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Protocol for #iBeatCRC: a community-based intervention to increase early-onset colorectal cancer awareness using a sequential explanatory mixed-methods approach

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ABSTRACT

Introduction The last two decades have seen a twofold increase in colorectal cancer (CRC) incidence among individuals under the recommended screening age of 50 years. Although the origin of this early-onset CRC (EOCRC) spike remains unknown, prior studies have reported that EOCRC harbours a distinct molecular and clinical phenotype in younger individuals. The sharp increase in EOCRC incidence rates may be attributable to a complex interplay of factors, including race; lifestyle; and ecological, sociodemographic and geographical factors. However, more research that address psychosocial experiences and accounts for lifestyle-related behaviours before, during and after an EOCRC diagnosis are warranted. This study aims to develop and pilot test a theory-driven, community-based intervention to increase awareness of EOCRC, reduce its associated risk factors and improve early detection among adults aged 18–49 years.

Methods and analysis Guided by the Behaviour Change Wheel, we will use a multistage mixed-methods study design. We will pilot a sequential mixed-methods intervention study as follows: (1) First, we will analyse linked quantitative data from the Utah Cancer Registry and National Cancer Institute Surveillance, Epidemiology and End Results registry, linked to state-wide demographic and vital records in the Utah Population Database to identify EOCRC hotspots in Utah by examining the EOCRC incidence and survival variance explained by personal and county-level factors. (2) Next, we will conduct one-on-one interviews with 20 EOCRC survivors residing in EOCRC hotspots to ascertain psychosocial and lifestyle challenges that accompany an EOCRC diagnosis. (3) Finally, we will consider existing evidence-based approaches, our integrated results (quantitative +qualitative) and community action board input to design a community-based intervention to increase EOCRC awareness that can feasibly be delivered by means of outdoor mass media, and via social media. We will pilot the multicomponent media campaign with a quasiexperimental design among 17 EOCRC hotspot residents and 17 EOCRC 'coldspot' residents.

Ethics and dissemination Ethics approval was obtained from the University of Utah Institutional Review Board (IRB_00138357). Signed informed consent will be obtained from all participants prior to any data collection. Study results will be disseminated through CRC community blogs, targeted infographics, conference presentations at national and international professional conferences and publications in peer-reviewed journals. Final intervention-specific data will be available on reasonable request from the corresponding author.

Strengths and limitations of this study

- By drawing on constructs of the Behaviour Change Wheel, our study will be among the first to offer a structured approach to designing a behaviour change-focused intervention for reducing early-onset colorectal cancer (EOCRC), while considering insights from a team of EOCRC advocates-survivors with research advocacy training and support expertise.
- Because African-American men are diagnosed with EOCRC at an earlier age and a more advanced stage compared with all other racial/ethnic groups, at least 10% of our interview sample will comprise members of this medically underserved population.
- Given the rising EOCRC burden among young adults, our study engages individuals diagnosed with CRC beginning at age 18 years.
- Although we may be unable to estimate EOCRC mortality rates in areas where mortality due to EOCRC is low, we will endeavour to do so, however, by using three spatial autocorrelation methods, including the Empirical Bayes smoothed rate method to account for counties with few cases, and by examining state-wide mortality data.
- Our study design and community-engaged approach of including EOCRC survivors in the research process will substantially enrich both the intervention development process and the validity of our findings and will provide a methodological example of a mixed-methods intervention design for this understudied, high-mortality cancer.

Trial registration number NCT04715074.

INTRODUCTION

Despite the life-saving potential of colorectal cancer (CRC) screening, 1 in 23 men and 1 in 25 women will die from CRC.[1] Mortality rates for CRC, once highest in the Northeastern United States, are now highest in the South and Midwest, a shift largely explained by race and socioeconomic status.[2] Although CRC incidence and mortality rates have declined among individuals aged 50 years and over,[2 3] they have increased among individuals younger than 50 years such that those born around 1990 have double and quadruple the risk of colon and rectal cancers, respectively, of adults born circa 1950.[4] By 2030, CRC incidence is predicted to increase by 28%–46% among young adults aged 35–49 years and by 90%–124% among those aged 20–34 years.[5] These trends demonstrate the importance of timely diagnosis among patients with early-onset CRC (EOCRC), who are often diagnosed at a more advanced disease stage.[6]

Although family history and genetic predisposition to CRC are significant contributors to CRC incidence,[7] the disease-specific risk factors for EOCRC are poorly understood. Recent studies propose that increasing EOCRC incidence may result from numerous early-life exposures (eg, obesity; physical inactivity; sedentary behaviours; fertility; smoking; antibiotic exposure; changes in microbial composition; increased consumption of high-glycaemic carbohydrates, high-fructose corn syrup and processed meat).[4 5 8–14] Shifting sociodemographics may play a role in early exposure through factors such as urbanicity.[15 16] Griffin *et al* found that African-American patients with CRC were more likely to reside in urban areas characterised by a higher prevalence of health risk factors such as obesity, diabetes, excessive drinking and smoking.[16] Urbanicity may also be characterised by the percentage of individuals eligible for Medicaid, percentage living in poverty, percentage higher education and higher median home values.[15] While urbanicity plays an important role in exposure, Carroll and Zhao reported conflicting results related to these sociodemographic and health risk factors, indicating a higher CRC survival when these elements are taken into consideration.[15] These complex urban contributions, as well as social influences on screening behaviours such as gender and cultural identity, specifically among African-American men, have not been well studied in EOCRC.[17 18] Although research on disease clustering in the USA has identified distinct geographic hotspots for CRC (ie, areas with the highest CRC mortality), such as the lower Mississippi Delta, west-central Appalachia and eastern Virginia/North Carolina,[19] these findings do not offer insights into the locations of EOCRC hotspots. Rogers *et al* recently addressed this gap by pinpointing national EOCRC hotspots in 232 counties in the lower Mississippi Delta, west-central Appalachia and eastern Virginia/North Carolina (notably, the same regions previously shown to have the highest CRC mortality).[13 14] To better understand the mechanisms underlying rising rates of EOCRC in geographic areas where CRC diagnoses are increasing, exploration of the potential causes of EOCRC from diverse perspectives is warranted.

Racial and ethnic disparities in EOCRC incidence and survival have grown more pronounced over the past decade,[3 8 9 20] with survival post-CRC diagnosis poorer among African Americans compared with Whites, even among patients with EOCRC.[9 16 21–25] Across all racial/ethnic and sex subgroups, African-American men have the lowest 5-year CRC survival and highest age-adjusted mortality rates.[24] Potential interactions associated with racial and ethnic differences in CRC incidence and survival among young populations include differences in CRC screening uptake, unequal access to high-quality treatment and clinical and molecular characteristics of EOCRC.[7 8] It remains unclear, however, whether these factors contribute to racial and ethnic disparities in EOCRC. Moreover, an ecological study by Rogers *et al.*, which used the Utah Population Database (UPDB) and linked Utah Cancer Registry (UCR) to characterise the contributions of race and cancer treatment to rural-urban disparities in CRC survival and risk among men in Utah,[25] supports the hypothesis that social and environmental conditions influence health behaviours and outcomes of rural and urban individuals with EOCRC, a phenomenon that merits additional in-depth exploration.

Study objectives

To better understand the aetiology of EOCRC and improve long-term survivorship and quality of life for EOCRC survivors around the world, we propose to:

1. Identify and characterise EOCRC hotspots in Utah by examining the EOCRC incidence and survival variance explained by personal and county-level factors (eg, marital status, race, tumour stage and grade, age, and receipt of surgery, chemotherapy or radiation therapy).
2. Pinpoint the psychosocial and lifestyle challenges that accompany an EOCRC diagnosis through interviews with 20 survivors residing in hotspots.
3. Develop and pilot *iBeatCRC*, a theory-driven, community-based intervention to increase awareness of EOCRC, its associated risk factors and the benefits of early detection among adults aged 18–49 years.

Our central hypothesis is that patients residing in Utah hotspots will have significantly worse EOCRC survival compared with those in other areas of the state. We also hypothesise that rurality and county-level access to healthcare will contribute to explaining EOCRC incidence and survival.

METHODS AND ANALYSIS

Study background and research design

We used the Standard Protocol Items: Recommendations for Interventional Trials checklist while developing this

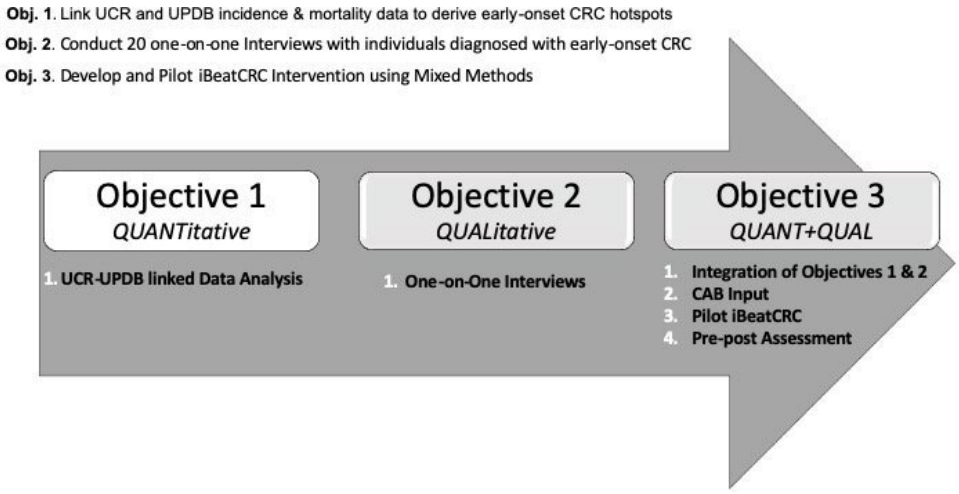

Figure 1 Community-engaged sequential explanatory intervention design. CAB, community action board; CRC, colorectal cancer; UCR, Utah Cancer Registry; UPDB, Utah Population Database.

manuscript,[26] and this study protocol has received ethics approval from the University of Utah Institutional Review Board (IRB_00138357), which will also be responsible for receiving communication updates about important protocol modifications. We will apply an explanatory sequential mixed-methods design for this study, which will be conducted across the state of Utah (figure 1). In detail, we will use quantitative methods for Objective 1 (Year 1) to link incidence and mortality data for the years 2000–2020 from the UCR linked to UPDB to derive county-level estimates of hotspots for EOCRC incidence and mortality among Utahns aged 18–49 years and obtain county-level estimates using our previous geospatial methods.[13 14] Counties with high EOCRC incidence and/or mortality rates (ie, in the fifth quintile of smoothed Empirical Bayes (EB) EOCRC mortality rates, a high-high cluster using local indicators of spatial association (LISA) and an EOCRC hotspot as defined by the Getis-Ord Gi* statistic) will be identified as hotspots.[13] Next, we will use UCR-UPDB linked data to determine the independent contributions of (1) geographical, (2) personal, and (3) county-level factors to EOCRC incidence and survival. We will perform hierarchical Cox regression models and implement a generalised R^2 analysis to determine the variance explained by each factor.

Next, in partnership with six EOCRC advocates-survivors, we will draw on factors associated with hotspots identified in Objective 1 and consideration of EOCRC-related literature—our team's prior research included—to inform the development of an interview guide for Objective 2 (Year 1).[13 14 27–30] Using the interview guide, we will conduct one-on-one interviews with 20 individuals who received a first diagnosis of CRC at ages 18–49 years. The qualitative data obtained from these interviews will be recorded, transcribed and analysed using Hatch's methods as previously used by our team.[31–33]

Lastly, Objective 3 (Years 1 and 2) will first focus on intervention development, which will be informed by integrating (1) the findings of Objectives 1 and 2 (quantitative +qualitative), (2) community action board (CAB) input, and (3) the Behaviour Change Wheel (BCW),[34] a step-by-step intervention development approach that uses theory and evidence-based methods to identify and address barriers. We will then pilot the *iBeatCRC* intervention, which may be based on a multicomponent media campaign, as endorsed by the Community Preventive Services Task Force for promoting CRC screening among individuals aged 50 years and over.[35 36] *iBeatCRC* may entail the use of both outdoor mass media and online social media and will target both EOCRC hotspots and 'coldspots'—(counties not categorised as hotspots)—in Utah. We will then conduct a pre-post assessment of the intervention among 17 hotspot and 17 coldspot residents.

Patient and public involvement

EOCRC survivors were involved in the conceptualisation of this study and will be involved in its future implementation and findings dissemination.

Hotspot identification

Participants and procedures

During the first 6 months of Year 1, we will link UPDB state-wide death certificate data from the years 2000 to 2020 to UCR[37 38] data to yield residential histories, demographics, clinical characteristics and survival information for each cancer diagnosis in Utah. Study participants aged 18–49 years at primary CRC diagnosis will be selected to reflect the state's ethnic and racial demographics: non-Hispanic White (NHW), Hispanic White, NH Black (NHB), NH American Indian/Alaska Native (NH AI-AN), NH Native Hawaiian/other Pacific Islander (NH Islander), NH and two or more races (NH Multiple), Hispanic and non-White, and Hispanic and two or more races (H Multiple). We will assess residence and county-level characteristics—for example, rurality, primary care physicians/population, household income below $20,000/year, unemployment rate and healthy

food access, among other factors—through publicly available American Community Survey and County Health Rankings databases.

To derive incidence and mortality hotspots, we will use ArcGIS V.10.5 and GeoDa V.1.6.7.9 to obtain county-level estimates using novel geospatial methodology that has been described previously by principal investigator and first author CRR and colleagues.[13] Using UPDB–UCR linked data,[37 38] we will define EOCRC incident cases and deaths among Utah residents. County-level total case numbers, crude rates and age-adjusted rates of EOCRC will be identified using International Classification of Diseases, Tenth Revision codes for colon-specific and rectum-specific cancers. Geospatial analyses will be performed using three geospatial autocorrelation measures: EB smoothed EOCRC mortality rates, LISA and the Getis-Ord Gi* statistic.[39–41] Counties with high rates of EOCRC incidence or mortality based on all three geospatial methodologies will be identified as hotspots.

Data analyses

We will compare patient and county characteristics using χ^2 tests for categorical variables, analysis of variance (ANOVA) for parametric continuous variables and Wilcoxon rank-sum tests for non-parametric continuous variables. Survival time will be calculated from diagnosis date to either the last follow-up date or the date of death. A two-sided p value <0.05 must be met for statistical significance. Kaplan-Meier analysis will compare overall survival by hotspot residence among patients of various racial demographics. Poisson regression will be used to calculate EOCRC incidence and Cox proportional hazards models to estimate EOCRC survival. Incidence per 1000 population, incidence rate ratios, HRs and 95% CIs will be estimated. Age will be included in adjusted models; we will adjust all models for patient-level factors that are found in bivariate analysis to reach statistical significance. We will also stratify all analyses by race and gender. Data may be excluded for participants with missing follow-up time, those diagnosed with a prior malignant cancer and those with an unknown surgical procedure.

A generalised R^2 analysis will be employed using a statistical macro developed by our team based on the likelihood ratio statistic reported from Cox regression. To estimate the total variance in outcome explained by each explanatory factor, we will calculate generalised R^2 using methods adapted for a Cox proportional hazards model by Allison[42] from the Cox and Snell[43] method. Statistical and geospatial analyses will be led by KMK using SAS V.9.4 (SAS Institute).

Sample size and power considerations

At the 5% significance level and 80% power, the minimum sample size needed to achieve Objective 1 is 5274 subjects in each stratum (race-gender combination). We assume (a) that the studied age group makes up about 48% of the population; (b) that the lifetime risk of developing CRC is 4.2%; (c) that the distribution by race is 78.8% NHW, 13.8% H, 1.1% NHB, 1.0% NH AI-AN, 2.4% NH Asian, 1.0% NH Islander and 2.0% NH Multiple; (d) that 8% of CRC cases will occur in hotspot counties; (e) an effect size of HR=2.0; and (f) a two-sided log-rank test. This number is achievable as the population of Utah includes 15 000 individuals aged 18–49 years in the smallest race category of NH Islander. An 80% power will still be maintained for the NHB race category even if the observed effect size is HR=1.7 (ie, 30% lower than we have hypothesised). Moreover, there is no loss of generality if a one-sided test is used instead, given the direction of the effect in previous research, which subsequently permits us to establish significance even for an effect size smaller than HR=1.7.

Interviews

Participants and procedures

During the last 6 months of Year 1, we will conduct (via video/audioconferencing considering the COVID-19 pandemic) 20 1-hour interviews—sufficient for data saturation[44]—with patients with EOCRC and EOCRC survivors who (1) reside in Utah, (2) were diagnosed with CRC at 18–49 years of age, (3) have a telephone, and (4) speak English. We will apply a sampling approach to be able to interview at least two (10%) eligible African-American men, since this population is diagnosed with CRC at an earlier age and a more advanced stage compared with all other racial/ethnic groups.[2 5 10] We will also interview at least three (15%) eligible Hispanics, since Hispanics make up Utah's fastest growing minority population.[45] For our participant-driven sampling technique, we will adapt marketing and recruitment strategies based on recommendations by six EOCRC survivors-advocates (PG, CH, WH, WJ, EN, CP) who are extensively trained on increasing CRC awareness and engagement with researchers, academia and cancer partners during the second and third quarters of Year 1. For example, if our EOCRC survivors-advocates are concerned about incorporating a range of younger (eg, 20–35 years) ages among the 18–49 group, or if there is a perspective that they believe is missing (eg, within the Hispanic population) we will adjust our sampling to expand recruitment to these groups. Interview participants will receive a $30 Amazon gift card. Advocate-survivor team members will be compensated at $25 per hour for an expected 50 hours in Year 1 and 10 hours in Year 2.

Data collection and analyses

A CRC advocate-survivor will obtain informed consent and facilitate the interviews using an 8–10 question topic guide developed by the survivor-advocate team, CRR and MADV. One of two study graduate-level research assistants (GRAs) will take notes. Informed consent will be obtained prior to each interview. Interviews will be recorded, professionally transcribed and validated. Qualitative methods akin to Hatch's nine-step inductive approach[31] will be employed. Two GRAs will analyse transcripts using multiple-cycle coding and constant comparative data

analysis methods.[46 47] TNR will referee coding disagreements. SAS V.9.4 will be used for interview-specific demographic data analysis.

Intervention

Integration

Consistent with a sequential explanatory study design as described by Fetters and colleagues,[48] we will merge quantitative and qualitative data from Objectives 1 and 2 to identify content areas for contrasting, comparing and synthesising. Two team members (MAH and CRR) will determine to what degree and how the findings from the combined data sets yield a richer understanding of the impact of psychosocial, lifestyle and familial aspects on an EOCRC diagnosis. What we learn via this process, which will begin in the last quarter of Year 1, will inform the development and implementation during the first 6 months of Year 2 of an intervention, *iBeatCRC*, to increase awareness of EOCRC and related risk factors.

Development

In collaboration with our CAB (comprising four members of the Utah Colorectal Cancer Roundtable, six advocates-survivors, and coauthor MADV), we will adopt the BCW[34] to develop a theory-driven intervention aimed at increasing awareness of EOCRC, its risk factors and the benefits of early detection. Information from (1) our integrated Objective 1 and 2 results; (2) input from MAH, CRR, and the CAB; and (3) existing CRC screening intervention evidence from Research-Tested Intervention Programs, The Community Guide and Cancer Control PLANET, among others,[49–51] will be used to apply the APEASE (*Acceptability, Practicability, Effectiveness/cost-effectiveness, Affordability, Safety/side effects, Equity*) criteria (table 1). This process will occur during four 90 min small-group discussions at which refreshments will be provided; CAB members will be compensated with a $50 Amazon gift card for each session that they attend (either in person or remotely).

iBeatCRC pilot testing

We anticipate using a professional outdoor advertising company (Outdoor Advertising Guide[52] or Capitol Outdoor[53]) who will provide the study team with daily effective circulation data (number of views) and demographic information (of most likely viewers) of *iBeatCRC* mass media ads,[54] which may entail digital video ads at gas station pumps, full-side bus panels, freeway billboards and small poster panels near bus shelters, transit stations and shopping malls. If this route is used, the BCW will assist with determining the best content for these platforms—culturally tailored marketing included for populations at highest risk for EOCRC. Similarly, Union Metrics[55] will provide in-depth analytics on social media posts across Twitter, Instagram and Facebook, including reach, engagement, content performance and competitive analysis. *iBeatCRC* is projected to last 4–6 months. Utah hotspots will be targeted for 50% of the pilot period; implementation in coldspots will provide a comparator. The CAB will also advise, if needed, on additional strategies to improve uptake of our proposed intervention.

Assessment overview of iBeatCRC impact

After obtaining informed consent, baseline knowledge (pretest) will be assessed among 17 hotspot and 17 coldspot residents—Utahans aged 18–49 years at primary CRC diagnosis—using a portion of the health information-seeking behaviours among individuals with young-onset and average-onset CRC survey developed by coauthor MADV.[28] Moreover, precautions expected by the IRB will be taken to protect the confidentiality of the potential and enrolled participations before, during and after the intervention.

Data analyses and sample size calculation

The intervention will be assessed with a post-test questionnaire among the above-mentioned 17 hotspot and 17 coldspot participants. Preintervention and postintervention mean score differences will be tested using repeated measures ANOVA. Preintervention and postintervention EOCRC awareness change will be analysed by McNemar's test. $P \leq 0.05$ will be considered statistically significant. This objective will be powered based on the hypothesis that a mean knowledge index score about EOCRC, its risk factors and early detection benefit in young to middle-aged adults will be significantly higher post-*iBeatCRC*. At the 5% significance level, and assuming 80% power,

Table 1 Behaviour Change Wheel activities to drive trial development

(1) Behavioural diagnosis	Use the BCW to determine what needs to change to increase family communication and awareness of EOCRC and early-detection screening among young to middle-aged adults.
(2) Intervention strategy selection	Use (1) to decide which BCW intervention functions to apply (eg, education, persuasion, enablement).
(3) Behaviour change technique identification	Develop a detailed intervention plan by selecting from among a range of specific, evidence-based behaviour change techniques (eg, freeway billboards providing information about the increasing rates of EOCRC both in Utah and nationally), while considering findings from Objectives 1 and 2.
(4) Draft full intervention specifications	Create the detailed intervention specifications, covering all aspects of content and delivery (3).

BCW, Behaviour Change Wheel; EOCRC, early-onset colorectal cancer.

a two-sided log-rank test and a medium effect size of Cohen's f=0.25, the minimum sample size to achieve this aim is 34 (17 hotspot and 17 coldspot residents). A correlation of 0.5 between repeated measurements and a non-sphericity correction of 1 will be assumed.

CONCLUSION

Completing our objectives will yield preliminary data for a full-scale efficacy trial. More broadly, this research will inform the national EOCRC research agenda and provide information that may be used to urge legislators to aid in improving CRC screening access and to prioritise funding for a disregarded and often misdiagnosed population. Overall, our efforts will both increase understanding of the aetiology of an EOCRC diagnosis and contribute to improving long-term survivorship and quality of life for EOCRC survivors worldwide by studying the burdens that accompany this condition. Although our results will be generalisable to other US populations which comprised primarily individuals of northern European descent, our findings will also set the stage for subsequent studies aimed at exposing the intricate factors underlying the disturbing increase in EOCRC incidence and provide an example of combining hotspot geographic information system (GIS) methodologies with localised participatory research. A better understanding of these factors will contribute to equitably improving outcomes for patients with EOCRC, resulting in reduced barriers to care and improved long-term survivorship (both of which are priorities in the 2016–2020 Utah Comprehensive Cancer Prevention and Control Plan)

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Contributors CRR: PI, conceptualisation, methodology, writing–original draft, writing–review and editing, supervision, project administration, funding acquisition. EB: writing–original draft, writing–review and editing, project administration. KC: conceptualisation, methodology, writing–original draft, writing–review and editing. FQ: conceptualisation, methodology, analysis plan, data curation, writing–original draft, writing–review and editing. TNR: conceptualisation, methodology, analysis plan, writing–original draft, writing–review and editing. EP, PG, CP, WJ, CH, WH, EN, MADV: writing–original draft, writing–review and editing. KMK: writing–review and editing. MAH: conceptualisation, methodology, analysis plan, writing–original draft, writing–review and editing, supervision. All authors read and approved the final manuscript. KMK, TNR, KC, MADV and MAH serve as data monitoring committee (DMC) members for this study; additional data monitoring, harms and auditing logistics are available from the University of Utah IRB. To ensure that the overall results of the pilot trial are not disclosed prior to the main publication, only the DMC will have access to the full data set. The DMC will also have the privilege of making the final decision to terminate the trial (if necessary), while CRR and EB will be responsible for communicating important protocol medications to the IRB. All authors agreed to be accountable for all aspects of the study to ensure that questions related to the accuracy or integrity of any part of the study are appropriately investigated and resolved.

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