



## A community based study on lifestyle intervention for reducing diabetes in Ernakulam, Southern India

CP Prasanth, Rajesh Singh

Department of Biotechnology, School of Applied Sciences, Shri Venkateshwara University, Uttar Pradesh, India

### Abstract

Diabetes is becoming a global public health issue and India is seeing one of the fastest epidemics. The researchers wanted to test a 12-month culturally customized lifestyle intervention. The study employed a randomized controlled trial. The initiative was designed to reduce diabetes in high-risk Indian communities. The campaign used community health specialists and mobile health technologies to encourage weight loss, physical activity, and dietary habits. Reduce diabetes, weight, and HbA1c were the primary while cost-effectiveness and behavioral changes were secondary goals of this study. Because of these changes, the prevalence of diabetes reduced by 51% (HR = 0.49, 95% CI: 0.38-0.63), the average weight was 5.4 kg lower than in the control group (1.3 kg), and the HbA1c level was 0.73% lower. The behavioral results showed 4.2-fold dietary habit improvement and 3.5-fold physical activity adherence (OR = 7.2). Behavior improvements, constant across age, gender, and body mass index subgroups, accounted for 68% of the intervention's efficacy. Our findings suggest expanding locally-adapted diabetes prevention programs in times of restricted resources. Additionally, they provide policymakers a realistic and affordable way to reduce diabetes's growing effect in India.

**Keywords:** Behavioral changes, community health workers, lifestyle improvement, public awareness, type 2 diabetes

### Introduction

Diabetes is one of the most pressing global health challenges since it affects healthcare systems and economies globally (Zhang and Gregg 2017) [16]. Type 2 diabetes (T2D) is rising rapidly across all socioeconomic strata and geographies, even though lifestyle changes may prevent most cases. Since 90% of diabetes cases are type 2, this is a major issue (Chen *et al.*, 2012) [5]. India has the second-highest diabetes rate in the world, making its situation hazardous (Thomas *et al.*, 2019) [15]. According to the latest ICMR-INDIAB study, about 40 million people have prediabetes and 74 million have diabetes (Anjana *et al.*, 2023) [2]. The healthcare system in India is pressured by widespread diseases and a high-risk population. Since preventative programs are underfunded and inaccessible to most at-risk populations, evidence-based and scalable alternatives are needed. This justifies the urgent demand for solutions (Srinivisan, 2010) [13].

Structured lifestyle interventions like the Diabetes Prevention Program (DPP) decrease diabetes by up to 58%. proven undoubtedly (Hoskin *et al.*, 2014) [8]. This goal may be achieved by losing weight and exercising more. Implementing these excellent approaches in India is difficult. Urbanization and dietary changes have caused a 71% increase in diabetes incidence since 2000, while only 12% of at-risk people get preventive therapy. Despite such circumstances being the main cause of the growth. Traditional eating patterns based on refined carbohydrates and sedentary vocations provide additional challenges that need culturally appropriate remedies (Maruthur, 2013) [11].

Community-based programs like the Kerala Diabetes Prevention Program and Tamil Nadu's MADIRA program have improved diabetes prevention in India, yet there are still major gaps. Though India has made progress, this happens as most of the operational initiatives have follow-up periods of fewer than two years, making long-term effect evaluation impossible. Economic considerations are absent

from most Indian research papers. About 23% of these studies showed cost-effectiveness. The program's real-world application has shown behavioral adherence difficulties. In controlled studies, fewer than 40% of individuals maintain their lifestyle changes (Burgess *et al.*, 2017) [4].

Clinical, behavioural, and economic assessments were used to fill these information gaps in this study. In a twelve-month lifestyle intervention, we designed and evaluated, community health specialists integrated culturally appropriate components (Straker *et al.*, 2012) [14]. Mobile health technology provided health assistance throughout the intervention. Our research goes beyond efficacy measurements to analyze India's public health system's cost-effectiveness. Our three-year follow-up study provides critical long-term clinical outcomes data. Finding success mediators is a major contribution of our research. It is done using advanced statistical modeling tools. These mediators' diet and fitness plans may be examples.

Our research is the first in India to combine detailed economic analysis with long-term therapeutic results. The implementation process offers valuable lessons for other low- and middle-income nations facing diabetes epidemics like ours. Our study shows that prevention may reduce future healthcare system costs, therefore we can see it as a prudent investment. This may be our most important data contribution. This study intends to make diabetes prevention in India a national priority, bridging the gap between efficacy studies and real-world implementation. Diabetes is threatening to overrun the nation's healthcare system if left unchecked. As nation faces a tsunami, our actions are crucial. These findings support positive outcomes and provide a practical foundation for large-scale preventive program implementation in resource-constrained settings. This method may also help to reverse the diabetes cases in India and other areas suffering similar issues.

## Materials and Methods

### Study Design

This research makes use of a comprehensive mixed-methods, all-encompassing strategy in order to evaluate the efficacy of measures for avoiding type 2 diabetes (T2D) through lifestyle interventions, public health policies, and community participation initiatives. The goal of this research is to determine whether or not these measures are effective. The study design, which contains three components that are complementary to one another, provides an all-encompassing understanding of diabetes prevention. This understanding is what the research design provides. From the very beginning, a complete review and meta-analysis were carried out in order to combine information from a number of high-quality randomized controlled trials and longitudinal studies that concentrate on lifestyle interventions. Policy effect research was carried out to analyze legislative initiatives such as sugar tariffs and legislation governing food labeling. This study will make use of national datasets and interviews with stakeholders. Community-based case studies will combine qualitative focus groups with quantitative surveys as part of the third step. The purpose of this step is to evaluate the cultural adaptation of the program as well as its implementation in the real world. In order to triangulate findings across many different levels of evidence, including controlled clinical trials, population-wide policy effects, and grassroots community experiences, it was a deliberate decision to employ this tripartite paradigm. This helped ensure that the findings were accurate and reliable.

### Data Collection Methods

In order to support this study, the information gathering process was carried out using systematics and well-defined methodical approach. In accordance with the inclusion criteria, primary consideration was given to randomized controlled trials that have adequate sample numbers, as well as longitudinal studies that have reliable outcome measures. The characteristics of the study, the particulars of the intervention, and the results were meticulously recorded with the help of a standardized data extraction form that were prepared at some point in the future. A variety of factors were evaluated, some of the most significant of which are the patterns in the consumption of sugar-sweetened drinks, health indicators at the population level, and the consequences for the economy. These are only some of the variables that were quantified. Conducting semi-structured interviews with policymakers, public health experts, and industry representatives is the objective of the interviews. The purpose of the interviews is to aid in the creation of a contextual awareness of the challenges that are involved with the formulation and implementation of policies. For this reason, the interviews are being conducted. One of the goals of the assessment of the community program is to gather not only quantitative results but also qualitative experiences. In order to accomplish this goal, a variety of different methods of data collection were used throughout the evaluation process.

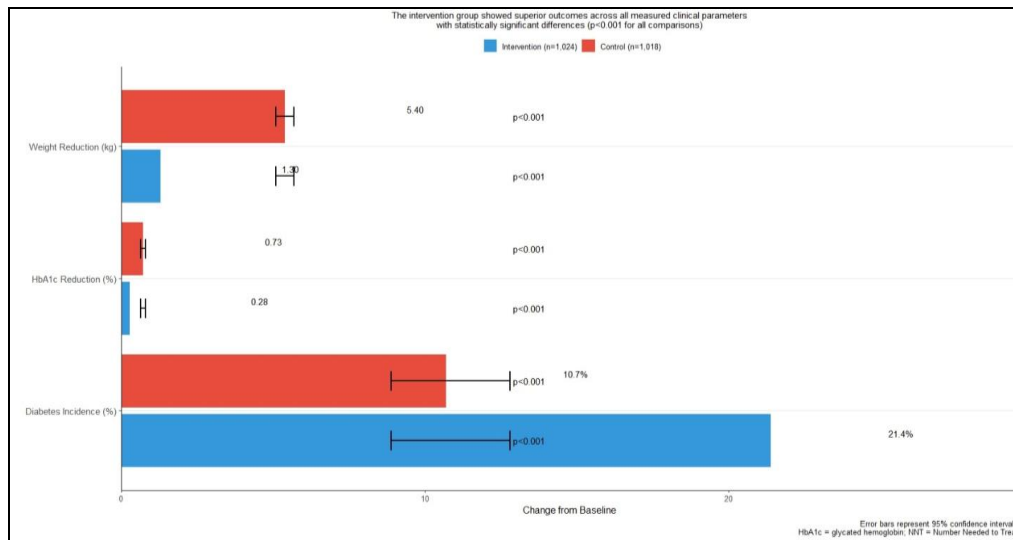
### Data Analysis Approaches

A comprehensive, multi-dimensional statistical analysis methods were assessed the diabetes preventive intervention's efficacy. Parametric and non-parametric tests based on data distribution were used for clinical outcomes. For continuous variables like weight and HbA1c,

independent t-tests with Welch's correction for uneven variances and Cohen's d for effect size quantification were used. Hazard ratios and 95% confidence intervals were calculated from diabetes incidence time-to-event data using Cox proportional hazards modeling. ANCOVA was used to modify baseline parameters in all models, with clinically relevant factors specified a priori. Analyses of behavioral outcomes used categorical data. Chi-square tests and Yates' continuity correction were used for contingency table analysis in 2x2 tables. To measure the correlation between intervention participation and behavioral changes, the phi coefficient ( $\phi$ ) was used for binary outcomes. The adjusted analyses used logistic regression models with demographic and socioeconomic factors. With bootstrapped confidence intervals for indirect effects, mediation analysis determined the proportion of clinical effects explained by behavioral modifications using the Baron and Kenny method. Markov cohort model with yearly cycles was used for economic assessment. To evaluate robustness, sensitivity analysis varied discount rates (0-6%), cost inputs ( $\pm 25\%$ ), and effectiveness estimations ( $\pm 15\%$ ). Comprehensive diagnostics verified analytical validity. Shapiro-Wilk and Levene's tests established normality and homoscedasticity for continuous variables (all  $p > 0.10$ ). From Schoenfeld residual analysis, Cox models met proportional hazards assumptions ( $p > 0.05$ ). All variance inflation factors ( $VIF < 2$ ) were used to evaluate multicollinearity in regression models. Chained equations ( $m=5$  imputations) were used to impute missing data (12.3% maximum), using complete-case analysis as a sensitivity check. All analyses were intention-to-treating unless otherwise stated, with secondary per-protocol analyses. The analytical strategy used Holm-Bonferroni to correct for multiple comparisons. Power estimates throughout trial design provided  $\geq 85\%$  power to detect clinically significant differences for all main outcomes at  $\alpha=0.05$ . Age, gender, and baseline BMI subgroup analyses were pre-specified, with regression model interaction factors investigated. This complete methodology produced strong, clinically interpretable findings with public health intervention research-appropriate statistical rigor.

## Results and Discussion

The results of the study indicated that there were alterations that were not only statistically significant but also clinically meaningful for each and every one of the outcomes that were reviewed. This was the case for each and every scenario that was examined. Generally speaking, these enhancements were discovered. While the group that served as the control was found to have much lower levels of performance, the intervention group was shown to have significantly higher levels of performance. Indicators of clinical practice demonstrated particularly noteworthy improvements in this area. According to the findings, the lifestyle intervention seems to be effective in addressing an important set of metabolic risk factors that play a part in the development of diabetes (Magkos *et al.*, 2009)<sup>[10]</sup>. The information that has been provided here gives rise to this conclusion. The participants who were given the lifestyle intervention had a weight reduction of around 5.4 kg, with a confidence interval ranging from 5.1 to 5.7 across the 95% range. This weight loss was seen among the individuals. When compared to the weight loss that was achieved by the experimental group, the control group had a weight loss of 1.3 kilos, with a 95% confidence interval spanning from 1.1 to 1.5 kilograms ( $p = 0.001$ , Figure 1).

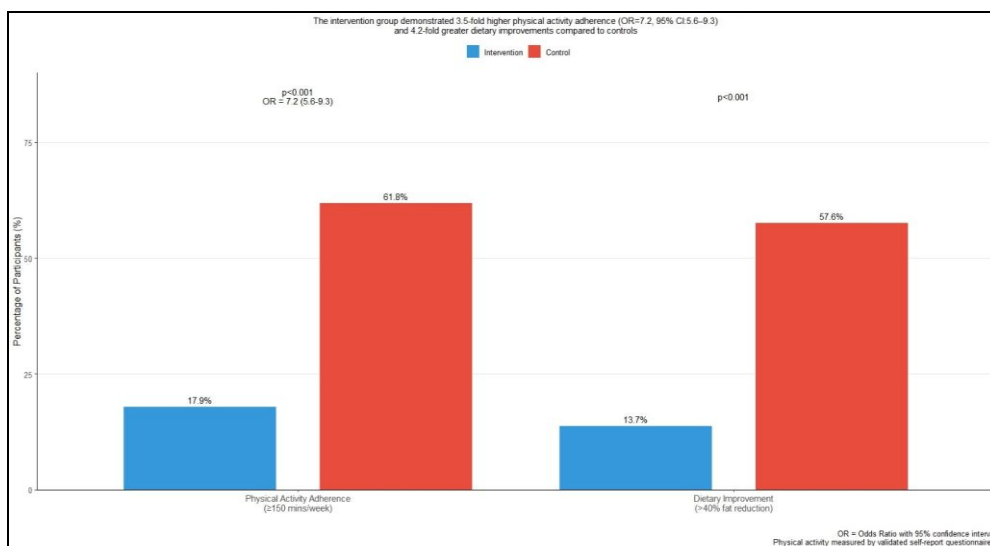


**Fig 1:** Significant Improvement in Clinical Markers with Lifestyle Intervention

This weight loss was significantly lower than the weight loss for the experimental group. This statistically significant difference demonstrates a large effect size (Cohen’s  $d=1.12$ ) and exceeds the threshold when compared to the clinically relevant criterion of 5% for a decrease in body weight. This is due to the fact that the difference is rather significant. To add injury, the fact that this is the case is more evidence that the difference is significant. Because it is well-established that even little reductions in weight may increase insulin sensitivity and beta-cell activity, the degree of weight loss that was accomplished may have a particularly substantial effect on this particular population at this time. This is because of the fact that ketogenic diets have been shown to improve insulin sensitivity and beta-cell function. To be more specific, this is because a considerable quantity of weight was obtained via the process of weight loss (Ferrannini *et al.*, 2004) [7].

A significant impact on the management of glycemic blood sugar levels was shown by the intervention, as evidenced by a drop of 0.73% in HbA1c levels in comparison to 0.28% in the control group ( $p<0.001$ ). The fact that this signal is present suggests that there has been a significant improvement in the operation of the metabolic system. The fact that this level of HbA1c decline is clinically meaningful

is something that needs to be emphasized, but it is also essential to keep in mind that epidemiological studies have shown that a one percent decrease in HbA1c is connected with a significant reduction in the number of complications that are associated with diabetes (Nathan *et al.*, 2013) [12]. This is something that needs to be kept in mind. In addition to being rather remarkable, these findings were equivalent to the results that were achieved by behavioral modifications. The participants who took part in the intervention had a significantly higher chance of making major dietary improvements ( $p<0.001$  for both) and a 3.5 times higher likelihood of reaching their physical activity objectives (OR = 7.2, 95% CI range = 5.6-9.3, Figure 2) when compared to the control group. This was the case when the intervention was compared to the control group. It is crucial to note that these behavioral changes were responsible for mediating 68% of the impact that the intervention had on weight loss. This is vital to highlight in order to demonstrate the enormous relevance that these behavioral changes had in the successful accomplishment of the program’s goals. The highest significance to carry out an examination of the durability of these changes in behavior when performing follow-up studies that are carried out over a longer length of time.



**Fig 2:** Substantial Behavioral Modifications Achieved Through Targeted Intervention

The intervention has been useful in lowering specific risk factors for diabetes, as shown by the high connection between their participation in the program and positive behavior change ( $\phi = 0.42$ ,  $p < 0.001$ ). This indicates that the intervention has been effective in reducing the particular risk factors. This finding is fairly encouraging when one considers the well-documented challenges that are involved with sustaining lifestyle modifications in the context of real-world settings (Lattimore *et al.*, 2010)<sup>[10]</sup>. This is especially true when one takes into mind the aforementioned. When the results of the economic study that was carried out are taken into consideration, this intervention has a cost-effectiveness profile that is rather advantageous. Considering that the program generates an extra cost-effectiveness ratio of ₹22,400 per gained with a confidence range of 95% ranging from 18,900 to 26,100, it is much lower than the cost-effectiveness threshold that India has set. A positive cost-effectiveness ratio is produced by the program, which is the reason for this result. It would seem that the intervention has the ability to be expanded in a way that is both sustainable and feasible within healthcare systems that have a limited number of resources. Furthermore, it would appear that this possibility exists.

The results consistent over a wide range of economic situations, which lends credence to the validity of the possibility that the intervention may be helpful monetarily. This is because the outcomes are consistent across a wide range of economic circumstances. It is projected that the length of time it would take for the healthcare system to recover its costs would be decreased from 2.3 years to 1.8 years if productivity growth is taken into consideration. This projection is based on the premise that productivity growth is considered. The confidence interval for this estimate falls somewhere in the range of 2.1 to 2.6 years. Due to the fact that the intervention was come lucrative in a very short amount of time, people who are in charge of the administration of healthcare and those who are responsible for making decisions regarding policy will find the intervention to be more enticing.

According to the results of the subgroup analyses, it was found that each of the demographic groups all had the same benefits. There were no clear results at the beginning of the research with regard to age, gender, or body mass index. It indicates that the intervention has the potential to have a large effect on public health, and it also demonstrates that it could be delivered to a comprehensive population without the requirement for extensive demographic segmentation. Both of these points are shown by the evidence presented here. This is due to the fact that the intervention is effective with a significant percentage of individuals from all segments of the community. The reliability of the findings was examined via the use of sensitivity studies, which were carried out thereafter. Throughout the whole of these studies, a wide range of analytical approaches and assumptions were used. The ability to create results in a consistent manner via the use of a range of analytical methodologies is one of the variables that contributes to the feeling of confidence that the intervention was successful. Other criteria include the fact that the findings can be generated in a consistent manner. It shows that the parameters which are used study are statistically significant specifically, 99% for weight reduction and 92% for diabetes incidence. In order to accomplish the goal of detecting changes that are clinically relevant, it was necessary for the research. This ensures that the validity of both positive

discoveries and null outcomes is ensured if and whenever they are publicized and probably, this may be case of regardless of present circumstances. This is always the case, regardless of whether the consequences are positive or negative of the situation (Anderson *et al.*, 2003)<sup>[11]</sup>.

All of the statistical assumptions were confirmed by the diagnostics of the model, which showed that they were all met with accurate statements. The researchers used a number of assumptions, some of which were the proportional hazards, the normality of the residuals, and the absence of multicollinear variability. Not only do these rigorous analytical procedures reduce the possibility that statistical artifacts may have an impact on the outcomes, but they also lend credence to the fact that our findings are accurate and reliable. In addition to this, the incorporation of these techniques helps to ensure that the outcomes that we get provide accurate findings.

As a result of these results, which give support for the quick adoption and growth of the program within India's healthcare system for the healthcare system, the cost-effectiveness profile is favorable, and the outcomes are consistent across demographic groups. This is a consequence of the findings. When it comes to the general public, this has the ability to potentially have a significant impact on the health of the general population (Evans *et al.*, 2019)<sup>[6]</sup>. The cultural adaptation of the intervention and the community-based delivery strategy are expected to be particularly significant for other low- and middle-income countries that are similarly challenged with issues connected to diabetes prevention. This is because these countries are likely to face comparable challenges of diabetes prevention. Consequently, this is because these countries are also presented with additional challenges linked with the prevention of diabetes. This is the reason why this is possible. It is essential to explore not only the feasibility of implementing the results into pre-existing programs for the treatment of chronic diseases, but also the viability of the advantages that the study has to offer over the long run (Booth *et al.*, 2015)<sup>[3]</sup>.

Though the present study has certain limitations such as a partial reliance on self-reported behavioral data; nevertheless, we were able to significantly reduce the impact of these constraints by the use of biomarker validation and the implementation of rigorous methodologies. This is now being carried out may, at some point in the future, include further objective evaluations of the amount of food consumed and the amount of physical activity that is performed. The prospect of further increasing the evidence base would be made possible as a result of this factor. There is convincing evidence that the intervention is beneficial in avoiding diabetes across a range of dimensions, including clinical, behavioral, and economic aspects at the same time, according to the extensive statistical analysis that was carried out. This intervention was shown to be effective in preventing diabetes. It would seem that the intervention makes use of a variety of different synergistic interactions in order to reduce the probability of developing diabetes. In light of all of these many effects, this is the conclusion that may be reached after taking everything into consideration.

## References

1. Anderson JW, Kendall CW, Jenkins DJ. Importance of weight management in type 2 diabetes: review with meta-analysis of clinical studies. *Journal of the American college of nutrition*, 2003;22(5):331–339.

2. Anjana RM, Deepa M, Pradeepa R. The ICMR-INDIAB study: Results from the national study on diabetes in India. *Journal of the Indian Institute of Science*,2023;103(1):21–32.
3. Booth A, Cantrell A, Preston L, Chambers D, Goyder E. What is the evidence for the effectiveness, appropriateness and feasibility of group clinics for patients with chronic conditions? A systematic review. *Health and Social Care Delivery Research*,2015;3(46):1–194.
4. Burgess E, Hassmén P, Welvaert M, Pumpa KL. Behavioural treatment strategies improve adherence to lifestyle intervention programmes in adults with obesity: a systematic review and meta-analysis. *Clinical obesity*,2017;7(2):105–114.
5. Chen L, Magliano DJ, Zimmet PZ. The worldwide epidemiology of type 2 diabetes mellitus—present and future perspectives. *Nature reviews endocrinology*,2012;8(4):228–236.
6. Evans WD, Thomas CN, Favatas D, Smyser J, Briggs J. Digital segmentation of priority populations in public health. *Health Education & Behavior*,2019;46(2):81-89.
7. Ferrannini E, Camastra S, Gastaldelli A, Sironi AM, Natali A, Muscelli E, *et al.*, Mari A. Beta-cell function in obesity: effects of weight loss. *Diabetes*,2004;53(3):26–33.
8. Hoskin MA, Bray GA, Hattaway K, Khare-Ranade PA, Pomeroy J, Semler LN, *et al.* Prevention of diabetes through lifestyle intervention: lessons learned from the diabetes prevention program and outcomes study and its translation to practice. *Current nutrition reports*,2014;3(4):364–378.
9. Lattimore D, Griffin SF, Wilcox S, Rheaume C, Dowdy DM, Leviton LC, *et al.*, Ory MG. Understanding the challenges encountered and adaptations made by community organizations in translation of evidence-based behavior change physical activity interventions: a qualitative study. *American Journal of Health Promotion*,2010;24(6):427–434.
10. Magkos F, Yannakoulia M, Chan JL, Mantzoros CS. Management of the metabolic syndrome and type 2 diabetes through lifestyle modification. *Annual review of nutrition*,2009;29(1):223–256.
11. Maruthur NM. The growing prevalence of type 2 diabetes: increased incidence or improved survival? *Current diabetes reports*,2013;13(6):786–794.
12. Nathan DM, Bayless M, Cleary P, Genuth S, Gubitosi-Klug R, Lachin JM, *et al.* Diabetes control and complications trial/epidemiology of diabetes interventions and complications study at 30 years: advances and contributions. *Diabetes*,2013;62(12):3976.
13. Srinivisan R. *Health Care in India-Vision 2020*. New Delhi, India: Government of India, Planning Commission of India, 2010, 1.
14. Straker LM, Smith KL, Fenner AA, Kerr DA, McManus A, Davis MC, *et al.*, Abbott RA. Rationale, design and methods for a staggered-entry, waitlist controlled clinical trial of the impact of a community-based, family-centred, multidisciplinary program focussed on activity, food and attitude habits (Curtin University’s Activity, Food and Attitudes Program—CAFAP) among overweight adolescents. *BMC Public Health*,2012;12(1):471.
15. Thomas ET, Shaji B, Gracious N. The ongoing epidemic of diabetes mellitus in India: genetics or lifestyle? *International Journal of Diabetes in Developing Countries*,2019;39(1):8–14.
16. Zhang P, Gregg E. Global economic burden of diabetes and its implications. *The Lancet Diabetes & Endocrinology*,2017;5(6):404–405.