A randomised controlled trial of a Teaser Campaign to improve recruitment in Primary Care

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ABSTRACT

Background: Marketing communication and brand identity is a fundamental principle of advertising and end user engagement. Health researchers have begun to apply this principle to trial recruitment in primary care. The aim of this study was to evaluate whether a Teaser Campaign using a series of postcards in advance of a conventional mail-out, increases the number of primary care clinics that engage with a clinical trial.

Methods: Randomised controlled trial across primary care clinics (General Practitioners and Physiotherapists) in the Sydney metropolitan area. Clinics in the Teaser Campaign group received a series of branded promotional postcards in advance of a standard letter inviting them to participate in a clinical trial. Clinics in the Standard Mail group did not receive the postcards.

Results: From a total of 744 clinics that were sent an invitation letter, 46 clinics in the Teaser Campaign group and 40 clinics in the Standard Mail group responded (11.6% total response rate). There was no between-group difference in the odds of responding to the invitation letter (odds ratio=1.18, 95% CI=0.75 to 1.85, *P*=0.49). For Physiotherapy clinics and General Practice clinics, the odds ratios were 1.43 (CI=0.82 to 2.48, *P*=0.21) and 0.77 (CI=0.34 to 1.75, *P*=0.54), respectively.

Conclusion: A Teaser Campaign using a series of branded promotional postcards, did not improve clinic engagement in a RCT in primary care.

Keywords: primary health care; recruitment; randomized controlled trial; research methods; back pain

INTRODUCTION

Recruiting patients into randomised controlled trials (RCT) is often challenging. From 114 trials funded by the UK Medical Research Council and Health Technology Assessment Programme between 1994 and 2003, 54% required an extension and only 31% recruited their target sample size (1). Insufficient sample sizes result in type-II errors, and limited recruitment of clinic sites can induce sampling bias (2,3). Trials that require extensions will incur additional costs, and in the long-run, suspend implementation of potentially effective interventions or the withdrawal of ineffective or harmful interventions (4,5). This problem is widely recognised and recruitment methodology is viewed as the "highest priority" by the UK Clinical Research Collaboration (6).

In primary care settings, researchers often rely on primary care clinicians to identify and refer patients to trials (7). A common approach in maximising study participant recruitment is to recruit a large representative pool of primary care clinics (2). Although some barriers to clinic recruitment have been identified, such as time constraints, forgetfulness, and concern for patients (8–12); very few RCTs have tested interventions that aim to boost recruitment of clinics (2,13,14) and recommendations to maximise clinic engagement are not available (15,16).

That marketing communication and brand identity are critical to end-user engagement is a fundamental principle of advertising (17) and health researchers have begun to apply this principle to trial recruitment (18). Colwell et al. (19) evaluated the effectiveness of a marketing strategy to recruit primary care clinicians working in Diabetes research. Their aim was to increase awareness and provoke

interest by making their trial more recognisable and memorable. Their marketing strategy was carried out in two phases. In phase one – 'Teaser Campaign', postcards were used to establish an identity for the trial; and in phase two – 'Outreach Activities', trial staff gave presentations to primary networks to advertise the trial. The authors concluded that their marketing strategy improved clinic recruitment 3-fold compared with a conventional recruitment method of mailing general information packages. However, it is difficult to know whether it was the Teaser Campaign or Outreach Activities, or a combination of both that was effective in improving clinic recruitment. If a simple Teaser Campaign similar to phase one in Colwell et al. can improve clinic engagement, this could represent an efficient and potentially cost-saving approach to recruitment in primary care settings.

The primary objective of this study was to evaluate whether a Teaser Campaign using a series of branded promotional postcards increases the number of clinics that respond to a subsequent mailed invitation to participate in a clinical trial. The secondary purpose was to evaluate whether the Teaser Campaign increases the number of responses to follow-up phone call invitations, interested clinics, enrolled recruiting clinics, and the number of referred patients.

METHODS

Study design

Two-arm RCT attached to a clinical trial of treatment for low back pain - PREVENT (Australian New Zealand Clinical Trials Registry, URL: https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=1261200118

0808) (20). The University of New South Wales Human Ethics Committee granted ethical approval (ref number HC12664).

The PREVENT trial

PREVENT is a RCT funded by the Australian National Health and Medical Research Council. The primary objective of PREVENT is to investigate the effectiveness of a pain education intervention for preventing chronic symptoms in patients who present to general practice (GP) or physiotherapy (PT) clinics with an acute episode of low back pain (20). Individual patients were randomised to two arms, but the purpose of recruitment was to recruit a maximum number of clinics to refer individual patients to the trial.

Study participants and setting

In this study, we selected a random sample of 744 primary care clinics (372 GP and 372 PT clinics) in the Sydney metropolitan area from a pool of clinics registered with the Royal College of General Practitioners and the Australian Physiotherapy Association. This study was conducted over four waves (each wave consisting of 186 clinics contacted over 6 weeks) between March 2014 and July 2015.

Randomisation

Primary care clinics were randomly allocated to one of two groups: Teaser Campaign group and Standard Mail group (372 per group). AT generated a 1:1

randomisation schedule using a random number generator. We stratified randomisation by clinic type (GP and PT) and wave number (1, 2, 3, and 4). We randomised clinics (not clinicians) to avoid cross-contamination within a clinic that employed more than one clinician. HL enrolled the clinics and assigned them to the interventions. The clinicians and support staff (practice managers and receptionists) were blind to the different recruitment strategies that were being tested in this study.

Interventions

Teaser Campaign group: The aim of the Teaser Campaign was to create an identity for the PREVENT trial and to make the trial conspicuous to prospective referrers. We did this by mailing a series of postcards that depicted the trial logo and research institute logos. The first postcard (Postcard A) contained the phrase "*a stitch in time...*" (a common phrase associated with the idea of "prevention") (21), but no information about the study or institutional affiliation (**Figure 1**). The second postcard (Postcard B) featured the same design, but included the study name "PREVENT", and featured our university and research institute logos. On the back of postcard B, the following statement was printed: "*look out for your invitation letter in the coming weeks…* " with contact details (**Figure 2**). This staged process of revealing the trial was based on the approach taken by Colwell et al. (19) and consistent with recommendations to promote brand recognition in the advertising literature (17). The postcards were designed in consultation with a graphic designer via a web crowdsourcing service (99designs.com.au). Clinicians received 'Postcard A' in the first week, followed by 'Postcard B' twice over two consecutive weeks. One week after posting the 3rd postcard, we commenced the standard approach by

posting formal invitation letters (described in **section 2.5.2**). **Standard Mail group:** To clinics allocated to the Standard Mail group, we posted personalized invitation letters that outlined key features of the trial, expected requirements, and compensations for enrolling participants ($50AUD for eligible participant referral and continuing professional development points). We asked clinicians to return an opt-in/opt-out response form by fax, e-mail, or phone, indicating their interest in becoming a recruiting clinician. If the clinicians did not respond to the invitation letter within one week, we followed up with a maximum of 3 telephone calls during the following week to determine their interest.

Outcome measures

The primary outcome was whether the invited clinics engaged with the trial (i.e. the unit of analysis is clinic, not clinician). Engagement was operationalised as responding to our invitation letter by fax/e-mail/phone (showing either a positive or negative interest in recruiting participants). Secondary outcomes were the proportion of clinics that responded when approached via follow-up phone calls ('phone-call invitations') but did not respond to our mail invitation, the number of clinicians that indicated an interest in recruiting participants ('interested clinics'), and the number of potential participants referred during the 6-month period after enrolment ('patient referrals').

Cost estimation

For descriptive purposes, we estimated costs for material, service, and staff time for both groups. We used these estimates to calculate the total cost for each group.

Material and service costs: We used Australian market prices (year 2015) to estimate material costs for paper, ink, envelopes, address labels, and postage stamps. We calculated per-unit costs for a single postcard and invitation letter. We then multiplied the per-unit costs by the total number of letters/postcards we produced for each group (1488 postcards and 372 letters in the Teaser Campaign group; and 0 postcards and 372 letters in the Standard Mail group). We also added service costs for the design of the postcard in the Teaser Campaign group. The market prices and per-unit costs for all items are presented in Supplementary 1.

Staff costs: We used the hourly wage for a research assistant (2015 University of New South Wales rate: $36.55AUD plus on-costs) to estimate staff costs to prepare and mail the postcards and letters. We estimated the time spent (hours) to prepare and post the postcards and invitation letters for each arm. This included time spent creating the clinician database, developing, printing, addressing, and posting the postcards and invitation letters. We then multiplied the time spent by the hourly rate to calculate total staff costs for each group.

Statistical analysis

For the primary outcome, we used multivariable logistic regression to estimate the main effect of group allocation (Teaser Campaign vs Standard Mail) on initial engagement, adjusting for clinic type (PT vs GP) as a covariate. For secondary outcomes, we used multivariable logistic regression to estimate main effects of group allocation on response to follow-up phone calls, and interested clinics, adjusting for

clinic type as a covariate. We used multivariable Poisson regression to estimate the main effect of group allocation on the number of participant referrals, adjusting for clinic type as a covariate. Poisson regression was chosen because the dependent variable (number of referrals) did not approximate a normal distribution, and the data were right-skewed. Analysis was by intention to treat.

To test whether clinic type would moderate the main effect of the intervention on the primary outcome, we added an interaction term between group allocation and clinic type into the logistic regression model. We calculated odds ratios (OR) from logistic regression models and an incidence rate ratio (IRR) from the Poisson regression model, with their 95% confidence intervals (CI), and *P*-value. We used Stata (Version 13.1, StataCorp) for all analyses. An a priori sample size calculation was not conducted because of the pragmatic nature of the nested design in the PREVENT trial and its stipulated recruitment protocol.

RESULTS

Clinic characteristics

From a total of 1772 clinics (1374 GP and 398 PT) identified through the Royal College of General Practitioners and Australian Physiotherapy Association databases, a random selection of 744 clinics (372 GP and 372 PT) were randomly allocated to the Teaser Campaign and Standard Mail groups (**Figure 3**). The mean number of clinicians per clinic was not statistically different between the groups (Teaser Campaign group mean = 1.21, Standard Mail group mean = 1.28; *P* = 0.34). Postcards/letters were returned to sender from 13 clinics in the Teaser Campaign

group and 12 clinics in the Standard Mail group; a further 29 clinicians in the Teaser Campaign group and 24 clinicians in the Standard Mail group had retired or moved location.

Primary outcome

From both groups together, 11.6% of clinics responded to the mail invitations. Response rate was 12.4% in the Teaser Campaign group, and 10.8% in the Standard Mail group. The Teaser Campaign did not increase the likelihood of a response to the subsequent letter (OR = 1.18, CI = 0.75 to 1.85, *P* = 0.49). Separate analyses for PT and GP clinics corroborated this result (**Table 1**). The interaction analysis showed that the group x clinic-type moderation effect (OR = 1.85, CI = 0.69 to 4.96) was not statistically significant (*P* = 0.22).

Secondary outcomes

From both groups together, we observed a 23.9% response rate to phone-call invitations (from clinics that did not reply to mail invitations), 11.7% were interested, 8.7% enrolled, and a total of 29 patients were referred over 6 months. Group specific data and comparisons are presented in **Table 2**. Our findings suggest that the teaser campaign did not increase the response rate to phone-call invitations, number of interested clinics, enrolled clinics, or patients referred.

Cost estimation

The total cost ($AUD) was estimated at $6,471.69 for the Teaser Campaign; and $1,804.89 for the Standard Mail approach. Material and service costs were estimated at $2,049.14 for the Teaser Campaign; and $379.44 for the Standard Mail approach. Staff costs were estimated at $4,422.55 for the Teaser Campaign; and $1,425.45 for the Standard Mail approach. The break-down of these costs are presented in Supplementary 2.

DISCUSSION

***Summary*:** A Teaser Campaign using a simple marketing strategy did not increase clinic engagement. Although the point estimate from our study suggested a small increase in engagement (OR = 1.18), there is uncertainty around this point estimate (CI = 0.75 to 1.85), and the effect is not statistically significant (*P* = 0.49).

The Teaser Campaign did not influence our secondary outcomes either (response to phone-call invitations, number of interested clinics, enrolled clinics, or patients referred). This finding is not surprising because the intervention was intended to improve initial clinic engagement. Outcomes such as the number of interested clinics, or the number of patients referred are more likely to be influenced by other operational and clinician- and patient-related factors (8) that occur after the initial engagement period.

The Teaser Campaign cost an extra $4,666.80 over the Standard Mail approach. Given that the Teaser Campaign was no more effective than the Standard Mail approach, this extra cost is not justified. It is plausible to hypothesize that the initial

costs for implementing the Teaser Campaign may have saved costs in subsequent phases of recruitment. For example, the campaign may have improved the number of responses to phone-call invitations. This means that fewer follow-up phone-calls would need to be made – which could potentially save costs. However, we only observed a difference of 3 clinics in our "response to phone-call" outcome. This suggests that it is unlikely that a Teaser Campaign could lead to any cost-savings even during later phases of recruitment. Given the small observed effect, and the added cost of implementing the Teaser Campaign, it would be reasonable to conclude that the use of postcards as a Teaser Campaign is not an effective approach to engage primary care clinics in a RCT.

***Comparison with existing literature*:** Colwell and colleagues (19) observed a 44% difference in the number of GP practices expressing interest by using a combined marketing approach of a Teaser Campaign followed by Outreach Activities. However, it was unclear whether it was the Teaser Campaign or Outreach Activities that contributed to the positive effect. Our study shows that the Teaser Campaign alone was not effective in a randomised controlled design. It seems plausible that Colwell et al. (19) observed a large effect because they supplemented their Teaser Campaign by visiting local primary care networks to advertise the study. Although their study was controlled, group allocation was determined by geographical location without random allocation. This means that their findings could have influenced by confounders (e.g. geographical location) that may have induced spurious effects (22,23). Thus, causal attribution is less clear. Our study adds knowledge to this area

by providing a less biased estimate for the causal effect of a Teaser Campaign to improve clinic recruitment.

Strengths and limitations, and future directions: A strength of this study is that it was a pragmatically designed trial - attached to a real clinical trial in primary care. Typically, clinical trials in primary care will approach approximately 400 clinics to engage in a trial (for example, 488 primary care clinicians were approached in Williams et al. (9) and 382 GP practices were approached in Colwell et al. (19)). In our study we approached 744 clinics. Therefore, although there is some uncertainty around our point estimates, given the pragmatic nature of this study, our estimated response proportions and odds ratios are informative for trialists in similar settings. The descriptive cost-analysis also provides useful information for trialists who are budgeting for recruitment strategies in primary care.

Contemporary marketing strategies are commonly employed in multiple stages – for example, positioning and communicating the brand followed by interactions with the receiver (e.g. customer service and integration) (17). In this study, we only tested the first stage. Therefore, subsequent follow-up and person-to-person interaction might have been necessary to facilitate engagement. In line with recommendations from the marketing field (24), Williams et al. (9) showed that operational procedures such as frequent personal contacts increased recruitment rates. Therefore, it is possible that a multi-staged approach that combines a teaser campaign with frequent face-to-face visits might lead to better outcomes. It would be important for future studies to

test the effectiveness and costs associated with a multi-staged marketing approach to recruitment.

CONCLUSION

A Teaser Campaign using a series of branded promotional postcards, did not improve clinic engagement in a RCT in primary care.

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Ethical approval: The University of New South Wales Human Ethics Committee granted ethical approval (ref number HC12664).

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REFERENCES

1. Campbell MK, Snowdon C, Francis D, Elbourne D, McDonald a M, Knight R, et al. Recruitment to randomised trials: strategies for trial enrollment and participation study. The STEPS study. Health Technol Assess. 2007 Nov;11(48):iii, ix – 105.

2. Bower P, Wallace P, Ward E, Graffy J, Miller J, Delaney B, et al. Improving recruitment to health research in primary care. Fam Pract. 2009 Oct;26(5):391–7.

3. Lovato LC, Hill K, Hertert S, Hunninghake DB, Probstfield JL. Recruitment for controlled clinical trials: literature summary and annotated bibliography. Control Clin Trials. 1997 Aug;18(4):328–52.

4. Foy R, Parry J, Duggan A, Delaney B, Wilson S, Lewin-Van Den Broek NT, et al. How evidence based are recruitment strategies to randomized controlled trials in primary care? Experience from seven studies. Fam Pract. 2003 Feb;20(1):83–92.

5. Bower P, Wilson S, Mathers N. Short report: how often do UK primary care trials face recruitment delays? Fam Pract. 2007 Dec;24(6):601–3.

6. Tudur Smith C, Hickey H, Clarke M, Blazeby J, Williamson P. The trials methodological research agenda: results from a priority setting exercise. Trials. 2014;15(1):32.

7. Ellis SD, Bertoni AG, Bonds DE, Clinch CR, Balasubramanyam A, Blackwell C, et al. Value of recruitment strategies used in a primary care practice-based trial. Contemp Clin Trials. 2007 May;28(3):258–67.

8. Steffens D, Maher CG, Ferreira ML, Hancock MJ, Pereira LSM, Williams CM, et al. Influence of Clinician Characteristics and Operational Factors on Recruitment of Participants With Low Back Pain: An Observational Study. J Manipulative Physiol Ther. National University of Health Sciences; 2015;38(2):151–8.

9. Williams CM, Maher CG, Hancock MJ, McAuley JH, Lin CWC, Latimer J. Recruitment rate for a clinical trial was associated with particular operational procedures and clinician characteristics. J Clin Epidemiol. Elsevier Inc; 2014;67(2):169–75.

10. Johnston S, Liddy C, Hogg W, Donskov M, Russell G, Gyorfi-Dyke E. Barriers and facilitators to recruitment of physicians and practices for primary care health services research at one centre. BMC Med Res Methodol. BioMed Central Ltd; 2010 Jan;10(1):109.

11. Page MJ, French SD, McKenzie JE, O'Connor D a, Green SE. Recruitment difficulties in a primary care cluster randomised trial: investigating factors contributing to general practitioners' recruitment of patients. BMC Med Res Methodol. BioMed Central Ltd; 2011 Jan;11(1):35.

12. Howard L, de Salis I, Tomlin Z, Thornicroft G, Donovan J. Why is recruitment to trials difficult? An investigation into recruitment difficulties in an RCT of supported employment in patients with severe mental illness. Contemp Clin Trials. Elsevier Inc.; 2009 Jan;30(1):40–6.

13. Watson JM, Torgerson DJ. Increasing recruitment to randomised trials: a review of randomised controlled trials. BMC Med Res Methodol. 2006;6:34.

14. Monaghan H, Richens A, Colman S, Currie R, Girgis S, Jayne K, et al. A randomised trial of the effects of an additional communication strategy on recruitment into a large-scale, multi-centre trial. Contemp Clin Trials. 2007 Jan;28(1):1–5.

15. Treweek S, Lockhart P, Pitkethly M, Cook J a, Kjeldstrøm M, Johansen M, et al. Methods to improve recruitment to randomised controlled trials: Cochrane systematic review and meta-analysis. BMJ Open. 2013 Jan;3(2).

16. Caldwell PHY, Hamilton S, Tan A, Craig JC. Strategies for increasing recruitment to randomised controlled trials: systematic review. PLoS Med. 2010 Jan;7(11):e1000368.

17. Madhavaram S, Badrinarayanan V, McDonald RE. Integrated Marketing Communication (Imc) and Brand Identity As Critical Components of Brand Equity Strategy. J Advert. 2005;34(4):69–80.

18. Gupta A, Calfas KJ, Marshall SJ, Robinson TN, Rock CL, Huang JS, et al. Clinical trial management of participant recruitment, enrollment, engagement, and retention in the SMART study using a Marketing and Information Technology (MARKIT) model. Contemp Clin Trials. The Authors; 2015;42:185–95.

19. Colwell B, Mathers N, Ng CJ, Bradley A. Improving recruitment to primary care trials: some lessons from the use of modern marketing techniques. Br J Gen Pract. 2012;(September):496–8.

20. Traeger AC, Moseley GL, Hubscher M, Lee H, Skinner IW, Nicholas MK, et al. Pain education to prevent chronic low back pain: a study protocol for a

randomised controlled trial. BMJ Open. 2014 Jun 2;4(6):e005505–e005505.

21. Fuller T. Gnomologia: Adagies and Proverbs; Wise Sentences and Witty Sayings, Ancient and Modern, Foreign and British. London: B. Barker; and A. Bettesworth and C. Hitch; 1732.

22. Greenland S, Morgenstern H. Confounding in health research. Annu Rev Public Health. 2001;22:189–212.

23. Hernan MA. A definition of causal effect for epidemiological research. J Epidemiol Community Heal. 2004;58(4):265–71.

24. Ghodeswar BM. Building brand identity in competitive markets: a conceptual model. J Prod Brand Manag. 2008;17(1):4–12.