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Research Article

Emailing is an Economical Strategy to Recruit Participants

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ABSTRACT

Background: In order to produce results from clinical trials that are statistically significant, researchers must enroll enough participants; however, it is often difficult to recruit a sufficient number of participants.

Methods: We analyzed different patient recruitment strategies using email, letters, and in person visits in the framework of the ADAPTABLE study which is a randomized controlled study of two dosages of aspirin in patients with established cardiovascular disease.

Results: Four hundred and nine patients enrolled in our trial over a 10-month period. 397 (97.06%) patients enrolled in the study *via* email. Letters were sent to 7,226 patients. Four (0.98%) patients contacted *via* letter enrolled in the study. Eight (1.96%) of the patients who were approached in person enrolled in the study. The cost of email campaign was $1.44/patient and the cost per enrollment was the least expensive, at $95.71. In person enrollment cost $23.34/patient and the total cost per enrollment was $417.12. The letter recruitment cost $0.30/patient, however, the cost per enrollment was the highest, at $542.26.

Conclusion: Email is an effective and economical way to recruit patients for clinical trials. Email allows researchers to contact more patients about proposed studies promptly and facilitates pragmatic research trials that achieve results in a timely and cost efficient manner.

Keywords: Adaptable; Aspirin; Patient recruitment; Email recruitment

Abbreviations: ADAPTABLE: Aspirin Dosing-A Patient-centric Trial Assessing Benefits and Long-Term Effectiveness; EHR: Electronic Health Records; PCORI: Patient-Centered Outcomes Research Institute

INTRODUCTION

Randomized controlled trials play a crucial role in practicing evidence based medicine. They are considered the gold standard when investigating new treatment methods, as well as examining new uses for already existing treatments [1-4]. There are several barriers to performing randomized controlled trials, one of which is adequate patient recruitment. This is important because if there are not enough patients for the study to be high powered, valuable findings may be reported as statistically insignificant [5]. This could preclude thousands of patients from receiving positive interventions. Several studies have investigated how often randomized controlled trials struggle to recruit an adequate number of patients. It is probable that close to 50% of studies does not reach their target number, and close to one third need an extension to reach target number [6].

The ADAPTABLE trial is an innovative pragmatic randomized controlled trial, designed not only to compare two doses of aspirin in patients with high risk of cardiac disease, but to also test novel research methods [7-10]. One goal of the ADAPTABLE trial is to test creative new ways to recruit a large amount of patients. It is the first trial using PCOR net, a large data network assimilated from aggregated Electronic Health Records (EHR), instituted to allow pragmatic, large scale, cost efficient randomized controlled trials to be conducted [11,12]. Each health system participating in the ADAPTABLE trial

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through PCOR net used the same eligibility criteria to identify patients eligible for the study. They were able to devise their own methods to contact and recruit patients to the study [13].

Traditional recruitment methods include in person recruitment, sending letters, posting flyers, using radio and TV advertisements, and word of mouth [14]. Researchers have started using the Internet to recruit study participants over the past several years. Some of the methods that utilize the Internet include online surveys, email, social media and online advertisements [15]. At Wake Forest Baptist Medical Center, we analyzed different recruitment strategies involving email, letters, and in person visits.

METHODOLOGY

This study is approved by the Institutional Review Board of the Wake Forest University School of Medicine (Study ID: IRB00050517). We used eligibility criteria set forth by the ADAPTABLE study protocol, which is included in Table 1. Patient eligibility was assessed by using a computable phenotype and EHR data mapped to the PCOR net common data model. Once identified, these patients fell into two groups. If the patient had an email address, they were in group one, and sent an email. If there was no email address, they were in group two, and a letter was mailed to their home address. The email group received a weekly email inviting them to participate in the study until they agreed on or declined to. In addition, patients were also recruited in person from the cardiology clinic or cardiac rehabilitation center. The majority of the patients recruited in person had already been stratified into one of our two groups and had therefore already received an email or letter. However, patients who had a recent diagnosis after we ran the computable phenotype were not listed either in our email campaign or the mail campaign, but could be eligible for our study. Thus, recruiting in person ensured all eligible patients were approached.

Table 1: Recruitment strategy and cost of each recruitment method at the Wake Forest University.

Campaign patient statistics	In person	E-mail	Letter
Number of patients contacted	143	26406	7226
Number of patients enrolled	8	397	4
Percentage of those contacted that enrolled	5.59	1.5	0.06
Percentage of total patients enrolled	1.96	97.06	0.98
Duration (months)	2	10	1
Overall Expense ($)	3337	37998	2169
Cost I Patient ($)	23.34	1.44	0.3
Cost I Enrollment($)	417.12	95.71	542.26

All eligible patients were given a link to the ADAPTABLE trial portal along with an access code, or "golden ticket" to enter in the portal to enroll. An explanatory video about the study and electronic informed consent were on the trial website. This could be accessed at home or during an outpatient clinic or cardiac rehabilitation visit. We were able to track which patients accessed the study site by tracking which golden tickets were entered in the portal. If a patient entered their golden ticket into the portal, but did not enroll, a follow up phone call was given to find out why they had not enrolled, and further explaining the study if they had any questions.

In addition, we looked into the cost of each campaign that we used for the recruitment. Because we designated a recruiter for the ADAPTABLE study, we were able to break her effort into each strategy. Since we joined the ADAPTABLE study late, in order to recruit patients in a timely manner, we focused on the email campaign first. We believe that once the standardized email is built up, it could deliver the messenger of the study promptly. We used the RED Cap (Vanderbilt University, TN), a browser-based, electronic data capture software to manage our database. We ran the email campaign throughout our recruitment period for a total of 10 months. However, the mail campaign was only carried out once. We did not repeat it because of its overall cost and relatively low yield. Because manually screening eligible patients was extremely time consuming, with the one designated recruiter we had for this study, we were only able to conduct in person visits once a week.

RESULTS

From September 2018 to June 2019 we had a total of 409 patients enroll in the ADAPTABLE trial. Emails were sent to 26,406 patients of the 26,406 patients contacted *via* email, 1,129 (4.28%) entered a golden ticket in the ADAPTABLE website portal, and 397 (1.50%) patients ultimately enrolled in the study. This accounts for 97.06% of our enrollment. Letters were sent to 7,226 patients, and only 4 (0.06%) patients consented in the study, contributing to only 0.98% of the enrollment. There were 240 eligible patients identified who had a cardiology clinic appointment. Of those identified, 117 (48.8%) were approached about the study in clinic and 7 (5.98%) enrolled in the study. Twenty-six eligible patients were identified and approached in the cardiac rehabilitation center and only 1 (3.85%) was successfully consented for our study. Altogether, in person recruitment contributes to 1.96% of the successful enrollment.

The 10-month recruiting period, we spent $37,998 on the email campaign and $2,169 on just one mail campaign. Breaking down the time our recruiter had spent on in person strategy, this approach costed $3,337. Knowing that 26,406 patients were contacted by email 7,226 patients received the letter once and only 143 patients were approached in person, the cost per patient for each campaign was $1.44, $0.30, and $23.34. Since we had successfully recruited 397 and 4 to 8 patients *via* the email, letter and in person campaigns separately, the cost per enrollment was $95.71 for email, $542.26 for letter and $417.12 for in person recruitment.

DISCUSSION

Although sending emails only yielded 1.50% success rate, due to a large amount of patients (26,406 in this case) that were contacted *via* email, this made up 97% of the total patients enrolled in the trial. Even though the most money was spent on the email campaign ($37,998) over a period of 10 months, since we were able to contact 26,406 patients, the cost per patient was only $1.44. Because we enrolled the most patients *via* email (397 patients), the cost per enrollment was the least expensive, at $95.71 for each enrollment.

Sending letters, a traditional recruitment method, had the lowest success rate of enrollment (0.06%). Only 4 patients were enrolled *via* letter, which accounts for 0.98% of the enrollment. Although the least amount of money was spent on the letter recruitment for one time delivery to 7,226 patients at $2,169, in other words, this appeared to be the cheapest way to contact eligible patients at $0.30 per patient, due to an extremely low success rate (0.06%), the cost per enrollment was the highest, at $542.26 being spent per each patient enrolled in the trial.

Even though in person recruitment resulted in the highest percentage (5.98%) of patients contacted enrolling in the trial, due to clinic timing and availability of study personnel, using this method only 143 patients (53.76% of those eligible) were approached about the study, resulting in 8 (1.96%) patients being enrolled successfully. In person enrollment cost a total of $3,337 and had the highest cost per patient at $23.34 for each patient approached. The total cost per enrollment for in person recruitment was $417.12.

Our data show that although patients recruited in person were more likely to enroll, using email allows contact with several thousand more patients. Using email is also less labor intensive than using in person recruitment. One email explaining the study can be drafted and used to send to thousands of people. Ultimately, using email to contact more patients than in person recruitment resulted in a much bigger patient enrollment. Thus, the cost per enrollment is the lowest *via* email recruitment.

Using letters for recruitment allows more patients to be contacted than in person recruitment. One letter can also be drafted, however this still has to be printed and mailed, and it would be cost prohibitive to mail letters frequently. Thus, only a few patients contacted *via* letter ultimately enrolled in the study. Overall, letter recruitment results in the highest cost per enrollment. These findings are consistent with other recent studies looking at novel recruitment methods [16].

Although more money was spent on the email recruitment method, the total cost for each patient enrolled in the study was far less than both in person recruitment and mailing letters. In fact, the cost per enrollment was over $300 less per patient with the email method. Spending over $400 for each patient enrolled as in the in person method, and over $500 per patient in the letter method makes an email recruitment strategy much more economically viable.

In summary, although for this trial we had more success using email to recruit patients, letters are still a good option for certain patient populations. Patients with a socio-economic disadvantage may not have access to internet regularly and would not receive an email. Only about 40% of adults over the age of 65 use email, and they are less likely to use email if they are disabled or have certain physical limitations [17]. Knowing this, letter and in person strategies are still needed to recruit those subjects.

CONCLUSION

In conclusion, email is an effective, efficient and economical way to recruit patients for clinical trials. By using email to broaden our reach, more patients can be contacted about studies, and ultimately enrolled in trials. This is especially important for pragmatic research trials which are designed to get results in a timely and cost efficient manner.

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