

An embedded randomised controlled trial of a Teaser Campaign to optimise 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: Embedded randomised recruitment 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 for a randomised controlled trial 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 embedded in 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](https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=12612001180808)

[0808](#)) (20). The University of New South Wales Human Ethics Committee granted ethical approval (ref number HC12664). This study has been reported in accordance with the reporting guidelines for embedded recruitment trials.(21)

The PREVENT trial (host 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 randomly sampled 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). An investigator not involved in outcome assessment generated a 1:1 randomisation schedule using a random number generator and assigned participants to the interventions. 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. 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”) (22), 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 to recruitment by posting formal invitation letters. This standard approach was identical to the control intervention (Standard Mail group). **Standard Mail group:** To clinics allocated to the Standard Mail group, we posted personalised 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. This standard approach was identical in both arms of the trial.

Outcome measures

The primary outcome was whether the invited clinics engaged with the trial (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. We combined positive and negative responses for this outcome because the primary purpose of the intervention was to improve initial engagement, not necessarily to improve the number of positive responses. We would consider that, during the initial stages of trial recruitment during which recognition of the host trial is important, that *any* response is a favourable outcome,

even if it is not an immediate positive response. Differentiating clinics that respond from those that do not, limits the number of follow-up phone calls to those clinics that do not respond to the initial invitation. This has the potential to save time and cost during the second phase of recruitment.

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 clinics that indicated a positive 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 the entire sample, 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 ($P = 0.22$), but showed a trend that the Teaser Campaign was more effective for PT clinics, than it was for GP clinics.

Secondary outcomes

From the entire sample, 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 their 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 ($P = 0.49$).

In general, a small number of clinics were recruited, and they referred a small number of participants. It is plausible that the Teaser Campaign might be more effective in clinical settings where there is greater interest or familiarity with the content of the host trial. Interestingly, the results of our interaction analysis shows a (non-significant) trend that the intervention might be more effective for PT clinics than it is for GP clinics. One reason for this might be that PT clinics were more familiar with or interested in the content of our host trial – testing an education intervention mostly delivered by Physiotherapists. However, we suspect that our interaction analysis was underpowered. Thus, it would be useful for future trials to test this hypothesis using larger samples.

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 trial. 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 been influenced

by confounders (e.g. geographical location) that may have induced spurious effects (23,24). 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.

An alternative explanation for the discrepancy between our findings and Colwell et al. (19) is that a Teaser Campaign may only function as an effect modifier of the active components of a combined recruitment strategy. For example, outreach activities combined with a Teaser Campaign might be more effective than outreach activities alone. Future embedded trials should test these interactive components of a 'complex' recruitment strategy using factorial designs.

Strengths and limitations, and future directions: A strength of this study is that it was a pragmatically designed trial – embedded in 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 working 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 (25), 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 is important that future studies 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).

Competing interests: H.L.: Grants (National Health and Medical Research Council of Australia); G.L.M.: Consultancy (Grunenthal, Australian Institute of Sport, Grunenthal, Kaiser Permanente California, Pfizer, Return to Work SA); Grants (National Health and Medical Research Council of Australia, ID 1061279; 0630431; 80 1008017; 1047317); Payment for lectures including service on speakers' bureaus (lectures for various companies on pain); Royalties (Explain Pain, Painful Yarns, Graded Motor Imagery Handbook, The Explain Pain Handbook: Protectometer, Noigroup Publications); S.J.K.: Consultancy (AO Spine: providing methodological advice for research projects); Employment (National Health and Medical Research Council of Australia); A.C.T.: Grants (National Health and Medical Research Council of Australia); I.W.S.: Grants (National Health and Medical Research Council of Australia); C.M.W is employed by Hunter Medical Research Institute; J.H.M.: Grants (National Health and Medical Research council of Australia, ID 1008003 and 1043621). The remaining authors have no conflicts of interest to declare.

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Table 1. Primary outcome – Responses to mail invitations

Outcomes	Teaser Campaign		Standard Mail		Odds ratio	95% CI
	<i>n</i>	%	<i>n</i>	%		
Overall	46	12.4	40	10.8	1.18	0.75 – 1.85
PT clinics	35	18.8	26	14.0	1.43	0.82 – 2.48
GP clinics	11	5.9	14	7.5	0.77	0.34 – 1.75

Table 2. Secondary outcomes

Outcomes	Teaser Campaign		Standard Mail		Odds ratio	95% CI
	<i>n</i>	%	<i>n</i>	%		
Responses to phone-call invitations	80	24.5	77	23.2	1.09	0.76 – 1.57
Interested clinics	43	11.6	44	11.8	0.97	0.62 – 1.54
Enrolled clinics	32	8.6	33	8.9	0.97	0.58 – 1.62
No. of patients referred	16	-	13	-	1.23 ^a	0.59 – 2.56

^a IRR from Poisson regression

A STITCH IN TIME...



Figure 1. *Postcard A*

Front:



Back:



Figure 2. Postcard B

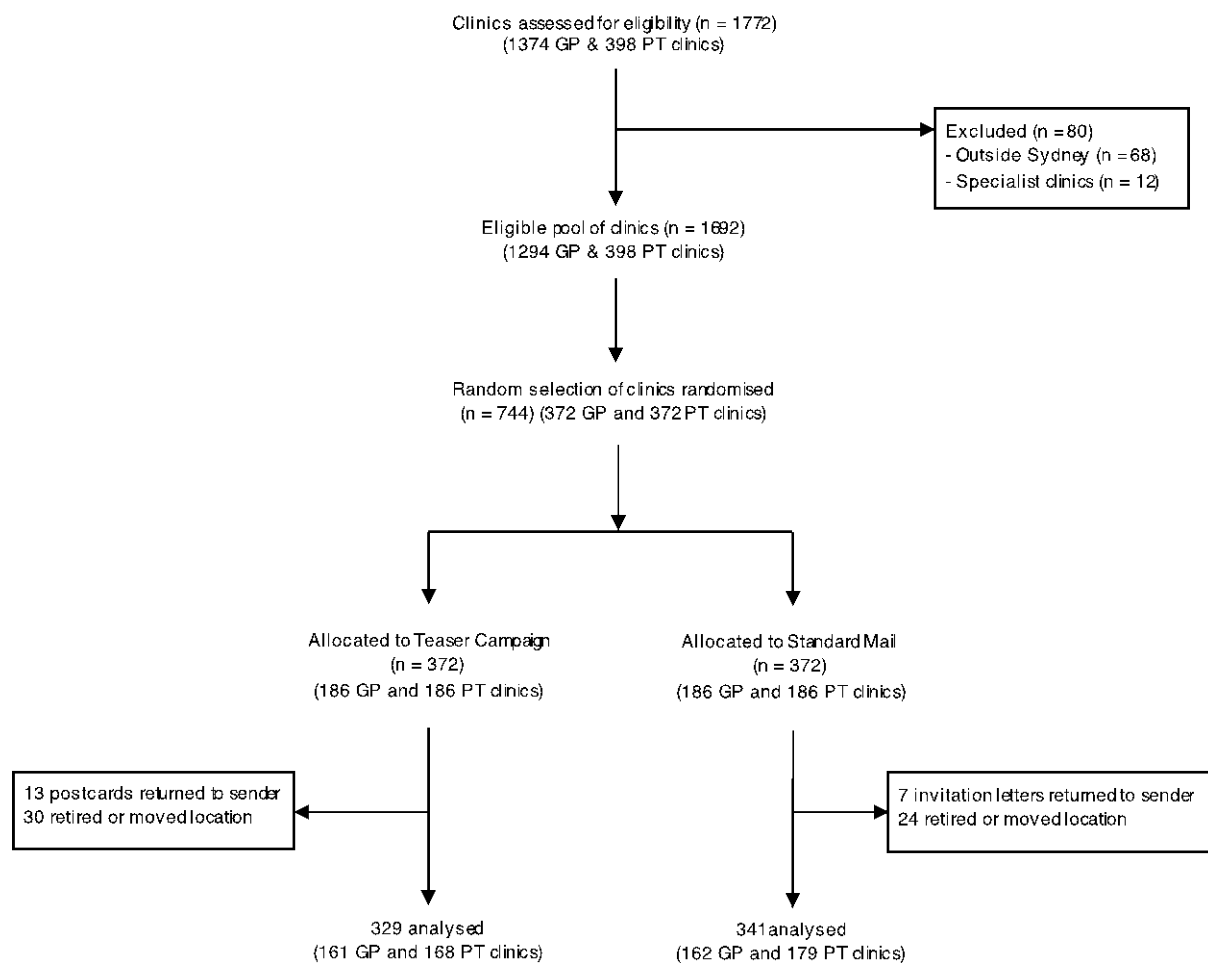


Figure 3. Study flow diagram

Supplementary 1. Item costs

Item costs	Cost per unit (Unit = 1 letter)
A4 paper	\$0.01
Ink	\$0.06
Postage stamp	\$0.70
Envelope	\$0.05
Address labels (stickers)	\$0.06
Postcard printing (a6 gloss)	\$0.54

Supplementary 2. Cost estimation

	Cost	Estimated time (hours)	No. of staff	Estimated cost / hour	Estimated staff costs (\$)	Estimated non-staff cost per unit	Estimated non-staff costs (\$)	Total staff and non-staff costs
Teaser Campaign Group	Postcard design	4	1	\$36.55	\$146.20	\$218.00	\$218.90	\$365.10
	Postcards (includes postcard printing, address labels, postage stamps)	na	na	na	\$0.00	\$1.30	\$1,450.80	\$1,450.80
	Letters (includes 3x A4 paper, printing cost, envelopes, address labels, and postage stamps)	na	na	na	\$0.00	\$1.02	\$379.44	\$379.44
	Mail merge database set-up	3	3	\$36.55	\$328.95	\$0.00	\$0.00	\$328.95
	Addressing and posting postcard (printing, addressing, and franking)	24	3	\$36.55	\$2,631.60	\$0.00	\$0.00	\$2,631.60
	Addressing and posting letters (printing information sheets, stuffing envelopes, addressing, and franking)	12	3	\$36.55	\$1,315.80	\$0.00	\$0.00	\$1,315.80
	Total cost							\$6,471.69



CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	4-5
	2b	Specific objectives or hypotheses	5
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	NA
Participants	4a	Eligibility criteria for participants	5
	4b	Settings and locations where the data were collected	5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	6
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	6-7
	6b	Any changes to trial outcomes after the trial commenced, with reasons	n/a
Sample size	7a	How sample size was determined	8
	7b	When applicable, explanation of any interim analyses and stopping guidelines	n/a
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	5
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	5
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	5
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	5-6
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	5-6

