PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	SCALE-UP II: Protocol for a Pragmatic Randomized Trial Examining Population Health Management Interventions to Increase the Uptake of At-Home COVID-19 Testing in Community Health Centers
AUTHORS	Del Fiol, Guilherme; Orleans, Brian; Kuzmenko, Tatyana; Chipman, Jonathan; Greene, Tom; Martinez, Anna; Wirth, Jennifer; Meads, Ray; Kaphingst, Kim; Gibson, Bryan; Kawamoto, K; King, Andy; Siaperas, Tracey; Hughes, Shlisa; Pruhs, Alan; Pariera Dinkins, Courtney; Lam, Cho; Pierce, Joni; Benson, Ryzen; Borsato, Emerson; Cornia, Ryan; Stevens, Leticia; Bradshaw, Richard; Schlechter, Chelsey; Wetter, David

VERSION 1 – REVIEW

REVIEWER	Serhal, Eva Centre for Addiction and Mental Health
REVIEW RETURNED	30-Jan-2024

GENERAL COMMENTS	Thank you for the opportunity to review this manuscript. I feel this protocol was well done, and has potential generalizability well beyond just the scope of Covid-19 tests. Overall, I think the authors did an excellent job. I have included a few notes for consideration and questions to address to improve clarity. How was the language/script validated to ensure if was easily understood and clear for study participants? Was there any pilot testing with a small group, or inclusion of people within the targeted study demographic group? How was the chat/text/navigation integrated within the EMR of the CHCs? What there any in session/in text evaluation of support/quality of the intervention? It says the patient navigator called within 48 hours. This is a long time to await a response. Was there any correlation with positive use and the amount of time in which someone called back? What was the 90 days chosen as the text follow-up timing? It seems like a long time to retain information. given this is self report, wouldn't you want to gather information as soon as possible, to ensure that it's as accurate as possible? Were all assessments linked by study participant?

	Did you look at total number of tests ordered as an outcome? Wouldn't this be a positive indicator to assess? It might also be a bit more reliable to than self report of total used (although think total used still important metric to include as well). How likely is the update of a 234 item questionnaire 97 days after the intervention? In limitations section, think need more info to address how mitigating that the study relies on self-report, and that it's almost 3 months after the intervention. I don't think it's fully addressed in this section. Also, is it possible to provide a clear definition or description to the user on what exactly you mean by total tests used (of the tests ordered, how many individual tests are used, how many boxes or kits-- would be good to ensure it's clear so that you're comparing like scenarios).

VERSION 1 – AUTHOR RESPONSE

Reviewer Report:

Reviewer: 1
Ms. Eva Serhal, Centre for Addiction and Mental Health, University of Toronto

Comments to the Author:

How was the language/script validated to ensure if was easily understood and clear for study participants? Was there any pilot testing with a small group, or inclusion of people within the targeted study demographic group?

Response: The text messaging and chatbot scripts were designed based on in-depth interviews and surveys with the target population and validated with a study and patient advisory committee composed of clinical staff and patients from the participating CHCs. This was clarified in the Chatbot subsection under Methods as follows (bold text has been added).

The chatbot script was designed and guided by findings from a national survey and in-depth interviews with participants in the targeted Utah population, both conducted by our team. The following topics are covered: benefits of testing (even when already vaccinated or previously had COVID), when to test, test accuracy, how to use a test, and what to do if a test is positive. ***Both text messaging and chatbot scripts were validated through feedback from the study and patient advisory committee composed of clinical staff and patients from the participating CHCs****.*

How was the chat/text/navigation integrated within the EMR of the CHCs?
Response: We clarified this point in the first paragraph of the “Study Interventions” section as follows.

Eligible patients and their demographics data (e.g, name, date of birth, race, ethnicity, language, address, cellphone) will be extracted from the CHC EHRs through EHR reports prior to the trial launch. Demographics data will be used to determine eligibility, to support study interventions, and for study analyses.

What there any in session/in text evaluation of support/quality of the intervention?

Response: Please see response above about validation of text messaging and chatbot scripts.

It says the patient navigator called within 48 hours. This is a long time to await a response. Was there any correlation with positive use and the amount of time in which someone called back?

Response: We anticipate that most calls would be completed much sooner, in less than 12 hours, but specified 48 hours as the upper limit (this was clarified in the text below). We have not analyzed the trial results yet, so we currently do not have data on test use and the amount of time it took for navigators to call back.

*Participants randomized to the PN condition who request to speak with a patient navigator will receive a phone call within 48 hours**, although it is anticipated that most patients would be called within the same day or in the next day**.*

What was the 90 days chosen as the text follow-up timing? It seems like a long time to retain information. given this is self report, wouldn't you want to gather information as soon as possible, to ensure that it's as accurate as possible?

Response: Excellent point. We considered sending the text follow-up a few days after mailing a test kit. However, study participants could request a test kit regardless of symptoms and/or exposure. Thus, if we captured the outcome more proximally to delivery of the test, we would fail to capture a notable portion of potential test use. Therefore, we decide to give participants more time to actually use the kit. We do recognize that this is an important limitation, so the "Limitations" section was edited as follows to address this issue.

Second, the study relies on self-report for the primary outcome with a 90-day follow-up interval (Testing). Patients may not recall test use and maybe less likely to self-report test use after 90 days of requesting a test. However, a 90-day follow-up was chosen to give participants sufficient time to actually use a kit, given that participants could request a test kit regardless of current symptoms and/or exposure, and use the test whenever needed. To maximize response rates, we use two approaches to collect the primary outcome: a quick question via text messaging 90 days after exposure to study interventions and a survey at the end of the study, using multiple contact attempts as well as pre- and post-participation incentives.

Were all assessments linked by study participant?

Response: Yes, both text messages and post-study surveys were linked to study participants.

Did you look at total number of tests ordered as an outcome? Wouldn't this be a positive indicator to assess? It might also be a bit more reliable to than self report of total used (although think total used still important metric to include as well).

Response: Yes, number of tests ordered is a secondary outcome: *Reach-Accept Testing, i.e.* proportion of participants who are offered at-home testing and request a test (see details under the "Secondary and Implementation Outcomes" section). We considered using *Reach-Accept Testing* as the primary outcome, but the funding agency required testing uptake (actual test use) to be the primary outcome in trials funded under this mechanism.

How likely is the update of a 234 item questionnaire 97 days after the intervention?

Response: We do recognize that this is a major challenge. The funding agency required the use of the Common Data Elements survey. To maximize the response rate, we contracted with a survey company that used multiple methods of contact along with a pre-incentive and post-incentive for survey completion (see “Study Assessment” section for details).

In limitations section, think need more info to address how mitigating that the study relies on self-report, and that it's almost 3 months after the intervention. I don't think it's fully addressed in this section. Also, is it possible to provide a clear definition or description to the user on what exactly you mean by total tests used (of the tests ordered, how many individual tests are used, how many boxes or kits-- would be good to ensure it's clear so that you're comparing like scenarios).

Response: We agree that self-report after 90 days is an important limitation. We revised the “Limitations” section as described in response to a previous comment above. We also revised the definition of the primary outcome to clarify that it is a binary outcome, indicating whether or not a patient used an at-home test at least once, regardless of how many times they used a test.

Primary Outcomes and Hypotheses. The primary outcome is Testing; the proportion of study participants who use an at-home COVID-19 test ***at least once*** *during the course of 90-day study follow-up as defined below.*