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Evaluating a Community-Partnered Cancer Clinical Trials Pilot Intervention with African American Communities

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Abstract

Objectives—Cancer Clinical Trial (CCT) accrual and retention rates remain disproportionately low among African Americans. Awareness and access to trials are crucial facilitators of trial participation. Strategies developed within a community-based participatory framework (CBPR) are potential solutions to increase awareness and access to CCTs. In this study, we describe the pilot phase of three innovative community-centered modules to improve basic CCT knowledge, awareness of locations to access CCT information, and opportunities to participate in CCTs.

Design—Four community organizations completed Community Bridges to CCTs training-of-the-trainer and recruited adult African American volunteers to participate in one of three CCT education modules: a workshop about CCTs; a role-play describing one person's experience with CCTs; or a call and response session reviewing myths and facts about CCTs. Pre- and post-test surveys were collected and analyzed using McNemar agreement statistic to evaluate changes in knowledge and attitudes regarding trials.

Results—Trainers enrolled 125 participants in the Call and Response (n=22), Role-play (n=60), and Workshop (n=43) modules. Module participants were mostly African American, female, and mean age of 53 years. Comparison of pre and post-test responses demonstrates favorable changes in awareness of CCTs and where to access to CCTs across the sample. Analysis by module type indicates significant increases for participants in the Call and Response ($p < 0.01$) and Role-Play modules ($p < 0.001$), but not the Workshop module.

Conclusion—Despite measures taken to increase the participation and retention rate of African Americans in clinical trials, little advancement has been made. Developing tailored community education modules on CCTs within the CBPR framework is a promising innovation to increase knowledge about CCTs and favorable attitudes about participation that are known precursors to trial enrollment.

Keywords

cancer clinical trials; minority recruitment; African American; community-based participatory research

Introduction

Cancer clinical trials (CCTs) are the emerging drivers of standard of care therapies. Notable inequities exist in regards to access to and participation in cancer clinical trials (CCTs). An Institute of Medicine (IOM) report suggests that “therapies offered through CCTs should ideally be considered the preferred treatment choice for physicians and patients, if they are available” [1]. Despite the IOM recommendations, CCT participation remains remarkably low, especially among underserved patient subgroups who have the highest burden of illness [2, 3].

Systematic reviews enumerate barriers to minority groups' participation in CCTs at the patient and provider level [4, 5]. Rivers and colleagues' identified 5 key elements that influence African American participation in CCTs: 1) negative beliefs about trials, 2) limited knowledge about trials, 3) influence of faith on participation decisions, 4) role of health care

providers in influencing participation in trials, 5) recommendations or previous experiences of friends and relatives [5]. These elements emphasize the influence of intrapersonal, family and community norms, and provider-patient interactions on trial decision-making process. Applying a health literacy framework to explore African American and Hispanic perceptions of CCTs, Evans and colleagues identified similar barriers and recommended education interventions that address scientific literacy (study design, risks and benefits, and accessibility of investigators and internal review boards when concerned about protections), civic literacy (evaluation of the sources of health information as trust worthy and decisions regarding CCT participation), and cultural literacy (reconciling health information, science, individual and collective action within the context of one's cultural understanding of health) to make CCT more accessible to minority populations [6]. Ford and colleagues proposed a conceptual model that describes the key domains that lead to CCT participation for minority communities: *awareness*, *opportunity*, and *decision* [4]. The model suggests that prior to the decision to accept or decline participation in a CCT, patients must first be aware of cancer trials as an option and informed of opportunities to participate in them. Facilitators of awareness encompass research and science literacy, basic knowledge of CCTs, and patient protections. Provider knowledge of the trial, time constraints, and perceptions of patient interest influence communication of the option of trials, while eligibility criteria is sponsor driven. This literature suggests that interventions designed to increase CCT accrual of racially/ethnically diverse populations must intervene at individual, peer, provider, and community levels to change understanding, endorsement of, and participation in CCTs, to do so interventions must be multilevel and extend beyond the clinic settings.

Empowering community members with basic information about CCTs can raise research literacy, prepare them to engage in dialogue with providers, inform decisions about their care, and/or support deliberation among family members facing cancer. While previous studies intervened in clinic settings to address barriers at the patient or provider level [7-13] few studies have employed these strategies in community settings. Clinic setting interventions may be impractical for targeting peer and community perceptions of trials that also influence patient decision-making [14].

Conducting CCT education interventions outside the clinic is a promising way to augment the efforts of clinic-based interventions. Communities as Partners in Cancer Clinical Trials: Changing Research, Practice, and Policy, a 2008 report based upon stakeholder input and government sponsored reports from the NIH, AHRQ, NCI, IOM, and the President's Cancer Panel enumerates over 50 recommendations to involve community members across all phases of CCT design, implementation, outreach, and accrual using Community-Based Participatory Research (CBPR) approaches (<http://www.enacct.org/sites/default/files/Communities%20Full%20Report.pdf>) [15]. One encouraging example is a pilot study by the Education Network to Advance Cancer Clinical Trials (ENACCT), a nonprofit organization specializing in provider and community education. ENACCT created a multi-site CCT education program with primary care providers, community leaders and clinical trial staff. ENACCTs use of community engagement was effective in increasing trial knowledge and advocacy among patients, as well as providers, and generating community dialogue and patient inquiries regarding trials [16]. ENACCT training materials framed CCT access as a

social justice and quality of care issue. Specific components were created to appeal to native Korean and Spanish speakers. Investigators from the University of North Carolina (UNC) at Chapel Hill approached ENACCT to expand adaption of their community leader training materials to African American community leaders using a community-based participatory research (CBPR) approach.

CBPR approaches promote ‘mutual transfer of expertise and power sharing in decision making and data ownership across community and academic partners’ [17]. Participatory approaches to research foster collaboration among researchers and community leaders to collectively design, initiate, and evaluate an intervention [18]. Our rationale for utilizing a CBPR approach was the recognition that researchers and community partners possess different expertise and understanding of the components necessary to change individual behavior and community norms and observation that some African American community-based organizations serve as community resources for cancer education and screening. This manuscript describes the pilot study of three innovative community-centered modules (Community Bridges to Cancer Clinical Trials) designed in collaboration with community organizations to increase community dialogue around CCTs. Our objectives were to increase knowledge of CCTs, awareness of sources to access CCTs, and intentions regarding CCT participation. We begin by describing training provided to community partners; we then present the recruitment and delivery of the three module types, results from the pilot of the Community Bridges to CCTs intervention and lessons learned.

Methods

Community-Academic Collaboration

Participants in this collaboration included investigators from UNC at Chapel Hill, ENACCT, and leaders of four community based organizations: Black Men's Health Initiative, Inc., Community Health Coalition, Inc., Crossworks, Inc., and the North Carolina Institute of Minority Economic Development's Health Workplace Initiative. We employed a CBPR approach to collaborate with ENACCT and community organizations throughout the research process. UNC created and issued a request for proposals to identify organizations and organized a peer review process that included community and academic reviewers. Review criteria prioritized organizations with expertise in breast and/or prostate cancer outreach and education within African American communities within a 13-county region and commitment to help revise and refine existing ENACCT Community Leader training materials, develop recommendations to make the materials more culturally relevant and realistic, attend a training-of-the-trainer session, and pilot revised materials within existing outreach networks. ENACCT and each selected organization received financial compensation as subcontractors for their participation on the intervention team and community organizations completed compliance agreements with the University of North Carolina at Chapel Hill (UNC) Institutional Review Board (IRB) to conduct activities within the Community Bridges to Cancer Clinical Trials (Community Bridges) intervention study protocol.

Intervention modules were developed using an iterative Learning and Feedback approach. ENACCT facilitated this step-wise approach by demonstrating three community education

modules originally developed for their Pilot Education Program [16] for the collaborating community organizations and UNC-based research team. Blakeney and colleagues [19] describe in detail the Learning and Feedback approach, recommended changes, and resulting content and structure adaptations to the three module formats. Learning and Feedback participants recommended tailoring modules to facilitate delivery to audiences within limited blocks of time, incorporate explicit acknowledgement of participant concerns including past research abuses within African American communities, adding personalized examples of individuals and communities benefiting from trials, and packaging the intervention with a succinct, memorable, and visually appealing call to action. We describe the modules and the process to determine which module was most effective.

Community Bridges Intervention Description

The three module formats (Call and Response, Role Play, and Workshop) are detailed here. The Call and Response format, entitled “Why Our Community Needs to Know about Cancer Clinical Trials” used a brainstorming session to guide dialogue about CCTs. This 40-minute format was designed to help participants distinguish facts and myths about CCTs. Trainers led a brainstorming session with the audience to record concerns and questions regarding CCTs, then tailored the module session to share content in response to these responses.

The Role Play format, “Mr. Wilson/Mrs. Woods Role-play”, used a role-play presentation featuring Mr. Woods or his female counterpart Mrs. Woods. The 40-minute role-play format describes the story of a breast (Mrs. Woods) or prostate (Mr. Wilson) cancer survivor discussing his or her experiences learning and determining treatment options. Trainers implemented this format using a script and volunteers to deliver information about CCTs in three scenes that include other referents in the decision process (family members, providers, and pastor). The main character's adult child considers a prevention trial in the final scene. Trainers referred to a brief discussion guide between scenes to engage the audience in dialogue about their perceptions and concerns.

Trainers delivered the Workshop format using a traditional 90-minute workshop entitled “What are Clinical Trials and What Do They Mean for My Community.” Trainers used a PowerPoint presentation and small group discussion to present basic information about CCTs. While the format varied, the content across all of the modules was similar. Content included basic information about CCTs and patient protections and rights. ENACCT provided trainers with optional video clips to supplement training materials. Video clips were collected from the National Cancer Institute, Ohio State University, and Dana Farber Cancer Institute and were used in prior ENACCT Pilot Education Program trainings. Clips featured perspectives of providers and African American patients and family members explaining clinical trials and patient protections and patients describing their trial decision-making processes. Though treatment trials were prominent in the core message, module content included examples of opportunities to participate in screening and prevention trials.

All modules began and ended with core messages. The Community-Academic Collaboration developed a social marketing and call to action message entitled, “Why CARE about Cancer Clinical Trials?” and corresponding logo (Figure 1). The CARE acronym summarized the core message and logo, Cancer clinical trials are a quality cancer treatment option, African

Americans should ask their doctor about CCTs, **R**ights are protected of everyone who participates in trials, **E**veryone in North Carolina is affected by cancer. Module sessions ended with interactive small group discussions to review the call to action and core messages. Participants were encouraged to consider CCTs as a viable treatment option, ask about trials during patient-provider interactions, and identify opportunities to share session materials within existing social networks. Session materials included the session slides (Workshop only), palm-sized cards with the CARE call to action and core messages, and Mr. Wilson or Mrs. Woods photonovels.

Community Bridges to Cancer Clinical Trials training-of-the-trainers

ENACCT developed and conducted a training-of-the-trainer session to prepare trainers from each community organization to deliver each module. The same community organization staff actively involved in the Learning and Feedback sessions [19] were invited to participate as trainers and encouraged to bring at least two additional members of their organizations to participate. Each organization selected at least one lead staff member (executive director or director of programs) to attend the training. The UNC research team provided Alternate Research Ethics Training and data collection training for trainers. In August 2009, twelve members from the four organizations participated in the two-day training (Table 1). Retention and delivery of content was assessed via teach back sessions. Post training, trainers were asked to conduct each module format with approximately 30 participants and invited to attend monthly conference calls to discuss experiences conducting sessions.

Participant Recruitment

Drawing upon their existing outreach network for breast or prostate cancer education, trainers requested presentation time from groups in the designated regions such as barbershops, retirement communities, Black nurse association chapters, churches, and departments within Historically Black Colleges/Universities (HBCUs). Participants were recruited through their social or formal membership with the community group approached by the trainer. Sessions were scheduled during or adjacent to a group's regularly scheduled meeting. Inclusion criteria limited participation to adults over 18 years. While African American audiences were targeted, participants of all races were included if they met the age requirement. Since our objective was to share information about CCTs prior to diagnosis, experience as a cancer patient was not an inclusion criterion. Module participants were recruited by trainers and were uncompensated volunteers. Trainers obtained informed consent from module participants in accordance with UNC IRB.

Community Bridges Intervention Evaluation

We used a single group pre-test/post-test study design to assess the impact of the Community Bridges to Cancer Clinical Trials intervention on community member knowledge and attitudes regarding CCTs. Trainers conducted community sessions using one of the three adapted education modules. Session participants completed pre-post surveys. All study activities were completed between January and July 2010.

Data Collection and Measures

A 14-item scale developed by ENACCT and previously used to assess proximal outcomes of CCT education participants [16] was used to assess changes in key domains - awareness of CCTs, patient protections, CCTs benefits, opportunities to participate, and decision-making intentions. Survey items were statements with a binary (true/false) response. We collected basic demographic variables (age, gender, and race). Participants completed the survey prior to and immediately following the module session.

Data Analysis

Pre-test and post-test responses were matched by participant to assess changes in knowledge and attitudes using the McNemar's test [20]. The percent of participants answering survey items in a favorable direction was computed for pre- and post-test surveys by intervention module and overall. All statistical tests were two-sided with a significance level of $\alpha=0.05$. Analyses were conducted using SAS® version 9.2 (SAS Institute, Cary, NC).

Results

Community Bridges Pilot Study Results

One hundred twenty-five adults participated in the pilot study of the Call and Response (n=22), Mr. Wilson/Mrs. Woods Role-play (n=60), and Workshop (n=43) modules. The majority of participants were female (74%), African American (95%), with a mean age of 53 (range 19-88) (Table 2). The percentage of respondents answering each question correctly or favorably towards CCTs is described in Table 3. Response categories display results by five domains: basic awareness, patient protections, CCT benefits, opportunities to access trials, and decision-making intentions.

At baseline, participant responses reflect basic understanding of CCTs and favorable attitudes regarding patient protections, CCT benefits, and decision-making intentions. Across all modules, we observed significant increases in awareness of CCTs, access to CCT opportunities, and CCT decision-making intentions. The Call and Response and Role Play formats yielded significant changes in awareness of CCTs and access to opportunities to participate in CCTs, while the Workshop yielded significant changes in willingness to consider a prevention trial.

Trainers offered their experiences scheduling and conducting each of the modules during monthly conference calls. Trainers identified groups with and without professional health expertise and remarked that all groups approached expressed interest in the sessions. Groups typically offered times during or adjacent to standing meetings. Working within designated meeting times, trainers identified the length of time required to consent, administer the surveys, and conduct the sessions as the primary implementation challenge. Time constraints and additional logistic complexity prohibited use of the video clips during sessions. Trainers preferred the Workshop and Role Play formats to the Call and Response format. The ordered structure of the workshop format was most familiar and consistent with previous training experiences. Trainers reported that participants connected with the Role Play characters and that the story telling format made it easier to discuss the taboo topic. Trainers agreed the

Call and Response format provided the most flexibility, allowing participants to guide the order content was covered, but also required a high level of mastery with the content to deliver.

Discussion

The Community Bridges to Cancer Clinical Trials pilot compared three adapted versions of community education modules designed to improve awareness, access, and informed decisions regarding CCTs. Our results demonstrate that community education modules can favorably influence the key domains that influence CCT participation which may lead to informed decisions regarding trial participation that are advantageous to participants, the trial, and the advancement of science. Study findings also support the use of CBPR approaches for delivering CCTs education in community settings.

Prior to module sessions, participants possessed basic understanding of CCTs and favorable beliefs that CCTs benefit individuals and communities. However, participants were less familiar with which actions to take to access trials. Observed findings do not pinpoint one module format as most effective. Rather findings suggest different formats may be more appropriate for conveying aspects of clinical trials education. The Call and Response and Role Play formats yielded significant increases in knowledge regarding CCTs and access to CCT resources. Only the Workshop format yielded significant increases in intention to participate in a cancer prevention trial. Nearly all Role Play and Call and Response participants expressed intent to participate in a prevention trial at baseline. Differences in module length and format may also account for this finding. The Workshop session was longer and participants in this session saw slides enumerating and defining trial types. The visual cue may have facilitated more explicit review of trial types than the other two formats. Only the Role Play format yielded increased interest to help increase community awareness about CCTs. We offer that a storytelling format appealed to a sense of community altruism. Other studies report similar increases in community altruism when using a brief animated module [21] and thus support the use of storytelling formats to inspire individual interest to change community norms about trials.

Our study findings complement Ford's conceptual model of CCT participation among minority patients, which emphasizes awareness and access as needed precursors to trial participation [22], but contrast other studies that found lack of knowledge of CCTs and low assessments of the benefits [6, 23]. Our findings also provide additional context to community understanding of CCTs. The study included a predominantly African American sample who at baseline were willing to consider trial participation for themselves or loved ones. They want, but are unaware of resources to access trial information. Approaches that clarify information about accessing CCTs and assure potential participants and their family members of patient protections and rights may minimize accrual barriers.

Prior research underscores the need for culturally appropriate approaches to increase suitable uptake of trials among African Americans. Our intervention used a CBPR framework with targeted messages framed to appeal to the priorities of the target group [9, 16, 24] and engagement of cultural brokers who have established relationships within the group [5, 12,

13, 15, 23, 25, 26]. The CBPR process involved community leaders who are locally known and respected for their expertise in cancer education and screening. Community partners were identified at the onset of the project, participated in the learning and feedback sessions, and were integral to the development of the materials and format in which materials were implemented and evaluated. ENACCT brought expertise in CCT education and application of adult learning principles to the training process and intervention design. Representatives from community organizations engaged in the development and implementation phases of the pilot as co-investigators, sharing their expertise as community advocates, educators, friends, and family members of African Americans with cancer. This level of involvement is not cursory, and requires a long-term commitment. Committing financial resources to each organization also aided their ability to maintain their organizational roles and level of engagement during the development and implementation phases of the pilot study. The adaptation of intervention materials and development of the *Why CARE?* logo and social marketing messages were tangible products that evolved from the CBPR process and encompass elements of cultural and civic literacy that may not be considered in interventions in which community expertise is absent from the research team. This study demonstrates the feasibility of developing CCT education interventions within the CBPR framework and thus represents an important contribution to research literature in this area and complement to clinic-based CCT education interventions.

Our pilot findings should be considered in the context its limitations. First, our small sample size, appropriate for a pilot study, limits our ability to distinguish one module type is more effective than the others. Missing demographic data further limits our analysis of the sample. Second, there is a possible risk of bias due to social desirability in self-reported responses because trainers and/or their reputations as grassroots cancer education experts were well known to the participants. Another potential source of bias may be trainer preferences in module implementation. Trainers were not randomized to different formats and conducted sessions using each module format for different participants. The small sample size prohibits meaningful analysis of differences by organization and trainer. Finally, in this study design we used a pre-post study design with participants serving as their own controls. Post-tests were administered immediately following the session and we are not able to assess maintenance of changes in awareness and use of information following the session. Future studies that incorporate a comparison group and follow-up assessment may minimize bias and increase generalizability of findings.

Lessons Learned

Proponents of community-based participatory research value the collective knowledge and experiences of community and academic partners and recognize the approach as a mechanism to bridge communities and researchers [17, 18]. Community-based organizations with expertise in cancer education and screening possess a great deal of insight into the community perceptions of cancer and CCTs, though traditionally community organizations are absent from the development of strategies that focus on CCT participation.

This study demonstrates that community organizations are important allies in developing effective strategies to increase informed uptake of CCTs within African American

communities. Adhering to the principles of CBPR is an iterative process that requires commitment from both community and academic partners and power sharing across all aspects of research. We encountered challenges. Adhering to community values and time frames and following training guidelines were at times in conflict. Trainers encountered challenges when the time allocated by community organizations was less than the scheduled time to present the module and conduct the evaluation. Respect for community values and time frame is a guiding principle of community-partnered research [17]. Another issue was data collection and management. For example, a printing error resulted in forms that were missing demographic questions resulting in missing data. Once identified, this error was corrected. Delayed detection of the error prevented data collection of demographic data with some module participants.

Conclusion

Innovative strategies are needed to achieve diverse participation in CCTs – the scientific enterprise for developing cutting edge procedures that effect cancer survivorship. Applying CBPR principles, this study demonstrates promising strategies towards increasing CCT participation in underserved communities. Strategies that intervene in community settings can reach a range of individuals affected by cancer and likely complement efforts within the clinic setting. Further investigation of CCT interventions using a CBPR framework may provide evidence of the effectiveness of multilevel CCT interventions.

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Key Messages

- This study presents an evaluation of culturally relevant CCTs education materials for African American community members developed within a community-based participatory research framework.
- Findings suggest African Americans possess basic knowledge regarding CCTs but are unaware of pathways to access additional information about local trials and are less certain their rights remain protected upon consent.
- Community-based organizations are appropriate co-investigators concerning the representation and broad access of minorities to CCTs.

HERE ARE A FEW KEY MESSAGES

about cancer clinical trials for you to know and do and that you may want to share with others. You can remember them with the word "CARE."



Cancer Clinical Trials are an option in quality cancer treatment
African Americans should ask their doctor about cancer clinical trials
Rights are protected of everyone who participates in research
Everyone in North Carolina is affected by cancer

Figure 1.
Why CARE? Logo and Key Messages

Table 1

Community Bridges to Cancer Clinical Trials Training-of-the-Trainers

<u>Training Content</u>	<u>Training Methods</u>
<ul style="list-style-type: none"> • Purpose, types, and phases of CCTs, how they work, where to get additional information • Comparing and contrasting standard care vs. care within a CCT • Cancer health disparities and their relation to clinical trials participation; • Factors influencing opportunities to participate in trials; patient protections and costs and insurance coverage for CCTs. • CCT referral process (provided by UNC Lineberger Comprehensive Cancer Center's Clinical Protocol Office) • Human Subjects training 	<ul style="list-style-type: none"> • Short didactic presentations • Clinical Trials Jeopardy • Paired Interviews • Scenario-based small group discussions • Demonstrations of CCTs modules • Practice facilitation of modules

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Table 2

Sample Demographics n(%)

	Call and Response (n=22)	Role Play (n=60)	Workshop (n=43)	All Modules (n=125)
Age				
Mean(SD)	56(15)	52(15)	53(14)	53(15)
Gender				
Female	20(91)	38(63)	35(81)	93(74)
Race				
African-American	21(96)	56(93)	42(98)	119(95)
Other	1(4)	4(7)	1(2)	6(5)

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Table 3

Percent of questions answered correctly in pretest and posttest by module type

Question (desired response)	Call and Response (n=22)		Role Play (n=60)		Workshop (n=43)		All Modules (n=125)	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post
Basic awareness of CCTs								
Cancer trials are research studies that test how well new medical approaches work for people. (T)	91	100	95	93	98	93	95	94
About 15% of U.S. adults with cancer participate in cancer clinical trials. (F)	59	68	33	38	54	56	45	50
In the last 12 months my personal knowledge about cancer clinical trials in my community has increased. (T)	36	82	42	75	40	56	40	70

Awareness of Patient Protections								
I believe the law protects me by requiring that doctors and nurses explain all procedures, risks, and benefits associated with a clinical trial, before someone agrees to join. (T)	82	100	85	93	84	91	84	94
								*
Patients may be placed into clinical trial without knowing it. (F)	82	82	77	77	77	84	78	80
Awareness of CCT benefits								
Because of progress made through clinical trials, many people are now living longer. (T)	96	100	90	93	95	100	93	97
When people like me participate in trials, the community can benefit. (T)	100	100	90	97	98	100	94	98
People of all backgrounds should have access equal access to cancer clinical trials. (T)	91	100	92	93	95	95	93	95
Access opportunities								
I know where to find information about cancer clinical trials in my community. (T)	27	77	53	88	58	77	50	82

I am interested in learning more about helping to increase others awareness about cancer trials. (T)	100	91	90	98	95	98	94	97
In my community, most people diagnosed with cancer know where to find information about cancer trials. (F)	5	23	28	50	14	19	19	34

I believe that more people in my community should know more about cancer clinical trials. (T)	100	100	97	97	100	100	98	98
Decision-making intentions								
I would consider participating in a cancer prevention clinical trial. (T)	91	86	87	92	72	93	82	91
								**
If someone I love were diagnosed with cancer, I would encourage him/her to find out more about all their treatment options, including cancer clinical trials (T)	100	100	92	93	98	95	95	95

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P-Values from McNemar agreement statistic. p<.05 indicates significant change from pretest for intervention group. Percentages rounded to whole numbers.

* p<0.05
** p<0.01
*** p<0.001