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Effect of mobile reminders on screening yield during opportunistic screening for type 2 diabetes mellitus in a primary health care setting: A randomized trial

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ABSTRACT

Objective. We wanted to study whether mobile reminders increased follow-up for definitive tests resulting in higher screening yield during opportunistic screening for diabetes. *Methods*. This was a facility-based parallel randomized controlled trial during routine outpatient department hours in a primary health care setting in Puducherry, India (2014). We offered random blood glucose testing to non-pregnant non-diabetes adults with age >30 years (667 total, 390 consented); eligible outpatients (random blood glucose ≥6.1 mmol/l, n = 268) were requested to follow-up for definitive tests (fasting and postprandial blood glucose). Eligible outpatients either received (intervention arm, n = 133) or did not receive mobile reminder (control arm, n = 135) to follow-up for definitive tests. We measured capillary blood glucose using a glucometer to make epidemiological diagnosis of diabetes. The trial was registered with Clinical Trial Registry of India (CTRI/2014/10/005138). *Results*. 85.7% of outpatients in intervention arm returned for definitive test when compared to 53.3% in control arm [Relative Risk = 1.61, (0.95 Confidence Interval — 1.35, 1.91)]. Screening yield in intervention and control arm was 18.6% and 10.2% respectively. Etiologic fraction was 45.2% and number needed to screen was 11.9. *Conclusion*. In countries like India, which is emerging as the diabetes capital of the world, considering the wide prevalent use of mobile phones, and real life resource limited settings in which this study was carried out, mobile reminders during opportunistic screening in primary health care setting improve screening yield of diabetes.

Introduction

In developed and developing countries, approximately 50–70% of diabetes mellitus remains undiagnosed (Mohan et al., 2006; Ramachandran et al., 2004). Opportunistic screening among adults may be a cost saving alternative or adjunct to population screening (Chatterjee et al., 2010; Evans et al., 2008; Li et al., 2010; Pereira Gray et al., 2012). It has been found that cost-effectiveness further increases by risk assessment before glucose testing (Kahn et al., 2010). Therefore under screening programs, definitive tests for diabetes are applied after an initial screening test.

Few studies from the west and India have documented the feasibility of opportunistic screening for diabetes. Available evidence suggests that after initial screening test, there was high loss to follow-up for definitive tests, resulting in low screening yield (Ealovega et al., 2004; Ginde et al., 2008; Klein Woolthuis et al., 2009; Shewade et al., 2015). Studies focusing on interventions to improve follow-up for definitive tests are required especially from real world primary care settings in developing countries.

India is fast emerging as the diabetes capital of the world (Mohan et al., 2007). To contain this, National Programme for Prevention and Control of Diabetes, Cardiovascular diseases and Stroke (NPCDCS) suggested opportunistic screening of persons above 30 years for diabetes mellitus (Operational guidelines. National programme for prevention and control of cancer, diabetes, cardiovascular disease and stroke (NPCDCS). Directorate General of Health Services, Ministry of Health

Abbreviations: NPCDCS, National Programme for Prevention and Control of Diabetes, Cardiovascular diseases and Stroke; RCT, randomized controlled trial; PHC, Primary Health Centre; OPD, Out Patient Department; RBG, random blood glucose; FBG, fasting blood glucose; PPBG, postprandial blood glucose; CI, confidence interval; NNS, number needed to screen; CTRI, Clinical Trial Registry of India; HbA1C, glycosylated hemoglobin.

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and Family Welfare. Government of India, 2011). India is also the second largest mobile phone user in the world with 900 million users. This potential of mHealth can be used to reach out to people (Press Information Bureau, Government of India, 2012).

Hence, this study was planned to determine the effect of mobile reminders on follow-up for definitive tests and screening yield in a primary care setting in India offering opportunistic screening for diabetes to outpatients. Specific objectives were: among outpatients eligible for definitive tests for diabetes mellitus in Primary Health Centre (Lawspet), Puducherry (India) i) to compare the follow-up rates for definitive tests among those who received mobile reminders with those who did not receive mobile reminders, ii) among those with mobile reminders, to determine the screening yield, screening yield attributable to mobile reminders and etiologic fraction and iii) to determine the number needed to screen to identify one patient with diabetes mellitus.

Material & methods

Study design

This study was a facility-based parallel randomized controlled trial (RCT), with 1:1 allocation ratio.

Study setting

The study was conducted in Primary Health Centre (PHC) Lawspet in Puducherry district (South India): one of the four districts in the Union Territory of Puducherry. PHC Lawspet caters to an urban population of 78,000 and has a daily patient load of approximately 150 patients in its routine Out Patient Department (OPD) and special clinics.

Routinely, opportunistic screening for diabetes at the PHC included an initial screening test, random blood glucose (RBG) for adults >30 years, followed by definitive tests, fasting blood glucose (FBG) and postprandial blood glucose (PPBG). At PHC level, blood glucose testing was done using a glucometer. Patients from PHC were referred to district hospital for confirmation of diagnosis (clinical diagnosis using standard venous plasma glucose testing) and treatment initiation. Patients were referred back to PHC for treatment continuation.

Study participants

All outpatients (>30 years) attending routine OPD were included in the study. Known patient with diabetes mellitus; pregnancy; alcoholics attending OPD who were not in the state of mind to give consent; and those requiring emergency care were excluded from the study. It is to be noted that access to mobile phone even if not personally owned was not an eligibility criterion. We had planned the study with background knowledge that most of the people in our study area had access to mobile phone. Outpatients, fitting the selection criteria and willing to participate in the study (after written informed consent) were the study participants. Study participants having RBG ≥6.1 mmol/l were the eligible outpatients (Somannavar et al., 2009).

Intervention and control arm

Eligible outpatients either received (*intervention arm*) or did not receive mobile reminder (*control arm*) for returning to PHC for definitive tests. Intervention was at individual level.

Study duration

Recruitment was done between 9–18 June 2014 over 8 PHC OPD days and all eligible outpatients were followed up for 3 working days to observe for return to PHC for definitive tests. Recruitment was stopped once desired sample size was reached.

Sample size and randomization

Sample size calculation was done for hypothesis testing for two proportions (large proportion — equal allocation) using nMaster sample size calculator 1.0 software developed by Christian Medical College, Vellore, India. Assuming proportion of eligible outpatients returning for definitive tests in intervention arm and control arm (*primary outcome*) to be 60% and 30% (Shewade et al., 2015) respectively; an alpha error of 5%; and power of 95% a minimum of 64 eligible outpatients were required in each arm. To allow for one sub-group analysis we doubled the sample size in each arm (n = 128).

Central randomization was used to randomize eligible outpatients into intervention and control arm. Computer generated random allocation sequence (block randomization, block sizes of four and six; random selection of blocks) was prepared beforehand and available with a statistician who didn't belong to the investigation team.

Procedure

The investigator was present next to the OPD registration counter. As soon as an outpatient was registered in the OPD and given an OPD slip, s/he was given the option of recruitment into the study by the investigator. After written informed consent, study participants were subjected to RBG testing by the investigator using a glucometer. All eligible outpatients were provided an investigation slip and asked to follow up for definitive test (in fasting state) on the next working day. After this, the investigator guided the patient to the medical officer chamber for OPD consultation. A mark was made on the top of the OPD slip of all eligible outpatients which hinted the medical officer to reinforce follow-up visit for definitive tests. After consultation, the medical officer also requested all eligible outpatients to meet the laboratory technician. The laboratory technician in addition to reinforcing the follow-up visit, in detail described what fasting state meant. The laboratory technician maintained (outcome assessor) register containing FBG and PPBG value of eligible outpatients who followed up. Each study participant was given a unique identifier which was used to trace the patient from initial screening test to definitive test.

After OPD on every afternoon, the investigator prepared a list of eligible outpatients in Microsoft Excel, with information on unique identifier. The excel sheet was emailed to the statistician who the same afternoon replied (through email) with arm allocation against each unique identifier. Those in intervention arm received a mobile reminder (a call on the same evening) by the investigator requesting them to come for definitive tests. In case they could not be reached in one call, maximum of three calls were made (each one hour apart). A call script was used uniformly for the mobile reminders.

All tests were performed on capillary blood (pin prick) using a glucometer (One Touch Select Simple Glucose Meter). Glucometers were standardized every morning against a standard glucose solution. For epidemiological diagnosis, FBG ≥7 mmol/l or PPBG ≥11.1 mmol/l was considered as diabetes mellitus. FBG between 6.1 and 6.9 mmol/l or PPBG between 7.8 and 11 mmol/l was considered as pre-diabetes (Definition and diagnosis of diabetes mellitus and intermediate hyperglycaemia: Report of a WHO/IDF consultation, 2006). Blinding of eligible outpatients was not possible for obvious reasons. Blinding was done at the level of outcome assessment and data analysis.

Data management and analysis

Data collected was recorded in a data collection form. Variables collected from study participants included: unique identifier (serial number), date of OPD, age, sex, RBG, eligible outpatient (yes/no), study arm(intervention/control/not applicable), call attended (yes/no/not applicable), follow-up done (yes/no/not applicable)), FBG and PPBG. Data were double entered, validated and analyzed using EpiData