and Tamil Nadu are now supporting the wider implementation of this approach to improve the implementation of India’s national program for the prevention and control of cancer, cardiovascular diseases, and stroke in order to achieve better outcomes for diabetes and hypertension over the next 5 years. This implementation will be supported by funding from a Global Alliance for Chronic Diseases grant (NHMRC ID 1169766)

Funding: This project was funded by the Kerala Diabetes Prevention Program, WDF 15-959.

Compliance with Ethical Standards

Conflicts of Interest: All authors declare that they have no conflicts of interest.

Authors’ Contributions: R.R. and G.K.M. drafted this article; The project design was developed by B.O. and K.R.T. and implemented by S.B.; B.O. and K.R.T. contributed to the conception, design and revision of the article with critical contribution for intellectual content; K.M. and S.T. contributed to the revision of the article with critical contribution for intellectual content; All authors read and approved the final manuscript.

Ethical Approval: All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. This article does not contain any studies with animals performed by any of the authors.

Informed Consent: Informed consent was obtained from all individual participants included in the study.

References

1. International Diabetes Federation. Type 2 Diabetes. Available at <https://www.idf.org/aboutdiabetes/type-2-diabetes.html>. Accessibility verified August 8, 2019.
2. Sarma PS, Sadanandan R, Thulaseedharan JV, et al. Prevalence of risk factors of non-communicable diseases in Kerala, India: Results of a cross-sectional study. *BMJ Open*. 2019;9(11):e027880.
3. India State-Level Disease Burden Initiative Collaborators. Nations within a nation: Variations in epidemiological transition across the states of India, 1990–2016 in the global burden of disease study. *Lancet*. 2017;390(10111):2437e60.
4. Crandall JP, Knowler WC, Kahn SE, et al; Diabetes Prevention Program Research Group. The prevention of type 2 diabetes. *Nat Clin Pract Endocrinol Metab*. 2008;4(7):382–393.
5. Knowler WC, Barrett-Connor E, Fowler SE, et al; Diabetes Prevention Program Research Group. Reduction in the incidence of type 2

- diabetes with lifestyle intervention or metformin. *N Engl J Med*. 2002;346(6):393–403.
6. Ramachandran A, Snehalatha C, Mary S, Mukesh B, Bhaskar AD, Vijay V; Indian Diabetes Prevention Programme (IDPP). The Indian Diabetes Prevention Programme shows that lifestyle modification and metformin prevent type 2 diabetes in Asian Indian subjects with impaired glucose tolerance (IDPP-1). *Diabetologia*. 2006;49(2):289–297.
 7. Tuomilehto J, Lindström J, Eriksson JG, et al.; Finnish Diabetes Prevention Study Group. Prevention of type 2 diabetes mellitus by changes in lifestyle among subjects with impaired glucose tolerance. *N Engl J Med*. 2001;344(18):1343–1350.
 8. Pan XR, Li GW, Hu YH, et al. Effects of diet and exercise in preventing NIDDM in people with impaired glucose tolerance. The Da Qing IGT and Diabetes Study. *Diabetes Care*. 1997;20(4):537–544.
 9. Zhong X, Potemans B, Zhang L, Oldenburg B. Getting a grip on NCDs in China: an evaluation of the implementation of the Dutch-China cardiovascular prevention program. *Int J Behav Med*. 2015;22(3):393–403.
 10. Gong Q, Zhang P, Wang J, et al.; Da Qing Diabetes Prevention Study Group. Morbidity and mortality after lifestyle intervention for people with impaired glucose tolerance: 30-year results of the Da Qing Diabetes Prevention Outcome Study. *Lancet Diabetes Endocrinol*. 2019;7(6):452–461.
 11. Herman WH, Hoerger TJ, Brandle M, et al.; Diabetes Prevention Program Research Group. The cost-effectiveness of lifestyle modification or metformin in preventing type 2 diabetes in adults with impaired glucose tolerance. *Ann Intern Med*. 2005;142(5):323–332.
 12. Ramachandran A, Snehalatha C, Yamuna A, Mary S, Ping Z. Cost-effectiveness of the interventions in the primary prevention of diabetes among Asian Indians: Within-trial results of the Indian Diabetes Prevention Programme (IDPP). *Diabetes Care*. 2007;30(10):2548–2552.
 13. Aziz Z, Absetz P, Oldroyd J, Pronk NP, Oldenburg B. A systematic review of real-world diabetes prevention programs: Learnings from the last 15 years. *Implement Sci*. 2015;10:172.
 14. Ramachandran A, Ma RC, Snehalatha C. Diabetes in Asia. *Lancet*. 2010;375(9712):408–418.
 15. Mahal A, Karan A, Engelgau M. *The Economic Implications of Non-Communicable Disease for India*. The International Bank for Reconstruction and Development/The World Bank; 2009. Available at <http://siteresources.worldbank.org/HEALTHNUTRITIONANDPOPULATION/Resources/281627-1095698140167/EconomicImplicationsofNCDforIndia.pdf>. Accessibility verified September 2, 2019.
 16. Absetz P, Valve R, Oldenburg B, et al. Type 2 diabetes prevention in the “real world”: One-year results of the GOAL Implementation Trial. *Diabetes Care*. 2007;30(10):2465–2470.
 17. Laatikainen T, Dunbar JA, Chapman A, et al. Prevention of type 2 diabetes by lifestyle intervention in an Australian primary health care setting: Greater Green Triangle (GGT) Diabetes Prevention Project. *BMC Public Health*. 2007;7:249.
 18. Sathish T, Williams ED, Pasricha N, et al. Cluster randomised controlled trial of a peer-led lifestyle intervention program: Study protocol for the Kerala diabetes prevention program. *BMC Public Health*. 2013;13:1035.
 19. Sathish T, Aziz Z, Absetz P, et al. Participant recruitment into a community-based diabetes prevention trial in India: Learnings from the Kerala Diabetes Prevention Program. *Contemp Clin Trials Commun*. 2019;15:100382.
 20. Sathish T, Shaw JE, Tapp RJ, et al. Targeted screening for prediabetes and undiagnosed diabetes in a community setting in India. *Diabetes Metab Syndr*. 2019;13(3):1785–1790.
 21. Mohan V, Deepa R, Deepa M, Somannavar S, Datta M. A simplified Indian diabetes risk score for screening for undiagnosed diabetic subjects. *J Assoc Physicians India*. 2005;53:759–763.
 22. American Diabetes Association. Standards of Medical Care in Diabetes - 2018/2019. Available at http://care.diabetesjournals.org/content/41/Supplement_1/S1. Accessibility verified August 20, 2019.
 23. World Health Organization. The WHO STEPwise approach to chronic disease risk factor surveillance. Available at http://apps.who.int/iris/bitstream/10665/43376/1/9241593830_eng.pdf. Accessibility verified July 10, 2019.
 24. Mathews E, Thomas E, Absetz P, et al. Cultural adaptation of a peer-led lifestyle intervention program for diabetes prevention in India: The Kerala diabetes prevention program (K-DPP). *BMC Public Health*. 2018;17(1):974.
 25. Thankappan KR, Sathish T, Tapp RJ, et al. A peer-support lifestyle intervention for preventing type 2 diabetes in India: A cluster-randomized controlled trial of the Kerala Diabetes Prevention Program. *PLoS Med*. 2018;15(6):e1002575.
 26. Kruk ME, Yamey G, Angell SY, et al. Transforming global health by improving the science of scale-up. *PLoS Biol*. 2016;14(3):e1002360.
 27. Johnson G, Martin JE, Timoshanko A. Preventing type 2 diabetes: Scaling up to create a prevention system. *Med J Aust*. 2015;202(1):24–26.
 28. Kudumbasree. State Poverty Eradication Mission, Government of Kerala. Available at <http://kudumbashree.org/>. Accessibility verified September 8, 2019.
 29. Daivadanam M, Absetz P, Sathish T, et al. Lifestyle change in Kerala, India: Needs assessment and planning for a community-based diabetes prevention trial. *BMC Public Health*. 2013;13:95.
 30. Friedewald WT, Levy RI, Fredrickson DS. Estimation of the concentration of low-density lipoprotein cholesterol in plasma, without use of the preparative ultracentrifuge. *Clin Chem*. 1972;18(6):499–502.
 31. Thankappan KR, Mini GK, Hariharan M, Vijayakumar G, Sarma PS, Nichter M. Smoking cessation among diabetic patients in Kerala, India: 1-year follow-up results from a pilot randomized controlled trial. *Diabetes Care*. 2014;37(12):e256–e257.
 32. Saaristo T, Moilanen L, Korpi-Hyövälti E, et al. Lifestyle intervention for prevention of type 2 diabetes in primary health care: one-year follow-up of the Finnish National Diabetes Prevention Program (FIN-D2D). *Diabetes Care*. 2010;33(10):2146–2151.