



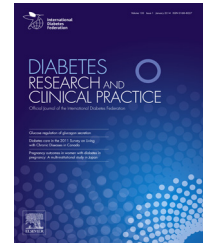
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Recruitment challenges in a diabetes prevention trial in a low- and middle-income setting

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ABSTRACT

Aim: To describe recruitment challenges in a randomized controlled translational trial (RCTT) of diabetes prevention in India.

Methods: The Diabetes Community Lifestyle Improvement Program (D-CLIP) is a RCTT, comparing standard of care to a step-wise model of diabetes prevention. Overweight adults with prediabetes were identified through a two-step screening process (1) field-based screening: minimal testing with a random capillary glucose measurement and (2) clinic-based screening including an Oral Glucose Tolerance Test (OGTT).

Results: Individuals from the community ($n = 19377$) were screened at residential locations, offices, educational institutions, places of worship, parks and beaches. Of these, 3535 (18.2%) 'high-risk' participants based on capillary glucose values were eligible for step 2 screening with OGTT. However, only 21.5% participated. An additional 521 participants directly entered step 2 via direct referrals from our clinical/research databases, study participant referrals and targeted advertisements. Of the 1285 individuals who underwent an OGTT, 710 (55.3%) were eligible for randomization, and 602 (84.8%) were randomized into the trial. The ratio of participants entering from step 1 to step 2 was 25:1 (3.9%) and from step 2 to randomization 2:1 (47%). Average staff time for recruitment was 350 h per week for an 11-person team.

Conclusions: Nearly 55 people needed to be screened with a questionnaire plus capillary glucose test to randomize one participant with prediabetes. Using a 2-step strategy requires additional staff time, but considerably reduces the need for OGTT's, thereby minimizing participant burden and study costs.

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1. Introduction

Strong evidence exists for the feasibility and effectiveness of preventing type 2 diabetes in high-risk groups [1–5]. Together, these studies show reductions in diabetes risk ranging from

31% to 67.4%, and further follow-up of these participants show the intervention effects to be long lasting [6–8]. These studies have shown beneficial effects on other cardio-metabolic outcomes, like weight, blood pressure, plasma lipids, and cardiovascular fitness [9,10]. Furthermore, with almost 60% of incident cases of diabetes being attributable to prediabetes,

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approaches directed at this high-risk group are likely to be most cost-effective [11]. The potential benefits of preventing diabetes in low- to middle-income country (LMIC) settings like India where the bulk of diabetes occurs [12,13] are huge.

However, diabetes prevention programs in India and similar settings face major challenges in recruiting participants. People are hesitant to get screened for diabetes due to lack of awareness about its chronic nature, causes, consequences, and management [14]. They are also oblivious to the possibility of transitioning from high-risk to the state of diabetes if preventive measures are not adopted. The silent nature of this chronic disease thus poses one of the most formidable challenges in recruitment of participants for diabetes prevention trials [15]. Recruiting individuals at high-risk for diabetes is unlike enrolling participants at high-risk for a breast cancer intervention trial where women tend to participate more easily as they tend to overestimate the threat [16].

Challenges of recruiting and sustaining high-risk populations for a primary prevention translational trial in India have never been reported and literature from elsewhere is scant [17–19]. For the interventions like the highly effective U.S. Diabetes Prevention Program (DPP) [1] to work in LMIC settings like India, the interventions will need to be generalized to all people with prediabetes, culturally modified, made low cost and sustainable and be conducted in a ‘real-life’ setting. The Diabetes Community Lifestyle Improvement Program (D-CLIP), a culturally specific community-based, low cost randomized, controlled, translational research trial for the prevention of diabetes in India, was designed keeping these needs in mind [20]. D-CLIP (NCT01283308, clinicaltrials.gov) was conducted in Chennai city, the largest metropolis of southern India and tested a step-wise model of diabetes prevention in a high-risk population. D-CLIP recruitment and classes were coordinated and conducted by a tertiary care diabetes centre. This paper reports on the following: the various recruitment strategies used for the enrolling participants into the trial; the potentially successful approaches for community-based recruitment to identify individuals with prediabetes; ways these recruitment strategies can be replicated in terms of yield for future diabetes prevention trials; the amount of staff time involved; and the challenges to recruitment.

2. Methods

2.1. D-CLIP methodology

The detailed methodology of the D-CLIP trial has been described elsewhere [20,21] and is briefly explained here. The lifestyle intervention trial included overweight or obese (BMI >22 kg/m² or waist circumference ≥ 80 cm in women/ ≥ 90 cm in men) men and women aged 20–65 years with prediabetes (impaired glucose tolerance [IGT], 2-h post load glucose 140–199 mg/dl [7.8–11.0 mmol/l] and/or impaired fasting glucose [IFG], fasting plasma glucose 100–125 mg/dl [5.6–6.9 mmol/l]). For most participants, a two-step screening method was used for identifying individuals with prediabetes: (1) Field-based screening with a short screening questionnaire,

basic anthropometry and a random capillary glucose measurement and (2) clinic-based screening with a confirmatory 3-sample Oral Glucose Tolerance Test (OGTT) conducted after an overnight fast of at least 8 h. A smaller sample of study participants were also identified at the study site using the electronic medical records system and the records of other trials; these individuals were scheduled for clinic-based screening only. The D-CLIP study was approved by the Emory University Institutional Review Board as well as the Ethics Committee of the Madras Diabetes Research Foundation.

2.2. Screening sources and recruitment strategies

The study participants for D-CLIP were recruited from various sources: community-based screening camps, direct referrals, print media (study clinic newsletter/vernacular daily's), advertisements across the study clinic and using health records at the study site. The goal of community screening was to identify the high-risk individuals and invite them for a confirmatory clinic-based testing. Initially, for the first few screenings, we invited individuals with fasting capillary blood glucose (F-CBG) 100–125 mg/dl (5.6–6.9 mmol/l) or random capillary blood glucose (R-CBG) 120–199 mg/dl (6.7–11.0 mmol/l); aged 20–65 years; and a waist circumference of ≥ 90 cm for males or ≥ 80 cm for females or a BMI of greater than 22 kg/m² to the clinic for baseline testing. However, these cut-offs were not sufficient to capture a large group of individuals with prediabetes. Hence, at later screening camps, the study team expanded the capillary glucose cut-offs to include individuals with F-CBG of 90–126 mg/dl (5.0–7.0 mmol/l) or R-CBG of 110–200 mg/dl (6.1–11.0 mmol/l). Screening and recruitment strategies differed by screening location/source as described below, and the results of each strategy are presented in Section 3.

2.3. Populations participating in two-phased screening

2.3.1. Community-based screenings (held in residential complexes, corporate offices, schools/colleges, parks, beaches and places of worship)

These screenings were primarily conducted in housing colonies/residential complexes, a cluster of apartment buildings and homes within a boundary, which may or may not be gated. In addition, screening camps were also conducted in corporate offices or worksites for their employees and employees' families; at private and government schools for faculty and staff; and at public locations (beaches, places of worship, parks, etc.) to mark special occasions such as World Health Day or World Diabetes Day.

Each community screening held at a residential complex or corporate office included a short survey to collect socio-demographic details and family history of diabetes, anthropometric measurements (including height, weight, and waist circumference) and an R-CBG test. Before screening, information was given to the individuals in charge at each screening site, and a leaflet, which described the screening procedures and purpose of the study, was distributed to potential participants prior to commencement of the screening camp.

Screening locations were selected to maximize study reach. These typically were apartments and colonies with a

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