Regular article

Community-based group intervention for tobacco cessation in rural Tamil Nadu, India: A cluster randomized trial

Muthusamy Santhosh Kumar, (M.P.H.) [a, b], P. Sankara Sarma, (Ph.D.) [a], Kavumpurathu Raman Thankappan, (M.D., M.P.H.) [a,*]

[a]Achutha Menon Centre for Health Science Studies, Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum, Kerala, South India
[b]WHO-NPSP, Tatanagar, Jharkhand, India

Abstract

The objective of this study was to determine the efficacy of community-based group intervention for tobacco cessation. We recruited 400 men (20–40 years) currently using any form of tobacco from 20 villages of the Indian State of Tamil Nadu and randomized them equally into intervention and control groups. A physician offered two sessions of health education 5 weeks apart along with self-help material on tobacco cessation to the intervention group. The control group received only self-help material. The contents of the sessions included tobacco-related health problems, benefits of quitting, and coping strategies for withdrawal symptoms. Follow-up data were available for 92%. Self-reported point prevalence abstinence of 12.5% in the intervention group was significantly higher than the 6.0% in the control group at 2 months. Community-based group intervention has the potential to increase the coverage of tobacco cessation services for men in rural Tamil Nadu.
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1. Introduction

Tobacco has been projected to cause 1 billion preventable deaths in the 21st century, of which more than 70% will occur in low- and middle-income countries (Peto & Lopez, 2001). The largest increase in tobacco-related mortality has been projected to occur in India and China (Murray & Lopez, 1997). The annual smoking-associated deaths in India were projected to be 1 million in this decade (Jha et al., 2008). As per the Global Adult Tobacco Survey, the current tobacco use in any form was 47.9% among adult males in India (Ministry of Health and Family Welfare, Government of India, 2010). The prevalence of tobacco use was significantly higher in rural, poorer, uneducated population compared with urban, wealthier, and more educated population (Rani, Bonu, Jha, Jguyen, & Jamjoum, 2003). All forms of tobacco use were increasing in India, and the largest increase was in the age group 15–24 years. (Thankappan & Mini, 2008).

Cessation by current smokers is the only way to avoid substantial proportion of tobacco-related deaths worldwide before 2050. Tobacco cessation is rare in most low- and middle-income countries. For example, the quit rate at population level in India was reported to be only 2%. Unless there is widespread cessation among smokers, 450 million deaths will occur in the world by 2050. Prevention of these deaths requires adult cessation (Jha, 2009). Seventy percent of the 1 million smoking-related mortality in India was projected to occur in the middle age of 30–69 years (Jha et al., 2008). The benefits of smoking were found to be largest in those who quit in the younger age group of 25 to 34 years (Doll, Peto,

Boreham & Sutherland, 2004). Therefore, any cessation intervention needs to focus on the younger age group.

A few available studies from India reported quit rates, although the primary objectives were not tobacco cessation intervention. A community-based intervention study among rural tobacco users for primary prevention of oral cancer reported a quit rate of 2% in Ernakulam district (Kerala), 1% in Bhavnagar (Gujarat), and 5% in Srikakulam (Andhra Pradesh) at the end of 1 year (Metha et al., 1982). Another community-based health education intervention program offered by health workers targeting the entire population of selected primary health center areas in Karnataka reported a quit rate of 26.5% in the intervention group compared with 1.1% in the control group at the end of 5 years (Anantha et al., 1995). The limitation of this study was that it was not randomized and mainly focused on prevention of cancer. The intervention was very intensive and delivered once a week by junior health workers and once a month by senior health workers for 3 years. It may be difficult to scale up such intensive interventions considering the limited human resources in the Indian rural health system (Rao, Rao, Shiva Kumar, Chatterjee & Sundararaman, 2011). An unpublished randomized control trial in Kerala reported continuous smoking abstinence of 10.1% at 6-month follow-up in the intervention group that received brief intervention by a doctor and counseling by a nondoctor health professional compared with the control group that received only brief intervention by the doctor (Pradeep Kumar & Thankappan, 2009).

Data from the World Health Organization supported 18 tobacco cessation clinics (TCCs) in India providing behavioral and pharmacological intervention reported a point prevalence abstinence of 14% at 6 weeks (Murthy, 2009). In a vast country like India, reaching every tobacco user with this clinic-based intensive specialist treatment is not feasible (Raw, McNeill & Murray, 2010). So there is a need to develop brief tobacco cessation techniques that focus on community and group settings (Murthy & Saddichha, 2010). Because such studies are not available in India, we decided to conduct this study to see the efficacy of such a study in Indian settings.

The main objective of our study was to determine the efficacy of community-based group intervention for tobacco cessation in rural Tamil Nadu. The secondary objective was to study the facilitators, barriers, and acceptance for conducting group interventions.

2. Materials and methods

2.1. Study setting

The study was conducted in Tiruchirapalli district, Tamil Nadu, South India. The district was administratively divided into 8 *taluks*, 14 community development blocks, and 479 villages with a total population of 2.42 million (52.9%) residing in rural areas. The literacy rate in this district was 78% (rural 70%). One of the *taluks*—Manaparai—with the largest number of villages was selected for the study. (Directorate of Census Operations, 2001).

2.2. Study design

We conducted a cluster randomized trial selecting 20 villages out of 96 based on probability proportion to the size of the population and randomized equally into intervention and control villages (Fig. 1) Based on a priori decision, contiguous villages were replaced by the next village in the case of five control villages to avoid contamination of intervention. No replacements were made in the intervention villages. Each village was considered as a cluster, and 20 participants were recruited from each cluster.

2.3. Sample size

Sample size was estimated a priori using 5% alpha error and 80% power with a design effect of two to account for cluster effect. The assumption was a quit rate of 15% in the intervention villages and 2% in the control villages.

2.4. Study participants

Participants were recruited to the study based on the following inclusion criteria: (a) men, (b) aged 20–40 years, (c) resident of the village, (d) current user of any form of tobacco, and (e) willing to participate in the study and provide informed consent. Men who were planning to migrate in the next 3 months were excluded from the study to reduce the loss to follow-up. Men older than 40 years were excluded to ensure group homogeneity.

2.5. Data collection

The baseline interview using a pretested structured interview schedule was done to collect sociodemographic details, tobacco use pattern, and determinants related to outcome. Fagerstrom Test for Nicotine Dependence was used to assess the dependence of smokers (Heatherton, Kozlowski, Frecker & Fagerstrom, 1991) and smokeless tobacco users (Ebbert, Patten & Schroeder, 2006). For individuals who were using both forms of tobacco, both scales were administered, and the highest score was taken as final score. The motivation to quit tobacco was assessed based on Prochaska's five stages of change model. (Prochaska, DiClemente & Norcross, 1992). The baseline assessments had taken around 10 minutes, and the poststudy assessment around 5 minutes.

The outcomes were measured using structured interview schedule 3 weeks after the second session, that is, 2 months after recruitment. The main trial outcome was self-reported point prevalence abstinence (no tobacco use in the past 7 days) at 2 months after recruitment. The secondary outcomes were quit attempt (any attempt to quit tobacco, which lasts