



Sustainability of barefoot nurse (BFN) project – Screening NCD and ensuring livelihood: A randomized control trial

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ABSTRACT

Cost-benefit analysis underlines the importance of screening non-communicable diseases (NCDs) and seeking treatment which can aid early detection, cutting expenses and averting deaths. The government of India NCD screening program leaves many to opportunistic screening whilst the health system is inadequate to deliver its goal due to short-staffing, underequipped, and incomplete data management. In order to ease the cost and convenience barrier faced by the Indian poor, we propose testing the efficacy and sustainability of Community Health Workers (CHW), referred to as Barefoot nurse (BFN) for screening NCD. The BFN intervention will be evaluated using a two-arm cluster randomized controlled trial. The participants of the study are residents of eight selected wards each of Doddabalapura and Hoskote respectively, North Bangalore, Karnataka. The intervention will be delivered by eight BFNs. The control area will receive usual care by the Auxiliary Nurse midwife (ANM). The primary outcome indicators are a) proportion of population screened for NCDs, b) proportion of population, diagnosed with NCDs repeated the screening, c) proportion of first-time detection and referral. The secondary outcome measures are a) average amount of money earned, b) timeliness and c) completeness of data entry. Cluster randomization will be done prior to recruitment of participants. Enrolment of cluster will ensure non-overlap of intervention and control wards. The net change in the key outcome measures will be assessed using the difference in difference (DID). Amidst huge NCD burden the proposed study seeks to test the efficacy of a self-sustainable CHW model in resource deficient areas.

1. Background

Non Communicable Disease (NCD) accounts for 63% of all deaths in India [1] in 2018. The NCD problem gets accentuated due to the sheer size of population and the worsening risk factors and rather quick economic growth [2]. Cost-benefit analysis underlines the importance of screening NCDs and seeking treatment at the primary level which can aid early detection of NCDs resulting in cutting expenses and averting deaths [3]. The National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDPS) in India has set up three tier NCD clinics at block, district and state level. However, this initiative leaves a huge population underserved because they are left to opportunistic screening of NCD only when they visit the primary health facility [4]. Further, the primary health system is inadequate due to short-staffing [5] and underequipped sub-centers does not attract many for opportunistic screening of NCDs in rural [6] and urban

India [7]. Additionally, the entry and update of data is completely missing at several urban health facilities. Unfortunately, the poor are hardly left with alternative because private health care is expensive [7]. Importantly, the access to these public health facilities also involves cost and inconvenience experienced by health seekers [7,8]. As part of the Karnataka NCD control program the Auxiliary Nurse Midwife (ANM) is assigned the task of screening NCD at the health facility. However, this provision is not helpful in addressing the cost and convenience barriers faced by people to seek health care at the public health facility.

Community health workers (CHW) have played a key role in maximizing reach of health service delivery in Bangladesh [9]. In China, trained and supervised CHWs are vouched [10] to be capable in administering primary level NCD preventive intervention. However, the government of Karnataka is facing challenge in recruiting CHW, namely, ASHA (Accredited Social Health Activist) in urban locations because livelihood in urban India cannot be met with the nominal financial

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incentives paid to this cadre.¹ Again, keeping the CHW motivated through financial incentive is crucial in order to bring commitment to their work [11]. For instance, the ongoing ASHA cadre in India suffers from lack of motivation due to meagre financial incentive [12]. This brings us to the important question: in a resource low context how do we introduce an adequate financial incentive that will motivate the CHW for screening NCDs? In other words, how do we ensure sustainability of CHW as a public health intervention for addressing the problem of NCD? Often, sustainability of public health intervention is not envisaged at the conceptual phase and is pushed to the end of an intervention. This certainly does not help in ensuring sustainability as it was not envisaged while designing the project [13]. However, embedment of sustainability as an evaluation objective of a project at its inception [14] will allow to incorporate and improvise the sustainability component. In order to ease the cost and convenience barrier faced by the Indian poor, we propose testing the efficacy and sustainability of Community Health Workers (CHW), referred to as Barefoot nurse (BFN) for screening NCD.

The primary objective of the study is to assess the effect of BFN in screening of NCD and management of data, as compared to ANM. Additionally, the study will assess the extent of self-sustainability of BFN model in meeting the livelihoods of the barefoot nurses.

2. Design

The BFN intervention will be evaluated using a two-arm cluster randomized controlled trial with follow-up measurement at 1, 3 and 6 months for both groups. A cluster for this study is a municipal ward of the urban area. The intervention arm consists of eight clusters that are catered by eight BFN. The control arm consists of eight clusters in an adjacent municipal ward catered by eight ANMs.

3. Methods

3.1. Setting

The study setting consists of two talukas, namely, Doddabalapura and Hoskote that are geographically adjacent to each other. The administrative body of Doddabalapura is city Municipal Council. It consists of 31 wards and has a population of about 110,000. The average literacy rate in Doddabalapura is 78%. It is situated to the North of Bangalore, Karnataka and traditionally been involved in weaving silk and many families earn their livelihood through power loom and silk saree business [15]. Hoskote is a taluka in the Bangalore rural district neighboring Doddabalapura. It consists of 23 wards and has a population of 56980, with average literacy rate of 83% [16].

3.2. Participants

The participants of the study are residents of the eight selected wards of Doddabalapura and eight selected wards of Hoskote Municipal area. The eligibility of the study participants depends on four criteria: 1) age 30 years or more, 2) residing in either treatment or control area, 3) willing to pay a nominal fee for the screening in the treatment area, and 4) consenting to participate in the study.

3.3. Details of the intervention and control

The intervention will be delivered by eight BFN, who are the women from the community having received training in the screening of NCD and other health problems such as kidney function, hemoglobin, eye test

for refractive error and BMI. By being from the community, they speak local language and have familiarity with the community and study site. The BFN receives a nominal fee from individuals who get screened based on a rate that is agreeable by the community. The BFN have also received rigorous training in data entry. The study coordinator will remain in close contact with the local coordinator for executing this study.

The control area will not have any BFN and will receive usual care of the health system of the government of Karnataka, where the ANMs are supposed to screen population for NCD markers.

3.4. Intervention material

The intervention material for training the BFN has two components, namely, non-technical and technical. An intensive module has been developed for the non-technical or soft skill building of barefoot nurse. This module gives a well-rounded culturally appropriate perspective to the BFN regarding her conduct and approach of dealing with the community, such as, knowing yourself, values, leadership, communication, decision making, negotiation and coordination skill. Separate technical modules have been developed for each ailment to train the BFN in all five ailments or conditions, namely, hypertension, diabetes, anaemia, refractive error and kidney disorder. Step by step guide towards screening of these conditions have been systematically detailed in these modules.

3.5. Staff training and supervision

The first step towards implementing the BFN will involve recruiting the BFN. The local coordinator and supervisor will search for the prospective BFN by informing the local community leaders. The interested candidates will be interviewed and trained using the developed technical and non-technical modules. Experienced doctors will give first-hand tutorial in using the screening instruments. The Information Technology expert will train the candidates in the working of the app on the smart phone which will be used to enter data in the field. Based on the performance of the trained candidates on all three components, namely, technical, soft-skills and technology, eight BFN will be recruited.

Technology will provide a sturdy base for the monitoring and evaluation of quality components of the project. The app will provide a real-time status of progress in project, namely, service coverage, health parameters and trends. Regular field visit will be conducted by the coordinator to ensure compliance of protocols, systems and app procedures. Weekly review will be conducted with the BFNs to assess population coverage, reach and service along with challenges of implementation and quality issues. Additionally, monthly review of the project will be conducted in order to assess overall coverage with breakup of services and impact of intervention in each of the services. Also, the analysis of data will be done regularly on a weekly and monthly basis in order to review the performance and give feedback for improvement. The planning and execution of work by BFN will be subject to scrutiny using app-based technology. Further, there will be audits conducted to assess skill and knowledge of BFNs in the system and procedure compliance along with feedback from beneficiaries.

3.6. Primary and secondary outcome measures and assessment points

The primary outcome indicators for the study include a) proportion of population screened for NCDs (diabetes, hypertension, anaemia, vision problems, and kidney ailment), b) proportion of population, who are diagnosed with NCDs repeated the screening, c) proportion of first-time detection and referral of NCDs. The secondary outcome measures will include average amount of money earned per week/month, per barefoot nurse, timeliness and completeness of data filled in data entry App. The key independent measures will include respondent's socio-

¹ A fact revealed by the Director of health, Department of Health and Family Welfare, Government of Karnataka when he was addressing a workshop held at the Indian Institute of Public Health, Bangalore while he was revealing the challenges faced by the health system.

economic characteristics, general health condition, substance use etc.

3.7. Recruitment procedures

The BFN will recruit participants at their homes following the four eligibility criteria. Importantly, the BFN will recruit only those community members who have consented to be part of this study after they have been explained the purpose and process of the study and what role they have in the study.

3.8. Randomization procedures

Cluster randomization will be done prior to recruitment of participants to avoid contamination between and within wards. The participants in the control area will receive usual care as part of the health system of the government of Karnataka, where the ANMs are supposed to screen population for NCD markers. The 16 clusters will be enrolled ensuring non-overlap between the intervention and control wards. Random allocation will be performed by two members of the study group. The 16 wards will be assigned serial numbers 1 to 16 that will be known by only one member of the team. These serial numbers would be noted in 16 small chits and will be placed in a bowl. The member of the team will randomly draw one chit at a time and put in one envelop (marked as intervention) and will put the chit from the second draw in another envelop (marked as control). This process will be repeated till she/he picks and place all the 16 chits. Thus, envelop marked as 'intervention' and envelop marked as 'control' each will have eight clusters allocated randomly. Participants will be recruited based on their inclusion in either the intervention or control area.

3.9. Statistical analysis including sample size calculations

The key outcome measure would be mean glucose level. The effect of the proposed intervention will be assessed using a two-arm cluster randomized controlled trial. The required number of clusters is calculated using the following formula²:

$$c = 1 + (Z_{\alpha/2} + Z_{\beta})^2 [(\sigma_0^2 + \sigma_1^2) / n + k^2(\mu_0^2 + \mu_1^2)] / (\mu_0 - \mu_1)^2$$

Where, c = number of clusters required.

$Z_{\alpha/2}$ and Z_{β} are the standard normal distribution values corresponding to upper tail probabilities of $\alpha/2$ and β respectively,
 μ_0 and μ_1 are the true (population) means,
 σ_0 and σ_1 are within cluster standard deviations,
 k is the coefficient of variation of true means between clusters within each group (arm),
 n is the number of individuals in each group

A cluster for this study will be a municipal ward of the urban area. There are 31 municipal wards in the study taluka. The mean population per cluster is 2859 (range 1179–8465). The estimated population in these clusters is 88,632 (based on the 2011 Indian census projections). With an assumed mean glucose level of 140 mg/dl with a standard deviation of 40 mg/dl among the diabetic individuals at baseline, we anticipate the mean glucose level would be 120 mg/dl with a standard deviation of 20 mg/dl through the proposed intervention. At 95% confidence level, 80% power and with a coefficient of variation of 0.10, the required cluster size in each of the intervention and control arm is eight. To determine the number of cluster pairs to be enrolled, we have estimated the coefficient of variation (k) in outcome between clusters and

the expected number of diabetic individuals per cluster over the time-scale of the study. Based on available information on diabetes in the study geography, we assumed a 'k' value of 0.10. We will estimate the intraclass correlation coefficient from retrospective glucose level data by a method based on analysis of variance within Stata version 15.

Bivariate and multivariate analyses will be done along with appropriate tests to examine the association between the dependent and independent variables. Intention-to-treat analysis at both cluster level as well as at individual level will be done to assess the effect of the intervention on the outcome measures. We will compare the mean glucose level between control and intervention groups, taking account of clustering, with hierarchical logistic models.

4. Discussion

NCDs are intensifying the burden of multimorbidity in LMIC [17]. A recent study among South Asians reveals that the adjusted prevalence of multimorbidity was 9.4% among adults who drink alcohol, Body Mass Index ≥ 25 m/kg², height waist circumference and a family history of chronic condition [18]. Specifically, in India there is very high level of hypertension is registered for both men and women, which does not show any signs of convergence with global targets [1]. Also, four out of five people in the world with diabetes live in LMIC [19]. This kind of NCD disease load warrants preventive measure to be undertaken by those who suffer from these ailments. In the light of shortage of health workforce in LMIC, and in order to overcome the access barrier CHW can serve as important agents for delivering health services addressing NCDs [20]. Preventive intervention operationalized by CHW exists specifically in Maternal and Child Health, family planning and nutrition [21]. The role of CHWs is well documented in the promotion of health seeking behaviour [20]. However, the effectiveness of CHW in administering primary preventive intervention for the management and control of NCDs is limited in LMIC [21]. Moreover, the preventive intervention where CHW screens community members for NCD is rather limited. Hence, the test of CHW effectiveness in screening for NCD is non-existent. This protocol sets out to bridge this gap by assessing the effect of BFN in screening of NCD and management of data, as compared to ANM. Additionally, the study will assess the extent of self-sustainability of BFN model in meeting the livelihoods of the bare-foot nurses. Outlines the implementation of such an intervention.

Trial registration

Clinical Trial Registry India.

Registration number

CTRI/2019/09/021469.

Was this trial prospectively registered?

Yes.

Date of trial registration

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Human research ethics approval committee

Institutional Ethics Committee, Indian Institute of Public Health, Bangalore.

² Hayes, R.J. and S. Bennett. Simple sample size calculation for cluster randomized trials, International Journal of Epidemiology 1999;28: 319–26, available at <https://academic.oup.com/ije/article/28/2/319/655247>.

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Declaration of competing interest

None.

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