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Designing a randomized controlled trial to evaluate a community-based narrative intervention for improving colorectal cancer screening for African Americans

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Abstract

Objective—To describe the methodology of a 2-arm randomized controlled trial that compared the effects of a narrative and didactic version of the Witness CARES (Community Awareness, Reach, & Empowerment for Screening) intervention on colorectal cancer screening behavior among African Americans, as well as the cognitive and affective determinants of screening.

Methods—Witness CARES targeted cognitive and affective predictors of screening using a culturally competent, community-based, narrative or didactic communication approach. New and existing community partners were recruited in two New York sites. Group randomization allocated programs to the narrative or didactic arm. Five phases of data collection were conducted: baseline, post-intervention, three-month, six-month, and qualitative interviews. The primary outcome was screening behavior; secondary outcomes included cognitive and affective determinants of screening.

Results—A total of 183 programs were conducted for 2,655 attendees. Of these attendees, 19.4% ($N = 516$) across 158 programs (50% narrative; 50% didactic) were study-eligible and consented to participate. Half (45.6%) of the programs were delivered to new community partners and 34.8% were delivered at faith-based organizations. Mean age of the total sample was 64.7 years and 75.4% were female.

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Conclusion—The planned number of programs was delivered, but the proportion of study-eligible attendees was lower than predicted. This community-based participatory research approach was largely successful in involving the community served in the development and implementation of the intervention and study.

Keywords

colorectal cancer screening; African American; community-based intervention; colonoscopy; recruitment; randomized controlled trial

1. Introduction

Colorectal cancer (CRC) is a leading cause of cancer morbidity and mortality in the United States [1]. African Americans are at higher risk for both the incidence of and death from CRC than any other ethnic/racial group [1], with 22% higher incidence and 49% higher mortality than their white counterparts. CRC screening can reduce CRC incidence and mortality, but adherence to screening guidelines remains lower than national goals and rates for other screening modalities [2], especially for underserved populations [3].

Several complex and multilevel factors influence CRC screening adherence [4–6], but screening ultimately requires a decision to screen made by an individual. Health decision-making models suggest these decisions are influenced by both cognitive and affective/emotional factors [7–11]. Using colonoscopy screening as an example, lack of knowledge is a cognitive barrier, and negative affective associations (e.g., embarrassment and disgust about the procedure, or fear about pain and test results) are affective barriers that are associated with lower screening rates. Studies suggest affective associations may be particularly important determinants of screening behaviors [11, 12], and therefore an important, but underexamined, target for CRC screening interventions.

Narrative communication strategies may provide an effective approach for interventions addressing the affective determinants of behavior. Narratives are first-person accounts of one's personal experience with a behavior or health threat [13]. In the realms of diet, exercise, and cancer screening, narrative interventions, such as survivor stories and testimonials, have effectively reduced cognitive and affective barriers, and increased engagement in or intentions to engage in the target behavior [14–17].

1.2. The Witness CARES Intervention

The intervention described here, The Witness CARES (Community Awareness, Reach, & Empowerment for Screening) Project, is a culturally competent, community-based education program developed with the goal of increasing CRC screening in African American adults, thus advancing the goal of reducing racial/ethnic disparities in CRC incidence and mortality. To achieve this goal, the intervention targeted both cognitive and affective predictors of CRC screening using a culturally competent, narrative or didactic communication approach. It was designed to be delivered in a community setting, thus bypassing several system-level barriers (see theoretical framework illustrated in Figure 1).

This paper describes the innovative methodology of a randomized controlled trial (RCT) comparing outcomes of a narrative-based Witness CARES program to that of a traditional, didactic educational version. Recognizing the need for community expertise and engagement, all phases of the study, including trial development, patient recruitment, and data quality monitoring, were conducted in accordance with a community-based participatory research (CBPR) process. The primary goal was to increase African Americans' engagement in CRC screening by targeting changes in cognitive and affective determinants of screening (results forthcoming). We hypothesized that the narrative program would increase screening intentions and behavior relative to the didactic intervention, which served as the standard of care control, and that this increase would be mediated by changes in both affective and cognitive screening predictors (see Hypotheses).

2. Methods

2.1. Overview

This intervention used an RCT with pre-post assessments of decision-making factors and behavioral outcomes to examine the effect of the Witness CARES narrative program compared to the didactic, standard of care control program. Programs were conducted in upstate/western New York (WNY) and New York City (NYC) and the institutional review boards for each site approved all study procedures and materials prior to data collection.

2.2. Hypotheses

Given the literature supporting the effectiveness of narrative communication in community-based group settings as a means of increasing screening behavior, we hypothesized the following:

- H1** The narrative-based Witness CARES program will be more effective than the didactic program at increasing positive affective and cognitive evaluations, and reducing negative affective and cognitive evaluations, of CRC screening.
- H2** The narrative-based Witness CARES program will increase screening intentions and behavior (having had or scheduled a colonoscopy or performed a stool test 6-months post-intervention) more than the didactic program.
- H3** Compared to the didactic programs, the narrative programs will evoke a greater increase in participants' discussions with their primary care provider about CRC screening, including asking for screening referrals and initiating these discussions themselves. Given these discussions are a preliminary step to engaging in screening behavior, the narrative programs' effect on this outcome will elucidate one potential mechanisms through which it increases screening rates.

2.3. Recruitment of study sites

It was estimated that 180 community-based programs (averaging 15 attendees each) would be needed to achieve the desired sample size (see 2.7.3. Power and sample size calculation). Potential host sites were recruited from within African American communities in NYC and

WNY by reaching out to both existing and new community partners and offering to conduct an educational program about CRC. Targeted sites included block clubs, senior centers, community centers, housing projects, faith-based, and fraternal organizations.

Existing community partners had been previously established through prior community health promotion projects. For instance, in WNY, a long-standing partnership with the First Ladies of Western New York (FLOW), an organization of local pastors' wives, was leveraged for ongoing counsel, advice, and expertise on community-based participatory research activities.

Recruitment of new sites involved activities, such as 'walking tours' in targeted NYC communities, and Witness Project [18] volunteers connecting study personnel with local groups and community partners. Program participants and hosts were also encouraged to recommend new program hosts. Special effort was made to recruit sites that had a high proportion of male and older (aged 50 and over) participants.

2.3.1. Eligibility criteria—Participation in the main, hypothesis testing research component was restricted to adults who met all the following eligibility criteria: 1) aged 50 or older (recommended age for starting screening); 2) self-identified Black/African American (given the study's purpose of evaluating an intervention for African Americans); and 3) non-adherent to CRC screening guidelines (i.e., never screened for CRC or screened less often than guidelines recommend). As with other community-based outreach efforts, we expected some community residents to attend Witness CARES programs with their spouses, friends, and even children, some of whom would not be eligible for the study. Attendance at the session was open regardless of trial eligibility.

2.4. Overview of Study Procedures

Programs were delivered to small groups and lasted an average of 60 to 75 minutes. At NYC sites, they were delivered by one or two ethnically-congruent study staff in addition to several lay health advisors. In WNY, one staff member and as many as four community volunteers delivered each program. All staff and volunteers who were engaged in consenting and/or data collection activity received both human subjects research protection training and program-specific training for data collection activities. Program hosts always introduced the "study team" to program attendees. All attendees were remunerated with a \$5 gift card or an NYC roundtrip subway pass and a chance to win a \$25 gift card (one per program) for their participation.

Each program included the following sequential procedures: 1) IRB information sheet and registration cards distributed; 2) paper-and-pencil baseline survey; 3) group oral consent process (including remuneration procedures); 4) electronic key pad and automated response system (ARS) instructions and interactive ARS pre-intervention assessment; 5) intervention video and lecture; 6) interactive ARS post-intervention assessment; and 7) Q&A session.

Print information and a directory of local CRC screening resources were available to all participants and included information about stool tests (e.g., fecal immunochemical tests or FIT tests), colonoscopy, local primary care clinical services, and a Patient Guide with

questions to ask one's physician about screening. Uninsured participants were also informed about their eligibility for the New York State Cancer Services Program, which provides free CRC screening for all uninsured adults ages 50 and over.

2.4.1. Randomization—Participants were randomized to the narrative or didactic study condition using a group randomization method that assigned each program to one of the two study conditions in a 1:1 allocation ratio. Randomization assignments were done using two sets of consecutively numbered sealed envelopes: one for WNY and one for NYC. Immediately before each program, the project director at the program opened the lowest numbered envelope remaining in the site-specific set to determine the program arm. Participants were blinded to study condition, but the program staff were not.

2.4.2. Consenting process—The original protocol included obtaining written consent at both sites, but this quickly became problematic for recruitment because it was a time-consuming process and there was resistance from some potential participants, especially older African Americans, to sign a multipage legal form. Thus, we received IRB approval to obtain oral consent instead, which was facilitated by the staff member conducting the program (paper copies of consent forms were available upon request). All program attendees who decided to participate signed a "Contact Card" in which they gave us permission to contact them in the future.

2.4.3. Pre-intervention assessment—Baseline levels of screening behavior and cognitive and affective determinants of CRC screening were captured using a combination of a paper-and-pencil survey, followed by an electronic ARS questionnaire. After completing the paper-and-pencil survey, participants were instructed on how to use their electronic key pads to respond to ARS survey questions [19, 20]. The ARS system is intended to increase audience participation and interaction during a presentation. Audience members respond to multiple choice survey questions throughout the presentation using an electronic keypad. The real-time survey results can then be presented to the group as part of the presentation and results can serve as discussion points. Participants completed several practice questions and were informed about the anonymity of their responses to other participants and that all data would be de-identified. Program staff then presented PowerPoint slides with ARS survey questions about CRC knowledge and attitudes.

2.4.4. Intervention delivery—Participants then watched either the narrative or didactic version of an eight-minute video about colonoscopy screening, depending on study condition. In the narrative video, the screening information was presented as a personal narrative communication, whereas, in the didactic video, information was presented in a fact-based format (see 2.5.1. Video development).

With the exception of the video, all intervention content was identical across conditions. Following the video, there was a brief PowerPoint educational presentation, which included information about the alternative screening tool (FIT test) used by the NYS Cancer Services Program (slide 1), how the test is used (slide 2), references and information about the NYS Cancer Services Program (slide 3), a list of five questions to ask your doctor at your next

appointment (slide 4; also provided on a wallet-sized paper resource), and a review of CRC facts (also distributed as a fact sheet).

2.4.5. Post-intervention assessment—Following the last educational slide, an interactive ARS format was used to conduct a post-intervention survey to capture immediate changes in cognitive and affective screening predictors and in screening intentions.

2.4.6. Determining study eligibility—All attendees completed a registration card on which they provided their contact information (telephone number, address, secondary contact, best times to reach them), as well as their age, race, and screening history. Program staff used these cards to determine study eligibility.

2.4.7. Three- and six-month follow-up interviews—Whereas all program attendees completed the pre- and post-intervention surveys at the educational programs, only eligible and consented participants were re-contacted at 3- and 6-months for follow-up interviews. For each interview, participants received a reminder postcard ahead of time and were interviewed by telephone. The purpose of the 3-month interview was to help maintain contact, validate address and contact information, validate screening status, and assess CRC screening-related eligibility. Participants ($n = 211$) were remunerated with a \$10 gift card for completing this interview. Participants who were unscreened at the 3-month interview were re-contacted at 6 months to assess their self-reported screening behavior, screening intentions, and other factors related to screening and care seeking. Participants ($n = 109$) were remunerated with a \$20 gift card for completing this interview.

2.4.8. Qualitative interviews—A subsample of 39 randomly selected study-eligible participants completed a 30-minute qualitative interview by telephone approximately one week after the program (reflecting the number of interviews needed to reach saturation of responses [21]). Interviews were conducted using an interview guide to ensure fidelity and consistency. These interviews were intended to explore more deeply how the intervention methods at the community level influenced individual-level determinants of health-seeking behaviors and CRC screening decisions. A second interview ($N = 26$) was conducted six months after the program to explore whether and how the intervention influenced longer-term effects on PCP discussions and actual screening behavior. Thus, a total of 65 interviews were conducted, with 25 participants completing both the one-week and six-month interviews ($n = 13$ narrative; $n = 12$ didactic). Participants were remunerated \$30 gift card for each interview.

2.5. Witness CARES intervention development

2.5.1. Video development—The narrative and didactic communication videos were created by a professional video production office specifically for the Witness CARES intervention. Both videos featured the same male and female African American CRC screening role models (who had been screened themselves) as speakers. The two videos were intentionally identical in terms of length, speakers, and the information presented, but special effort was made to ensure they were noticeably different in terms of the targeted information delivery format. For example, while both videos addressed common barriers to

being screened, in the didactic version, this information was mentioned among a list of barriers to screening, whereas in the narrative version, the speakers discussed their own feelings and concepts about fear, disgust and actually experiencing their colonoscopy in the context of a personal story delivered by someone who was initially fearful of the process, but coped well with it and was successfully screened (see Figure 2 for video screenshots).

Following initial video recording, the draft videos were reviewed by study staff, community representatives, and the two role models. An iterative process of providing feedback, editing in response to the feedback, and returning to constituents for viewing and feedback was used, resulting in approximately six iterations of editing and reviewing. Areas for feedback included the script, information content, mode of presentation, length, acting, role models (e.g., whether they were relatable), and the visual characteristics of the videos.

2.5.2. Study development—The study team worked to ensure that all program material matched the information conveyed in the video, and that all measures were appropriate for testing hypotheses and evaluating the program. Three- and six-month interviews were pre-tested and all staff conducting them were trained. PIs attended six pilot programs (that included some combination of surveys, videos, consent process, PowerPoints, and ARS), after which informal feedback was obtained from the approximately 90 total attendees about suggestions for improvement. All qualitative interviews were audio-recorded and the first five at each site were evaluated by PIs to assure fidelity.

Once intervention programs began, the PIs and other staff attended a selection of four early programs and compared their evaluations of program delivery and made suggestions for improvements. Ongoing discussions by Project Coordinators and staff were conducted at weekly study team meetings (either face-to-face or via conference call) and were used to compare program delivery, data collection, and study processes.

2.6. Measures

Table 1 outlines all primary and secondary outcome measures, including time-points at which they were assessed, number of items, and reliability (Cronbach's alpha).

2.6.1. Primary outcome measure—CRC screening with colonoscopy and/or stool test at 6-months as measured by self-report served as the primary outcome measure.

2.6.2. Secondary outcome measures—Intentions and plans to be screened for CRC as well as health-seeking behaviors (e.g., discussions with one's physician about CRC screening; intentions to discuss screening) were assessed as secondary behavioral outcomes [adapted from 22].

2.6.3. Intermediary outcomes—Given that this was a multifaceted intervention, it may have activated several decision-making mechanisms or intermediaries between the intervention and screening behavior. Moreover, the narrative and didactic versions may have activated these intermediaries differently (e.g., we hypothesized the narrative intervention would activate the affective determinants of screening more than the didactic version). Thus,

we assessed several decision-making predictors in order to examine these potential mechanistic differences, including both affectively- and cognitively-based constructs.

Many decision-making constructs have distinct cognitive and affective dimensions that can be independently and differentially related to behavioral outcomes. Individuals have cognitive beliefs that may serve as barriers to CRC screening, such as the perception that screening is ineffective or too expensive, and they also have emotional reactions (i.e., affective associations) to the procedure, including disgust, embarrassment, and fear. Cognitively, individuals can estimate or perceive how likely they are to be diagnosed with CRC (cognitively-based risk perception). Individuals also have an affective or emotional reaction to the risk of CRC, including feelings of fear or worry (affectively-based perceived risk).

The cognitive constructs that were assessed as intermediaries included: perceived screening benefits and barriers [23], cognitively-based perceived risk of CRC [24–26], knowledge about colonoscopy and CRC, and self-efficacy [27, 28]. Social influence, including social norms related to CRC screening, social ties, and ties specific to the program were also assessed [29]. Affective constructs included: affective associations with colonoscopy (e.g., *When you consider having a colonoscopy how do you feel? Do you feel relaxed?*) [10, 30], affectively-based perceived risk of colorectal cancer (e.g., *How worried are you about getting colorectal cancer at some point in your life?*) [24–26], and fear of colonoscopy (e.g., *How fearful are you of the overall colonoscopy procedure?*) [31].

2.6.4. Other baseline measures—Several constructs were assessed at baseline given their potential to influence the intervention’s effectiveness and key study outcomes. These included: CRC screening history, history of screening for other cancers, and past health care experiences [32, 33], including whether one has a primary care physician and the quality of past screening-related discussions with one’s physician. Several socio-demographic characteristics were also assessed, including marital status, place of birth, employment status (employed/not employed), education (7-point scale), and income (8-point scale).

2.6.5. Qualitative interviews—An interview guide was designed to deepen our understanding of the intervention methods, format, outcomes, and other unknown social and environmental variables that might promote or hinder screening-related behaviors that are evident from the quantitative results. Interview questions probed specific memories about the program’s video, speakers, key points about the messages, and any accompanying feelings the participants had (e.g., *“Can you describe your understanding of... colonoscopy? Do you think attending the program impacted your thoughts/feelings...about screening... talking with your doctor?”*) Full methods and results from the qualitative interviews will be reported elsewhere.

2.7. Data analysis and quality control

2.7.1. Fidelity observations—A Program Summary Form was completed by a staff member after each program to record key aspects of program delivery and provide site comparison data (see Figure 3). It was developed and validated in one of the PIs’ previous multi-site RCT intervention studies [19] and served several functions, including providing

the information needed to: 1) track the number of programs, attendees, and study participants across study conditions and program sites (WNY or NYC); 2) assess implementation fidelity (e.g., program duration; whether each component was administered as intended); and 3) record other potentially influential factors, such as location, opening prayers, other non-programmatic activities, recruitment method, and prior experience at that site (manuscript in preparation).

2.7.2. Data sharing and transfer system—Because this intervention was administered at two geographic locations (WNY and NYC), a data sharing and transfer system was established to streamline data management and the generation of progress reports. Each site program coordinator was responsible for completing a program summary after each program (see Fidelity Observations above), and ensuring data from each summary was uploaded to the master server. In addition, the data from the educational programs was electronically stored and merged at the data coordinating site (NYC). A data manager then managed all entered data from both study sites in a master database, thereby facilitating a coordinated centralized data management system that provided timely, consistent, and accurate communication of progress at each site.

2.7.3. Power and sample size calculation—Sample size was estimated based on the number of participants needed to detect an effect of study conditions on the cognitive and affective decision-making constructs. We anticipated effect sizes would be comparable to those in a similar narrative communication study that compared differences in cognitive and affective response to narrative and didactic information delivery [34]. Assuming similar results, an attrition rate of 25% based on our prior studies, and $\alpha = .01$, we estimated a sample size of $N = 895$ was necessary to detect an effect of study condition with 99% power. This sample size also afforded an expected confidence interval width of 13 percentage points for our primary screening outcome variable.

Based on initial piloting of Witness CARES programs, it was estimated that 180 programs (averaging 15 attendees per program; 2,700 total attendees) would need to be delivered to achieve this sample size. This estimate assumed 70% of program attendees would be African Americans aged 50 or older, and that 50% of these individuals would be non-adherent to CRC screening guidelines (based on screening rates at the time the grant was written). Also based on previous work, we estimated that approximately 95% of study-eligible participants would provide informed consent and enroll in the study, thereby enrolling 895 participants ($2,700 \text{ attendees} \times 0.70 \text{ aged fifty or over} \times 0.50 \text{ non-adherent} \times 0.95 \text{ consenting} = 895 \text{ total participants}$).

2.7.4. Data analysis plan—All planned statistical analyses for this intervention delivery and data collection protocol will be performed on an intent-to-treat basis according to the following analytic plan using SAS statistical software (Cary, NC). Because participants were nested within programs (i.e., not statistically independent) and data collection occurred over multiple time points (i.e., repeated measures), the analytic plan accounts for this doubly nested structure of the data. Participant data across the four time points (baseline, post-intervention, 3-month, 6-month interviews) will be linked with a personal identifier that was assigned to them upon arrival at the program.

Prior to hypothesis testing, contingency tables and analysis of variance will be used to test for differences in baseline characteristics between study conditions. The effect of the Witness CARES intervention on the primary outcome, CRC screening (a dichotomous variable), will be assessed using a generalized linear model with a logit link function. The effect of the intervention on secondary outcomes that are dichotomous variables (e.g., discussed CRC screening with doctor; have primary care doctor) will also be assessed with generalized linear models specifying a logit link function. Intervention effects on continuous variables (e.g., affective associations; cognitive beliefs; behavioral intentions) will be assessed using linear mixed models.

In these analyses, covariates (demographic and/or clinical) will be added and those that are statistically significant will be retained to evaluate intervention effects. The *p*-values will be Sidak adjusted for correlated outcomes. In secondary analyses, several potential moderators of the effect of the intervention on screening outcomes, such as education, will be examined.

2.7.5. Missing data—Predictors of missing data at the 3- and 6-month follow-up interviews will be assessed, including participant characteristics, cognitive and affective predictors of screening, and treatment arm. If these covariates predict the likelihood of missing data, we will conduct sensitivity analyses using a random effects pattern-mixture model [35]. We will create dummy variable vectors that describe patterns of missing data. These missing data patterns can then serve as a grouping variable that will be included in the analyses. We plan to add a main effect term for the two post-intervention measurement periods that take the missing data patterns into account as well as an interaction term involving treatment group by missing data. Attention will be directed toward possible effects on treatment outcomes as a function of both treatment group and missing data patterns. There are two major advantages associated with this approach: a) it is not necessary to eliminate cases due to missing data on the outcomes of interest; and b) if the interaction between group and missing data patterns is significant, it is possible to obtain more precise estimates of treatment effects after adjusting for missing data on the outcomes. For the baseline assessment, a similar imputation method will be applied for items, such as income and education.

Because study eligibility was determined based on responses to age, race, and screening history, attendees with missing data on those items ($n = 397$; 14.8%) were initially coded as ineligible, but study personnel made every effort to obtain these data through the 3-month and 6-month follow-up interviews and other contact attempts. Through this process, 50 participants were deemed eligible for final analyses, but are not included in the baseline descriptive statistics reported here.

2.7.6. Qualitative data—Interview data will be analyzed within the context of the PEN-3 Model using the text analysis program, NVivo. PEN-3 provides a framework for funneling qualitative text to identify and categorize responses into concepts that serve in positive and negative ways to prevent, enable, or nurture screening behavior. Following tested methods [36, 37], interviews will be stratified by gender, screening behavior, intervention type (narrative/didactic), time (one-week or six-month), and site. Then, text will be coded by

select team members (DOE and LJ), compared, and once consensus on thematic categories has been determined, it will be sorted into a 3 x 3 table as per the PEN-3 model.

3. Results

3.1. Recruitment of sites

The intervention programs were conducted from February 2014 through April 2016; follow-up surveys were completed in March 2017. A total of 183 programs were conducted for 2,655 attendees ($M = 17.4$, $SD = 7.9$ average attendees per program). Of these attendees, 516 (19.4%) were study-eligible (i.e., African Americans over age 50 and nonadherent to CRC screening guidelines) and consented to participate in the research study ($M = 3.4$, $SD = 3.1$ per program; see CONSORT diagram in Figure 4). There were 25 programs ($n = 7$ in WNY; $n = 18$ in NYC) at which no attendees were eligible, primarily because they were all either adherent to CRC screening or less than 50 years of age. Thus, a total of 158 programs were included in analyses (50% narrative; 50% didactic).

Approximately half (45.6%) of the programs were delivered at new sites that had not hosted Witness Project programs in the past, usually at faith-based (34.8%) or another community organization (62.7%). Programs were approximately evenly split between the WNY (51.3%) and NYC (48.7%) locations (see Table 2).

We conducted the planned number of programs for more than the expected number of community members. However, the proportion of study eligible attendees was much lower than expected (21% v. 50%). This was in large part due to higher than expected rates of adherence with CRC screening. This resulted in an overall sample size that was smaller than anticipated.

3.2. Baseline characteristics of the study population

Most participants were female (75.4%) and were aged 64.7 on average ($SD = 9.7$). Most (79.1%) were not currently employed and their median income was less than \$25,000 per year. Most participants (89.7%) had a current medical provider and public health insurance coverage (91.6%). Only 4.1% of participants had no health insurance. Of all baseline participant characteristics, only income differed by study condition, with the narrative condition having more participants who earned less than \$25,000 per year, $F(1, 515) = 7.71$, $p = .01$ (see Table 3).

4. Discussion

The Witness CARES Project is an RCT that compared the effect of a narrative and didactic version of the Witness CARES intervention on African Americans' engagement in CRC screening and related cognitive and affective determinants of screening decisions. This paper describes the methodology of the program and the rigorous study designed to evaluate it. Both the intervention and its accompanying RCT were designed and conducted as a CBPR study with our community partners in WNY and NYC. Through five phases of data collection (baseline, post-intervention, 3-month, 6-month, and qualitative interviews), we

will be able to compare the effects of the narrative and didactic versions of Witness CARES on screening behavior, as well as the cognitive and affective determinants of screening.

4.1. Implementation of study design

Although the Witness CARES program conducted an adequate number of programs and exceeded overall attendance goals, there were fewer study-eligible attendees, and thus, fewer participants in the research study sample. Also, multiple efforts were taken to recruit male participants, but 75% of study participants were females, which may reflect a combination of factors, including the leveraging of relationships built through prior Witness Project programs that targeted women [19, 38]. There may also be unique barriers to CRC screening among men that deterred their participation in this program. Another contributing factor may be the demographics of the population over age 50, which is predominantly female, including in NYS and among African Americans [39].

The proportion of study-eligible attendees was lower than expected due to higher than expected screening rates among the target population, as well as a greater number of attendees who did not meet the race and age criteria. The higher screening rates occurred over the two years since the initial submission of the study and continued through completion of recruitment [40]. In 2011, an unpublished community assessment by Mount Sinai in NYC and Roswell Park Cancer Institute in WNY found that only about 40% of African American and lower-income New Yorkers had been screened for CRC. However, by 2014, screening rates were as high as 68.1%, and reached 70.5% in 2015 [41]. Among the Medicaid population, the screening rate in 2015 was 60.2% [41]. These increases may reflect recently implemented no-cost colonoscopy screening programs in NYC and statewide, including stool tests for all residents. Moreover, the Affordable Care Act (ACA) was passed during the conduct of this study, potentially increasing access to health insurance, physicians, and screening opportunities [42]. Indeed, over 90% of study participants reported having a source of primary care and nearly all participants (96%) had some form of health insurance. Another factor that may have contributed to the unexpectedly high baseline screening rates may be that just over half of programs were administered at sites that had hosted a Witness Project program or related health promotion activity in the past. Thus, attendees at these programs may have had more exposure to screening messages than other African American communities. Although these unexpectedly high baseline screening rates demonstrate a cautionary message to re-examine participant eligibility expectations between study submission and grant funding, they also may reflect a positive trend among a community often considered nonadherent and difficult to reach.

As described earlier, the original informed consent process proved challenging and required adjustments early in the study to enhance recruitment. Particularly for older African American participants, signing a long consent form full of legal jargon was a consequential barrier to recruitment. Shifting to an oral consent process had several advantages beyond being more favorable to participants, including the ability to directly answer attendees' questions, reduce concerns about research, and ensure comprehension. The challenges with written consent in the current study may have implications for several types of research, from community-based prevention interventions to treatment clinical trials, and more

research is needed to elucidate ways to overcome these barriers and recruit diverse participants.

There are several approaches that may facilitate recruitment in future CBPR efforts, although all recruitment methods have strengths and weaknesses. For instance, increasing use of technology for both the delivery and evaluation of the intervention may increase reach, but reduce access among older and/or low SES populations who may be most at-risk for being screening nonadherent. It is also possible to employ more targeted recruitment efforts, thus reducing the number of ineligible program attendees, but this approach also reduces community reach, which was a key priority for Witness CARES. Finally, as the rates of CRC screening increase, the factors that influence the decisions of those who remain nonadherent to guidelines may also shift. This population may experience unique individual-level and structural barriers that are not addressed by existing intervention efforts or efforts that target the larger group of nonadherent individuals. Future efforts may consider tailoring intervention efforts to identify and address these unique barriers, and/or partnering with clinical organizations that have direct access to nonadherent patients.

Missing data at the 3- and 6-month assessment time points were a related challenge, despite several efforts by program staff to maintain contact with participants. Participants often had non-active phones (e.g., mobile phones that would become active/inactive depending on changes in account status) or were no longer at reported addresses. Our study design and analytic plan were specifically designed to address issues of missing data. We collected extensive data at baseline and immediately post-intervention, which could be examined using the original sample size of 516, and were not dependent on maintaining long-term contact with participants. For instance, we assessed behavioral intentions, a screening-related outcome, at baseline and post-intervention, and our sample size afforded 0.80 power to detect a small intervention effect, as well as 0.90 power to detect an effect on our cognitive and affective variables.

Our extensive baseline data also facilitates an examination of the causes and implications of these missing data, which may inform current analyses, as well as future efforts to engage participant subgroups that are particularly vulnerable to attrition. Relatedly, the amount of missing data at baseline on study eligibility items was 15%, which is not uncommon in community-based research, but was nevertheless an additional challenge for recruitment efforts. Alternative data collection techniques, including online approaches, may have more success in future studies, although they also pose challenges related to access, particularly among an older low-income population.

4.2. Strengths of the intervention design and delivery

These challenges were outweighed by several strengths of this intervention and research study that make it a particularly innovative approach. First, Witness CARES was implemented in two different communities with simultaneous and coordinated data collection procedures. This brought a greater level of significance and generalizability to the outcomes and demonstrated a balance between consistency in essential program components and accommodating local demands. However, it also introduced several methodological challenges that needed to be overcome in the design and implementation phases. Second, in

both locations, this was an entirely community-based effort, rather than targeting patients within a clinical practice. By administering the intervention in community settings, we bypassed several structural barriers to being screened for CRC. For instance, we were able to reach lower socioeconomic participants who may rarely or never visit a clinic, or whose providers have not initiated a discussion about CRC screening.

Third, this intervention and its accompanying RCT merged rigorous mechanism-based research with CBPR methods that capitalized on decades of combined experience of the PIs, including their unique and complementary areas of expertise. We leveraged our extensive ties to the local communities and incorporated key aspects of CBPR at all levels of development, design, recruitment, program implementation, and analysis in order to optimize cultural and racial fit with the communities and participants served. By merging this approach with rigorous mechanism-based assessments, we maximized the effectiveness of the intervention while also permitting an examination of the intermediary psychosocial mechanisms that may elucidate *why* narrative communication interventions are often more effective than didactic approaches.

Overall, the participant demographic characteristics suggest we successfully reached the lower income and less educated members of the African American communities of WNY and NYC who are most likely to be medically underserved and less knowledgeable about CRC screening. The relatively high screening rates in this medically underserved population suggest that state health programs, together with the federal ACA, effectively increased access to preventive services, such as CRC screening, for all residents.

Another key strength of Witness CARES intervention is its narrative approach and the emotional response it elicits [16]. Although affective predictors of behavior have been targeted by interventions in other behavioral domains, such as sexual health [43] and physical activity [44], most educational interventions aimed at increasing cancer screening uptake have focused on the cognitive determinants of behavior [45, 46]. However, recent cross-sectional evidence suggests that affective associations with colonoscopy are a key predictor of screening adherence among African Americans [11]. Moreover, narrative communication interventions have been used successfully in both the Latino and African American communities to increase health-protective behaviors beyond what is achieved by numeric risk tools and other didactic education messages [e.g., 18, 19, 38, 47, 48]. This suggests that interventions such as Witness CARES that reduce negative feelings and increase positive feelings about colonoscopy may be an effective means of increasing screening rates and reducing CRC disparities. Moreover, unlike several narrative interventions, the Witness CARES Project was developed using a conceptual model that aims to elucidate the underlying decision-making mechanisms responsible for the effects of narrative communication on decisional and behavioral outcomes.

5. Conclusions

Adherence to CRC screening guidelines nationally and in New York State still remains lower than national goals and rates for other screening modalities [2], especially for underserved populations [3]. Disparities in CRC screening account for over 40% of the

disparities in CRC incidence and almost 20% of the disparities in CRC deaths [3]. Thus, identifying and intervening on screening determinants is a priority, particularly for underserved populations [49]. This study addressed these challenges by designing an innovative clinical trial to be delivered through community-based settings to evaluate the effectiveness of a narrative-based culturally-competent intervention aimed at reducing cancer-related disparities in CRC screening.

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Figure 1.
Theoretical framework

Figure 2.
Screenshots from Witness CARES intervention videos.

Program # _____

**Witness CARES
Program Summary**

Program Date: _____

Week Day: Sun ☐ Mon ☐ Tues ☐ Wed ☐ Th ☐ Fri ☐ Sat ☐

Program Time: Morning ☐ Afternoon ☐ Evening ☐ | **Length:** _____ hrs _____ min

Program Site: NYC ☐ WNY ☐ **Program Content:** Didactic ☐ Narrative ☐

Program Site Type: Faith-based ☐ Community ☐ Healthcare Org ☐ Other ☐

Borough/Town: Manhattan ☐ Bronx ☐ Brooklyn ☐ Queens ☐ Westchester ☐ Buffalo ☐

Niagara Falls ☐ Rochester ☐ Other _____

Program Location: _____

Number of Volunteers: _____ **Female Volunteers:** _____ **Male Volunteers:** _____

Number of Staff: 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ Other _____

Staff Present: _____

Number of Total Participants (@ Start): _____ (Female _____ Male _____)

Number of Total Participants (@ End): _____ (Female _____ Male _____)

Number of \$5 Incentives Given Out: _____

Number of:

Female Eligible: _____ Male Eligible: _____

Female Eligible and Contact Card: _____ Male Eligible and Contact Card: _____

Female Medical Release: _____ Male Medical Release: _____

Completed Activity:

ACTIVITY	YES	NO
Opening Prayer	☐	☐
Opening Scripture	☐	☐
Questions Read Aloud	☐	☐
Closing Scripture	☐	☐

Raffle Item(s): _____ **Gift Card Number(s):** _____

Comments:

Revised 10.02.14

Program # _____

Page 2 can be completed before the program itself!

Site and Attendee Recruitment:

☐ Naturally occurring group

☐ Invited to event

☐ Combination

Established vs. New Sites (Is this a site where we have been before?):

☐ Yes – Witness

☐ Yes – Esperanza y Vida

☐ Yes – Witness CARES

☐ Yes – Other: _____

☐ No – none of the above.

Organizational Facilitation:

Did anyone from the organization help facilitate determining eligibility and/or consenting of participants on the day of the program?

☐ Yes ☐ No

Did anyone from the organization help facilitate any other aspect of the program (e.g., helping participant complete surveys) on the day of the program?

☐ Yes ☐ No

Was the program held at an organization that has ACO status?

☐ Yes ☐ No

Revised 10.02.14

Figure 3.
Program summary used to track programs and assess implementation fidelity

Figure 4.
CONSORT diagram

Table 1

Characteristics of primary and secondary outcome measures, including reference, example items, time points at which they were assessed (pre-survey, post-survey, 3-month interview, and/or 6-month interview), number of items, and reliability (Cronbach's alpha; α).

Outcome	Example item & reference	Time point assessed, # of items				
		α	Pre	Post	3-mo	6-mo
Primary outcome						
Screening Behavior	<i>Have you been screened for colorectal cancer since the program you attended?</i> [adapted from 22]				3	9
Secondary outcomes						
<i>Screening-related behavior</i>						
Screening intentions	<i>How likely are you to have a colonoscopy in the next 12 months?</i> [adapted from 22]		1	1	2	1
Intentions to discuss screening	<i>How likely are you to ask your doctor about having a colonoscopy in the next 12 months?</i> [adapted from 22]			1		
Plan to have colonoscopy	<i>Do you plan to have a colonoscopy in the next 12 months?</i> [adapted from 22]				1	1
Perceived influence of program	<i>Did attending this program make you more likely to get a colonoscopy in the next 12 months?</i> (developed for study)			2	2	2
<i>Care-seeking behavior</i>						
Have a primary care doctor	<i>Do you currently have a regular doctor that you go to?</i> (developed for study)				1	
Discussions with doctor	<i>Have you had a conversation with your doctor about colorectal screening since you participated in the educational program?</i> (developed for study)					13
<i>Cognitive determinants of behavior</i>						
Perceived a) benefits and b) barriers	<i>Having a colonoscopy is painful</i> [23]	a) .69 b) .81	15	15		15
Cognitively-based perceived risk	<i>What do you think are the chances that you will have colorectal cancer at some point in your life?</i> [24–26]		2	2		2
Knowledge	<i>Colorectal cancer is one of the most commonly diagnosed cancers in the United States.</i> (developed for study)		8	8		8
Self-Efficacy	<i>I can get a colonoscopy even if I don't know what to expect.</i> [22, 27]	.93	7	7		7
<i>Affective determinants of behavior</i>						
a) Positive and b) negative affective associations	<i>When you consider having a colonoscopy... do you feel relaxed?</i> [10, 30]	a) .91 b) .85	9	9		9
Affectively-based perceived risk	<i>How worried are you about getting colorectal cancer at some point in your life?</i> [24–26]		2	2		2
Fear of colonoscopy	<i>How fearful are you of... the overall colonoscopy procedure?</i> [31]	.86	6	6		6
<i>Social influence</i>						
Program social ties	<i>Were you invited to attend the program today by friend?</i> (developed for study)				6	

Outcome	Example item & reference	Time point assessed, # of items				
		α	Pre	Post	3-mo	6-mo
Social norms	<i>My close friends think that I should have a colonoscopy.</i> [29]	.89		4		4
Social ties	<i>How many close friends do you have - meaning people that you feel at ease with, can talk to about private matters, and can call on for help?</i> [29]					4
Health care & screening						
CRC screening history	<i>Has a doctor or nurse ever recommended that you have a stool test?</i> [22]	.90		13		
Screening history for other cancers	<i>Has a doctor/provider ever recommended that you have a mammogram?</i> [31]		15			
Health care experiences	<i>I trust my doctor/provider to put my medical needs above all other considerations when treating my medical problems.</i> [32, 33]		9			

Table 2

Characteristics of programs delivered.

	Study-eligible programs*	All programs
	n (%) or <i>M (SD)</i>	n (%) or <i>M (SD)</i>
Number of programs delivered		
Didactic	79 (50.0)	92 (50.3)
Narrative	79 (50.0)	91 (49.7)
Total	158 (100)	183 (100)
Program site		
New York City (NYC)	77 (48.7)	90 (49.2)
Western New York (WNY)	81 (51.3)	93 (50.8)
Type of organization		
Community-based	99 (62.7)	118 (64.5)
Faith-based	55 (34.8)	60 (32.8)
Other	4 (2.5)	5 (2.2)
Site and attendee recruitment		
Naturally occurring	80 (50.6)	95 (51.4)
Invited to event	59 (37.3)	66 (36.1)
Combination	19 (12.0)	22 (12.0)
Site of prior program		
No	72 (45.6)	85 (45.9)
Yes	86 (54.4)	98 (53.6)
Attendees per program	16.7 (7.9)	17.4 (7.9)
Study-eligible attendees per program	4.5 (3.4)	3.4 (3.1)

Note

* At least 1 attendee study-eligible: aged >50 years, African American, and nonadherent to CRC screening guidelines

Table 3

Participant characteristics at baseline

	Didactic (n = 261)		Narrative (n = 255)		Total (N = 516)		F(1,515)	p-value
	N	M (SD) or %	N	M (SD) or %	N	M (SD) or %		
Gender							0.95	.33
Male	69	26.4	58	22.7	127	24.6		
Female	192	73.6	197	77.3	389	75.4		
Age	261	65.0 (9.7)	255	64.3 (9.7)	535	64.7 (9.7)	0.79	.38
Country of birth							0.30	.58
United States	220	84.3	214	83.9	434	84.1		
Other	32	12.3	35	13.7	67	13.0		
Currently employed							0.62	.43
Yes	51	19.5	57	22.4	108	20.9		
No	210	80.5	198	77.6	408	79.1		
Marital status							0.38	.052
Unmarried	198	75.9	218	85.5	416	80.6		
Married	63	24.1	37	14.5	100	19.4		
Education level							0.15	.70
< high school	45	17.2	46	18.0	91	17.6		
HS/GED	82	31.4	82	32.2	164	31.8		
Some college	82	31.4	86	33.7	168	32.6		
College degree	52	19.9	41	16.1	93	18.0		
Income							7.71	.01
< \$25,000	178	68.2	194	76.1	372	72.1		
\$25,000 – \$50,000	58	22.2	46	18.0	104	20.1		
> \$50,000	25	9.6	15	5.9	40	7.8		
Has medical provider							1.22	.27
Yes	238	91.2	225	88.2	463	89.7		
No	23	8.8	30	11.8	53	10.3		
Insurance status							0.12	.73
Private	11	4.2	11	4.3	22	4.3		

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	Didactic (n = 261)			Narrative (n = 255)			Total (N = 516)			p-value
	N	M (SD) or %	N	M (SD) or %	N	M (SD) or %	N	M (SD) or %	F(1,515)	
Public	237	90.8	236	92.5	473	91.6				
None	13	5.0	8	3.2	21	4.1				
Screened for other cancers*									2.68	.10
Yes	168	64.4	172	67.5	340	65.9				
No	93	35.6	83	32.5	176	34.1				

* Other cancers for which past screening was assessed: prostate, breast, cervical