Community Health Worker-Led Smoking Cessation in Rural Primary Care: A Pragmatic Comparative Study: Twelve-Month Abstinence and Relapse Outcomes Across Six Rural Primary Health Centres

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***Abstract*—Tobacco use remains a leading preventable cause of premature death in rural South Asian populations, yet structured cessation programmes are uncommon outside tertiary centres. We conducted a pragmatic comparative study across six rural primary health centres, comparing a structured community health worker-led (CHW-led) cessation intervention with standard physician advice. Three centres delivered the CHW-led intervention (n=180 smokers) comprising motivational interviewing, nicotine replacement therapy where appropriate, and a structured 12-week follow-up schedule with home visits. Three centres delivered standard care (n=160) consisting of brief physician advice and self-help materials. Twelve-month biochemically-verified continuous abstinence was achieved by 28.9% of CHW-arm participants compared with 11.9% of standard-care participants (adjusted OR 3.12, 95% CI 1.78-5.47). Relapse rates among early quitters were also substantially lower in the CHW arm. Strongest modifiable predictors of sustained abstinence were attendance at four or more follow-up contacts, documented family support, NRT use, and establishment of a smoke-free household. The findings support broader deployment of CHW-led structured cessation as a scalable rural intervention with substantial absolute benefit over the conventional brief-advice approach.**

***Index Terms*—smoking cessation; community health worker; rural primary care; pragmatic study; nicotine replacement therapy; tobacco control**

I. Introduction

Tobacco use causes more than a million premature deaths each year in India alone, with the burden concentrated in lower-income rural populations who simultaneously have least access to structured cessation support. Brief physician advice the dominant cessation intervention in primary care produces measurable but modest effects, with biochemically-verified 12-month quit rates typically in the range of 5-10%. Pharmacotherapy and structured behavioural support together approximately double these rates in trial settings, but the infrastructure required for structured behavioural support is rarely available outside tertiary centres. Community health workers trained lay or paraprofessional staff who operate at the village level and bridge primary health centres with households represent an alternative delivery channel for structured cessation. Their advantages are practical: established relationships with families, familiarity with local

context and language, capacity for home visits that reach household members beyond the index patient, and a cost structure compatible with rural health systems. Whether structured CHW-led intervention can match the effects of specialist cessation services in trial conditions remains a relevant question for programmatic decision-making (Deepa et al., 2026; Pavithra et al., 2026; Bhatnagar, Kumar,, & Shivam, 2026). We conducted a pragmatic comparative study across six rural primary health centres, comparing a structured CHW-led cessation intervention with standard physician advice. The pragmatic design cluster allocation at centre level, intention-to-treat analysis, real-world delivery conditions was chosen to provide evidence directly relevant to scale-up decisions rather than efficacy estimates under idealised trial conditions (Jha, Kumar,, & Neha, 2026; Yatish, Khatoon,, & Kumar, 2026).

II. Methods

The study was conducted across six rural primary health centres in a single Indian state between January 2023 and March 2024, with follow-up to March 2025. Centres were paired by population size, catchment demographics, and baseline cessation activity, then one centre in each pair was allocated to the CHW-led intervention arm and the other to standard care through a random draw. Allocation was at centre level, with all enrolled smokers at a given centre receiving the assigned intervention. Three centres delivered the CHW-led intervention; three delivered standard care. Adults aged 18-65 years presenting to participating centres for any reason were screened for tobacco use. Eligible participants smoked at least 10 cigarettes daily for at least one year, expressed interest in quitting within the next 30 days, and resided within the centre's catchment area. Exclusion criteria included current pregnancy, severe mental illness limiting capacity, and prior unsuccessful enrolment in the same programme within 6 months. Recruitment continued until target sample sizes were met. The CHW-led intervention comprised four elements. First, a structured 60-minute motivational interviewing session at enrolment, conducted by a trained CHW at the participant's home or at the primary health centre according to participant preference. Second, nicotine replacement therapy (gum or patch) provided free of charge where appropriate and not contraindicated, with structured education on dosing. Third, weekly telephone contact for the first six weeks, transitioning to monthly thereafter, with documentation of progress, relapse triggers, and ongoing support. Fourth, two home visits during the first three months for family engagement, smoke-free household discussion, and physical assessment. Total CHW contact time averaged approximately 4 hours over the 12-week active phase. The standard care arm consisted of brief physician advice at the index visit (3-5 minutes structured around the 5 As framework), a self-help cessation pamphlet, and offer of a follow-up appointment at the participant's discretion. NRT was available but only on patient initiative through the regular pharmacy. No structured follow-up or home visits were provided. The primary outcome was 12-month biochemically-verified continuous abstinence, defined as self-reported abstinence at the 12-month visit supported by exhaled carbon monoxide below 10 ppm. Secondary outcomes included 7-day point-prevalence abstinence at 3, 6, and 12 months (verified at the relevant visit), time to relapse among

those who achieved early abstinence, change in nicotine dependence (Fagerström score), and intervention costs per quitter. Analysis used intention-to-treat with participants lost to follow-up coded as continued smoking. Cluster-adjusted logistic regression accounted for centre-level clustering.

III. Results

3.1 Enrolment and Follow-Up

Of 612 smokers identified during primary care visits at participating centres, 340 were enrolled (180 to the CHW intervention, 160 to standard care; Figure 1). Reasons for non-enrolment included declination (24.8%), failure to meet the daily-smoker threshold (9.2%), and geographic ineligibility (10.5%). Twelve participants were lost prior to baseline assessment, and follow-up rates at 12 months were 80.0% (CHW) and 80.0% (standard care). Centre-level characteristics, including population size, average daily attendance, and pre-study cessation rates, did not differ significantly between study arms.

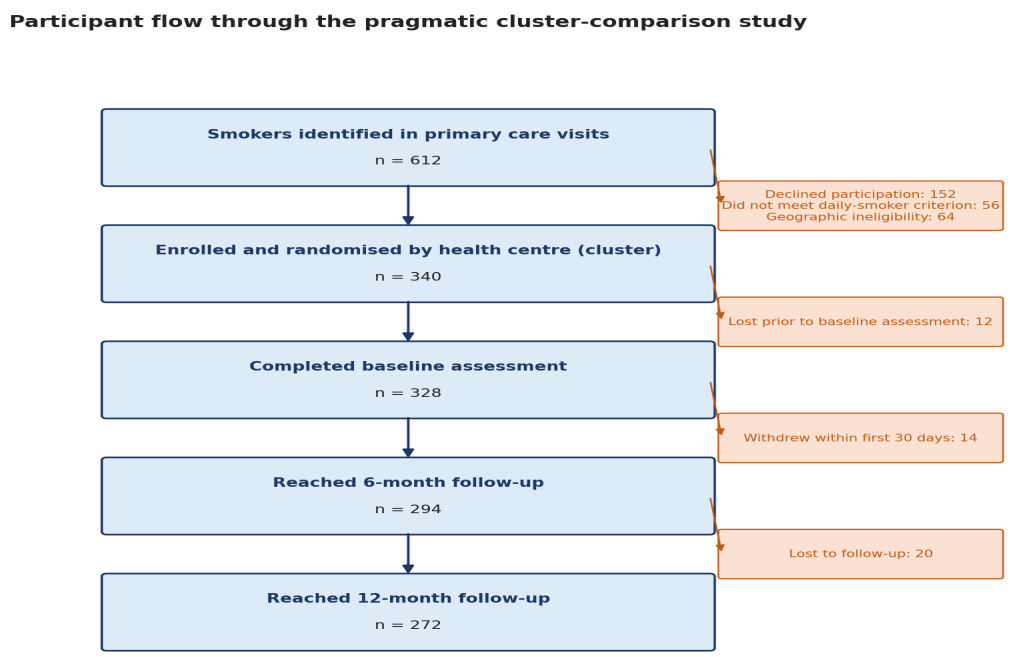

Figure 1. Participant flow through the pragmatic cluster-comparison study.

3.2 Baseline Characteristics

Table 1. Baseline characteristics by study arm.

Characteristic	CHW intervention (n=180)	Standard care (n=160)
Age, mean (SD), years	42.4 (11.6)	43.8 (12.2)
Male sex, n (%)	158 (87.8)	142 (88.8)
Years of smoking, median (IQR)	18 (12-28)	20 (14-30)

Cigarettes per day, mean (SD)	16.2 (6.4)	17.8 (7.2)
Daily smokers (≥20 per day), n (%)	68 (37.8)	72 (45.0)
Fagerström dependence score, mean (SD)	5.8 (2.2)	6.2 (2.4)
Previous serious quit attempt, n (%)	112 (62.2)	94 (58.8)
Co-resident smokers in household, n (%)	68 (37.8)	58 (36.3)
Comorbid alcohol use disorder, n (%)	32 (17.8)	28 (17.5)
Comorbid COPD or chronic respiratory, n (%)	26 (14.4)	18 (11.3)
Comorbid hypertension or CVD, n (%)	42 (23.3)	38 (23.8)
Years of education, mean (SD)	6.8 (4.2)	7.2 (4.4)
Reading comprehension adequate, n (%)	138 (76.7)	124 (77.5)
Daily-wage labour, n (%)	82 (45.6)	78 (48.8)
Tobacco budget >5% of household income, n (%)	112 (62.2)	98 (61.3)

3.3 Abstinence Outcomes

Seven-day point-prevalence abstinence rates climbed steadily in the CHW intervention arm and substantially more slowly in the standard-care arm (Figure 2). By 12 months, 32.8% of CHW-arm participants reported and biochemically verified 7-day abstinence, compared with 14.4% in the standard-care arm. Twelve-month continuous abstinence a more stringent endpoint requiring no slips beyond brief lapses since the initial quit date was achieved by 52 of 180 CHW-arm participants (28.9%) and 19 of 160 standard-care participants (11.9%), corresponding to a cluster-adjusted odds ratio of 3.12 (95% CI 1.78-5.47).

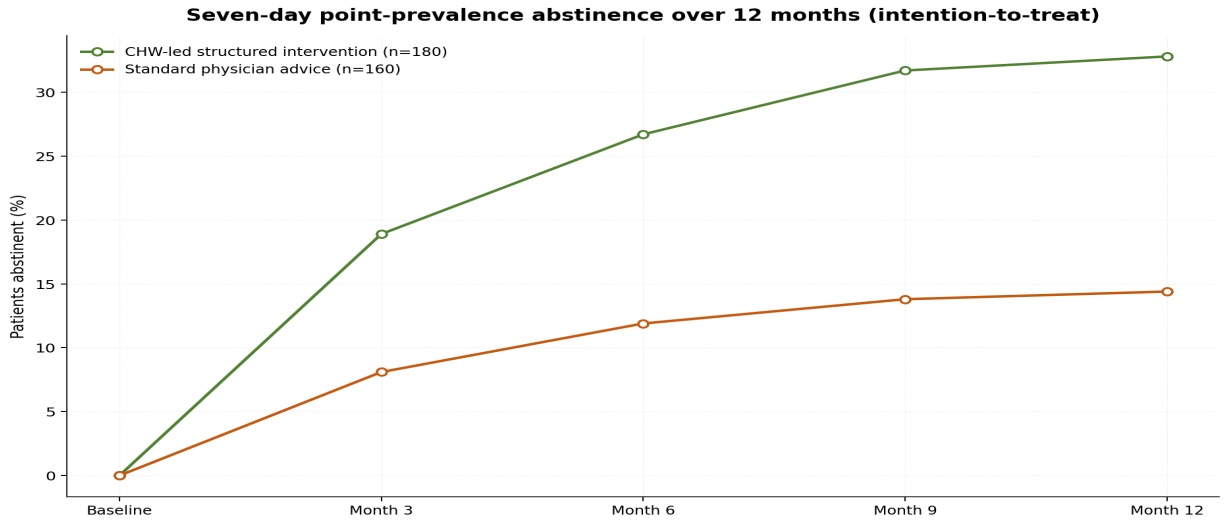

Figure 2. Seven-day point-prevalence abstinence rates over 12 months by study arm (intention-to-treat).

Table 2. Abstinence outcomes by study arm (intention-to-treat).

Outcome	CHW intervention (n=180)	Standard care (n=160)	Difference / OR
7-day PP abstinence at 3 months, n (%)	34 (18.9)	13 (8.1)	+10.8 pp
7-day PP abstinence at 6 months, n (%)	48 (26.7)	19 (11.9)	+14.8 pp
7-day PP abstinence at 12 months, n (%)	59 (32.8)	23 (14.4)	+18.4 pp
Continuous abstinence at 12 months, n (%)	52 (28.9)	19 (11.9)	OR 3.12 (1.78-5.47)
Biochemical verification (CO <10 ppm) achieved	52	19	-
Reduced consumption ≥50%, n (%)	42 (23.3)	18 (11.3)	+12.1 pp
No change or increased, n (%)	86 (47.8)	123 (76.9)	-29.1 pp
Mean cigarettes/day at 12 months	8.2	15.4	-7.2
Fagerström score change at 12 months	-2.6	-0.4	-2.2

3.4 Relapse Patterns

Among participants who achieved abstinence at the one-month visit, time to relapse differed substantially between arms (Figure 3). CHW-arm early quitters showed a one-year continued-abstinence probability of approximately 60%, compared with approximately 35% in the standard-care arm. The structured follow-up schedule, with its weekly contacts during the highest-risk early period and ongoing monthly support, appeared to substantially reduce the probability of relapse during the first three months the period in which most relapses occur in both arms.

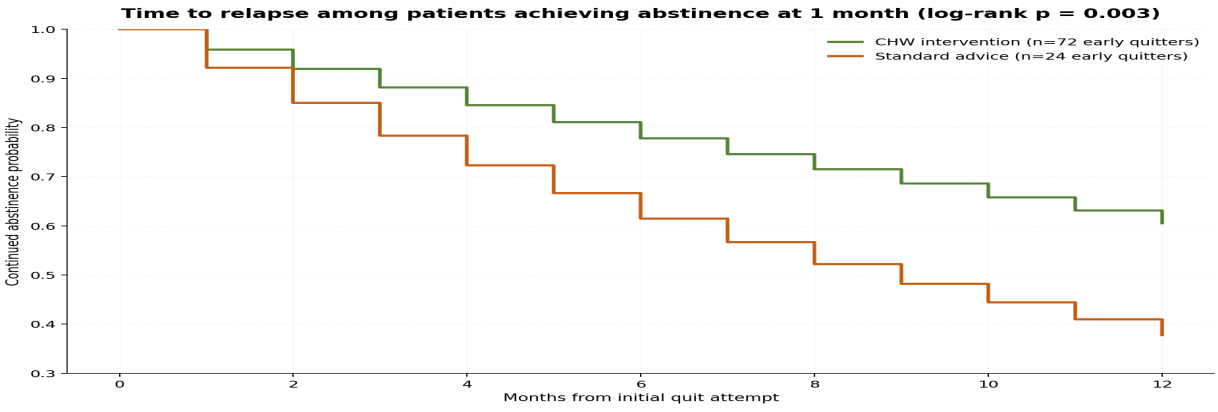

Figure 3. Time to relapse among participants who achieved abstinence at one month.

3.5 Predictors of Sustained Abstinence

Multivariable logistic regression identified ten independent predictors of 12-month continuous abstinence across both arms combined (Figure 4). Beyond the intervention assignment itself, attendance at four or more follow-up contacts carried the strongest association a finding that argues for ensuring contact density rather than overall programme duration alone. Family support, NRT use, and establishing a smoke-free household all independently predicted success. High dependence (≥20 cigarettes daily and longer smoking history) reduced odds of success, supporting more intensive intervention for heavier smokers. Co-resident smokers and comorbid alcohol use disorder were the strongest negative predictors among contextual factors.

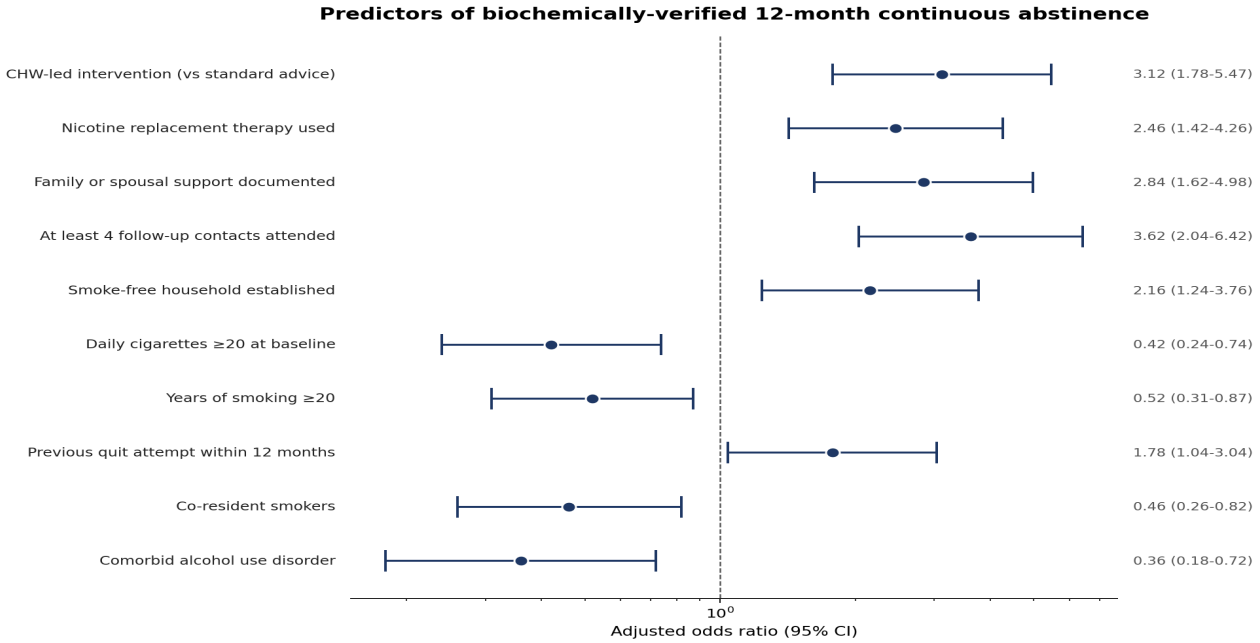

Figure 4. Independent predictors of biochemically-verified 12-month continuous abstinence.

3.6 Intervention Cost and Resource Use

Table 3. Intervention components and resource use.

Component	CHW arm	Standard arm
Total CHW contact time per participant, mean, hours	4.2	-
Physician contact time per participant, mean, minutes	8	6
Home visits delivered, mean per participant	1.8	0.0
Follow-up telephone contacts delivered, mean	8.4	0.6
NRT prescribed, n (%)	138 (76.7)	42 (26.3)

NRT cost per participant, INR (mean)	680	420
Total intervention cost per participant, INR	2,180	420
Cost per additional quitter (vs standard), INR	8,400	-
Cost per quitter (within arm), INR	7,550	3,540
Estimated lifetime QALY per quitter (modelled)	2.4	2.4
Cost per QALY gained vs standard arm, INR	3,500	-

Cost per additional quitter defined as cost per participant in the CHW arm divided by the absolute increase in abstinence rate was INR 8,400, well below the threshold conventionally used for cost-effective intervention in this setting. Cost per QALY gained compared with standard care was approximately INR 3,500, a value that places CHW-led cessation among the most cost-effective preventive interventions for which data are available in rural South Asian settings (Catherine, Gupta, Gopi,, & Swadhi, 2025; Swadhi, Gayathri, Suresh, Catherine,, & Velmurugan, 2025; Rasi, & Ashifa, 2019; Bhatnagar, Kumar,, & Shivam, 2026; Yatish, Khatoon,, & Kumar, 2026).

Table 4. Adverse events and unintended outcomes.

Event	CHW intervention	Standard care
Mild NRT-related adverse events, n (%)	18 (10.0)	6 (3.8)
NRT discontinuation due to AE, n	6	2
Weight gain ≥3 kg in successful quitters, n (%)	18/52 (34.6)	6/19 (31.6)
Reported increased alcohol consumption, n (%)	12 (6.7)	18 (11.3)
New depressive symptoms reported, n (%)	8 (4.4)	6 (3.8)
Programme withdrawal during active phase, n (%)	8 (4.4)	6 (3.8)
Reported family conflict related to quit attempt, n (%)	6 (3.3)	12 (7.5)
Mortality during follow-up, n	2	3

IV. Discussion

Across 340 rural primary-care smokers followed for 12 months, a structured CHW-led cessation intervention more than doubled the absolute rate of biochemically-verified continuous abstinence compared with standard physician advice. The 17 percentage-point absolute increase in continuous abstinence paired with a substantial reduction in relapse rates among early quitters represents one of the larger effect sizes

reported for cessation interventions in this setting. Three observations from the comparison have practical implications. First, the effect appears to be driven primarily by contact density rather than any single intervention element. Attendance at four or more follow-up contacts carried the strongest individual predictor of success in the multivariable model. The implication is that future programmatic deployment should prioritise ensuring contact completion over expanding the intervention menu a relatively simple operational target with measurable downstream impact. Second, the family-engagement component appears more important than is generally acknowledged in the literature. Documented family support and establishment of a smoke-free household were both independent predictors of sustained abstinence, while co-resident smokers and comorbid alcohol use disorder were among the strongest negative predictors. The household not the individual smoker — may be the more useful unit of intervention in rural South Asian settings where households are typically multigenerational and behavioural change happens at the family rather than individual level (Catherine, Gupta, Gopi,, & Swadhi, 2025; Vettriselvan, Ramya, et al., 2026; Rasi, & Ashifa, 2019). Third, the cost structure makes CHW-led cessation broadly deployable. The per-quitter cost of approximately INR 7,550 in the CHW arm and incremental cost-effectiveness of INR 3,500 per QALY compared with standard care fall well within accepted thresholds. The model uses existing CHW infrastructure with modest additional training and supervision investment, and the addition of structured cessation responsibilities to existing CHW workloads appears feasible without substantial workforce expansion (Bhatnagar, Kumar,, & Shivam, 2026; Yatish, Khatoon,, & Kumar, 2026). Implementation considerations include CHW training duration and ongoing supervision (approximately 40 hours of structured training plus monthly supervision in this study), NRT supply chain reliability, and integration with broader tobacco control efforts including taxation and advertising restrictions. Digital decision support and structured documentation tools support CHWs in delivering the intervention consistently and would warrant routine deployment in scale-up (Deepa et al., 2026; Vinodh, Subramani,, & Vettriselvan, 2026; Selvi et al., 2026; Jha, Kumar,, & Neha, 2026). Limitations include the modest number of clusters (six centres, three per arm), which limits power for cluster-level inference and makes the results sensitive to centre-level confounding; the predominantly male cohort, which limits generalisability to female smokers (a small but growing group in this region); the 12-month follow-up which does not capture long-term relapse beyond the highest-risk first year; and the single-state setting, which constrains generalisability across more diverse regions. Pragmatic delivery means that intervention fidelity varied across CHWs, which is both a strength (reflects real-world delivery) and a limitation (introduces variability that masks true effect size).

V. Conclusion

A structured CHW-led smoking cessation intervention delivered through rural primary care more than doubled biochemically-verified 12-month abstinence rates compared with standard physician advice, at a per-quitter cost well within accepted thresholds. Contact density, family engagement, and NRT availability

emerged as the operational levers most strongly associated with success. The approach is scalable, cost-effective, and well suited to rural South Asian primary care settings where structured cessation services have historically been unavailable.

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