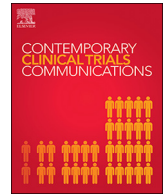




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Participant recruitment into a community-based diabetes prevention trial in India: Learnings from the Kerala Diabetes Prevention Program



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ABSTRACT

Background: Data on participant recruitment into diabetes prevention trials are limited in low- and middle-income countries (LMICs). We aimed to provide a detailed analysis of participant recruitment into a community-based diabetes prevention trial in India.

Methods: The Kerala Diabetes Prevention Program was conducted in 60 polling areas (electoral divisions) of the Neyyatinkara taluk (subdistrict) in Trivandrum district, Kerala state. Individuals (age 30–60 years) were screened with the Indian Diabetes Risk Score (IDRS) at their homes followed by an oral glucose tolerance test (OGTT) at community-based clinics. Individuals at high-risk of developing diabetes (IDRS score ≥ 60 and without diabetes on the OGTT) were recruited.

Results: A total of 1007 participants (47.2% women) were recruited over nine months. Pilot testing, personal contact and telephone reminders from community volunteers, and gender matching of staff were effective recruitment strategies. The major recruitment challenges were: (1) during home visits, one-third of potential participants could not be contacted, as they were away for work; and (2) men participated less frequently in the OGTT screening than women (75.2% vs. 84.2%). For non-participation, lack of time (42.0%) was most commonly cited followed by 'I am already feeling healthy' (30.0%), personal reasons (24.0%) and 'no benefit to me or my family' (4.0%). An average of 17 h were spent to recruit one participant with a cost of US\$23. The initial stage of screening and recruitment demanded higher time and costs.

Conclusions: This study provides valuable information for future researchers planning to implement community-based diabetes prevention trials in India or other LMICs.

Trial registration: Australia and New Zealand Clinical Trials Registry: ACTRN12611000262909.

1. Introduction

Type 2 diabetes is a major public health issue worldwide, affecting an estimated 425 million people, and of which more than 75% live in low- and middle-income countries (LMICs) like India [1]. Furthermore, diabetes impacts negatively on the health and wellbeing of individuals and their families, and also has broader social and economic effects on the wider community as well as health care systems [1]. Therefore, prevention of type 2 diabetes has become extremely important.

A number of randomized controlled trials (RCTs) have been conducted to examine the effects of lifestyle interventions (i.e. promoting physical activity, healthy dietary habits and weight loss) or medications to prevent type 2 diabetes among high-risk individuals [2]. While the results from these trials are encouraging with both lifestyle interventions and medications being effective and cost-effective [2,3], little is known about the recruitment challenges and the modes of participant recruitment into these trials. Recent systematic reviews have emphasized the need for better reporting of participant recruitment in diabetes

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prevention trials to improve the translation of findings into policy and practice, thereby enhancing the public health impact of those findings [4,5]. Furthermore, reporting on participant recruitment will enable future researchers to devise strategies to achieve better recruitment outcomes [6].

The Kerala Diabetes Prevention Program (K-DPP) was a cluster-RCT of a peer-support lifestyle intervention program conducted among individuals at high-risk of developing diabetes in India. High-risk individuals were identified on the basis of a diabetes risk score who either had normal glucose tolerance or prediabetes. The details of the study design, development of the intervention program, baseline characteristics, and trial outcome and implementation results have been previously reported [7–11]. In the present study, we aimed to provide a detailed analysis of participant recruitment into K-DPP in terms of: (1) effective strategies for participant recruitment; (2) challenges; (3) costs and staff time; and (4) reasons for non-participation in the trial.

2. Methods

2.1. Study design

The details of the K-DPP study design have been published previously [7]. Briefly, K-DPP was a two-year cluster-RCT implemented in 60 polling areas (electoral divisions) of the Neyyattinkara taluk (sub-district) in Trivandrum district of Kerala state in India. The 60 polling areas were randomly allocated (1:1) to an intervention group (received a group-based peer-support lifestyle intervention program for 12 months) or a control group (received a booklet on lifestyle modification) by an independent statistician using a computer-generated randomization sequence.

2.2. Screening and recruitment of participants

A total of 80 individuals (50 males and 30 females), aged 30–60 years, were selected randomly from the electoral roll of each of the 60 polling areas. Details on how we arrived at the number of 80 individuals per polling area are given in the published study protocol [7]. These 80 individuals were then approached at their homes by trained field staff (“home visits”). Individuals who were not willing to participate in the trial were asked about the reason(s) for their decision using a questionnaire. Consenting individuals were screened with the following eligibility criteria: no history of diabetes or other major chronic illness, not pregnant, literate in the local language and not taking drugs known to affect glucose tolerance. We used a two-step screening procedure to recruit participants, which has been detailed elsewhere [12]. Briefly, the first screening involved administration of the Indian Diabetes Risk Score (IDRS). The IDRS is a simple, non-invasive screening tool consisting of four parameters namely, age, family history of diabetes, waist circumference and physical activity [13]. The IDRS has been validated widely in India for detecting people with undiagnosed diabetes [14], including in our study area, where a score of ≥ 60 had a sensitivity of 85.7%, specificity of 59.4% and accuracy of 80% [15]. The second screening step consisted of an oral glucose tolerance test (OGTT) among those with an IDRS score ≥ 60 at community-based clinics. Clinics were organized during weekends in the local community itself using community buildings e.g., schools, community halls and library halls. Individuals diagnosed with diabetes based on the American Diabetes Association (ADA) criteria [16] were excluded from the study, and were referred to healthcare facilities for treatment and care. The remaining individuals were recruited to the trial.

2.3. Strategies employed for recruiting participants

The strategies employed for recruiting participants for the trial are given in Table 1.

2.4. Recruitment team

The recruitment team consisted of 76 members including one project manager, one project assistant, one field assistant, 10 field staff (5 males and 5 females), 3 phlebotomists and 60 LRPs. The recruitment team met on a regular basis to discuss the challenges and difficulties faced, and how to tackle the issues raised. In addition, they tracked the recruitment progress, and prepared recruitment reports to share with the study investigators. The project manager was available by phone to clarify any doubts or issues the field staff might be facing at the time of recruitment.

2.5. Data analysis

Data were summarized using frequencies and percentages. The recruitment costs were calculated across the following categories: home visits, community-based clinics, training sessions for the field staff and LRPs and administrative costs. Personnel costs were based on the actual salary (or remuneration) paid to the recruitment staff, and were estimated for the time they spent on various recruitment activities. Non-personnel costs (IDRS printing charges, OGTT costs, training sessions for the field staff and LRPs, travel costs, rent for clinic venues, communication costs and administrative costs) were estimated based on the actual expenditure for those items. The cost figures were obtained from the finance registers. The cost estimates in Indian Rupees (INR) were converted to US\$ using an exchange rate of INR 58.6 = 1US\$ for the year 2013 [20]. All analyses were performed using Microsoft Excel 2016 (Microsoft Corporation, Redmond, Washington, USA).

2.6. Ethics approval

K-DPP was approved by the Health Ministry Screening Committee of the Government of India, and ethics committees of the Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCT/IEC-333/May 2011), Trivandrum, India, and Monash University (CF11/0457–2011000194) and The University of Melbourne (1441736) in Australia. Written informed consent was obtained from all study participants.

3. Results

The screening and recruitment took place over a period of nine months from January 26, 2013 to October 27, 2013. Fig. 1 shows the screening and recruitment flow chart. Home visits were made to a total of 5517 individuals, of which 3689 (66.9%) were contacted. The reasons for not being able to contact 1828 individuals were: left for paid work at the time of home visit (73.7%), migrated overseas (11.6%), status of the individual not known (11.4%) and died (3.2%). Of those contacted, 137 (3.7%) were aged < 30 or > 60 years, and were therefore excluded. The remaining 3552 individuals (age 30–60 years) were invited to participate, of which 3421 (96.3%) consented.

Of 3421 consenting individuals, 835 (24.4%) did not satisfy the eligibility criteria, and the remaining 2586 were screened with the IDRS. Of these, 1529 (59.1%) had a score of ≥ 60 , and therefore invited to undergo OGTT at community-based clinics. Males were less likely to have IDRS score ≥ 60 compared to females (49.8% vs. 78.6%). A total of 1209 (79.1% of those invited) individuals attended community-based clinics and underwent an OGTT. Of the initial non-attendees ($n = 333$), 26 expressed willingness to attend follow-up clinics but only 13 (50%) of those attended in reality. A lower proportion of males (75.2%) attended clinics compared to females (84.2%). After excluding 202 individuals (18.7% males; 14.4% females) with diabetes on the OGTT, the remaining 1007 (46.9% females) were recruited. The baseline characteristics of participants have been reported elsewhere [14].

Fig. 2 shows the number of participants recruited each month during the 9-month recruitment period. During most of the months

Table 1
Strategies employed for recruiting participants.

Recruitment strategy	Description
Pilot study	We pilot tested the recruitment protocol in two polling areas in 2012–13 [7]. During the pilot, study packs (invitation letter from the Indian principal investigator, consent form, study information sheet and the schedule of upcoming home visit) were mailed to 160 potential participants (@80 per polling area), at least a week in advance of the scheduled home visit. Due to incorrect home addresses, nearly half of the posted packs were returned or did not reach the intended individuals. Therefore, to locate the households of potential participants, the study team decided to engage trained volunteers from the local community. Additionally, the pilot study showed that in order to achieve a gender balance in the study sample, it is essential to screen more men than women for the following reasons. Compared to women, men were less likely to have IDRS score ≥ 60 and to attend for the OGTT screening, and more likely to have diabetes on the OGTT. Thus, of the 80 individuals who were selected randomly from each polling area, 50 were men and 30 were women.
Engaging community leaders and local resource persons	We approached the elected representatives (referred as community leaders hereafter) of the 60 polling areas, and requested they identify a community volunteer (referred as local resource persons (LRPs) hereafter) for their polling areas. LRPs were female community health workers, educated up to secondary school or higher, and they have a good rapport with the people in the local community. LRPs were formally recruited to the K-DPP recruitment team. During home visits, LRPs accompanied the field staff and helped them in locating the correct home address of potential participants, gave participants a telephone reminder on the day before their scheduled clinic date and assisted in organizing clinics.
Gender matching of staff	Experience from our previous studies in the study region [17–19] have shown that men are generally less likely to be available at home in the morning hours, owing to work commitments. Therefore, we gender matched our recruitment staff i.e. male staff to contact male participants and female staff to contact female participants, so that male staff could contact male participants during late evening hours after they had return from work.
Follow-up clinics	Participants who were not able to attend clinics in the first instance were invited to attend follow-up clinics. Each follow-up clinic was conducted for participants from two to three neighborhoods within close proximity.

(excluding first and last month with less number of recruitment days), 100 or more participants were recruited, except during local festival seasons (March and September) where lower number of participants (74–80) were recruited.

Table 2 shows the staff time spent for recruitment. A team of 76 staff members spent a total of 16,864 h over nine months to recruit 1007 participants. Thus, on average, 17 h were spent to recruit one participant. Of the total staff hours (16,864 h), home visits demanded a large proportion (77.5%) followed by training sessions for the field staff and LRPs (12.2%) and conducting community-based clinics (10.3%).

Table 3 shows the screening and recruitment costs. In total, US \$23,525 were spent for recruiting participants, which translates to an average of US\$23 to recruit one participant. The largest cost contributor was home visits (59.9%), followed by community-based clinics (30.7%), administrative costs (6.6%), and training sessions for the field

staff and LRPs (2.9%). Personnel costs (US\$14,931) were nearly two-third (63.5%) of the total costs.

Of the 131 individuals who refused to participate, 81 (61.8%) did not provide a specific reason for their decision. Among those providing a reason (n = 50), lack of time (42.0%, n = 21) was most commonly cited followed by ‘I am feeling healthy and therefore not in need of any intervention’ (30.0%, n = 15), personal reasons (24.0%, n = 12) and ‘no benefit to me or my family’ (4.0%, n = 2).

4. Discussion

K-DPP is the first RCT from a LMIC to evaluate the effectiveness of a peer-support lifestyle intervention delivered primarily by lay peer leaders for the prevention of type 2 diabetes. This paper provides valuable information on participant recruitment for future researchers planning

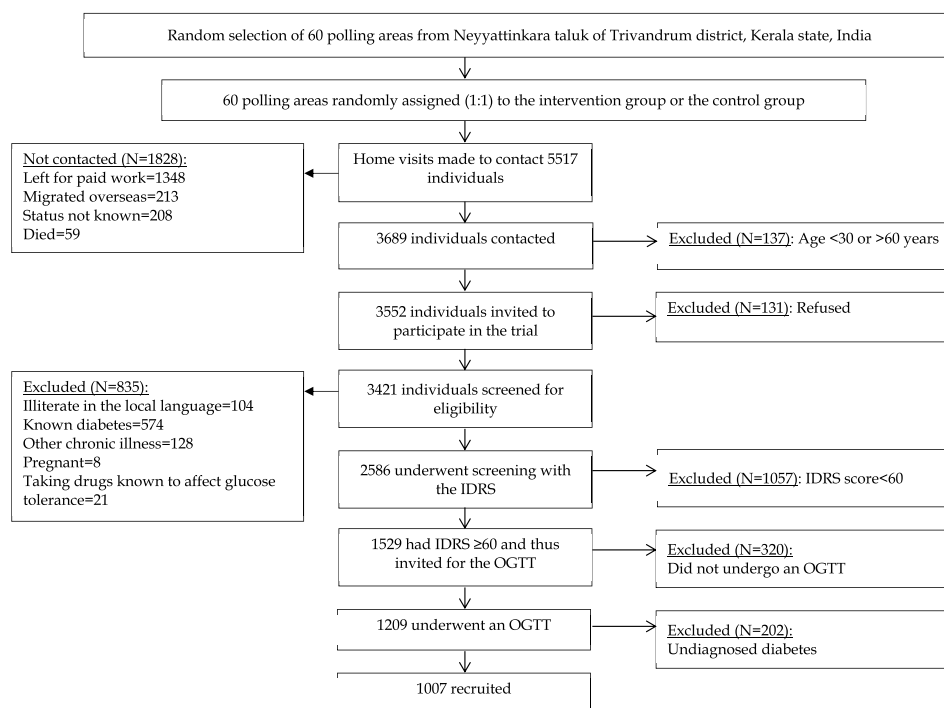


Fig. 1. K-DPP screening and recruitment flow chart.

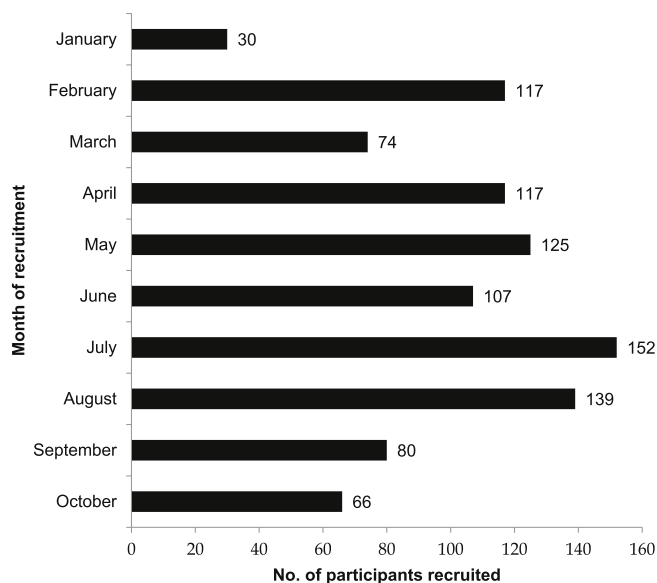


Fig. 2. K-DPP recruitment progress.

to implement community-based diabetes prevention trials in India or other LMICs.

4.1. Effective recruitment strategies

Appropriate recruitment strategies is the key to delivering an effective intervention, achieving better outcomes and generalizability of the study findings. In our trial, we could reach the recruitment target within the expected time frame through learnings from the pilot study, community engagement and gender matching of staff. Consequently, we could start and complete the intervention without any undue delay. Furthermore, learnings from the pilot study were instrumental in achieving a gender balance in the study sample, thereby advancing the generalizability of the study findings to both sexes. We also believe that the good rapport that LRPs have with the people in the community may not only have enhanced the recruitment but also improved the attendance in intervention sessions [21].

4.2. Recruitment challenges

There were some challenges during recruitment. First, one-third of individuals, for whom initial home visits were made, could not be contacted. The main reason was that many of these individuals were not available at home due to work commitments. Screening at worksites

may be a more effective strategy for reaching such individuals, however, these individuals will generally be employed at many different workplaces and often at some distance from the community where they live. Another important reason was that a substantial number of individuals had migrated overseas (either temporarily or permanently), mainly to Gulf countries. According to the latest Kerala Migration Survey, 19% of households in Kerala had emigrants in 2014, and they were predominantly men (86%) [22]. The other challenge was that during festive seasons it was difficult to recruit participants. During the month of Ramadan, Muslim participants were not able to attend clinics for the OGTT in a fasting state, hence, we had to postpone some clinics. Also, during Onam festival (local festival) in September, we had to stop recruitment for at least two weeks as it was difficult to mobilize people to the clinics. Finally, the participation rate for the OGTT was lower among males as compared to females (75.2% vs. 84.2%). Since we anticipated this based on pilot study findings, for the main trial, we conducted clinics only during weekends so that working men could attend. Although, this strategy improved the attendance in men (from 50% in the pilot study to 75.2% in the main trial), the rate was still lower than in women. One possible reason for this is that manual laborers go for paid work even during weekends and they leave for work early in the morning, and therefore they cannot stay at the clinic for 2 h for the OGTT. In our previous research, men had a much higher response rate (~96%) for a one-time blood test (i.e. fasting plasma glucose) [19]. Therefore, it might be surmised that the lengthy nature of the OGTT may have dissuaded some men from attending, particularly manual laborers.

4.3. Staff time and recruitment costs

An average of 17 h were spent to recruit one participant with a cost of US\$23. Home visits demanded a substantial proportion of the staff time (77.5%) and recruitment costs (59.9%), emphasizing the importance of the initial screening stage in the recruitment process, which is line with findings from other diabetes prevention trials [23]. The recruitment cost (US\$23 per participant) was much lower than that in other diabetes prevention trials. For example, in the Indian Diabetes Prevention Programme [24], the cost of identifying one participant was US\$117 (year 2006) and in the United States Diabetes Prevention Program it was US\$139 (year 2000) [25]. These numbers are, however, not strictly comparable with ours, given the difference in the way high-risk individuals were defined across these studies. Nevertheless, it is worth mentioning that to recruit participants, we used a diabetes risk score in a stepwise screening approach, which reduced the number of OGTTs required, thereby possibly reducing the overall recruitment costs [26]. In a program setting, we anticipate that our recruitment costs would be even lower, as community health workers and

Table 2
Staff time for recruitment.

Recruitment staff	Task (s) related to recruitment	Total hours
Project manager (n = 1)	To meet community leaders	42
	To train the field staff	8
	To train LRPs	20
	To manage community-based clinics	264
Project assistant (n = 1)	To assist the project manager with recruitment-related activities	334
	To make phone calls to the field staff and LRPs for attending training sessions	58
Field assistant (n = 1)	To manage community-based clinics	240
Field staff (n = 10)	To make home visits, and screen the potential participants with the eligibility criteria and the IDRS	12,378
	To attend the training sessions	144
	To assist the field staff in identifying the home address of potential participants	600
LRPs (n = 60)	To attend the training sessions	1800
	To give telephone reminders to participants to attend for the OGTT	32
	To collect blood samples for the OGTT at community-based clinics	945
Phlebotomists (n = 3)		
Total		16,864

IDRS, Indian Diabetes Risk Score; LRP, local resource person; OGTT, oral glucose tolerance test.

Table 3
Screening and recruitment costs.

Categories	Inputs	Total cost (US\$)	Percent of total cost
Training sessions (four for field staff and five for LRP)		672	2.9%
	Personnel costs	161	
	Travel, food and logistics costs	450	
Home visits (to contact 5517 potential participants)	Phone call costs	61	59.9%
	Personnel costs	13,626	
	IDRS printing charges	66	
Community-based clinics (n = 63)	Phone call costs	389	30.7%
	Personnel costs	1144	
	OGTT costs	3817	
	Travel costs	2123	
	Rent for clinic venues	87	
Administrative costs	Phone call costs	52	6.6%
		1549	
Total costs		23,525	100%

LRP, local resource person; IDRS, Indian Diabetes Risk Score; OGTT, oral glucose tolerance test. Rent was charged only for some of the venues. Costs in Indian Rupee (INR) were converted to US\$ using an exchange rate of INR58.6 = US\$1 for the year 2013

healthcare providers will screen and identify high-risk individuals as part of the routine healthcare service [27].

4.4. Reasons for non-participation in the trial

A large proportion of potential participants did not provide a reason for choosing not to participate. Of those who did, *lack of time* was the most frequently cited reason. Flexibility in the delivery of intervention may address this barrier to a certain extent. For example, as an alternative to personal contact sessions, mobile phones could be used to deliver the intervention, given the widespread use of mobile phones in India and other LMICs, and its proven feasibility and effectiveness in diabetes prevention [28]. Interventions could also be delivered at worksites. *'I am feeling healthy and therefore not in need of any intervention'* also emerged as a significant reason. This probably reflects the low awareness about diabetes, low risk perception and low self-efficacy to make lifestyle changes among high-risk individuals in India [29]. Moreover, the risk of acquiring diabetes is not a major factor in the food decision-making process in Indian households [30], and the cultural norms and certain misconceptions negatively influence women to engage in physical activity [31]. Other Indian investigators have pointed out that the "hidden" nature of prediabetes is a big challenge to sensitize people to their risk and to the benefits of making lifestyle changes for diabetes prevention.

4.5. Strengths and limitations

This study adds to the very limited body of literature on participant recruitment into diabetes prevention trials in LMICs. To our knowledge, K-DPP is the first diabetes prevention trial from a LMIC to provide data on reasons for non-participation. The limitation was that we did not ask the non-attendees for the OGTT screening the reason (s) for their decision. Future research, preferably a qualitative research, should try and elicit the barriers for attending the OGTT screening, particularly among men.

To conclude, the K-DPP recruitment experience offers important lessons for researchers planning to design and implement diabetes prevention trials in community settings in India or other LMICs: (1) pilot testing the recruitment protocol may help to identify some of the challenges and difficulties, thereby providing an opportunity to revise the recruitment approaches; (2) engaging the community in recruitment is valuable. We were able to engage the community and create ownership in the community leaders and LRPs who effectively promoted recruitment; (3) gender matching of staff may be required to enhance the reach of men; (4) local festive seasons should be accounted

for in the recruitment schedule as delays might be expected; (5) the initial stage of recruitment demanded more staff time and costs compared to later stages, and this should be considered when budgeting the trial expenses; (6) a step-wise screening procedure involving a diabetes risk score reduced the number of OGTTs required, thereby reducing possibility reducing the overall recruitment costs; and (7) it is important to raise awareness among people about prediabetes and diabetes, and the role of lifestyle changes in diabetes prevention through health education programs.

Conflicts of interest

Authors have nothing to disclose.

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