



BMJ Open Community health worker-led, technology-enabled private sector intervention for diabetes and hypertension management among urban poor: a retrospective cohort study from large Indian metropolitan city

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ABSTRACT

Objectives We assessed the effectiveness of community health workers (CHWs)-led, technology-enabled programme as a large-scale, real-world solution for screening and long-term management of diabetes and hypertension in low-income and middle-income countries.

Design Retrospective cohort design.

Setting Forty-seven low-income neighbourhoods of Hyderabad, a large Indian metropolis.

Participants Participants (aged ≥20 years) who subscribed to an ongoing community-based chronic disease management programme employing CHWs and technology to manage diabetes and hypertension.

Primary and secondary outcome measures We used deidentified programme data between 1 March 2015 and 8 October 2018 to measure participants' pre-enrolment and post-enrolment retention rate and within time-interval mean difference in participants' fasting blood glucose and blood pressure using Kaplan-Meier and mixed-effect regression models, respectively.

Results 51 126 participants were screened (median age 41 years; 65.2% women). Participant acquisition rate (screening to enrolment) was 4%. Median (IQR) retention period was 163.3 days (87.9–288.8), with 12 months postenrolment retention rate as 16.5% (95% CI 14.7 to 18.3). Reduction in blood glucose and blood pressure levels varied by participants' retention in the programme. Adjusted mean difference from baseline ranged from –14.0 mg/dL (95% CI –18.1 to –10.0) to –27.9 mg/dL (95% CI –47.6 to –8.1) for fasting blood glucose; –2.7 mm Hg (95% CI –7.2 to 2.7) to –7.1 mm Hg (95% CI –9.1 to –4.9) for systolic blood pressure and –1.7 mm Hg (95% CI –4.6 to 1.1) to –4.2 mm Hg (95% CI –4.9 to –3.6) for diastolic blood pressure.

Conclusions CHW-led, technology-enabled private sector interventions can feasibly screen individuals for non-communicable diseases and effectively manage those who continue on the programme in the long run. However, changes in the model (eg, integration with the public health system to reduce out-of-pocket expenditure) may be needed to increase its adoption by individuals and thereby improve its cost-effectiveness.

Strengths and limitations of this study

- The study provides real-world evidence on effectiveness of a large-scale pragmatic programme in practice to screen and manage chronic diseases at a community level.
- It adjusted for the contextual factors overlooked by regimented studies carried out in controlled settings that may change the impact of the intervention.
- It reports the benefits and shortfalls of the private sector for bolstering primary care for non-communicable diseases in resource constraint settings.
- The study findings were not compared with a control group to obtain the incremental effect of the intervention.
- The determinants of programme sustainability, that is, programme cost and participant cost incurred and averted were not analysed.

INTRODUCTION

Non-communicable diseases (NCDs) cause 35 million of the 53 million annual deaths worldwide, 80% of which occur in low-income and middle-income countries (LMICs).^{1 2} In India, NCDs account for more than 60% of all deaths,³ with cardiovascular diseases (CVDs) being the leading cause and accounting for more than a quarter of these deaths.^{4 5} CVDs, along with diabetes mellitus, are projected to result in a US\$2.32 trillion loss in India's national income between 2012 and 2030, largely driven by the high and rising prevalence of uncontrolled hypertension and blood glucose.^{5 6} Among the urban adult population in India, more than 1/3rd are estimated to have hypertension⁷ and more than 1/10th are estimated to have diabetes; a substantial fraction of these being from population

segments with lower socioeconomic status.⁸ The number of people with hypertension is estimated to increase to 213.5 million in 2025⁹ whereas those with diabetes is estimated to increase to 123.5 million by 2040.^{8, 10} Multiple studies have reported poor awareness, treatment and control of these two conditions in India.^{11, 12} One study reported that around 30% of the people with diabetes, across three states and a union territory, had controlled blood glucose¹³ whereas another study found that around 20% of the people with hypertension in urban areas had controlled blood pressure.⁷

Management of NCDs such as hypertension and diabetes in many LMICs such as India is constrained by weak health systems and shortage of qualified physicians and health workers, who are overburdened with tackling infectious diseases and maternal and child health challenges.^{14–16} Consequently, experts have argued for an integrated primary and community care approach involving task-sharing and task-shifting to non-physician and lay community health workers (CHWs)¹⁵ based on robust evidence about its effectiveness in screening for as well as management of hypertension and diabetes.^{16, 17} Multiple controlled studies in India as well as neighbouring countries in South Asia have also evaluated and found support for this approach's effectiveness.^{18–21}

However, whether findings from these resource-intensive, limited-scale, controlled studies can be transferred to a large-scale, real-world implementation in the Indian health system is not known. First, these studies were embedded in the public health facilities whereas more than 80% of outpatient visits in India occur in the private sector,²² which is often characterised by low quality of care.²³ Second, study participants often do not have to pay for the services they receive but more than 70% of the health expenditure in India is out of pocket,²⁴ which is a major cause of economic hardship for households.²⁵

In this paper, we attempt to bridge this gap with evidence from a CHW-led, technology-enabled intervention of diabetes and hypertension screening and management in the private sector aimed at urban poor population in a large Indian metropolitan city. In particular, we analyse the retention of participants on the programme and the change in their blood pressure and blood sugar over the course of their engagement with the programme.

Community-based programme

We studied an ongoing community-based programme of screening, diagnosis, and management of hypertension and diabetes that leverages trained and certified CHWs and an integrated proprietary technology platform. The programme is targeted towards adults (>20 years) in 47 low-income neighbourhoods of the city of Hyderabad in Telangana state of India. Most individuals in the target population are employed in the unorganised sector of the economy and earn US\$215–US\$430 per month per household compared with the national average per capita income of US\$1243.²⁶ The programme also has a network of empaneled providers such as formally

qualified physicians, licensed pharmacies, laboratories and dieticians who offer services at incentivised rates to participants.

Case finding/detection

CHWs conduct free screening to identify participants at-risk for diabetes (fasting blood glucose (FBG) ≥ 100 mg/dL, random blood glucose (RBG) ≥ 140 mg/dL or those on prescribed antiglycaemic) and hypertension systolic/diastolic blood pressure (SBP/DBP $\geq 120/80$ mm Hg or those on prescribed antihypertensive medication). Screening is conducted through screening camps, which are held twice in the first month of operation in every neighbourhood, and subsequently through household visits. During screening, CHWs collect information on demographics, medical history and chief complaints of all willing individuals in the household using a structured questionnaire. CHWs measure anthropometric measurements (height, weight, waist and hip circumference), SBP and DBP, respectively, and RBG and FBG, respectively using handheld tablets against a unique identifier. Physical measurements (anthropometrics and blood pressure at rest) and blood glucose levels are measured using standardised instruments for each participant. The height and weight of participants are measured while they were bare-foot with light clothing. Weight is measured to the nearest 10 g using an electronic scale, while height is measured to the nearest 0.1 cm using anthropometric tape. Blood pressure is measured on the right arm using an appropriately sized cuff connected to a digital device (Digital Omron BP apparatus). Blood pressure measurements are taken for each participant at rest in the sitting position. A dry chemistry method is used to measure blood glucose using capillary blood glucose measurement device (Abbott Freestyle Optium Neo). The testing for FBG is done after >8 hours of fasting. Screened participants, who are found at-risk, are contacted, at their residence, for reassessment within 3 days to minimise incidental false-positive findings. Participants, who are found at-risk on reassessment, are referred to one of the programme's empaneled laboratories or physicians for confirmation of diagnosis and initiation of antidiabetes or antihypertensive treatment. Participants pay out-of-pocket for testing and consultation services at a discounted rate.

Case monitoring and management

Participants who receive a confirmed diagnosis of diabetes or hypertension by the empaneled physician and those with history (defined as self-reported with antiglycaemic or antihypertensive medication usage) are encouraged to enrol in the disease management plan (DMP) for a monthly subscription fee of about USD 1.4. On enrolment, participants receive monthly in-person visits at their residence by CHWs as a part of the DMP. During these visits, CHWs measure participants' health parameters (anthropometrics and FBG), perform standard screening assessments (eg, diabetic foot examination), counsel on medication compliance and lifestyle modifications (eg,

diet as suggested by the programme dietician, consumption of tobacco and alcohol, physical activity), and facilitate referral to empaneled qualified physicians for more advanced clinical needs. At-risk participants, who refuse to enrol, are counselled for lifestyle modification and to get a quarterly screening to monitor disease progression. Low-risk participants (FBG <100mg/dL and/ or SBP/DBP <120/80 mm Hg) are advised to enrol for free biannual screening. Participants who refuse to seek care under the plan typically practice self-management or avail of intermittent treatment and care for hypertension and diabetes from other providers.

Community health workers

CHWs are trusted female residents in the target neighbourhoods with high school education, good communication skills in the local language and working knowledge of English. They are recruited through a standardised aptitude and behaviour test and undergo rigorous week-long initial training and a weekly 6 hours refresher training session. Training is focused on risk assessment, disease management, use of point-of-care devices, tablet-based application and various operational protocols. All training sessions are conducted by the programme's in-house qualified physicians in local language and are adapted to the local cultural setting. CHWs work 4–5 hours per day for a combination of fixed salary and performance-based incentives. Each CHW, equipped with a point-of-care diagnostic kit called Doc-in-a-Bag that includes a tablet-based module, has an outreach population of around 5000.

Technology platform

All programme activities are supported by an integrated proprietary technology platform, which is developed and maintained by an in-house team. It comprises of a tablet-based application that is used by the CHWs to record participant data during screening and monthly management visits. The application has an inbuilt algorithm to assess participants' risk level and provide recommendations on the appropriate DMPs or referrals to physicians by highlighting abnormal values of clinical parameters. The data entered by the CHWs are transferred to a central database which is hosted on a server cloud. The application also helps CHWs to manage their tasks through push notifications and reminders and tracking their completion against timelines. Data stored on the central server can be accessed by CHWs and by empaneled physicians in subsequent visits for coordinated care delivery. Programme managers can also use the database to monitor CHWs' performance using several operational metrics (eg, number of new enrolment per month, number of visits per day).

METHODS

We conducted a retrospective cohort study of the programme participants from 47 low-income

neighbourhoods of Hyderabad, India using routinely collected programme data.

Study participants

We defined eligible participants as those who were first screened between 1 March 2015 and 15 March 2017. For pre-enrolment analysis, we excluded those who satisfied at least one of the following criteria: underwent subsequent screenings after 3 months of the last screening, visited empaneled doctors or enrolled in the programme before their last screening visit, did not undergo more than one screening, were untraceable, or were reported as being dead during subsequent visits pre-enrolment. For post-enrolment analysis, we further excluded those participants who either did not have any follow-up visit or had missing any recorded measurements of FBG/BP during follow-up visits before the end of study period.

Patient and public involvement

Patients and the public were not involved in the design, or conduct, or reporting, or dissemination plan of our research.

Data collection

We collected deidentified programme data comprising information recorded during screening and follow-up visits between 1 March 2015 and 8 October 2018. It included demographics (age, gender), diagnostics (doctor's diagnosis, date of diagnosis, confirmation test), physical measurements (anthropometrics and SBP/DBP), biomarkers (FBG/RBG), medical and family history, chief complaints, date and type of each visit (screening vs follow-up) and participant status at the visit (screened, diagnosed, enrolled, refused for screening, untraceable, dropped-out, unavailable, not-alive). Definition of each status is presented as online supplemental table 1.

Statistical analysis

Our coprimary outcome measures were participants' pre-enrolment and post-enrolment retention rate and mean change in blood pressure (SBP, DBP) and blood glucose (FBG) from baseline.

For analysis of participant retention, we defined four stages of participants' care seeking: (1) screened by CHWs, (2) reassessed by CHWs, (3) diagnosed by doctor and (4) enrolled. We estimated pre-enrolment retention rate as a proportion of screened participants who proceeded to stages (2), (3) and (4). We estimated post-enrolment retention rate as a proportion of participants with diabetes or hypertension, who remained enrolled on the plan until the date on which last post-enrolment visit was recorded using Kaplan-Meier method. We used log-rank test to determine differences in retention rates by gender (male vs female), disease (hypertension vs diabetes vs hypertension and diabetes) and prior history of the treatment (yes vs no). We also calculated additional post-enrolment retention metrics: drop-out rate (number of participants who dropped out from the plan per 1000 person-months) and median retention period (in days).

For analysis of health outcomes, we calculated the change in mean FBG, SBP and DBP among enrolled participants with diabetes and hypertension, respectively, from baseline at multiple follow-up intervals. We defined baseline as the date of diagnosis, or the date of last screening visit or the first day of enrolment, whichever was latest. We defined six follow-up intervals starting from 30th day after baseline and each measuring roughly 6 months. Details are presented in online supplemental table 2. For each health outcome (FBG, SBP, DBP), we fitted six linear mixed models, each estimating the average change in that outcome from baseline over one of the six follow-up intervals. Each model was estimated using a subset of the entire data comprising observations from the baseline and the corresponding follow-up interval. The dependent variable in each model was the relevant outcome (FBG, SBP, DBP). In the unadjusted model, the main explanatory variable was a categorical variable indicating whether the observation was for baseline or follow-up interval. In the adjusted model, we also included a set of potential confounders (eg, age, gender, baseline value, body mass index (BMI), family history, comorbidity). All models included a random effect of area of residence to account for the clusters and allowed for an unstructured correlation matrix. All statistical analyses were conducted using STATA software V.15.

RESULTS

Baseline characteristics of screened participants

Approximately 3% (1386) of the eligible participants (52 512) were excluded from this analysis as per the pre-enrolment selection criteria (online supplemental table 3). Included participants (51 126) were younger, had lower BMI and waist circumference (WC), lower blood pressure than those excluded (online supplemental table 4).

Table 1 shows the characteristics of these participants. Median age of the participants was 41 years. Majority (65%) of the participants were women. Small proportion of the participants had a history of diabetes (11%) and hypertension (15.9%). Median BMI of the participants was 24.2 kg/m² and majority (61.4%) had abdominal obesity. Median FBG and RBG of the participants were 113.0 mg/dL and 117.0 mg/dL, respectively, 38.8% and 9.7% of the participants had FBG ≥ 126 mg/dL and RBG ≥ 200, mg/dL respectively. Median SBP and DBP were 124.0 mm Hg and 82.0 mm Hg, respectively, 23.3% and 27.9% of the participants had SBP ≥ 140 mm Hg and DBP ≥ 90 mm Hg, respectively. More detailed distributions of these characteristics are available in online supplemental table 5.

Pre-enrolment retention rate

Figure 1 shows the number of participants across various stages from screening until enrolment. During the first screening, 23 908 out of 51 126 participants (46.8%) were found to be at-risk of diabetes or hypertension. Of these, 15 113 (63.2%) were reassessed, 5812 (24.3%)

Table 1 Baseline characteristics of participants screened by community health workers for diabetes and hypertension

	Total participants (N=51 126)*
Age (years), median (IQR)	41.0 (32.0–52.0)
Gender	
Male, N (%)	17 811 (34.8)
Female, N (%)	33 315 (65.2)
BMI (kg/m ²), median (IQR)	24.2 (21.1–27.7)
Waist Circumference (cm), median (IQR)	86.4 (81.3–94.0)
Abdominal obesity†	
Yes, N (%)	31 398 (61.4)
No, N (%)	19 728 (38.6)
Fasting plasma glucose level (mg/dL)‡§¶	
Median (IQR)	113.0 (98.0–154.0)
≥126 (%)	38.8
Random blood glucose (mg/dL)‡§¶	
Median (IQR)	117.0 (100.0–143.0)
≥200 (%)	9.7
Systolic blood pressure (mm Hg)‡	
Median (IQR)	124.0 (112.0–138.0)
≥140 (%)	23.3
Diastolic blood pressure (mm Hg)‡	
Median (IQR)	82.0 (75.0–90.0)
≥90 (%)	27.9
History of diabetes	
Yes, N (%)	5626 (11.0)
No, N (%)	45 500 (89.0)
History of hypertension	
Yes, N (%)	8156 (15.9)
No, N (%)	42 970 (84.1)

*Missing data not presented.

†Abdominal obesity measured as waist circumference ≥ 90 cm in men and ≥ 80 cm in women.

‡Include those who were on medication.

§Percentages represent sets of observations of participants with measures of either random blood glucose or fasting blood glucose.

¶Column per cent of the subset population, n=655 for fasting blood glucose and n=50 401 for random blood glucose.

BMI, body mass index.

were lost to follow-up, 729 (3.0%) directly enrolled in the plan, 227 (0.9%) went directly for doctor's consultation and 2027 (8.5%) were not followed up until the end of study period. Of the 15 113 reassessed participants, 9688 (64.1%) were again found at-risk. Of these 2671 (27.6%) agreed to visit the doctor for obtaining confirmed diagnosis, 1056 (10.9%) directly enrolled in the plan, 4568 (47.2%) were lost to follow-up and 1393 (14.4%) were not followed up until the end of study period. On a doctor visit, 2361 of the 2898 participants (81.5%) were

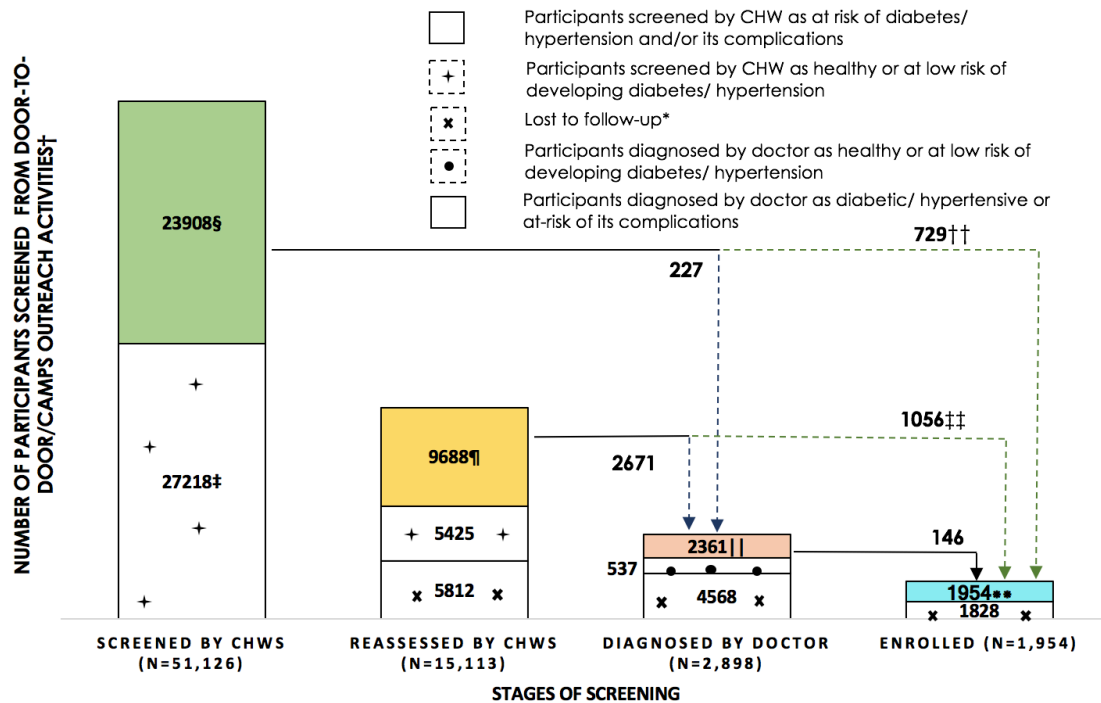


Figure 1 Participants screening cascade: participants screened by community health workers (CHWs) for diabetes and hypertension. *These include participants who either refused to continue with the programme, or were un-trackable, or were found unavailable at their homes during follow-up screening visit before the end of study period. †The screening cascade represents N=51 126 participants and is limited until the participant enrolled in the plan or was lost during follow-up before the end of the study period. ‡Total 52 participants were eventually screened/diagnosed as at-risk of diabetes/hypertension. §2,057 participants did not have a follow-up visit before the end of study period. ¶, ||, **, 43%, 53%, 47%, 74% respectively had previous history of diabetes/hypertension or both.

diagnosed with diabetes or hypertension and 537 participants (18.5%) were diagnosed healthy. Of those diagnosed with diabetes or hypertension, 146 participants (6.1%) eventually enrolled in the plan before the end of study period. Overall, 1954 participants enrolled on the plan representing 4% of the total screened. About half (47.2%–57.1%) of the participants at various stages of screening were newly detected cases, that is, they were not aware of their condition (online supplemental table 6).

Postenrolment retention rate

Approximately 14% (273) of the enrolled participants (1954) were excluded from this analysis as per the postenrolment selection criteria. Figure 2 shows the Kaplan-Meier curves for retention of participants in the programme after enrolment. Retention rates (95% CI) were 75.3% (73.1% to 77.3%), 44.0% (41.6% to 46.4%), 27.9% (25.7% to 30.1%), 16.5% (14.7% to 18.3%) and 9.7% (8.3% to 11.2%) at 3, 6, 9, 12 and 15 months postenrolment, respectively. Retention rates were not significantly different across various subgroups based on age, gender, etc (online supplemental table 7). Overall, 1577 participants dropped out over an observation period of 11 469.8 person-months yielding a drop-out rate of 137.4 per 1000 person-month. Average retention period was around 213.5 days whereas median retention period was 163.3 days.

Baseline characteristics of enrolled participants

Approximately 43% (844) of the enrolled participants (1,954) were excluded from this analysis as per the postenrolment selection criteria. Table 2 shows a summary of the key characteristics. Median age of the participants was 53 years and the majority (59.6%) of the participants were females. Median BMI was 25.9 kg/m² with more than three-fourths (77.9%) being abdominally obese (defined as ≥90 cm in men and ≥80 cm in women). Median FBG was 141.5 mg/dL whereas median SBP and DBP were 137 mm Hg and 90 mm Hg, respectively. Participants enrolled in the plan were older, had higher BMI and WC, higher median FBG, SBP and DBP compared with those screened (online supplemental table 8). Among enrolled participants, participants with history of diabetes had a higher median FBG at baseline compared with those without (167 mg/dL vs 120 mg/dL; p<0.001). Similarly, participants with history of hypertension had higher median SBP (139 mm Hg vs 135 mm Hg; p=0.002) but similar median DBP (89.0 mm Hg vs 90.0 mm Hg; p=0.29) compared with those without. See online supplemental table 9 for a detailed comparison of other attributes.

Health outcomes of enrolled participants

Table 3 shows the change in FBG from baseline until different follow-up periods. After adjusting for confounders, mean change in FBG was statistically

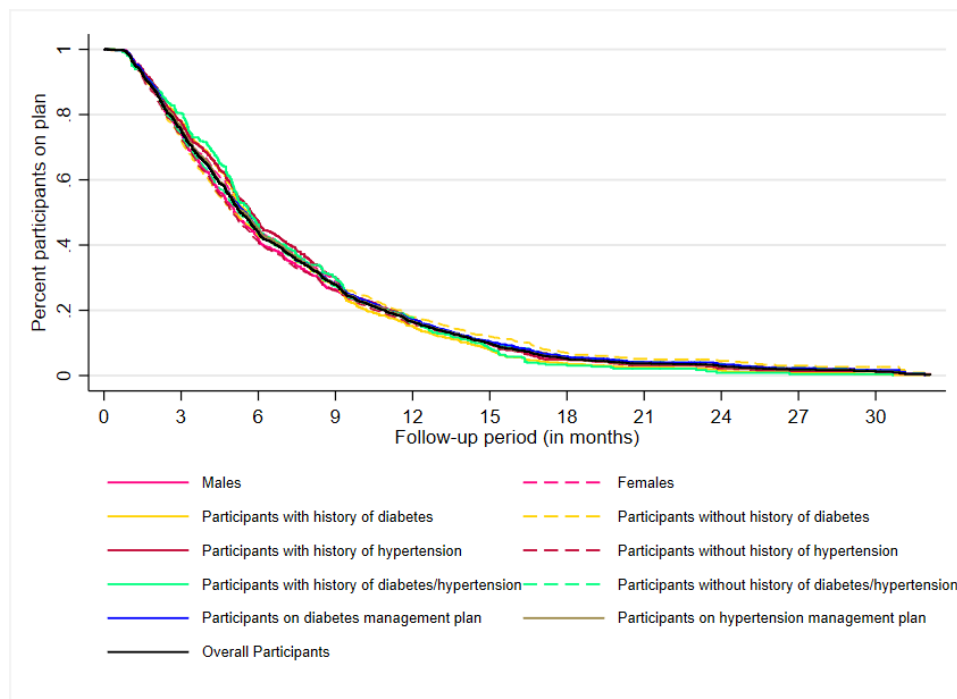


Figure 2 Cumulative retention rate* of participants enrolled under diabetes and/or hypertension management programme. *Kaplan-Meier method for cumulative retention rate. Terminal statuses were defined as the last recorded status of the participant which include dropped-out or enrolled on the plan. Not-alive or on-hold participants were also considered as dropped-out. Days on plan were calculated as days for which a participant was enrolled in the plan starting from the start date (date their baseline value was measured) till the end-date (date their terminal status was recorded). Participants who were unavailable for more than 3 post-enrollment visits with days between either of the two consecutive visits as more than 90 days were considered as dropped-out from the plan, and the date on which they were first found to be unavailable was considered as their end-date on the plan. Loss to follow-up included participants who were found unavailable at their homes during follow-up screening visit, before the end of study period.

significant at all follow-up periods. It varied from -14.0 mg/dL ($p < 0.001$; 95% CI -18.1 mg/dL to -10.0 mg/dL) at Period 1 to -27.9 mg/dL ($p < 0.05$; 95% CI -47.6 mg/dL to -8.1 mg/dL) at Period 6. Results were similar for participants with history of diabetes; mean change in FBG varied from -11.8 mg/dL ($p < 0.001$; 95% CI -16.7 mg/dL to -7 mg/dL) at Period 1 to -33.7 mg/dL ($p < 0.05$; 95% CI -58.7 mg/dL to -8.6 mg/dL) at Period 6. For participants without a history of diabetes, mean change in FBG was statistically significant at Periods 1–4 but not for Periods 5 and 6. The proportion of total participants with controlled measures of FBG varied from 22.7% in period 6 to 35.5% in Period 5 (online supplemental table 10).

Tables 4 and 5 show a reduction in mean SBP and DBP from baseline at all follow-up periods. For SBP, after adjusting for confounders, mean change from baseline was statistically significant for Periods 1 through 5. It varied from -5.3 mm Hg ($p < 0.001$; 95% CI -6.4 mm Hg to -4.3 mm Hg) at Period 1 to -4.4 mm Hg ($p < 0.05$; 95% CI -8.1 mm Hg to -0.8 mm Hg) at Period 5. Results were similar when estimated separately for participants with and without treatment history of hypertension. The proportion of total participants with controlled measures of SBP varied from 64.6% in period 3 to 72.5% in period 6 (online supplemental table 10). For DBP, after adjusting for confounders, mean change from baseline

was statistically significant for Periods 1–4. It varied from -3.2 mm Hg ($p < 0.001$; 95% CI -3.8 mm Hg to -2.5 mm Hg) at Period 1 to -3.4 mm Hg ($p < 0.001$; 95% CI -4.9 mm Hg to -1.9 mm Hg) at Period 6. Again, results were not very different when estimated separately for participants with and without history of hypertension.

DISCUSSION

This study provides real-world evidence from a large-scale, CHW-led, technology-enabled intervention for screening and management of diabetes and hypertension targeted at urban poor in India. Our findings demonstrate the feasibility of employing lay health workers with minimal training in screening at-risk participants and in reducing SBP/DBP and FBG for participants who remained enrolled in the DMP. However, the programme faced difficulties in retaining enrolled participants over longer durations, which could limit its impact on health outcomes as well as its financial sustainability.

The fraction of adult population identified by CHWs to be at-risk was similar to that reported for urban Telangana in a nationally representative survey, both for hypertension (SBP ≥ 140 mm Hg; 23.2% vs 25.5%) and diabetes (RBG ≥ 200 mg/dL; 9.7% vs 9.0%).²⁷ A large proportion (81.5%) of the participants screened to be at-risk by the

Table 2 Baseline characteristics of participants enrolled in diabetes and/or hypertension management programme

	Total Participants (N=1110)	Participants without history of diabetes (N=518)††	Participants with history of diabetes (N=592)††	P value	Participants without history of hypertension (N=487)‡	Participants with history of hypertension (N=623)‡	P value
Age (years), median (IQR)	53.0 (46.0–63.0)	52.0 (43.0–62.0)	56.0 (48.0–63.0)	0.00*	50.0 (43.0–58.0)	57.0 (49.0–65.0)	0.00*
Gender							
Male, N (%)	448 (40.4)	198 (38.2)	250 (42.2%)	0.17	210 (43.1)	238 (38.2)	0.09
Female, N (%)	662 (59.6)	320 (61.8)	342 (57.8%)		277 (56.9)	385 (61.8)	
BMI, median (IQR)	25.9 (23.3–29.5)	26.1 (23.4–30.0)	25.7 (23.1–29.1)	0.37	25.4 (23.0–29.1)	26.2 (23.5–30.1)	0.00†
Waist circumference (cm), median (IQR)	91.4 (86.4–99.1)	91.4 (86.4–99.1)	91.4 (86.4–99.1)	0.78	91.4 (83.8–99.1)	91.4 (86.4–101.6)	0.00*
Abdominal obesity§							
Yes, N (%)	865 (77.9)	402 (77.6)	463 (78.2)		357 (73.3)	508 (81.5)	0.00†
No, N (%)	245 (22.1)	116 (22.4)	129 (21.8)	0.81	130 (26.7)	115 (18.5)	
Fasting plasma glucose level (mg/dL), median (IQR)¶	141.5 (110.0–205.0)	120.0 (100.0–162.0)	167.0 (128.0–227.0)	0.00*
Systolic blood pressure, median (mm Hg) (IQR)¶	137.0 (125.0–153.0)	135.0 (121.0–151.0)	139.0 (126.0–154.0)	0.00†
Diastolic blood pressure, median (IQR)¶	90.0 (82.0–97.0)	90.0 (82.0–98.0)	89.0 (82.0–97.0)	0.29

*P<0.001.

†P<0.05.

‡The participants in these groups are not mutually exclusive.

§Abdominal obesity measured as waist circumference ≥90 cm in men and ≥80 cm in women.

¶Include those who were on medication.

BMI, body mass index.

Table 3 Change in FBG from baseline to multiple end line intervals for participants enrolled in diabetes management programme

Period\$	Total observations			Observations for participants without history of diabetes			Observations for participants with history of diabetes		
	Unadjusted		Adjusted	Unadjusted		Adjusted	Unadjusted		Adjusted
	n	Change in FBG, mg/dL (95% CI)¶	n	Change in FBG, mg/dL (95% CI)¶	n	Change in FBG, mg/dL (95% CI)¶	n	Change in FBG, mg/dL (95% CI)¶	
Period 1	3198	-13.9 (-19.5 to -8.2)	3198	-14.0 (-18.1 to -10.0)	859	-20.7 (-27.1 to -14.4)	2339	-11.8 (-16.7 to -7.0)	
Period 2	2189	-18.9 (-25.5 to -12.4)	2189	-18.8 (-24.0 to -13.5)	612	-26.2 (-35.7 to -16.6)	1577	-15.4 (-21.5 to -9.4)	
Period 3	1219	-16.7 (-25.6 to -7.7)	1219	-18.0 (-25.1 to -10.9)	291	-24.4 (-35.8 to -13.0)	928	-16.4 (-24.6 to -8.2)	
Period 4	706	-20.4 (-32.6 to -8.2)†	706	-20.2 (-29.6 to -10.9)	183	-21.0 (-36.1 to -5.8)‡	523	-20.1 (-30.8 to -9.4)	
Period 5	380	-26.8 (-43.3 to -10.4)†	380	-26.4 (-39.3 to -13.6)	105	-10.9 (-29.1 to 7.4)	275	-32.3 (-47.7 to -17.0)	
Period 6	160	-15.8 (-42.8 to 11.3)	160	-27.9 (-47.6 to -8.1)‡	43	-16.5 (-42.5 to 9.4)	117	-33.7 (-58.7 to -8.6)‡	

Adjusted for age groups, gender, baseline FBG, BMI, hypertension, family history of diabetes.

*P<0.001.

†P<0.01.

‡P<0.05.

\$All observations recorded between 311th–189th day from start date were grouped in period 1, 190th–378th day in period 2, 379th–566th day in period 3, 567th–755th day in period 4, 756th–943th day in period 5–944th to till end of the study period in period 6.

¶Difference in mean change; a negative change indicates a fall in average from baseline to end line.
BMI, body mass index; FBG, fasting blood glucose.

Table 4 Change in SBP from baseline to multiple end line intervals for participants enrolled in hypertension management programme

Total observations			Observations for participants without history of hypertension			Observations for participants with history of hypertension		
Unadjusted			Adjusted			Adjusted		
Period§	n	Change in SBP, mm Hg (95% CI)¶	n	Change in SBP, mm Hg (95% CI)¶	n	Change in SBP, mm Hg (95% CI)¶	n	Change in SBP, mm Hg (95% CI)¶
Period 1	4308	-5.5 (-6.9 to -4.1)*	4308	-5.3 (-6.4 to -4.3)*	1661	-6.0 (-7.7 to -4.4)*	2647	-4.9 (-6.3 to -3.5)*
Period 2	2843	-6.3 (-8.0 to -4.6)*	2843	-6.3 (-7.7 to -4.9)*	1088	-9.2 (-11.3 to -7.0)*	1755	-4.5 (-6.3 to -2.7)*
Period 3	1402	-7.1 (-9.7 to -4.5)***	1402	-7.0 (-9.1 to -4.9)*	540	-9.6 (-12.5 to -6.8)*	862	-5.3 (-8.0 to -2.5)*
Period 4	779	-6.8 (-10.1 to -3.4)***	779	-6.2 (-8.9 to -3.5)*	299	-10.4 (-14.6 to -6.3)*	480	-3.5 (-7.0 to -0.1)‡
Period 5	435	-5.1 (-9.2 to -0.9)*	435	-4.4 (-8.1 to -0.8)‡	193	-7.2 (-12.1 to -2.3)†	242	-2.4 (-7.4 to 2.5)
Period 6	182	-2.7 (-8.4 to 3.1)	182	-2.2 (-7.2 to 2.7)	92	-7.0 (-14.6 to 0.5)	90	2.1 (-2.7 to 7.0)

Adjusted for age groups, gender, baseline SBP, BMI, diabetes, family history of hypertension.

*P<0.001.

†P<0.01.

‡P<0.05.

§All observations recorded between 311th–189th day from start date were grouped in period 1, 190th–378th day in period 2, 379th–566th day in period 3, 567th–755th day in period 4, 756th–943th day in period 5 and 944th to till end of the study period in period 6.

¶Difference in mean change; a negative change indicates a fall in average from baseline to end line. BMI, body mass index; SBP, systolic blood pressure.

Table 5 Change in DBP from baseline to multiple end line intervals for participants enrolled in hypertension management programme

Period§	Total observations			Observations for participants without history of hypertension			Observations for participants with history of hypertension		
	Unadjusted			Adjusted			Adjusted		
	n	Change in DBP, mm Hg (95% CI)¶	n	Change in DBP, mm Hg (95% CI)¶	n	Change in DBP, mm Hg (95% CI)¶	n	Change in DBP, mm Hg (95% CI)¶	
Period 1	4308	-3.3 (-4.1 to -2.4)*	4308	-3.2 (-3.8 to -2.5)*	1661	-3.6 (-4.7 to -2.6)*	2647	-2.9 (-3.7 to -2.1)*	
Period 2	3272	-4.5 (-5.3 to -3.6)*	3272	-4.2 (-4.9 to -3.6)*	1268	-6.4 (-7.5 to -5.4)*	2004	-2.9 (-3.8 to -2.1)*	
Period 3	1402	-3.9 (-5.4 to -2.4)*	1402	-3.9 (-5.1 to -2.7)*	540	-6.2 (-8.0 to -4.4)*	862	-2.5 (-4.0 to -0.9)†	
Period 4	779	-3.7 (-5.7 to -1.8)*	779	-3.4 (-4.9 to -1.9)*	299	-5.5 (-7.8 to -3.3)*	480	-2.0 (-3.9 to -0.02)‡	
Period 5	435	-2.2 (-4.8 to 0.3)	435	-2.0 (-4.1 to 0.2)	193	-4.6 (-7.5 to -1.7)†	242	-0.2 (-3.0 to 2.6)	
Period 6	182	-2.3 (-6.0 to 1.3)	182	-1.7 (-4.6 to 1.1)	92	-5.8 (-10.0 to -1.6)†	90	2.2 (-0.7 to 5.3)	

Adjusted for age groups, gender, baseline SBP, BMI, diabetes, family history of hypertension.

*P<0.001.

†P<0.01.

‡P<0.05.

§All observations recorded between 311th–189th day from start date were grouped in period 1, 190th–378th day in period 2, 379th–566th day in period 3, 567th–755th day in period 4, 756th–943th day in period 5 and 944th to till end of the study period in period 6.

¶Difference in mean change; a negative change indicates a fall in average from baseline to end line.

BMI, body mass index; DBP, diastolic blood pressure; SBP, systolic blood pressure.

CHWs received a confirmed diagnosis on visiting a qualified doctor but this rate of agreement is lower than that reported in previous controlled studies involving CHWs and non-physician health workers.^{28 29} This difference could be attributed to greater emphasis on training and use of simpler algorithms in controlled studies, which is difficult to replicate in real-world programmes due to operational challenges such as staff turnover. On the other hand, these findings are noteworthy precisely because they demonstrate that lay workers from the community with no formal medical education can be used to scale up screening and management of NCDs in the private sector, where nurses and trained non-physician health workers are in short supply.

Our results show that the reduction in FBG was significant for all follow-up periods and ranged from 14.0 mg/dL to 27.9 mg/dL. This is comparable to the reduction reported in earlier observational studies from resource-limited settings that implemented task shifting to non-physician clinicians in primary care clinics.^{30 31} Reduction in FBG was greater for longer follow-up periods compared with shorter ones but the differences in the reduction were not statistically significant. Overall, newly diagnosed participants showed better control in FBG compared with those with treatment history, but the results were not consistent. Higher improvement among newly diagnosed participants could be due to the novelty effect, that is, participants may be more adherent at the beginning of their enrolment in the programme.

We found that the reduction in SBP was generally greater (-2.2 mm Hg to -7.0 mm Hg) than the reduction in DBP (-1.7 mm Hg to -4.2 mm Hg) for all follow-up periods. These reductions were lower than those reported in previous studies. An observational study in Cameroon found that task shifting to non-physician clinicians reduced SBP by 22.8 mm Hg and DBP by 12.4 mm Hg.³¹ More recently, a randomised controlled trial across multiple countries in South Asia reported a reduction in SBP by 9.04 mm Hg and DBP by 6.07 mm Hg in its intervention arm²¹ whereas a trial in Argentina reported 19.3 mm Hg reduction in SBP and 12.2 mm Hg reduction in DBP.³² These larger effects may be due to tighter integration between the activities of the CHWs and the care provided by the physicians in the health facilities as well as repeated training provided to the physicians. Although the programme in this study also engaged with empanelled private physicians, it may not have been able to influence physician practices and ensure seamless transition between referral by a CHW and actual clinic visit by the participant. However, it is worth noting that the reductions in SBP and DBP reported in our study are within the range of effects reported in a recent systematic review and meta-analysis.¹⁶ It found significant variation in the effect size across. Of particular relevance to our study, the reduction in SBP and DBP in interventions involving CHWs was significantly lower than that achieved in interventions involving pharmacists and nurses. Taken together, these findings suggest that insights from controlled studies

in LMICs can be successfully transferred to the real world setting of fragmented private healthcare system with autonomous private physicians, but with reduced effectiveness.

Our estimates of improvement in FBG, SBP and DBP should not be interpreted as causal effects because of the lack of a comparison group. Participants who did not enrol in the programme could have received care from other providers and experienced a comparable improvement in their health outcomes. This is particularly important as two recent controlled studies conducted in rural India found that the effect of task-shifting aided by electronic decision support system was not significantly greater than the enhanced usual care provided in control arm.^{18 33} However, this is unlikely to be the case in our context for multiple reasons. First, we observed an improvement in health outcomes for study participants with treatment history as well, indicating that the programme's effect may be incremental to routine care. Second, our study period did not coincide with any other intervention in the community or large changes in health and wellness seeking behaviour. Finally, the quality of routine NCD care received by urban poor in private sector in urban India is likely to be substantially lower than that in the enhanced usual care arm in these controlled studies.³⁴ Therefore, comparable control population without this intervention may not have experienced similar improvement in health outcomes although rigorous large-scale pragmatic trials or quasi-experimental studies are needed to confirm this.

Our results may have been affected by participant attrition. We estimated the improvement in health outcomes only for those participants who enrolled in the programme and remained enrolled for at least 2 months. Since the programme does not collect data on participants after they drop-out, we could not estimate the long-term effect of the programme on dropped-out participants. Participants who refused to enrol and/or dropped out at various stages after enrolment may be self-selected due to low effectiveness (actual or perceived). However, baseline values of key characteristics were not substantially different between participants who enrolled and those who did not (online supplemental table 11). Similarly, retention rate after enrolment was also similar across gender, previous medical and treatment history, and current DMP. Finally, we found that improvement in health outcomes was not a statistically significant predictor of participant retention, that is, change in health outcomes, controlling for the time spent in the programme, is comparable between participants who dropped out after enrolment and those who did not (online supplemental table 12). We could not ascertain whether the changes in FBG, SBP and DBP were sustained beyond the study period although our follow-up period (36 months) is comparable to most previous studies.^{18 35 36}

Admittedly, participant retention on the programme was low with only 16.1% of the participants still enrolled in the programme at 12 months, which is not very different from

the range of retention rates observed in previous studies of similar nature (18%–25% at 12 months).^{31–37–39} A retrospective cohort study in the slums of Nairobi also found low retention among hypertensive individuals and cited treatment costs and lack of symptoms as primary reasons for high drop-out rate.³⁹ These findings are consistent with those observed in a study among Malawian adults, which reported high transportation cost, loss of productive time, and difficulty in adherence to appointments due to repeated follow-ups to healthcare providers as associated factors.³⁸ An additional important driver in our setting may also be low perceived value of services provided, which in turn could have multiple underlying drivers. First, the study population may lack awareness and urgency of managing diabetes and hypertension at an early asymptomatic stage resulting in low motivation to pay for the programme for benefits that accrue in the long term.⁴⁰ This is particularly relevant as participants incurred out-of-pocket costs in the short term: programme subscription fees (which covers for routine tests) as well as physician consultation fees and medication costs. Second, the perceived efficacy of the programme might be low due to lack of trust in counselling provided by lay CHWs on lifestyle aspects such as diet, exercise, tobacco and alcohol consumption, which are typically considered to be outside of the health domain. Third, even in the absence of the above barriers, participants may switch to self-management or their regular healthcare provider after diagnosis due to comfort and familiarity or perceived lack of expertise among empaneled providers. Such provider switching behaviour is common among patients in India's healthcare sector, which lacks formal gatekeeping and referral pathways typically associated with a central payer.⁴¹

Participant attrition adversely impacted the financial sustainability of the programme as costs incurred on screening potential participants (ie, personal, commodities and supplies, training cost) are not adequately recovered through revenue from enrolled participants over longer periods. Some of these effects could be mitigated through additional activities known to improve participant awareness and engagement, for example, community gatherings/peer-support groups, automated calls, SMS (short-message-service) reminders, radio jingles which were not an integral part of the intervention.^{37–42} However, these activities themselves are costly; hence, their net impact on the financial sustainability of the programme is not clear and needs to be carefully analysed. Other short-term levers for improving sustainability include identifying predictors of high acquisition and retention rates and prioritising efforts on such participants. For instance, our preliminary analysis suggested certain participant factors (history of diabetes/hypertension, gender, age) and certain programme factors (follow-up visit within 3 days of initial risk confirmation) to be strong predictors of participant acquisition from screening to enrolment. However, in the long term, sustainability of such programmes may be driven through partnership with public health payers, especially if they are found to be cost saving or cost-effective at a societal level. For instance, these programmes can act as intermediaries to ensure that public expenditure on control

of NCDs efficiently reaches patients who predominantly seek care in private sector thereby complementing the care provision in the public health system through a growing, but still limited, network of Health and Wellness Centres. Similar efforts have been successful in engaging private sector for effective tuberculosis control and are being scaled up across India.⁴³ Such integration is also crucial to ensure that publicly funded health insurance schemes such as Prime Minister's Jan Arogya Yojana, which have significantly expanded coverage of tertiary care, do not lead to exponential rise in government's healthcare expenditure without commensurate gains in the health outcomes.

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