

Cover Page for ClinicalTrials.gov

Document:

Study Protocol

Official Study Title:

A proof-of-concept study evaluating a theory-based motivational letter to increase attendance to a one-year post-cardiac rehabilitation risk factor check

Document Date:

January 26, 2024

Title: A proof-of-concept study evaluating a theory-based motivational letter to increase attendance to a one-year post-cardiac rehabilitation risk factor check

Background. Cardiovascular diseases (CVD) are among the leading causes of mortality worldwide¹. Cardiac rehabilitation (CR) can improve medical and psychological outcomes for patients with CVD². Patient follow-up appointments in the months and years following CR may support long-term medication management and maintenance of health behaviours (i.e., adherence to exercise regimen, dietary recommendations, smoking cessation)³. Despite the importance of long-term follow-up, unpublished internal data from TotalCardiology Rehabilitation (TCR) indicates that ~20-30% of patients do not attend these visits. Suboptimal attendance at one-year post-CR appointments may be influenced by 1) a patient lack of awareness, 2) patient perceptions of the appointment as unnecessary, 3) practical or scheduling issues, 4) comorbid health concerns and 5) anticipated unpleasant experiences at the appointment⁴. The use of motivational theory may be particularly useful for improving patient attendance at one-year post-CR appointments⁵. Previous studies have demonstrated low-cost letters based on theories of behaviour change can improve initial CR attendance, but this approach has not been tested in the context of follow-up care after CR. The theory of planned behaviour (TPB)⁶ and health action process approach (HAPA) represent psychological frameworks which posit that intention to engage in a behaviour (e.g. appointment attendance) is influenced by an individual's attitudes about a behaviour, perceived control over the behaviour, and subjective norms associated with performing the behaviour. TPB and HAPA may inform cost-effective written communications to improve maintain exercise and other health practices following CR.

Current study. This presents the ideal opportunity for an evidence- and theory-driven approach to promote cardiac patient attendance at one-year post-CR follow-up appointments. The current study will evaluate the impact of a letter rooted in the TPB⁶, HAPA, and based on earlier qualitative work on barriers to TCR one-year appointment attendance⁴, mailed out to patients 6 months in advance of their one-year post-CR follow-up appointment. This study is also guided by the ORBIT model,⁷ which recommends the use of theory and early-phase qualitative research to optimize the design and efficacy of behaviour change interventions.

Objectives. The proposed project aims to evaluate the influence of a motivational reminder letter on patients' one-year post-CR appointment attendance. *Primary objective.* To assess whether a theory-based reminder letter increases patient attendance at a one-year follow-up compared to patients who receive their care as usual. *Secondary objectives.* a) To assess whether a theory-based reminder letter improves risk factor control (e.g., cardiorespiratory fitness, lipid control) compared to usual care; b) To assess demographic and clinical and risk factor variables associated with attendance of the one-year post-CR appointment; c) To describe trajectories of risk factor changes following cardiac rehabilitation. **Methods.** *Sample:* Prospective participants will be recruited in person at their post-CR (12-week) appointment by TCR administrative staff. *Inclusion criteria:* Participants will be patients who: 1) have provided written consent to participate, 2) attended their 12-week post-CR visit, 3) program status not listed as "discharged" or "deceased," and 4) have a pre-booked 1-year visit marked in their patient chart. *Study design:* Eligible participants who have consented to participate will be randomly assigned to either

Ethics ID: REB23-1586

Study Title: A proof-of-concept study evaluating a theory-based motivational letter to support maintenance of health practices following cardiac rehabilitation

PI: Tavis Campbell

Version 1.1: January 26, 2024

receive the motivational letter reminder, or care as usual. Theory-based letters will be mailed directly to participants' home addresses at approximately 6-months post-CR (i.e. 6-months before their scheduled one-year appointment). *Outcome measures. Primary outcome.* Attendance at the one-year follow-up appointment (assessed by a binary, yes or no). *Secondary outcomes.* Demographics, clinical characteristics, and risk factors will be collected as part of standard care at TCR, then collected by researchers via TCR medical chart review.

Analytic plan: Assuming 80% power, an alpha of 0.05, assuming 90% of patients in the intervention group attend their 1-year follow up, and a 5% attrition rate (i.e., due to death, or program drop out), approximately 102 participants (51 participants per group with complete data) will be recruited to participate in this study. The *primary outcome* will be evaluated using chi-square and descriptive statistics. *Secondary outcomes* will be assessed using descriptives and t-tests.

Implications. Demonstrating a clinically significant increase in post-CR follow-up attendance will be important for optimizing patient attendance and translating findings into standard practice at TotalCardiology. If the letter is shown to increase attendance, it would represent a low-cost way to increase uptake to follow-up care after CR. This study will provide important data on maintenance of risk factor control after CR.

References

1. World Health Organization (WHO), 2023. Retrieved from https://www.who.int/health-topics/cardiovascular-diseases#tab=tab_1
2. Bellmann, B., Lin, T., Greissinger, K., Rottner, L., Rillig, A., & Zimmerling, S. (2020). The beneficial effects of cardiac rehabilitation. *Cardiology and therapy*, 9(1), 35-44.
3. Bellmann, B., Lin, T., Greissinger, K., Rottner, L., Rillig, A., & Zimmerling, S. (2020). The beneficial effects of cardiac rehabilitation. *Cardiology and therapy*, 9(1), 35-44.
4. Giannoccaro, J. D., Aggarwal, S., Grace, S. L., Campbell, T. S., Hauer, T., Arena, R., & Rouleau, C. R. (2020). Factors Associated with Attendance at a 1-yr Post-Cardiac Rehabilitation Risk Factor Check. *Journal of Cardiopulmonary Rehabilitation and Prevention*, 40(3), E22-E25.
5. Mosleh, S. M., Bond, C. M., Lee, A. J., Kiger, A., & Campbell, N. C. (2014). Effectiveness of theory-based invitations to improve attendance at cardiac rehabilitation: A randomized controlled trial. *European journal of cardiovascular nursing*, 13(3), 201-210.
6. Ajzen, I. (1991). The theory of planned behavior. *Organizational behavior and human decision processes*, 50(2), 179-211.
7. Czajkowski, S. M., Powell, L. H., Adler, N., Naar-King, S., Reynolds, K. D., Hunter, C. M., ... & Charlson, M. E. (2015). From ideas to efficacy: The ORBIT model for developing behavioral treatments for chronic diseases. *Health Psychology*, 34(10), 971.
8. Ritchey MD, Maresh S, McNeely J, Shaffer T, Jackson SL, Keteyian SJ, Brawner CA, Whooley MA, Chang T, Stolp H, Schieb L, Wright J. Tracking Cardiac Rehabilitation Participation and Completion Among Medicare Beneficiaries to Inform the Efforts of a National Initiative. *Circ Cardiovasc Qual Outcomes*. 2020 Jan;13(1):e005902. doi: 10.1161/CIRCOUTCOMES.119.005902. Epub 2020 Jan 14. PMID: 31931615; PMCID: PMC8091573.

Ethics ID: REB23-1586

Study Title: A proof-of-concept study evaluating a theory-based motivational letter to support maintenance of health practices following cardiac rehabilitation

PI: Tavis Campbell

Version 1.1: January 26, 2024