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A pragmatic and scalable strategy using mobile technology to promote sustained lifestyle changes to prevent type 2 diabetes in India—Outcome of screening

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ABSTRACT

Aims: We describe a two-step screening approach using non-invasive risk assessment and glycated hemoglobin (HbA1c) to identify participants for a diabetes prevention trial.
Methods: A total of 6030 non-diabetic persons of 35–55 years were screened using risk assessment for diabetes. Those with three or more risk factors were screened using point of care HbA1c test. For this study, participants in HbA1c categories of 6.0% (42.1 mmol/mol)–6.4% (46.4 mmol/mol) were selected and their characteristics were analyzed.
Results: Among 6030 persons, 2835 (47%) had three or more risk factors for diabetes. Among those screened with HbA1c, 43.2% (1225) had HbA1c values of <6.0% (42.1 mmol/mol), 46.8% (1327) had HbA1c values between 6.0% (42.1 mmol/mol) and ≤6.4% (46.4 mmol/mol) and 10% (283) had undiagnosed diabetes with ≥6.5% (47.5 mmol/mol). Positive family history was present in 53.2%, 81.7% were obese and 14.8% were overweight.
Conclusions: Opportunistic screening using a two-step approach: diabetes risk profile and HbA1c measurement detected a large percentage of individuals with prediabetes. Prediabetic persons recruited to the trial had higher percentage of obesity and presence of positive family history than those who had lower HbA1c values. Outcomes from this trial will enable comparisons with the previous prevention studies that used blood glucose levels as the screening criteria.

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Abbreviations: BMI, body mass index; FBG, fasting blood glucose; GTT, glucose tolerance test; HbA1c, glycated hemoglobin; IDF, International Diabetes Federation; IFG, impaired fasting glucose; IGT, impaired glucose tolerance; LMIC, low and middle income countries; 2hPG, 2-hour post glucose; SMS, short messaging service; T2DM, type 2 diabetes; TTM, transtheoritical model.

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1. Introduction

The rising prevalence of type 2 diabetes (T2DM) is a major healthcare challenge globally. The burden is the highest in developing countries where more than 80% of the people with diabetes live [1]. According to the recent International Diabetes Federation (IDF) estimates, there were more than 65 million people with diabetes in India in the year 2013. With the current rising trend, the prevalence is bound to increase further to a 100 million in the next 20 years' time [1].

Primary prevention of diabetes is of paramount importance in reducing the burden of the disease. There is unequivocal evidence showing that T2DM is a preventable disorder in populations of varied ethnicity [2,3]. Studies in India have shown the efficacy of lifestyle modification (LSM) in preventing the onset of T2DM in persons with persistent impaired glucose tolerance (IGT) [4–6]. A recent study by our team has shown that text messaging via short messaging service (SMS) using mobile phones can be effectively used for sustained motivation of the participants to follow healthy lifestyle changes to prevent diabetes [6]. This is likely to be a cost-effective method to implement primary prevention strategies in large-scale community projects.

In continuation of our efforts to identify effective methods of reaching the public at large for primary prevention of T2DM, we have taken up another collaborative study with researchers in the UK with the objective of developing 'a pragmatic and scalable strategy using mobile technology to promote sustained lifestyle changes to prevent type 2 diabetes in India and the UK' (Clinical Trials.gov No NCT01570946, Clinical Trials Registry of India No. CTRI/2014/07/004799, ICMR Ref. No. 58/1/6/MRC-ICMR/2009/NCD-II).

In this communication we describe the methodology used in India for selection of the study participants in this prospective program and the outcomes of the screening. The benefits of early screening and intervention in diabetes have been demonstrated in earlier studies [2]. However, an effective strategy for opportunistic screening of a large-scale population for dysglycemia remains elusive. Most of the primary prevention programs in diabetes were in persons with IGT and or Impaired Fasting Glucose (IFG), categorized based on the plasma glucose criteria [2,3,7]. The American Diabetes Association (ADA) recommends that HbA1c values between 5.7% (38.8 mmol/mol) and 6.4% (46.4 mmol/mol) indicate the presence of prediabetes [8]. Our earlier primary prevention studies among Asian Indians have indicated that 60% of the incidence of diabetes occurred with HbA1c values of $\geq$6.0%(42.1 mmol/mol) [9]. So, the selection criterion used in this protocol was an HbA1c value of 6.0% (42.1 mmol/mol) to $\leq$6.4%(46.4 mmol/mol). This was done to improve the power of the study by faster and higher conversion rate to diabetes. It has also been suggested by the International Expert Committee convened by the World Health Organisation (WHO) and International Diabetes Federation (IDF) that persons with a HbA1c level between 6.0% (42.1 mmol/mol) and 6.5% (47.5 mmol/mol) are at high risk and might be considered for lifestyle intervention programs [10]. In our country this is the first study to report screening using the HbA1c values for prediabetes.

2. Materials and methods

2.1. Objectives

The main objective of this paper is to describe the methods used for selection of participants for the primary prevention study using HbA1c as the diagnostic tool to identify individuals with high risk of conversion to diabetes.

As mentioned earlier, although HbA1c values of 5.7% (38.8 mmol/mol) and 6.4% (46.4 mmol/mol) have been recommended for identifying the state of prediabetes, we have chosen only persons with HbA1c values of (6.0% (42.1 mmol/mol) to $\leq$6.4% (46.4 mmol/mol)) for this study.

We also describe the methodology using SMS by mobile technology for education and reinforcement of lifestyle advice (diet and physical activity) given to the participants in the intervention arm of the study. This method was found to be an effective strategy in primary prevention of T2DM in Asian Indian men with IGT, in a two-year prospective; randomized controlled study [6].

The transtheoretical model (TTM) of behavioral change was used in tailoring the contents of the SMS sent for this purpose [11].

2.2. Study population

Organizations such as the Indian Railways and other industrial organizations in Chennai city and its peripheral areas were chosen as sites to enroll the study participants. These sites were selected since the working population was mostly non-transferable and therefore were available for a follow-up for two years. Written permissions from the respective administrative authorities were obtained to conduct the study at the work sites. Men and women without known diabetes and aged 35–55 years were invited for screening from 15 sites.

Recruitment was carried out between April 2012 and September 2013. There were a total of 6995 eligible persons aged 35–55 years, without a history of diabetes (Stage 1). Among them, 6030 responded (response rate: 86.2%) to the invitation to undergo screening. Stage 2 of screening was done using non-invasive risk assessment to identify persons at risk of developing diabetes (Fig. 1).

Since the number of women employed in the industrial organizations were less than that of men and many of the women were unwilling or did not satisfy the inclusion criteria there was only a small proportion of women in the study.

Persons with any major illness such as cancer, chronic liver or kidney disease, cognitive impairment, severe depression or mental imbalance and any form of physical disability were excluded. Only those who owned a mobile phone, were able to read English and were familiar in accessing text messages were included because of the nature of the intervention in the trial. Written informed consent was obtained from all participants after explaining the study protocol.

After the initial inclusion criteria (Stage 2) the selected persons were screened with the point-of-care HbA1c testing