## PEER REVIEW HISTORY



## ARTICLE DETAILS

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| **TITLE (PROVISIONAL)** | Study Protocol for Developing a Barbershop-Based Trial on Masculinity Barriers to Care and Colorectal Cancer Screening Uptake among African-American Men Using an Exploratory Sequential Mixed-Methods Design |
| **AUTHORS** | Rogers, Charles R.; Okuyemi, Kola; Paskett, Electra D; Thorpe Jr, RJ; Rogers, Tiana N; Hung, Man; Zickmund, Susan; Riley, Colin; Fetters, Micheal D |

## VERSION 1 – REVIEW

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| **REVIEWER** | Mary Kwaan<br>U.C.L.A. Department of Surgery<br>U.S.A. |
| **REVIEW RETURNED** | 15-Mar-2019 |

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| **GENERAL COMMENTS** | For the pilot study is the primary outcome FIT test compliance, or is it "recruitment, sample size estimation, preliminary efficacy and acceptability"? the latter concepts are not intuitively quantifiable- will need further explanation. Overall the manuscript is quite long some aspects in the methods could be abbreviated. |

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| **REVIEWER** | Frances Drummond<br>University College Cork, Ireland |
| **REVIEW RETURNED** | 11-Apr-2019 |

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| **GENERAL COMMENTS** | The aim of this paper is to develop, test and validate a culture specific Masculinity Barriers to Care Scale, evaluate the association between it and CRC screening among an online target pop, and to use info from their qualitative and quantitative findings to develop an intervention which can be delivered in a barber shop.<br><br>Targeting this population is important to reduce their cancer burden and possibly extend survival. I do find the paper to be a little confused and at times repetitive in its current state.<br><br>However I find their introduction on the effect of masculinity on CRC screening underdeveloped - please expand. Also I do not think the 'psychosocial factors' section addresses this topic sufficiently either and both of these paragraphs are dealing with masculinity primarily. Reference figure 1 in this section.<br>The authors propose that their study will address the gap between uptake and intention - did the authors of the MISTER B study find that masculinity constructs among AA men was one of the reasons for this gap? |

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| | Is the MBCS already developed? If so is there a reference for this? Who developed it - what does it consist of - there is no details on this, please add to the text. It is only when we come to page 11 that the authors discuss 'development' of the MBCS.<br><br>The study objectives on page 9 do not match those in the abstract.<br><br>In Materials and Methods - reference Figure 2 in line 3, page 9.<br><br>Important sociodemographic factors such as education and employment see to be not considered in this study? pf 11,<br><br>A priori - they assume that focus groups with 96 participants will result in saturation, this is alot of participants for a qualitative study - alot of data to code and manage.<br><br>Please elaborate on the incentives being offered (pg 13).<br><br>Reference needed re existing measures that examine masculinity (pg 13)<br><br>Will any of the target population be asked to participate in the cognitive interviewing? Will the MBCS be modified as a result of the CI? If so, please state this. Will they do any psychometric testing at any point during the study?<br><br>Again, please give the value of the gift card for transparency reasons on page 14?<br><br>How did the authors arrive at n=400 for the online survey - sample size calculation? (pg 14) - Refer to section on pg 15 when the sample size is first mentioned.<br><br>Will the barbers introduce the study to customers? Is this the only means of recruitment that will be used? What information will they be given? Will participation barbers receive any training or inducements?<br>Again - what incentives (1/5)? pg 14<br>Is there consideration given to the health literacy of the target population? What is the readability score of the 2 BRFSS questions?<br>Do the authors not think that medical mistrust, social support (, beliefs and attitudes will not be captured on their new MBSC scale? (pg 15)<br>Again, employment is not mentioned in the demographic covariates - a major factor in masculinity constructs (pg15).<br>What intended measures e.g. likert scales, are going to be used for each question and the intended scoring (e.g. raw/transformed scores etc) and interpretation are planned?<br>Pg 16 - their is no mention of what design will be used before the hypothesis ; so the trial will compare screening uptake among; (i) MI+FIT kits in the barber shop v (ii) FIT kits in the barber shop for AA men. It is not quite accurate to describe the former as culturally specific as both arms are.<br>Typo - pg 19, 'to a collaborator'<br>Unclear exactly what is being tested in the exit interviews? |

**VERSION 1 – AUTHOR RESPONSE**

| Reviewer #1 Comments | Research Team's Response |
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| For the pilot study is the primary outcome FIT test compliance, or is it "recruitment, sample size estimation, preliminary efficacy and acceptability"? the latter concepts are not intuitively quantifiable- will need further explanation. | Thanks for bringing this to our attention. As mentioned in the text and abstract, our primary outcomes for the pilot are recruitment, sample size estimation, preliminary efficacy, and acceptability. How the feasibility of the study protocol will be evaluated is explicitly provided in detail in the Analyses sub-section of the Two-Arm Intervention section. |
| Overall the manuscript is quite long some aspects in the methods could be abbreviated. | Great feedback. This is a multistage project as well as a mixed methods project. Thus, explaining the full protocol with sufficient detail justifies the length. With our original submission, the piece was still below the word limit for BMJ Open. |
| **Reviewer #2 Comments** | **Research Team's Response** |
| I find their introduction on the effect of masculinity on CRC screening underdeveloped - please expand. Also I do not think the 'psychosocial factors' section addresses this topic sufficiently either and both of these paragraphs are dealing with masculinity primarily. Reference figure 1 in this section. | Thank you for your comment. We agree with the Reviewer that that the masculinity and psychosocial factors were overlapping and/or underdeveloped. Thus, (1) the masculinity paragraph has been updated such that it is more substantive, and (2) the psychosocial-focused paragraph has been expanded upon and combined with the masculinity paragraph such that the introduction section is strengthened. Since our Exploratory Sequential Intervention Design (Figure 1) primarily reflects our approach for the proposed study, we feel that it is best to remain at the beginning of the Methods & Analysis section (the Overall Study Design subsection, specifically). |
| The authors propose that their study will address the gap between uptake and intention - did the authors of the MISTER B study find that masculinity constructs among AA men was one of the reasons for this gap? | This is a great point and thank you for raising it. The MISTER B study did not examine constructs of masculinity nor male role norms. The PI of the current paper identified the gaps after years of investigation as well as via the systematic review mentioned in the opening paragraph that he led. |

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| Is the MBCS already developed? If so is there a reference for this? Who developed it - what does it consist of - there is no details on this, please add to the text. It is only when we come to page 11 that the authors discuss 'development' of the MBCS. | Great point to bring to our attention. The MBCS has not already been developed. Yet, what the draft scale, pending modifications post-focus group data collection, currently entails has been added to the text. Specifically, the section now read as follows:<br><br>"For Objectives 1A and 1B (Years 1–2), we will collect and analyze qualitative data from focus groups and cognitive interviews to validate and test a culture-specific MBCS among African-American men. Questions for the MCBS will stem from modifications to the (a) the *Barriers to Help Seeking Scale* developed by Mansfield, Addis, and Courtenay [38], (b) the *Group-Based Medical Mistrust Scale* developed by Thompson et al. [39], (c) Mincey and colleagues' *Masculinity Inventory Scale* [40], (d) the *Male Role Norms Inventory-Short Form* by Levant, Hall, and Rankin [31], Bowleg and colleagues' *Black Men's Experiences Scale* [41], and the *Masculinity Salience* scale developed by Hammond et al. [13]." |
| | Thank you for bringing this to our attention. After reviewing the study objectives starting on page 9 previously and those in the methods & analysis section of our abstract, they indeed do match. |
| | The conceptual framework (Figure 2) for this study is already referenced in page 9, line 3's section entitled Methods & Analysis. |
| The study objectives on page 9 do not match those in the abstract. | |
| | Education and employment are included in the demographic characteristics captured in the Theoretical Foundation section ("We will also assess demographic characteristics (e.g., age, marital status, health insurance status) that…). |
| In Materials and Methods - reference Figure 2 in line 3, page 9. | Great observation. Twelve focus groups with a target of 8 men in each is indeed more than enough to reach saturation interventions. Yet as discussed, each group will be clustered |

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| Important sociodemographic factors such as education and employment see to be not considered in this study? pf 11, | by age and CRC screening status (**Table 1**), as they may be more comfortable with other African-American men of similar age who have/have not completed CRC screening. Since men in MN may not have the same views as men in UT, it is important for the samples to be created as such and compared accordingly. The team has substantial experience is qualitative data management and analysis. |
| A priori - they assume that focus groups with 96 participants will result in saturation, this is alot of participants for a qualitative study - alot of data to code and manage. | Thank you for your comment. We have elaborated such that the text now reads:<br>"Each participant will receive a $20 Target gift card and participants may choose to be entered into a random drawing to win 1 of 3 incentives: (1) an $100 pre-paid Visa gift card, (2) two tickets to a Utah Jazz or Minnesota Timberwolves basketball game in Fall 2019 (respective of your home state), or (3) a Samsung 55" 4K UHDTV." |
| | Noted. The draft MCBS measures have been added as reference. |
| Please elaborate on the incentives being offered (pg 13). | Participants from the focus groups will not be asked to participate in the CI's to avoid research participation burden, but members of the target population may indeed participate since CI's are open to CRC advocates and survivors from across the U.S. Since the MBCS may be modified as a result of the CI's, this note has been added to the text. Due to the study being a career development award (K01), the reviewers/funders felt psychometric testing and more focus on survey development could be another K01 solely. Thus, this piece was removed from one of the earlier proposals for the project, but the team will consider psychometric testing since the PI and one of the team members have expertise in this area. |
| | Noted. The amount of the gift cards has been added. |

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| Reference needed re existing measures that examine masculinity (pg 13) | |
| Will any of the target population be asked to participate in the cognitive interviewing? Will the MBCS be modified as a result of the CI? If so, please state this. Will they do any psychometric testing at any point during the study? | Correct: how we arrived at the n of 400 for the online survey is provided in the *Sample Size and Power Considerations* section. |
| Again, please give the value of the gift card for transparency reasons on page 14? | Unfortunately, we are unclear of what phase of our multi-stage project you are referring to. For the focus groups and online survey, as aforementioned, *we will use culture-specific marketing materials to promote the study through existing social networks, including newspaper advertisements, social media, predominantly African-American churches, air time on 2 radio stations (1 in Minneapolis, 1 in Salt Lake City) with a predominantly African-American male audience, and African-American male–serving barbershops*. In detail, the barbers' aid for the online survey phase will include them posting the culture-specific marketing materials in their shops. The barbers provided letters of support for the proposed study, so they are very aware of its goals. As a community-based participatory research study, the first author also communicated with his network of barbers frequently to obtain their thoughts on the best routes to take to effectively execute the proposed study. Accordingly, the first author (PI) will continue to do such until study completion as well. |
| How did the authors arrive at n=400 for the online survey - sample size calculation? (pg 14) - Refer to section on pg 15 when the sample size is first mentioned. | Duly noted. The incentives have been added. |
| Will the barbers introduce the study to customers? Is this the only means of recruitment that will be used? What information will they be given? Will | Yes, health literacy was considered. The *Male Role Norms, Knowledge, Attitudes, and Perceptions associated with CRC Screening* (MKAP-CRCS) survey developed by the PI has been utilized and published extensively on African-American men ages 18+. Thus, our team is confident that marrying these items to the MBCS will not hinder our target |

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| participation barbers receive any training or inducements? | population's participation considering the rigorous scale development and evaluation proposed (i.e., focus groups, cognitive interviews, & expert review).<br><br>Further, the BRFSS is the nation's premier system of health-related telephone surveys that collect state data about U.S. residents regarding their health-related risk behaviors, chronic health conditions, and use of preventive service. Even though we are not confident of the readability for the 2 BRFSS questions, we have used similar questions in the past for our studies with African-American men and do not foresee any issues with the 2 questions which will serve as dependent variables. |
| | Great point! Only medical mistrust will be captured in our new MBCS, so it has been removed from the sentence on pg. 15. |
| Again - what incentives (1/5)? pg 14 | "Other covariates" was initially provided to save text, but employment was always included. Nonetheless, employment has been added to the text. |
| Is there consideration given to the health literacy of the target population? What is the readability score of the 2 BRFSS questions? | Readers may refer to the published studies on the MKAP-CRCS scale to learn its response format. The response format for the Masculinity Barriers to Care sub-dimension will have a true (i.e., completely true, mostly true…not at all true) or frequency (i.e., Always, usually,…never) scale. The research team currently has the MBCS set up as items assigned to 6 factors. Intended scoring is forthcoming, yet the following has been added to the text:<br><br>"Six factors are expected for the underlying structure of the 21 items in the MBCS: (1) Need for Control and Self-Reliance, (2) Minimizing Health Problems and Resignation (3) Medical Mistrust, (4) Privacy, (5) Emotional Control, and (6) Black Masculinity. For all |
| Do the authors not think that medical mistrust, social support (, beliefs and | |

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| attitudes will not be captured on their new MBSC scale? (pg 15)<br><br>Again, employment is not mentioned in the demographic covariates - a major factor in masculinity constructs (pg15).<br><br>What intended measures e.g. likert scales, are going to be used for each question and the intended scoring (e.g. raw/transformed scores etc) and interpretation are planned?<br><br>Pg 16 - their is no mention of what design will be used before the hypothesis ; so the trial will compare screening uptake among; (i) MI+FIT kits in the barber shop v (ii) FIT kits in the barber shop for AA men. It is not quite accurate to describe the former as culturally specific as both arms are.<br><br>Typo - pg 19, 'to a collaborator'<br><br>Unclear exactly what is being tested in the exit interviews? | factors, individual items will be assessed on a Likert-type scale. Higher scores will indicate a greater degree of endorsement of masculinity barriers to care."<br><br>The use of a cluster-randomized design is mentioned in the *Participant and Procedures* section following the *Development* section. As noted in the Development section, the first author's research and evidence-based strategies will drive the control's arm. Yet, the culture-specific arm will result from data integration and the activities outlined extensively in Table 2.<br><br>Duly noted, and corrected.<br><br>Our text has been updated accordingly to note the following:<br><br>"Exit interviews will permit us to obtain rigorous outcomes data as well as participant accounts of what worked well and what did not for our two-arm intervention's implementation." |