



Contents lists available at ScienceDirect

Exploratory Research in Clinical and Social Pharmacy

journal homepage: www.elsevier.com/locate/rcsop

Effectiveness and cost analysis of methods used to recruit older adult sedative users to a deprescribing randomized controlled trial during the COVID-19 pandemic



Andrea L. Murphy^{a,*}, Justin P. Turner^{b,c}, Malgorzata Rajda^d, Kathleen G. Allen^e, Kamilla Pinter^e, David M. Gardner^f

^a College of Pharmacy and Department of Psychiatry, Dalhousie University, Halifax, Nova Scotia, Canada

^b Centre for Medicine Use and Safety, Faculty of Pharmacy and Pharmaceutical Science, Monash University, Melbourne, Victoria, Australia

^c Centre de recherche, Institut universitaire de gériatrie de Montréal, Montréal, Québec, Canada

^d Sleep Disorders Clinic, Nova Scotia Health, and Department of Psychiatry, Dalhousie University, Halifax, Nova Scotia, Canada

^e Department of Psychiatry, Dalhousie University, Halifax, Nova Scotia, Canada

^f Department of Psychiatry and College of Pharmacy, Dalhousie University, Halifax, Nova Scotia, Canada

ARTICLE INFO

Keywords:

Patient selection
Randomized controlled trials
Cost and cost analysis
Aged
Sedative-hypnotics
Deprescribing
Pandemic

ABSTRACT

Background: Recruitment to clinical trials is a challenge for researchers that became more pronounced because of COVID-19 public health protective measures, especially with respect to studies enrolling older adults. We completed an effectiveness and cost analysis of the recruitment methods used in The Your Answers When Needing Sleep in New Brunswick (YAWNS NB) study, a randomized controlled trial of a deprescribing intervention that recruited older adults with chronic use of sedatives during the pandemic.

Methods: Study recruitment began during the COVID-19 pandemic. Strategies included random digit dialing (RDD), a targeted mail campaign and advertising through newspapers, online platforms (Google and Facebook), and television. Other awareness raising and recruitment strategies involved seniors' organizations, pharmacies, television news stories, and referrals. Recruitment effectiveness and cost analysis involved enrollment rate (ER), cost per randomized participant (CPRP), fractional cost (FC), fractional enrollment (FE), fractional enrollment-cost ratio (FEC), and efficacy index (EI) calculations.

Results: There were 1295 interested older adults with 594 randomized into the study for an enrollment rate of 46%. The efficacy index (EI) was highest for Facebook ads (EI = 0.683) followed by television (EI = 0.426), and newsprint ads (EI = 0.298). The cost of RDD was highest per randomized participant at \$1117.90 and produced the lowest EI (0.013).

Conclusion: Facebook ads had the best efficacy index for recruiting older adults to the YAWNS NB study during the COVID-19 pandemic and television ads produced the most enrollments. RDD was expensive and yielded few recruits. Recruitment costs can be significant for recruiting community-dwelling older adults. This experience can inform recruitment strategy and budget development for future community studies enrolling older adults, especially in the context of the COVID-19 pandemic.

Introduction

Efficient recruitment of the targeted sample size of study participants within the planned timeline of a randomized controlled trial is the exception rather than the rule.¹ The identification of specific factors necessary for recruitment success remain elusive, however best practices indicate that successful recruitment requires the development and implementation of a recruitment strategy inclusive of what is often a substantial portion of

the project's budget.² Much depends on the success of the study's recruitment efforts, as a study that falls well below its planned recruitment is at risk of failing to answer its research questions and in so doing, squander its funding.³ The complexity and intensity of the recruitment strategy and its apportioned budget vary depending on numerous factors including access to potential participants, trust of the researcher by study candidates, participant interest in the project's objectives, and effort required by participants to complete the study.⁴ Even a well-planned and sufficiently funded

* Corresponding author.

E-mail address: andrea.murphy@dal.ca (A.L. Murphy).

<http://dx.doi.org/10.1016/j.rcsop.2022.100214>

Received 13 September 2022; Received in revised form 16 November 2022; Accepted 13 December 2022

Available online xxx

2667-2766/© 2022 The Authors. Published by Elsevier Inc. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

recruitment plan may be disrupted by one or more unforeseen challenges to recruitment; for example, pandemic-related public health measures limiting direct access to potential study candidates.

A combination of traditional recruitment methods (i.e., print/flyers, word-of-mouth) with online free and paid promotion advertising (i.e., social media) are recommended as potentially cost-effective and often necessary ways of spreading awareness to potential participants including hard to reach populations.⁵⁻⁷ Older adults can be particularly difficult to recruit to randomized controlled trials due to health status impairments, comorbidities, restricted enrollment criteria, and a diversity of health beliefs.⁸⁻¹¹ The COVID-19 pandemic has created additional challenges with reaching, engaging with, and recruiting older adults to clinical research, leading researchers to increasingly rely on online methods of recruitment.¹²

The Your Answers When Needing Sleep in New Brunswick (YAWNS NB) was a randomized controlled trial that investigated the impact of sending a direct-to-patient educational intervention package to older adults.¹³ YAWNS NB study recruitment launched approximately 6 months after the COVID-19 pandemic was declared. This necessitated a shift in the original recruitment strategy and budget by suspending plans for direct engagement at in-person events run by seniors' organizations and requiring a reappraisal of the effectiveness of various non-face-to-face recruitment methods. This analysis reports the comparative effectiveness and cost analysis of several traditional and online recruitment methods of older adults used for recruiting participants to the YAWNS NB study during the height of COVID-19 pandemic public health protections across the province of New Brunswick, Canada.

Methods

Participants

New Brunswick is a Canadian province of over 71,000 km² and 794,000 people. It has the second highest proportion of people 65 and older in Canada (22.7%), a large proportion of the population living rurally (50%) or in small population centres (19%), and has the highest rate of chronic use of BZRAs among older adults (25%) living in Canada.¹³⁻¹⁵

The YAWNS NB study (registration NCT04406103) was a randomized, parallel assignment, three-arm, open-label trial.¹³ Participants were English-speaking residents of New Brunswick, community-dwelling, aged ≥ 65 years, responsible for their healthcare decisions, and long-term users of benzodiazepine receptor agonists (BZRAs), the most commonly prescribed sedative-hypnotics for insomnia. All study participants were invited to complete a 60-min telephone interview at baseline and a 6-month follow-up telephone interview of similar duration. The study did not require participant travel or any in-person assessments. The target number of completers per group was 188 for a total of 564 completers across three groups. To account for a dropout rate of up to 25%, the planned recruitment sample size was 705 randomized participants. Ethics approval was received by the Ethics Board of Dalhousie University. All participants consented prior to enrollment.

Recruitment approaches

The YAWNS NB study used several recruitment strategies over 13 months. Random digit dialing (RDD) involved direct, unsolicited telephone calls by a contracted vendor using an undifferentiated list of active New Brunswick telephone numbers and a preliminary screening tool. All other methods used various mechanisms to raise awareness of the study and invited potentially interested individuals to contact the researchers for more information and initial screening. Strategies included traditional advertising and announcements in newspapers, television (TV), and targeted mailing using postcards and pamphlets. Online Google and Facebook paid advertising were also used. Mailings were sent via Canada Post routes selected based on their high proportion of older adults. Other strategies included reaching out to NB seniors' organizations by email requesting

sharing of notifications, using NB pharmacies to distribute YAWNS NB study postcards to people taking BZRAs, news media reports about BZRA use in older adults and the YAWNS NB study, and referrals from healthcare professionals and others. Strategies were staggered, beginning with RDD and newspaper ads, and subsequently transitioning to mail campaigns, social media, TV ads, and other methods.

Analysis

As per the methods of Chin Feman and colleagues (2008), we used several metrics to determine the most effective recruitment strategies used for the YAWNS NB study.¹⁶ They included:

Enrollment rate (ER): The proportion of participants who enrolled in the study compared to all who expressed initial interest. ER was calculated by dividing the number of participants randomized by the total number interested.

$$ER = \frac{n \text{ randomized per method}}{n \text{ interested}}$$

Cost per randomized participant: total cost of the recruitment strategy divided by number randomized attributed to that recruitment strategy.

$$CPRP = \frac{\text{recruitment method cost}}{n \text{ randomized}}$$

Fractional enrollment (FE): Fractional enrollment is the ratio of the number of enrollments for an individual recruitment method over the total number of enrollments.¹⁶ FE measures the contribution that a recruitment type brought to the overall effort. FE was calculated by dividing the number randomized per recruitment method by the total randomized.

$$FE = \frac{n \text{ randomized per method}}{\text{total } n \text{ randomized}}$$

Fractional cost (FC): The fractional cost is the ratio of the cost of each recruitment strategy over the total cost of recruitment. FC measures the proportion of the overall budget consumed by each individual recruitment strategy. FC was calculated by dividing the cost of each individual recruitment strategy by the total cost of recruitment.

$$FC = \frac{\text{recruitment method cost}}{\text{total recruitment cost}}$$

Fractional enrollment-cost (FEC) ratio: The ratio of the fractional enrollment (FE) over the fractional cost (FC) for each recruitment type indicates its relative performance in terms of benefit versus cost. Ratios >1 indicate better than average performance and <1 indicate less than average performance.

$$FEC = \frac{FE}{FC}$$

Efficacy index (EI): EI is a dynamic measure that combines the relative cost effectiveness of each recruitment method with its fractional contribution to the recruitment strategy. It adjusts the fractional enrollment-cost ratio based on overall fraction of enrollments per recruitment method. EI calculations yield a precise comparison of recruitment method effectiveness. When two methods have similar FEC ratios, the recruitment method that yielded a higher number of enrollments would have a higher efficacy index. Likewise, when two methods lead to a similar number of enrollments, the preferred method is the one that is less costly. As such, the higher the EI values, the more cost effective the method. The EI is calculated by

multiplying each method's fractional enrollment-cost ratio by its fractional enrollment.

$$EI = \frac{FE}{FC} \cdot FE$$

Results

A total of 1295 people were screened for eligibility (244 referred from RDD, 583 study website contacts, 438 study telephone calls received, and $n = 29$ other methods (e.g., referrals)). Of the 1295 screened, 350 were ineligible, 263 declined to participate, and 650 agreed to receive a consent form by mail. Of those 650 individuals, 594 consented to participate and were randomized, yielding an enrollment rate of 46%.

The total cost of recruitment for the YAWNS NB trial was \$132,479 (\$223/participant) representing 33% of the total budget. RDD consumed the largest portion of the budget (\$44,716) followed by TV ads (\$39,965) and the targeted mail campaign (\$31,251). The remaining recruitment strategies were used less intensively and were significantly less costly (e.g., newspaper print ads, pharmacy outreach, online ads), and several methods were free of charge (e.g., referrals). The CPRP, FC, FE, FE/FC, and EI are presented in Table 1. Facebook, TV, and newspaper ads had the most favourable EIs and RDD the least.

Discussion

Overall recruitment cost per participant (CA\$223) was less than half the median recruitment cost from 30 clinical trials (US\$409 is ~CA\$540) reported by Speich and colleagues.² The efficacy index was highest for Facebook ads (0.683) followed by TV ads (0.426) and newspaper ads (0.298) for recruiting older adults to the YAWNS NB study during the COVID-19 pandemic. The EI for these strategies were greater than their respective FE values, demonstrating their superiority at recruiting participants over other strategies.¹⁶

Recognizing social media's potential value in recruitment, the National Institute on Aging Recruiting Older Adults in Research (ROAR) toolkit includes sample messaging for platforms such as Facebook.¹⁷ Generally, evidence for recruiting older adults via social media remains limited, especially during the pandemic, but promising research from other hard to reach groups shows successes with recruitment at reasonable costs.¹⁸ Additionally, Facebook advertising click-through rates may be higher with older adults compared to younger age groups.¹⁹ TV ads may be well suited for recruiting older adults as research participants. >80% of those ≥ 65 years old watch approximately 4 h of TV daily, thus creating opportunities for recruitment ads that target this age group.²⁰

Table 1

Recruitment metrics based on recruitment strategies in the YAWNS NB study.

Recruitment source	Study months	Enrolled	Total cost	Cost per randomized participant (CPRP)	Fractional enrollment (FE)	Fractional cost (FC)	Fractional enrollment-cost ratio (FEC)	Efficacy index (EI)
Random digit dialing †	1–4	40	\$44,716	\$1117.90	0.067	0.338	0.200	0.013
TV Ads ‡	4–13	213	\$39,965	\$187.63	0.359	0.302	1.189	0.426
Targeted mail ^	2,3,6–11	58	\$31,251	\$538.81	0.098	0.236	0.414	0.040
Newsprint ads	1,4,6	81	\$8280	\$102.22	0.136	0.063	2.182	0.298
Pharmacies	3–7	19	\$5851	\$307.95	0.032	0.044	0.724	0.023
Facebook Ads	5–7,9–13	62	\$2113	\$34.08	0.104	0.016	6.544	0.683
Google Ads	2	0	\$303	–	0.000	0.002	–	–
News report (any medium)	2–4	66	0	–	0.111	0.000	–	–
Friend/family	Any	30	0	–	0.051	0.000	–	–
Seniors' organizations	Any	13	0	–	0.022	0.000	–	–
Healthcare provider referral	Any	7	0	–	0.012	0.000	–	–
Other*	Any	5	0	–	0.008	0.000	–	–
TOTAL		594	\$132,479	Mean \$223.03				

† 32,224 calls were attempted. 244 of 4751 potentially eligible contacts agreed to having their contact information shared with the YAWNS NB researchers.

‡ TV advertisements included paid ($n = 451$) and bonus ($n = 817$) advertising slots.

^ The mail campaign averaged 13,640 recruitment items mailed per month over 8 months. Cost of mailing included a 43.1% volume discount.

* Other recruitment methods including community posters, referrals from religious and community leaders, etc. All costs are Canadian dollars.

The RDD method failed to provide an acceptable recruitment yield (EI = 0.013). It was both costly and had a low FE. The RDD process uses the completes per hour (CPH) metric, which is the number of individuals willing to provide contact details to researchers called per hour. The estimated CPH before recruitment was 0.7 to 1.3, but the actual CPH was 0.23. Research has shown that older adults may be vulnerable to telephone scams²¹ and, more recently, scam awareness campaigns may have improved vigilance against information sharing between older adults and unknown callers.²² Anecdotally, telephone scams may have become more prevalent during the pandemic. Facebook ads, in contrast, which are passive versus RDD, may provide opportunities to consider and check the credibility of the invitation.

More research regarding whether social media, TV ads, and RDD are trusted and appropriate for older adults in the context of the pandemic should be conducted and deposited in the Online Resource for Research in Clinical trials (ORRCA).²³ Research within ORRCA would provide investigators with evidence regarding the challenges and opportunities with recruitment and retention strategies of older adults in trials during pandemic times.²³ The YAWNS NB trial followed the best practices outlined by Pitkala and Strandberg (2022) during participant recruitment and retention practices. This included using several recruitment strategies to reach potential participants and using various sensitive practices to increase participant retention.²⁴ A limitation of this analysis is that research staff time (i.e., salary) was not factored into cost recruitment calculations.

Conclusion

Recruiting older adults to a deprescribing study during the COVID-19 pandemic was supported most with Facebook, TV, and newspaper ads. Random digit dialing was costly without producing the desired results. The recruitment results corroborated other findings demonstrating recruitment costs can be significant. More research regarding recruiting older adults during the pandemic would support investigators' recruitment strategies.

Funding statement

The YAWNS NB study (C0046) was one of the studies funded through The Healthy Seniors Pilot Project (HSPP) grant competition. The HSPP is an agreement between the Government of New Brunswick and the Public Health Agency of Canada, jointly led by the Government of New Brunswick's Department of Social Development and the Department of Health through the Seniors and Healthy Aging Secretariat. The results and conclusions are those of the authors and no official endorsement by the government of New Brunswick was intended or should be inferred.

This study was approved by the Institutional Review Board for Dalhousie University (research ethics board number 2020-5184; clinical trial registry NCT4406103) and all participants reviewed a physical or electronic version of the consent form before providing verbal consent.

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.

Acknowledgements

Sandra Magalhaes, PhD of the NB-Institute for Research, Data, and Training and Department of Sociology, University of New Brunswick, Fredericton, New Brunswick, Canada is a team member of the study and primarily responsible for statistical analysis of administrative data.

References

- McDonald AM, Knight RC, Campbell MK, et al. What influences recruitment to randomised controlled trials? A review of trials funded by two UK funding agencies. *Trials* 2006;7:9.
- Speich B, von Niederhäusern B, Schur N, et al. Systematic review on costs and resource use of randomized clinical trials shows a lack of transparent and comprehensive data. *J Clin Epidemiol* 2018;96:1-11.
- Bower P, Brueton V, Gamble C, et al. Interventions to improve recruitment and retention in clinical trials: a survey and workshop to assess current practice and future priorities. *Trials* 2014;15:399.
- Campbell M, Snowdon C, Francis D, et al. Recruitment to randomised trials: strategies for trial enrolment and participation study. The STEPS study. *Health Technol Assess* 2007;11 (48). iii, ix-105.
- Frandsen M, Thow M, Ferguson SG. The effectiveness of social media (Facebook) compared with more traditional advertising methods for recruiting eligible participants to health research studies: a randomized, controlled clinical trial. *JMIR Res Protoc* 2016;5(3):e161.
- Frandsen M, Walters J, Ferguson SG. Exploring the viability of using online social media advertising as a recruitment method for smoking cessation clinical trials. *2014;16(2): 247-251.*
- Kayrouz R, Dear BF, Karin E, et al. Facebook as an effective recruitment strategy for mental health research of hard to reach populations. *Internet Interv* 2016;4:1-10.
- Ridda I, MacIntyre CR, Lindley RI, et al. Difficulties in recruiting older people in clinical trials: an examination of barriers and solutions. *Vaccine* 2010;28(4):901-906.
- Forsat ND, Palmowski A, Palmowski Y, et al. Recruitment and retention of older people in clinical research: a systematic literature review. *J Am Geriatr Soc* 2020;68 (12):2955-2963.
- Denson AC, Mahipal A. Participation of the elderly population in clinical trials: barriers and solutions. *Cancer Control* 2014;21(3):209-214.
- Buttgereit T, Palmowski A, Forsat N, et al. Barriers and potential solutions in the recruitment and retention of older patients in clinical trials-lessons learned from six large multicentre randomized controlled trials. *Age Ageing* 2021;50(6):1988-1996.
- Sharma RK, Teng A, Asiro MG, et al. Challenges and opportunities in conducting research with older adults with dementia during COVID-19 and beyond. *J Am Geriatr Soc* 2022;70(5):1306-1313.
- Murphy AL, Turner JP, Rajda M, et al. A protocol for a randomized controlled trial comparing Sleepwell, EMPOWER, and treatment-as-usual for benzodiazepine receptor agonist discontinuation in older adults: the Your Answers When Needing Sleep in New Brunswick (YAWNS NB) study. *Explor Res Clin Soc Pharm* 2022;7: e100164.
- Government of Canada SC. Demographic estimates by age and sex, provinces and territories: Interactive dashboard. <https://www150.statcan.gc.ca/n1/pub/71-607-x/71-607-x2020018-eng.htm>. (2020, accessed 15 November 2022).
- Government of Canada SC. Annual demographic estimates, rural and urban areas: Interactive dashboard. <https://www150.statcan.gc.ca/n1/pub/71-607-x/71-607-x2021030-eng.htm>. (2022, accessed 15 November 2022).
- Chin Feman SP, Nguyen LT, Quilty MT, et al. Effectiveness of recruitment in clinical trials: an analysis of methods used in a trial for irritable bowel syndrome patients. *Contemp Clin Trials* 2008;29(2):241-251.
- National Institute of Health. *Recruiting Older Adults into Research (ROAR) Toolkit*. National Institute on Aging. 2015. <https://www.nia.nih.gov/health/recruiting-older-adults-research-roar-toolkit>. (accessed 5 July 2022).
- Wozney L, Turner K, Rose-Davis B, et al. Facebook ads to the rescue? Recruiting a hard to reach population into an internet-based behavioral health intervention trial. *Internet Interv* 2019;17:100246.
- Cowie JM, Gurney ME. The use of Facebook advertising to recruit healthy elderly people for a clinical trial: baseline metrics. *JMIR Res Protoc* 2018;7(1):e7918.
- Government of Canada SC. A day in the life: how do older Canadians spend their time? <https://www150.statcan.gc.ca/n1/pub/75-006-x/2018001/article/54947-eng.htm>. (2018, accessed 11 July 2022).
- James BD, Boyle PA, Bennett DA. Correlates of susceptibility to scams in older adults without dementia. *J Elder Abuse Negl* 2014;26(2):107-122.
- Government of Canada. What every older Canadian should know about: fraud and scams. <https://www.canada.ca/en/employment-social-development/corporate/seniors/forum/fraud-scams.html>. (2016, accessed 11 July 2022).
- Kearney A, Ashford P-A, Butlin L, et al. Developing an online, searchable database to systematically map and organise current literature on retention research (ORRCA2). *Clin Trials* 2022;19(1):71-80.
- Pitkala KH, Strandberg TE. Clinical trials in older people. *Age Ageing* 2022;51(5): afab282.