DOES HANDING OUT LEAFLETS TO PATIENTS AT REGISTRATION INCREASE DIABETES SCREENING UPTAKE? — A PILOT RANDOMISED CONTROLLED TRIAL

Dr Teo Boon See, A/Prof Gerald Koh Choon-Huat, A/Prof Lim Fong Seng

ABSTRACT

Background: Among Singaporeans with diabetes, 1 in 3 have not been diagnosed. A large proportion of Singaporean adults are not current for their recommended diabetic screening.

Objective: To determine whether handing out diabetes screening leaflets to patients at the point of registration in a general practice (GP) clinic would influence their uptake of diabetes screening.

Design: A randomized controlled trial with a follow-up period of 3 months. Outcome measured was whether patients did the diabetes screening test (fasting plasma glucose).

Intervention: A leaflet on diabetes screening was given to patients when they registered in the GP clinic. The control group did not receive a leaflet.

Setting: A GP clinic in Toa Payoh, a suburb in central Singapore.

Participants: 97 patients 40 years old and above who were not known diabetics.

Results: There was no significant difference in the uptake of diabetes screenings between the intervention and the control group (p=0.740).

Conclusion: Handing out leaflets at registration in the GP clinic does not change uptake of diabetes screening.

Keywords: Pamphlets; Mass Screening; Diabetes Mellitus; Health Promotion

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INTRODUCTION

Diabetes is the 10th leading cause of death in Singapore. The proportion of people affected by diabetes here has increased from 8.2 percent in 2004 to 11.3 percent in 2010.[1]

Due to its slow onset, the condition can remain undetected for many years. It is estimated that 45.8 percent of diabetes cases in adults worldwide are undiagnosed.[2] In Singapore, 1 in 3 diabetes sufferers are undiagnosed.[3] Undiagnosed diabetes can lead to serious complications which could have been prevented with early diagnosis and treatment.[2]

In Singapore, a diagnosis of diabetes is made with a fasting plasma glucose test. The Ministry of Health (MOH) recommends that if a patient has no known risk factors, screening should begin at 40 years of age. In reality, a large proportion of adults are still unscreened — the National Health Survey 2010 found that among adults without known diabetes, only 63.5 percent had been screened within the last 3 years.[4]

Mailed informational leaflets have been shown to be effective in promoting cancer screening tests.[5] Informational leaflets are accessible, cheap and easily reproducible. In local GP clinics, they are commonly displayed in waiting areas. We are unaware of previous studies that have tested the strategy of giving out leaflets to increase diabetes screening uptake.

We conducted a pilot randomised controlled trial to evaluate the hypothesis that giving out leaflets about diabetes screening at registration will increase diabetes screening uptake.

METHODS

Trial Design

The trial was a parallel randomised controlled trial. The allocation ratio was close to 1:1.

A total of 97 participants were recruited. 48 patients were in the control group and received usual care without a leaflet, while 49 were in the intervention group and received a leaflet upon registration in addition to usual care.

It has been shown that when subjects are aware that they are participating in a study, there is an impact on their behaviour, known as "Hawthorne effect".[6] In order to avoid this, consent was not taken before the study. The National University of Singapore Institutional Review Board (NUS IRB) approved this on the following grounds:

1. The research posed minimal risk to subjects.
2. Rights and welfare of subjects were not adversely affected by the waiver.
3. Subjects were provided with pertinent information after participation.
4. Research could not be practicably carried out without waiver.

TEO BOON SEE
Family Physician and Medical Director, Camry Medical Centre
Adjunct Assistant Professor, NUS Yong Loo Lin School of Medicine
Adjunct Assistant Professor, Duke-NUS School of Medicine
Clinical Practice Facilitator, Lee Kong Chian School of Medicine

GERALD KOH CHOON-HUAT
Associate Professor, Saw Swee Hock School of Public Health, NUS

LIM FONG SENG
Associate Professor, Yong Loo Lin School of Medicine, NUS

Patients received the leaflet without knowing they were in a study. 100 patients were initially studied. After the 3-month follow-up period, consent was then requested from patients via mailed debriefing material per NUS IRB's requirements. At this point, 3 opted out, so their data was not included in the analysis.

Recruitment took place from 25 October 2016 to 26 November 2016. The follow-up period ended 24 February 2017, 3 months after the final recruitment date. The study was registered with NUS IRB with the code B-16-22.

Study Setting and Population

The study was conducted in Camry Medical Centre, a GP clinic in Toa Payoh, a suburb in central Singapore. It is a two-doctor practice. On days when the study was conducted, both doctors were seeing patients simultaneously.

A practice profile of the clinic done in 2009 by the principal investigator showed that the clinic patient base was representative of the Toa Payoh population in terms of ethnicity. Toa Payoh is 81.8 percent Chinese, slightly more than the national average. A large proportion of Toa Payoh residents are elderly, with 14.9 percent being over 65.[7]

Clinical practice guidelines published by the MOH stipulate that in adults without risk factors, testing for diabetes should begin at 40 years of age.[1] We aimed to study the impact of our intervention on patients fitting this profile and hence decided that the inclusion criteria for the study should be: patients 40 years old and above who came to the clinic to see a doctor.

The exclusion criteria were: a previous diagnosis of diabetes; intellectual impairment; cognitive impairment; visual impairment; or illiteracy.

Patients' diabetic status was determined from the patient records at the point of registration if they were existing patients. New patients were asked if they had diabetes in the course of registration.

Patients with known hypertension and hyperlipidaemia were not excluded from the study as long as they were not known diabetics.

There were 2 patients excluded on the grounds of illiteracy. They were regular patients of advanced age. The clinic staff were aware that they were illiterate and informed the research assistant.

Intervention

We searched the Health Promotion Board's educational materials for a leaflet on diabetes screening, but found none on the topic. Therefore, we designed a single-sided colour leaflet intended to provoke the patient to question the doctor. The leaflet featured a photograph of ants drinking urine, accompanied by the words "How do you know you don't have diabetes? Ask your doctor today." (See Figure 1 for leaflet.) The leaflet was translated into the 4 official languages of Singapore: English, Chinese, Malay and Tamil. Cultural tailoring, which includes language adaptation of materials, has been used in cancer screening programmes targeting diverse ethnic groups and has demonstrated a positive impact on screening rates.[8]

Figure 1: Leaflets

The leaflet was kept simple because many of the patients who visited the clinic were sick and may not have had the patience to read long texts. A simple leaflet would also be accessible to patients of every educational level. Senore et al, 2010, found that people of a lower educational level were less likely to read leaflets.[9]

Outcome

The primary outcome assessed was whether patients did a diabetes screening (fasting plasma glucose) at the clinic within 3 months of recruitment.

Sample Size

This is a pilot study. The sample size was set at 100.

Randomisation

Before the study began, a randomisation plan was computer-generated via a website (http://www.graphpad.com/quickcalcs/randomize1.cfm).[10] The website used a random number generator which was seeded with the time of day to generate a random sequence. This sequence was then used to randomly allocate 100 code numbers (001, 002… 099, 100) into 2 groups of 50. The randomisation plan was then printed out.

Allocation concealment

Allocation concealment was not feasible as we did not have the resources to hire a third party to do the allocation. As the clinic often ran at a fast pace, it was also impractical for the research assistant to call a third party to check every patient's allocation at the point of registration.

Recruitment

A research assistant (RA) was engaged to do the recruitment and administer the intervention. Every patient who registered to see a doctor at the counter was checked for eligibility by the RA. Eligible patients were recruited consecutively. As each patient was recruited, his name was entered into a printed subject coding form, which assigned each patient a code number consecutively (e.g. 001, 002, 003).

The RA had the printed randomisation plan on hand. The patient's code number would then be checked against the randomisation plan. If that code number was in the intervention group, the RA would then give the patient a leaflet while he was waiting. No leaflet would be given if the code number was in the control group.

Blinding

It was impossible to blind participants as the intervention was a leaflet which had to be read. The 2 doctors in the clinic were blinded for the 3-month period while recruitment was being done and the leaflet given at the counter outside their rooms.

The doctors would do the FPGs and update the medical records without knowing if patients had received a leaflet. Having said that, it was possible for the doctor to know that a patient had received the intervention if the patient entered the room holding the leaflet.

The outcome was determined by the RA, who checked the patient's medical records for FPG tests after the 3-month follow-up period was over.

Statistical Methods

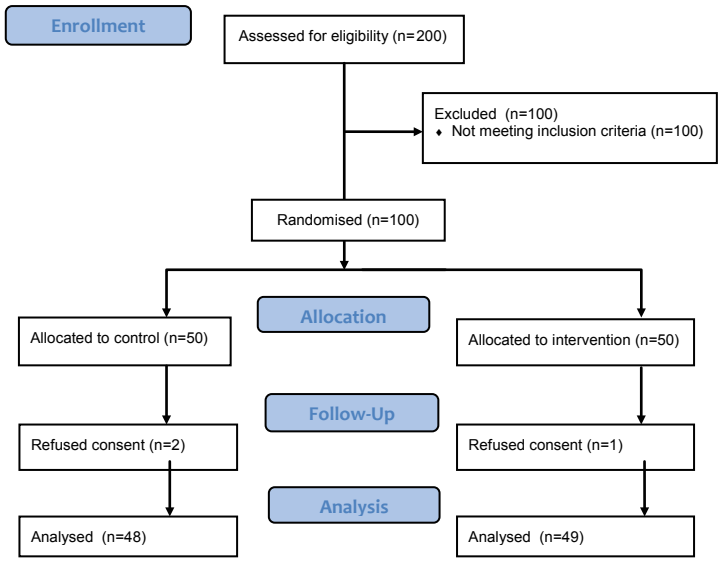
The data was analysed using the SPSS software. Comparisons between study groups' characteristics were performed with an independent sample t-test (for age) and with chi-square analysis for all other characteristics.

Chi-square analysis was used to compare study groups' with outcomes. Statistical significance was set at $p<0.05$. Subsequently, subjects who had done a diabetes screening within the last 3 years were excluded and the remaining subjects were re-analysed.

RESULTS

Recruitment was done over 7 days during the period of 25 October 2016 to 26 November 2016. The target recruitment was achieved. The trial ended on 24 February 2017, 3 months after the final patient completed the follow-up period.
Intervention and control groups were each assigned 50 patients. After the 3-month follow-up period, consent was taken. 3 patients opted out of the study — 1 from the intervention group and 2 from the control group. Thus, 49 patients were analysed in the intervention group and 48 in the control group. (See Figure 2: Flow diagram.)

Figure 2: Flow diagram



Baseline Data

Table 1: Baseline characteristics of all study participants

	Intervention n=49	Control n=48	p-value*
Age			
range	40–88	40–92	
mean	57.29	59.04	0.533
Sex			0.153
Male	25 (51%)	17 (35%)	
Female	24 (49%)	31 (65%)	
Marital status			0.240
Married before	34 (69%)	39 (81%)	
Not married before	15 (31%)	9 (19%)	
Race			0.524
Chinese	42 (86%)	44 (92%)	
Non-Chinese	7 (14%)	4 (8%)	
Doctor seen			0.576
Dr A	40 (82%)	42 (88%)	
Dr B	9 (18%)	6 (12%)	

* As age was a continuous variable, the independent sample t-test was used to calculate p-value. The other variables (sex, marital status, doctor seen and race) were categorical, thus the chi-square test was used to calculate p-value. p-value recorded is the Exact sig. (2-sided).

There were no significant differences between intervention and

control groups in terms of their baseline characteristics (age, sex, marital status and race). There was also no significant difference in terms of which doctor they saw. P-value was more than 0.05 for all of the above variables. (See Table 1: Baseline characteristics of all study participants.)

Numbers Analysed

49 patients were analysed in the intervention group, and 48 in the control group. Intention-to-treat analysis was done.

Outcomes and Estimation

Percentage of patients who did the screening within 3 months was 8.2 percent in the intervention group and 10.4 percent in the control group. However, the difference was not significant (p=0.740). The odds ratio for intervention versus control groups was 0.764 (95% CI: 0.192–3.037). This suggests that giving the pamphlet did not significantly increase uptake of screening tests. (See Table 2: Results of all study participants.)

Table 2: Results of all study participants

	Intervention n=49	Control n=48
Did screening	4 (8.2%)	5 (10.4%)
Did not do screening	45 (91.8%)	43 (89.6%)

(p-value=0.740)

Subgroup Analysis

The recommended frequency for diabetes screening in patients 40 years and older with no risk factors is once every 3 years. Whether a patient was current for diabetic screening could have been a confounding variable in our study.

However, we did not make this an exclusion criterion because at the point of registration it was difficult to check if a patient was current for screening. This would involve a time-consuming search of his medical records. Therefore, we did a subgroup analysis instead.

Upon checking patients' medical records, we found that 20 subjects in the intervention group and 20 subjects in the control group were current for diabetes screening as they had been screened in the last 3 years. These were excluded from the subgroup analysis.

The remainder, who had not been screened in the last 3 years, were re-analysed. Baseline characteristics did not differ significantly between intervention and control groups (see Table 3: Baseline characteristics of study participants not current for screening.) There were no significant differences in terms of age, sex, marital status and race (p>0.05 for all variables). There was also no significant difference in which doctor was seen (p=1.00).

It was found that among patients who had not been screened in the last 3 years, the intervention did not make a significant difference to uptake (see Table 4: Results of study participants not current for screening). Although 2 patients (6.9%) of the intervention group took up the test, as opposed to 0 patients (0.0%) in the control group, the p-value was 0.491, suggesting that the result was not significant.

Table 3: Baseline characteristics of study participants not current for screening

	Intervention n=29	Control n=28	p-value*
Age			
range	40-82	40-91	
mean	54.21	54.11	0.977
Sex			0.429
Male	14 (48%)	17 (61%)	
Female	15 (52%)	11 (39%)	
Marital status			0.092
Married before	16 (55%)	22 (79%)	
Not married before	13 (45%)	6 (21%)	
Doctor seen			1.000
Dr A	25 (86%)	25 (89%)	
Dr B	4 (14%)	3 (11%)	
Race			0.297
Chinese	22 (76%)	25 (89%)	
Non-Chinese	7 (24%)	3 (11%)	

Table 4: Results of study participants not current for screening

	Intervention n=29	Control n=28
Did screening	2 (6.9%)	0 (0%)
Did not do screening	27 (93.1%)	28 (100%)

(p-value=0.491)

DISCUSSION

Several studies on cancer screenings have shown that mailing pamphlets to patients is an effective strategy to increase screening uptake.[11,12] 1 study done in Australia (Harris et al, 2000)[13] found that giving out a pamphlet at the reception also increased screening uptake. However, in our study, the leaflet had no significant effect on uptake.

We examined the possible reasons why the pamphlet did not work in this study. First, barriers to screening may have prevented them from pursuing action. A fasting plasma glucose test involves coming down on another day, fasting, and enduring the pain of a needle. A local study done in 2010 among a low-income community[14] found that the top reasons given for not participating in regular diabetes screening were 1) too busy to go; 2) screening is not important; 3) not at risk; and 4) too

expensive.

Second, they could be in a stage of pre-contemplation — the stage in which people are not intending to take action in the foreseeable future.[15] A study has shown that pamphlets on screening do not change pre-contemplators into contemplators.[16] In Harris et al, 2000,[13] the successful intervention targeted patients who had a first-degree relative with colorectal cancer—these people may already have been contemplators on the verge of taking action. Third, patients who come to the clinic are already concerned with another medical issue and may not be in the frame of mind to consider screening.

Denberg et al, 2006, found that low income patients are less likely to be adherent to screening despite being sent a brochure.[5] The cost of doing the screening, while low at S$9, may be a barrier as well, which can be reduced by financial incentives or subsidies.

Several methods have been tested to enhance a pamphlet intervention. Evidence from studies on colorectal cancer screening has shown that counselling and physician recommendations increase uptake. In a local study, Chua and Koh, 2014,[17] found that primary physicians delivering a standardised education protocol to patients significantly increased uptake. In a study from the United States, Walsh et al, 2014,[8] found coupling a brochure with phone counselling increased uptake more than a brochure alone. It may thus be more useful to target interventions at physicians. Sequist et al, 2009,[12] found that electronic reminders to physicians increased uptake among adults who more frequently see their primary care physicians.

The brochure intervention could be enhanced by adding a physician's letter. Letters have been shown to be effective, especially when the mailing is linked to the patient's electronic health record and sent when they are overdue for screening. Addressing the patient personally and having his GP sign the letter personally has also been effective (Hewitson et al, 2011).[11] A follow-on study, with mailings linked to patients' screening status as recorded in the electronic database, could be tested for effectiveness. A qualitative study on what the barriers to screening are might also be useful to shed light on future interventions.

Limitations

This study had a small sample size and a short duration. The study also did not capture if the patient did the test at other centres, or after 3 months. There was no data on how this clinic's patient base compared to other GP clinics, polyclinics or tertiary institutions.

Around half of the patients in this study had been previously screened, which could make them unlikely to repeat the FPG test. Future studies should be multi-centre and should exclude previously screened patients.

CONCLUSION

Giving a leaflet on diabetes to patients at registration does not significantly increase uptake of diabetes screening.

CORRESPONDING AUTHOR

For correspondence and reprints, please contact:
Dr Teo Boon See
Camry Medical Centre
Blk 95 Toa Payoh Lorong 4, #01-66, Singapore 310095.
Telephone: +65 62580553. Email: drteobs@gmail.com

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