



A randomized comparison of recruitment messages for a weight loss clinical trial targeting men working in trade and labor occupations

Melissa M. Crane^{*}, Bradley M. Appelhans

Department of Family and Preventive Medicine, Rush University Medical Center, 1700 W. Van Buren St., Ste 470, Chicago, IL 60612, USA

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ABSTRACT

Background: Engaging diverse populations in clinical trials is vital to research. This study evaluated the effects of varying recruitment messages for a clinical trial.

Methods: The messages were evaluated in a randomly assigned, factorial design that tested enhanced trust (vs. standard) and participant endorsement (vs. standard) messaging.

Four postcards were developed and randomly assigned to 4000 potential participants' addresses. Except for the messages of interest, the cards were identical, and participants were directed to four identical study websites and screening forms. Outcomes include unique website visits, visit conversion rate, screening forms completed, and participants randomized into the parent study.

Results: Study websites received 74 visits (range by message type 9 to 34). There was no significant difference by message type ($p = 0.79$). Online screening forms were completed by 15 participants (range by message type 0–6), representing a conversion rate of 20.3% of website visits. Seven participants were randomized into the study in response to the postcards (range by message type 0 to 3; 46.7% of screenings). Overall, 0.2% of individuals who received a postcard were randomized into the study.

Conclusion: Despite developing recruitment messages with participant input, the enhanced messages did not yield a greater response than standard messages. However, this method of evaluating recruitment messages shows promise.

Evaluating the messages used to recruit participants is crucial to better engage underrepresented populations in clinical trials [1–3]. Specifically, it is essential to match recruitment messages to the priorities of the target population. This study evaluated the effects of varying recruitment message content on recruitment into a clinical trial evaluating behavioral weight loss treatments for men working in labor and trade occupations. These occupations, including construction, manufacturing, installation, transportation, and maintenance (formerly called “blue-collar”), represent approximately one-third of men in the workforce in the United States [4,5]. Within this group, obesity and related comorbidities are high [6,7], but engagement in evidence-based weight loss programs and clinical trials evaluating these programs is low [8,9]. Therefore, there are grounds to evaluate how to increase the engagement of this population in clinical trials focused on evaluating weight control programs.

Our prior work and other studies have found that men, particularly those in trade and labor occupations, value trustworthy programs (e.g., evidenced-based, effective) [10,11]. Further, hearing from other men

that their experiences with the program were positive is critical [11–13]. With this in mind, recruitment messages were evaluated in a randomly assigned, factorial design that tested enhanced trust messaging (Yes/No) and participant endorsement messaging (Yes/No). We hypothesized that the enhanced trust and endorsement messages would result in greater engagement with the study, operationalized as more website visits, more eligibility screeners completed, and more randomized participants.

1. Methods

This study was conducted in the context of a randomized feasibility study testing a behavioral weight loss program tailored to men working in trade and labor occupations compared to a standard of care program (overall recruitment goal $N = 60$). The programs being evaluated were matched for time and mode of contact. The Rush University IRB approved all procedures for this study before execution.

^{*} Corresponding author.

E-mail address: Melissa_m_crane@rush.edu (M.M. Crane).

1.1. Design and preparation

Recruitment messages and materials were developed based on individual interviews (n = 20) [11] and focus groups (N = 5; n = 24) and in consultation with a community advisory board (six meetings; five participants) comprised of men who work in eligible occupations. Messages were developed using an iterative process. The study team developed messages based on the interviews, which were evaluated by the focus groups and finalized in collaboration with the community advisory board.

The general message emphasized improving energy, a common goal for men initiating weight loss that was identified during preparatory work. This study manipulated two message factors: enhanced trust and endorsement from a prior participant. Interview and focus group participants indicated that trust in the program developers and delivery agents of a weight loss program is crucial in deciding to participate in a weight loss program. The wording of the enhanced trust messaging was developed in conjunction with the community advisory board. Second, interview and focus group participants reported that they would like to hear from prior participants that the program worked for them (another specific demonstration of trust). The advisory board selected the quote used in the recruitment mailing from program evaluations from a prior men’s weight loss program that is the basis for the tailored program [14]. Four postcards were developed using a 2 (Trust Y/N) x 2 (Endorsement Y/N) factorial design to test the effects of these two message options. The final postcard with the Trust and Endorsement messages is shown in Fig. 1.

1.2. Participants

A mailing list of 4000 names and addresses was purchased from a marketing firm. Inclusion characteristics included: male adult, living within 10 miles of the research site, and occupation associated with manufacturing, construction, transportation, or production. Major eligibility requirements for the home study include body mass index $\geq 25 \text{ kg/m}^2$, interest in weight loss, ability to participate in weekly web conferencing group discussions, and availability for follow-up assessments over six months. Exclusions include serious health conditions that would interfere with weight loss or present a safety concern for unsupervised physical activity.

1.3. Procedures

The list of names and addresses was randomly assigned to receive one of four postcards during two batch mailings (to coincide with the development of study cohorts for group intervention). Mailings occurred in September 2022 and January 2023. Each postcard directed interested participants to separate but identical study websites that described the study in detail. The websites also included links to an online screening form to determine initial eligibility.

Website visits were tracked using the analytics service provided by the hosting website (Wix) between September 1, 2022, and April 1, 2023. Website visits that were unlikely to be potential participants (e.g., international sources that visited multiple study websites on the same day) were removed from the visit data (n = 8). Screening form completion and randomization into the study were tracked using REDCap [15,16].

The outcomes of interest for this study included the reach of the postcards at the points of website visit, screening form completion, and randomization into the study. Using Fisher’s exact test, data for website visits were compared across the four message groups. Due to a cell with no respondents in the screening and randomization analyses, data were not analyzed statistically for the completed screenings and randomization and are presented descriptively only.

2. Results

Four thousand addresses were randomly assigned to receive one of each of the four recruitment cards over two mailings. Of these, 307 were returned undelivered. The recruitment websites received 74 unique visits during the 30 weeks of recruitment, representing a 2% response rate (see Table). There were no differences in website visits by message type (Fisher’s Exact test: $p = 0.79$). Of those who visited the websites, 15 (20.3%) completed an online screener for the study. Conversion of website visits to screener completion ranged from 0 to 35.7% for each message type. Of those who completed the online screener, seven (47%) were randomized into the study (20–75% by message type). Participants



Figure. Recruitment postcard
Note. Purple dashed lines indicate enhanced trust messaging. Green dotted lines indicate endorsement messaging.

Table

Count data for recruitment stages by message type.

	Standard Message	Standard & Endorsement	Standard & Trust	Standard, Endorsement, & Trust
Unique website visits*	34	17	14	9
Online screening forms completed**	6	4	5	0
Participants randomized into parent study**	3	3	1	0

Note. *Fisher’s Exact test: $p = 0.79$. **These values were not statistically compared.

who were not randomized into the study either did not complete the screening process ($n = 5$) or did not meet the study criteria ($n = 3$). The messages that did not include the enhanced trust message yielded the greatest number of participants ($n = 3$; 0.3%). Overall, 0.2% of postcard recipients were randomized into the study.

3. Discussion

This study used a factorial, randomized design to evaluate two aspects of recruitment messages for a trial suggested by preparatory work: enhanced trust and participant endorsement. Results indicate few differences between recruitment messages and trends identified favored messages with less information, which will need to be confirmed in future studies. This was contrary to the study's hypotheses.

Although the hypotheses guiding this study were not supported, this study demonstrated one approach to experimentally evaluating recruitment messages. This approach was able to track the reach and engagement of the potential participants with little additional staff time. The development of the four postcards required additional design time, but this was minimal beyond developing the standard message. Similarly, the identical websites required additional recruitment costs for website hosting (\$976.80), but no additional costs were incurred. Thus, this approach is a feasible way to incorporate a study within a trial focused on recruitment [17,18]. For example, researchers could test the effects of social media campaigns with varying messages and/or imaging by sending interested participants to separate websites for further information or screening forms. This will track participants' behavior more closely than social media company metrics alone and more accurately than self-report alone. Results from social media could then be used to inform direct mail recruitment strategies, which are often more costly and more difficult to change in response to participant engagement.

This study also provides estimates for engagement with recruitment materials sent into the community directly. In this study, 2% of individuals who received a postcard visited the study website, 0.4% completed an online screening form, and 0.2% were randomized into the study. These values could be used to estimate the number of direct mailings needed for future studies. Previous studies have reported initial response rates to direct mail for clinical trials focused on weight between 0.7% and 1.3% [19,20]. This information should be considered when developing a similar study to ensure comparisons have sufficient power for statistical comparisons.

This study used an experimental design with objective measures of engagement. Though this study used direct mail as the medium, similar methodologies could be used in modes of recruitment, such as during social media recruitment campaigns. Further, engagement was tracked through randomization into a study rather than relying on cross-sectional analysis, where participants evaluate recruitment messages in a hypothetical situation. Finally, this study focused on a high-need but underrepresented group in health promotion. Limitations of this study include using only one contact medium to engage participants. Other mediums, such as flyers or electronic recruitment, may have yielded different effects. Second, the study was designed as part of a parent feasibility trial, and the lack of statistically significant differences in results is likely due to a lack of power. Finally, this study focused on a specific population, so it is unclear if the results of the messaging type would generalize to other groups.

CRedit authorship contribution statement

Melissa M. Crane: Writing – review & editing, Writing – original draft, Methodology, Investigation, Funding acquisition, Formal analysis, Conceptualization. **Bradley M. Appelhans:** Writing – review & editing, Supervision, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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References

- [1] C. Houghton, M. Dowling, P. Meskell, A. Hunter, H. Gardner, A. Conway, et al., Factors that impact on recruitment to randomised trials in health care: a qualitative evidence synthesis, *Cochrane Database Syst. Rev.* (10) (2020).
- [2] S. Treweek, M. Pitkethly, J. Cook, C. Fraser, E. Mitchell, F. Sullivan, et al., Strategies to improve recruitment to randomised trials, *Cochrane Database Syst. Rev.* (2) (2018).
- [3] B.E. Bierer, S.A. White, L.G. Meloney, H.R. Ahmed, D.H. Strauss, L.T. Clark, Achieving Diversity, Inclusion, and Equity in Clinical Research Guidance Document Version 1.1, Cambridge and Boston, MA: Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center) (2021). Available at: <https://mrctcenter.org/diversity-in-clinical-trials/>.
- [4] U.S. Bureau of Labor Statistics, Labor force statistics from the current population survey 2021 [December 9, 2021]. Available from: <https://www.bls.gov/cps/cpsaat11.htm>.
- [5] Statistics USBoL, Educational attainment for workers 25 years and older by detailed occupation 2021 [December 9, 2021]. Available from: <https://www.bls.gov/emp/tables/educational-attainment.htm#top>.
- [6] J.K. Gu, L.E. Charles, K.M. Bang, C.C. Ma, M.E. Andrew, J.M. Violanti, et al., Prevalence of obesity by occupation among US workers: the national health interview survey 2004–2011, *J. Occup. Environ. Med.* 56 (5) (2014) 516–528.
- [7] J.E. Mabry, K. Hosig, R. Hanowski, D. Zedalis, J. Gregg, W.G. Herbert, Prevalence of metabolic syndrome in commercial truck drivers: a review, *J. Transport Health* 3 (2016) 413–421.
- [8] M.D. McDonald, K. Hunt, H. Sivaramakrishnan, J. Moullin, A. Avenell, D.A. Kerr, et al., A systematic review examining socioeconomic factors in trials of interventions for men that report weight as an outcome, *Obes. Rev.* 23 (7) (2022) e13436.
- [9] J.R. Strickland, S. Wagan, A.M. Dale, B.A. Evanoff, Prevalence and perception of risky health behaviors among construction workers, *J. Occup. Environ. Med.* 59 (2017) 673–678.
- [10] B.C. Tilley, I.I.I.A.G. Mainous, R.P. Amorrtortu, M.D. McKee, D.W. Smith, R. Li, et al., Using increased trust in medical researchers to increase minority recruitment: the RECRUIT cluster randomized clinical trial, *Contemp. Clin. Trials* 109 (2021) 106519.
- [11] M.M. Crane, K. Newman, J. Herbert-Beirne, E.P. Abril, L.H. Powell, B. M. Appelhans, Weight loss program preferences of men working in blue-collar occupations: a qualitative inquiry, *Am. J. Men's Health* 16 (5) (2022).
- [12] P.J. Morgan, J.M. Warren, D.R. Lubans, C.E. Collins, R. Callister, Engaging men in weight loss: experiences of men who participated in the male only SHED-IT pilot study, *Obes. Res. Clin. Pract.* 5 (2011) e239–e248.
- [13] K. Hunt, C.M. Gray, A. Maclean, S. Smilie, C. Bunn, S. Wyke, Do weight management programmes delivered at professional football clubs attract and engage high risk men? A mixed-methods study, *BMC Publ. Health* 14 (50) (2014).
- [14] M.M. Crane, L.D. Lutes, D.S. Ward, J.M. Bowling, D.F. Tate, A randomized trial testing the efficacy of a novel approach to weight loss among men with overweight and obesity, *Obesity* 23 (12) (2015) 2398–2405.
- [15] P.A. Harris, R. Taylor, B.L. Minor, V. Elliott, M. Fernandez, L. O'Neal, et al., The REDCap consortium: building an international community of software platform partners, *J. Biomed. Inf.* 95 (2019) 103208.
- [16] P.A. Harris, R. Taylor, R. Thielke, J. Payne, N. Gonzalez, J.G. Conde, Research electronic data capture (REDCap)—a metadata-driven methodology and workflow process for providing translational research informatics support, *J. Biomed. Inf.* 42 (2) (2009) 377–381.
- [17] S. Treweek, S. Bevan, P. Bower, M. Campbell, J. Christie, M. Clarke, et al., Trial forge guidance 1: what is a study within a trial (SWAT)? *Trials* 19 (2018) 1–5.
- [18] C. Boxall, S. Treweek, K. Gillies, Studies within a trial priorities to improve the evidence to inform recruitment and retention practice in clinical trials, *Res. Methods Med. Health Sci.* 3 (4) (2022) 121–126.
- [19] S.D. Brown, K. Lee, D.E. Schoffman, A.C. King, L.M. Crawley, M. Kiernan, Minority recruitment into clinical trials: experimental findings and practical implications, *Contemp. Clin. Trials* 33 (4) (2012) 620–623.
- [20] M.M. Crane, J.G. LaRose, M.A. Espeland, R.R. Wing, D.F. Tate, Recruitment of young adults for weight gain prevention: randomized comparison of direct mail strategies, *Trials* 17 (2016).