**The Ohio State University Comprehensive Cancer Center**
**Comparative Effectiveness of Interventions to Improve Screening among Rural Women: Rural Interventions for Screening Effectiveness (RISE)**
**NCT02795104**

## Principal Investigators


Electra Paskett, PhD
1590 North High Street, Suite 525
Columbus, OH 43201
Phone: (614) 293-3917
Fax: (614) 293-5611
Email: electra.paskett@osumc.edu

Victoria Champion, RHD,RN,FAAN
600 Barnhill Drive NU 340G
Indianapolis, IN 46202
Phone: (317) 274-4187
Fax: (317) 278-2021
Email: vchampio@iu.edu


## Co-Investigators


Mira Katz, PhD, MPH
1590 North High Street, Suite 525
Columbus, OH 43201
Phone: (614) 293-6603
Fax: (614) 293-5611
Email: mira.katz@osumc.edu

Susan Rawl, PhD, RN, FAAN
600 Barnhill Drive, NU 345E
Indianapolis, IN 46202
Phone: (317) 278-2217
Fax: (317) 278-2021
Email: srawl@iu.edu

Eric Seiber, PhD
1841 Neil Avenue
210 Cunz Hall
Columbus, OH 43201
Phone: (614) 247-4471
Fax: (614) 247-1955
Email: seiber.7@osu.edu

Yi (Wendy) Xu, PhD
1841 Neil Avenue
208 Cunz Hall
Columbus, OH 43201
Phone: (614) 292-0662
Email: yu.1636@osu.edu

Gail Grever, MD
2050 Kenny Road
Morehouse Pavillion
Columbus, OH 43201
Phone: (614) 293-8054
Fax: (614) 293-6890
Email: gail.grever@osumc.edu

Tamika Dawson, MD
1 American Sq, Ste 185
One America Tower
Indianapolis, IN 46282
Phone: (317) 948-6161
Fax: (317) 638-0678
Email: tdawson1@IUHealth.org


## Biostatisticians


Greg Young, MS
320 Lincoln Tower
1800 Cannon Dr
Columbus, OH 43210
Phone: (614) 293-6491
Fax: (614) 688-6600
Email: gregory.young@osumc.edu

Patrick Monahan, PhD
Indiana University
410 W. Tenth St., Suite 3000
Indianapolis, IN 46202-3002
Phone: (317) 278-8086
Fax: (317) 274-2678
Email: pmonahan@iu.edu


## Project Staff


Ryan Baltic, MPH
1590 North High Street, Suite 525
Columbus, OH 43201
Phone: (614) 293-4121
Fax: (614) 293-5611
Email: ryan.baltic@osumc.edu

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## 1.0 Overview

### 1.1 Title

Comparative Effectiveness of Interventions to Improve Screening among Rural Women: Rural Interventions for Screening Effectiveness (RISE)

### 1.2 Introduction

A multi-disciplinary research team from The Ohio State University and Indiana University School of Nursing will develop and implement an intervention testing the comparative effectiveness of a tailored interactive computer program delivered via DVD (TIDVD) vs. a TIDVD + telephone-based patient navigation (PN) intervention (TIDVD + PN) vs. Usual Care (UC) to increase guideline-based screening rates for Breast Cancer(BC), Cervical Cancer(CC), and Colorectal Cancer(CRC) among women age 50 to 74 living in 32 rural counties of Ohio (OH) and Indiana (IN).

### 1.3 Aims and Hypotheses

The specific aims are to:

**Aim 1:** compare the effectiveness of a tailored and interactive DVD (TIDVD) vs. TIDVD + telephone-based PN intervention (TIDVD + PN) vs. UC, to increase guideline-based cancer screening rates at 12 months post randomization for BC, CC, and CRC among 1058 women age 50 to 74 living in rural northwest Ohio and northeast Indiana

**Hypothesis 1:** Women in the TIDVD+TPN group will have higher rates of within guideline adherence to all screening tests via MRR at 12 months compared to those who receive the TIDVD alone or UC.

**Aim 2:** compare the cost effectiveness of the TIDVD and the TIDVD + PN intervention vs. UC, for adherence to each screening outcome or combination of screening tests.

**Hypothesis 2:** The TIDVD + TPN intervention will be more cost-effective than the TIDVD intervention or UC for adherence to each or combination of screening tests.

We will also identify associations between theoretical variables (community, social, and individual) and screening outcomes, including interactions with the interventions. If found to be cost effective, either or both interventions have the potential to be immediately disseminated to increase BC, CC, and CRC screening rates and ultimately reduce cancer disparities for underserved rural women. This project will use an overall theoretical framework to understand health disparities that includes individual, social and community level variables, and a conceptual model for the intervention which uses a multiple behavior theoretical approach, all of which have demonstrated efficacy in improving adherence to single screening test behaviors, as well as other preventive health behaviors.

## 2.0 BACKGROUND AND RATIONALE

### 2.1 Magnitude of the Problem

The cancer burden among rural and underserved populations is significant. Residents living in rural areas in the U.S. experience higher cancer incidence and mortality rates, as well as lower screening rates.[1-5] The breast cancer mortality rates in the 32 targeted Ohio and Indiana counties are 9.7% and 5.8% greater, respectively, than that for the U.S., while the cervical cancer mortality rate is 12.5% greater, and the CRC mortality rates are 10.4% and 6.1% greater, respectively, than that for the U.S. This results in 106 excess deaths in these counties per year. Reasons for cancer disparities among rural populations are due to many social determinants of health including lower socioeconomic status (SES), lower educational levels, lifestyle factors, genetics, limited access to healthcare, lack of health insurance, or a combination of these factors.[3-6] Screening adherence rates for BC, CC, and CRC cancers, for which there are validated screening tests available, are lower for those with less education, a proxy for SES.[7,8] The rural counties targeted for this project (Figure 1), include mainly White, poorer, and less educated populations with limited access to health care. Thus, it is essential to intervene in these rural counties to reduce cancer disparities. Many rural women do not complete screening at recommended intervals.[5] In a recently completed observational study among rural women in Ohio, medical record validated completion of screening within recommended guidelines was: 32% for mammography, 36% for Pap test, and 30% for a CRC test.[9] Only 8.6% had completed all three tests within guidelines.[9] This suggests the need for cost effective interventions to provide rural women with the latest information about screening recommendations and needed tests.[10,11]

### 2.2 Justification for the Study

The significance of this study is enhanced by the potential to develop a stronger more efficacious intervention through the combination of two previously tested interventions (tailored interactive programs and patient navigators). This research will test the hypothesis that the addition of a Patient Navigator (PN) to the tailored program will be more effective than a tailored approach alone or UC. This study will determine the cost-effectiveness of interventions that vary in complexity, time, and cost. We will determine if adding a telephone-based PN will be worth the additional costs by comparing the TIDVD intervention with and without PN vs. UC.

### 2.3 Intended/Potential Use for Study Findings

If either or both interventions are shown to be cost-effective compared to UC to improve screening rates, they can be quickly/easily disseminated to rural areas where access to health care is suboptimal, and cancer mortality rates for CC, BC, and CRC are higher than non-rural areas.

## 3.0 METHODS

### 3.1 Research Design

#### 3.1.1 Participants

Our study will target women aged 50 to 74 who reside in 32 rural counties in northwest OH and northeast IN (Figure 1). In these counties (2010), there were 173,812 women in the appropriate age category, 96% who are White (non-Hispanic). We will enroll 1058 women 50-74 years in the designated counties, stratified by Rural Urban Commuting Area (RUCA) code. U.S. Preventive Services Task Force cancer screening guidelines will be used for all screening tests to determine eligibility (Table 1).

**Figure 1. Map of Intervention Counties**

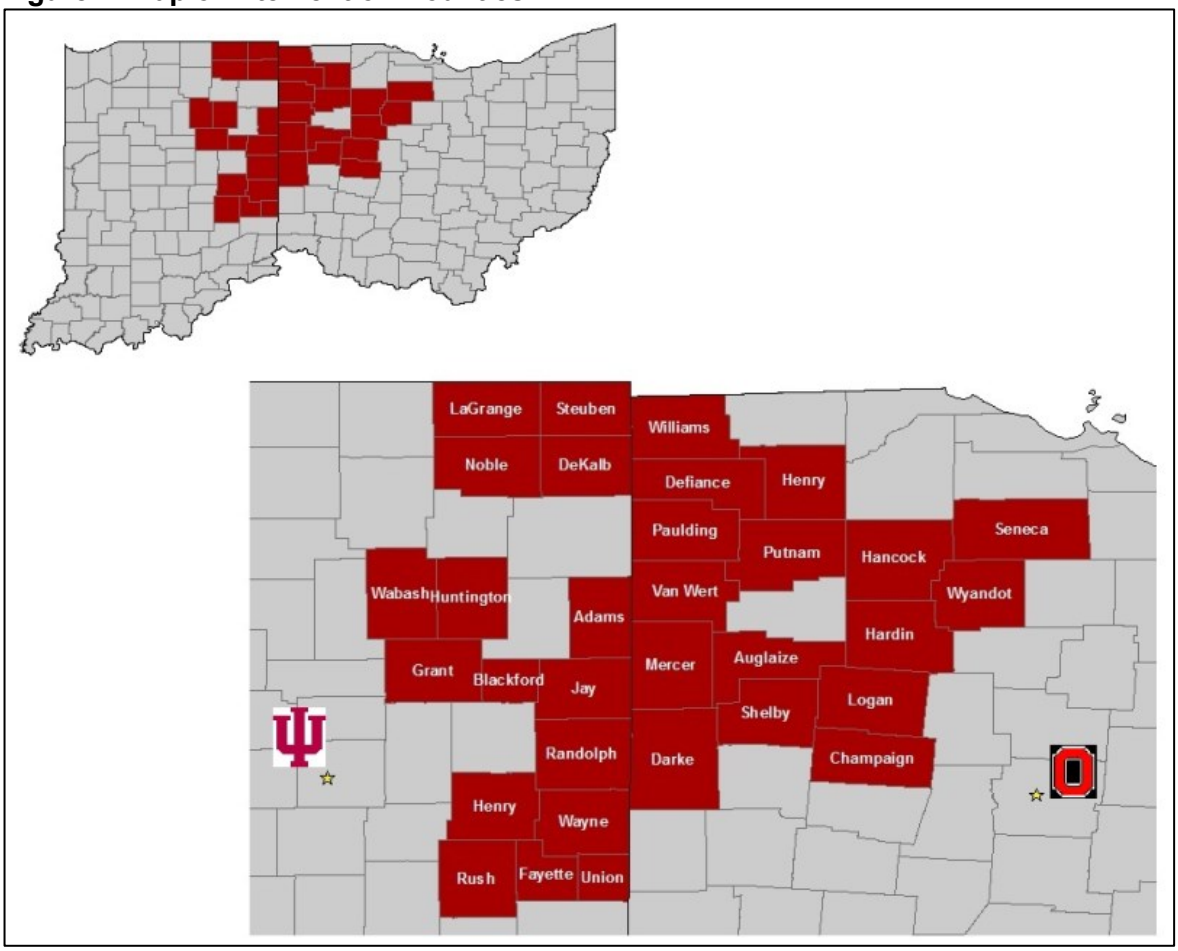


**Table 1. United States Preventive Services Task Force Screening Guidelines**

| Site | Guideline |
|---|---|
| BC | Women ages 50-74: mammogram every 2 yrs. |
| CC | Women ages 50-65: Pap test every 3 yrs. or Pap test and HPV co-testing every 5 yrs. Discontinue after age 65 for women with 3 consecutive negative cytology results or 2 consecutive negative HPV results in last 10 yrs. |
| CRC | Women ages 50-75: stool test (FOBT/FIT) annually or colonoscopy every 10 yrs. For those at increased risk; colonoscopy is recommended. |

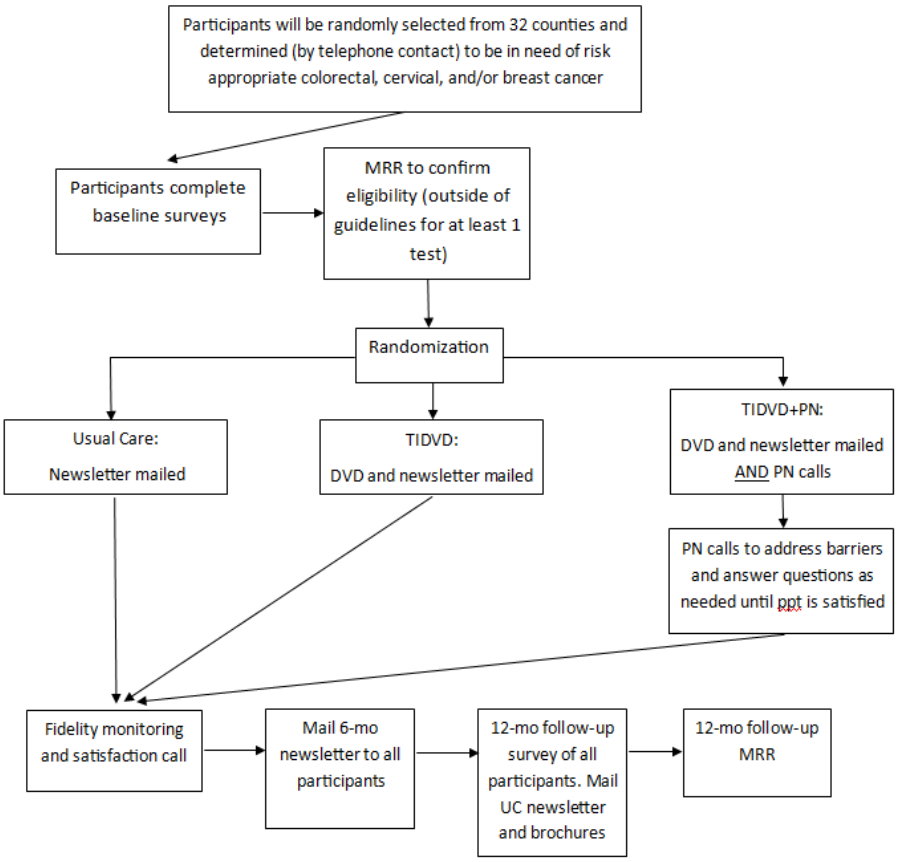
**3.1.2 Eligibility criteria**. To be eligible, women must:

1) be aged 50-74 years (inclusive);
2) be non-adherent to one or more recommended screenings for BC, CC, or CRC by MRR;
3) reside in one of 32 rural counties in IN or OH;
4) provide informed consent;
5) able to speak/read English; and
6) have access to a DVD player or computer that can play DVDs.

**3.1.3 Exclusion Criteria.** Women will be excluded if they:

1) have a personal or family history of any hereditary/genetic cancer syndrome such as BRCA1 and BRCA2 polymorphisms, hereditary nonpolyposis colon cancer, or familial adenomatous polyposis;
2) have a personal history of inflammatory bowel disease (Crohn's disease or colitis), colon polyps, or a history of cancer except non-melanoma skin cancer;
3) have more than one first degree relative with a history of colorectal cancer or one first degree relative who was diagnosed with colorectal cancer before the age of 60;
4) plan to move outside of the country within the next year;
5) reside in a nursing home or other institution; or
6) are pregnant or intend to become pregnant during the study period.

**Figure 2: Study Schema**



### 3.2 Recruitment Process:

#### 3.2.1 Sample Selection

Eligible female residents of each of the 32 study counties will be randomly selected from a customized list provided by Marketing Systems Group (white pages, commercial and United States Postal Service (USPS) lists) that includes female county residents age 50-74, inclusive (N=173,812). In order to ensure a sufficient number of truly rural women are enrolled, the sample selection will be stratified by Rural-Urban Commuting Area (RUCA) code which is assigned at the census tract level. An equal number of women will be sampled from tracts with RUCA codes of 4-6 and 7-10. Codes 4 through 6 represent micropolitan areas in and around towns with 10,000-50,000 residents where some residents may commute to a larger urban core. Codes 7 through 10 indicate small towns (population 2,500-9,999) and rural areas with little commuting to larger urban clusters. Mr. Young will provide selected names monthly to the OSU Behavioral Measurement Shared Resource (BMSR). We estimate that 55% of the women will be eligible and 70% of eligible women will participate; thus to achieve our sample size of 1058, we will need to mail approximately 2,750 letters.

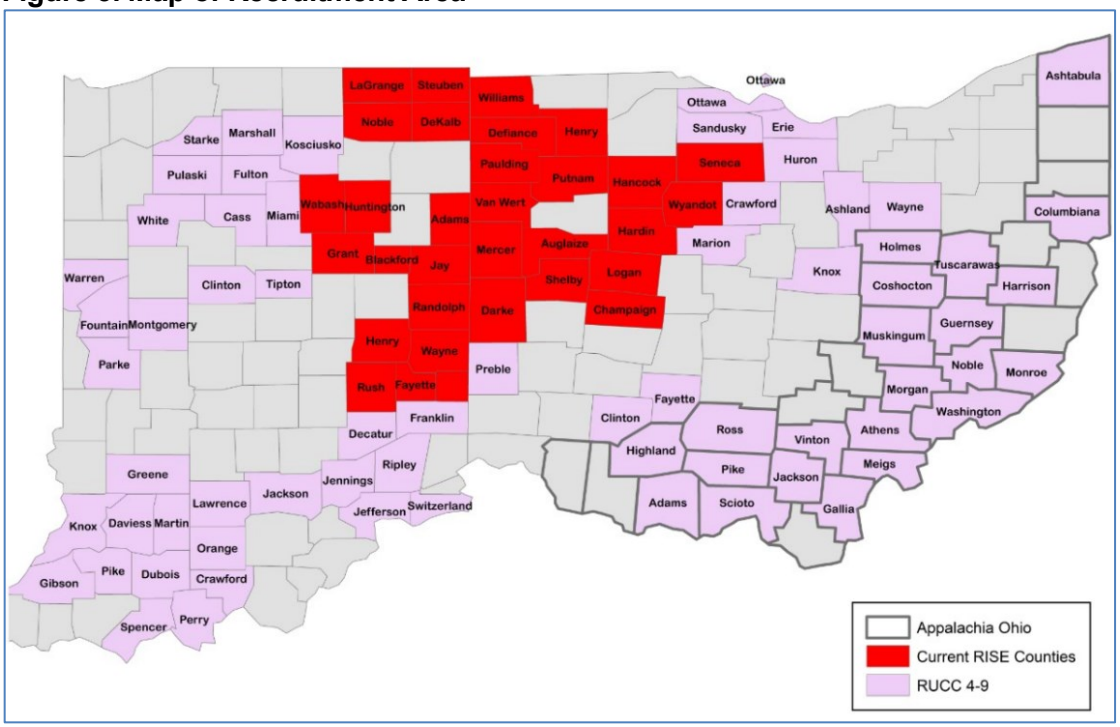
In addition to mailing and calling, promotional materials encouraging women in these regions to volunteer to participate in the study will be placed within the target communities. Promotional materials (flyers/brochures/postcards) may be displayed within public spaces where women in the age group may frequent, such as libraries, senior centers, health departments, etc. to promote the study and increase credibility. OSU CCTS Recruitment and Retention Services and potentially IU CTSI Research Recruitment Program will be employed to promote the study. We are requesting the use of Research Match (ResearchMatch.org) and Study Search (studysearch.osumc.edu) for participant recruitment on this protocol. Through these promotional materials and advertisements, potentially eligible women will be encouraged to call study staff via a toll-free number to determine eligibility and schedule a call with an interviewer to complete the consent process and baseline survey.

Targeted Facebook ads will be posted to 50-year-old and older women's Facebook pages who live in counties of interest. These ads will be promoted by the OSUMC Communications and Marketing team through The Ohio State University and Wexner Medical Center Facebook pages.

#### 3.2.1.a Phase 2 Sample Selection (beginning January 2018)

The recruitment area will be expanded to additional rural counties in both Indiana and Ohio (see map – Figure 3) in order to improve enrollment rates. Promotional materials will be sent to locations in these communities and Facebook ads will target these additional counties. Mail/call lists of female residents may be purchased for these additional counties as well. Craigslist advertisements will be developed and placed on community pages for the geographic areas from which we are recruiting.

**Figure 3. Map of Recruitment Area**



### 3.2.2 Contact

Selected women will be mailed a letter and information sheet introducing the study, followed by a telephone call by BMSR trained interviewers approximately one week after mailing the letter. The interviewers will attempt to contact their assigned list of potential participants by phone. They will make at least 10 attempts (calling at different times of the day, weekday, and weekends) to reach the listed county resident. After 10 attempts, if they have not been able to reach the participant, they will send a "no contact" letter to request that the participant contact the project office. Potentially eligible women may also contact us via a toll-free number or the study email address to participate. With prior approval from the potential participant, text messaging may be employed. Email may be used to communicate with and respond to potentially eligible women once they initiate communication with the project and permission is obtained to do so. The content of the emails or text messages will depend on the information requested by or needs of the participant. The project staff will not initiate communication by email or text without the permission of the potential participant.

Figure 3 summarizes communications between study staff, participants, and clinics.

Women who click targeted ads will be taken to a REDCap landing page (go.osu.edu/RISE) with a brief description of the study, eligibility criteria, and a brief set of questions to partially assess eligibility and determine best time for an interviewer to contact her to complete the consent process and baseline survey.

### 3.2.3 Consent for Participation

Once the participant is reached, the study will be explained, permission to verify eligibility will be obtained, the eligibility screener will be administered and if eligible, informed verbal consent will be obtained. After the verbal consent process is completed, the baseline telephone survey (1a) will be administered.

### 3.2.4 Eligibility Verification

After completion of the baseline telephone survey, participants will be mailed a medical record release form with a stamped, pre-addressed envelope to mail the medical record release form back to the OSU study office. Those who do not return the release form within two weeks will be re-contacted by the interviewer. Study staff will review and verify screening tests received by MRR and if the woman is still eligible, she will be enrolled and randomized to one of 3 study arms. The trained interviewers will be familiar with screening, determining eligibility, administering telephone surveys, and have a keen understanding of rural culture.

## 3.3 Randomization

Once eligibility is confirmed via medical record review, participants will be randomly assigned to one of 3 study arms -1)TIDVD alone, 2)TIDVD + PN, or 3)UC. A centralized web-based system at OSU will be used to randomize participants to one of the 3 study arms. Randomization will be stratified by age (50-64 vs. 65-74) and by seven screening categories representing which screening test(s) each woman needs (BC, CC, CRC, BC+CC, BC+CRC, BC+CC+CRC, or CC+CRC).

## 3.4 Data Collection and Measurements

Trained interviewers will collect data via REDCap (Research Electronic Data Capture) at baseline, 2 and 12 months from date of enrollment, and these data may also be collected using paper-based surveys (Teleform). We will collect information on outcomes as well as covariates and mediators. Self-report of cancer screening will be obtained at baseline, 2 and 12 months with MRR data collected at baseline and 12 months to verify screening status. Most recent height and weight measurements will be collected from chart review. Variables such as demographics that will not change will be measured only at baseline. The 12 month survey will also include open-ended questions to assess why women are adherent to specific cancer screening tests and not adherent to other screening tests. Constructs to be measured are described below and when each will be collected in Table 2.

### 3.4.1 Participant Surveys

Participants will complete surveys which will address demographics, medical history, health insurance, personal cancer screening history, cancer screening knowledge and beliefs, perceived cancer risk, benefits and barriers of cancer screening, self-efficacy, social support, and satisfaction with intervention materials. Surveys will be administered at baseline via telephone (1a) and paper (1b), two months into the intervention (TIDVD and TIDVD+PN arms) via phone (2) and at 12-months via paper (3).

**Figure 4: Contact Flow Diagram**

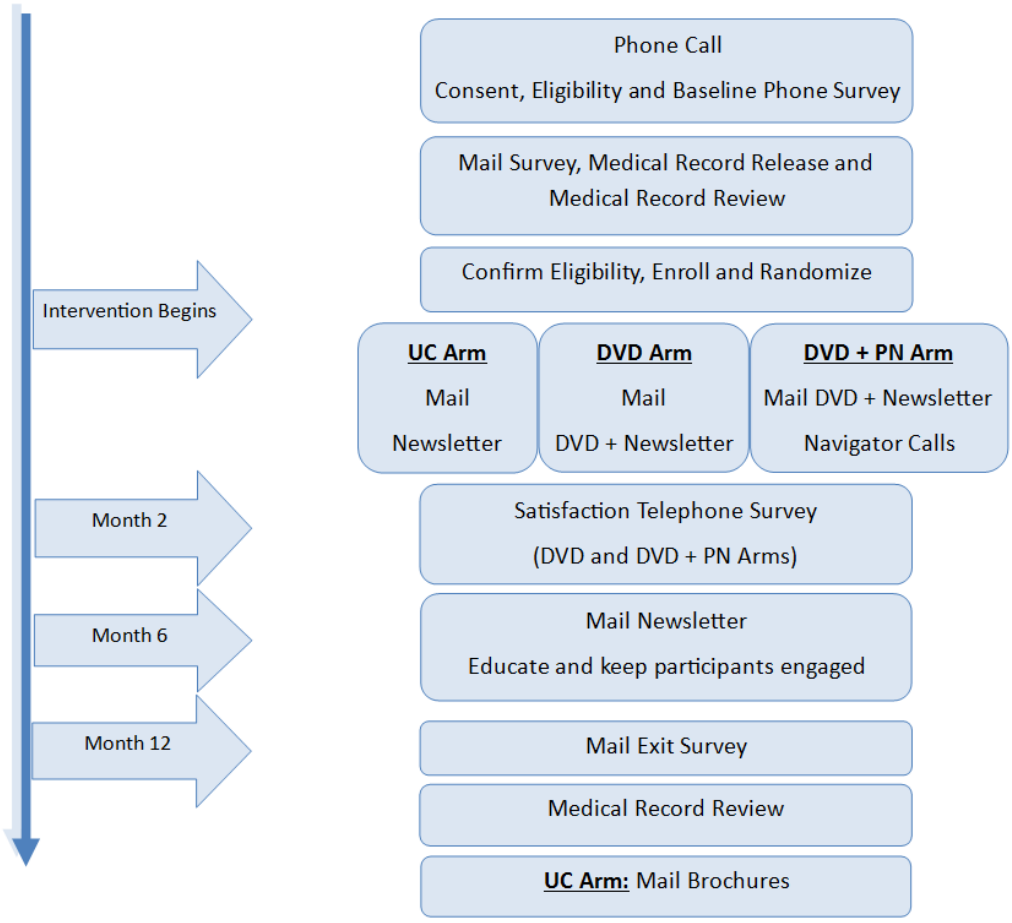



**Table 2. Data Collection: Constructs and Time Points**

| | Data Collection Timing | | | |
|---|---|---|---|---|
| | Baseline | | 2-month | 12-month |
| | 1a | 1b | 2 | 3 |
| Demographics | x | | | |
| General Health/Co-Morbidities | x | | | |
| Social Support | | x | | x |
| Personal Cancer History | x | | | x |
| Cancer Risk/Worry | | x | x | x |
| Cancer Knowledge/Attitudes/Beliefs | | x | x | x |
| Screening: Behavior/Barriers/Benefits/Self-Efficacy | | x | x | x |
| Staging | | x | x | x |
| Screening Intention | | x | x | x |
| Satisfaction with DVD | | | x | |
| Satisfaction with Navigator | | | x | |
| Contamination | | | | x |
| Medical Record Review | x | | | x |

1a) Baseline Telephone 1b) Baseline Paper 2) 2-month Phone 3) 12-month Paper

### 3.4.2 Community-Level Variables

Effect of community (neighborhood) factors, using geographic information system (GIS), on outcomes of

receipt of needed screening tests will be evaluated. Participant addresses will be geocoded and accessibility to health care will be determined by measuring the number of facilities within a given distance of each geocoded address. Geocoded addresses will be spatially joined to a U.S. Census Topologically Integrated Geographic Encoding and Referencing (TIGER) zipcode shapefile containing demographic data. An area deprivation index score will be created using the health care accessibility variable and 21 U.S. Census data variables, including social and economic conditions (e.g. education, employment/occupation, housing conditions, income/ poverty, racial composition, residential stability).[12-15]

**3.5 Incentives**

A total of $25 in incentives will be distributed to participants as a sign of gratitude for taking the time to complete and return the surveys. Amounts and timing are detailed in Table 3.

**Table 3. Gift Card Distribution**

| Time | Action | Amount |
|---|---|---|
| Pre-enrollment | Complete phone survey and send medical record release | $5 |
| Baseline | Complete and return paper survey | $10 |
| Month 12 | Complete and return paper survey | $10 |

**3.6 Training of Interviewers**

Interviewers will be trained, supervised, and monitored by the BMSR staff, in collaboration with the PIs and the Program Managers**.** Training manuals for interviewers developed for prior studies will be modified for the proposed study and will include: 1) overview of study objectives; 2) description of interventions; 3) protection of human subjects, HIPAA, and confidentiality issues; 4) cultural sensitivity; 5) roles and responsibilities; 6) documentation and reporting requirements; 7) data monitoring and quality assurance procedures; 8) handling problems/questions during recruitment/data collection; 9) effective interviewing techniques; and 10) use of the REDCap telephone interview system. Following practice sessions, interviewers will role-play and receive feedback until they have reached 100% compliance with recruitment and data collection integrity.

**3.7 Quality Assurance**

Performance of interviewers will be closely monitored by the project manager and the BMSR supervisors. Approximately 10% of all interviews and recruitment calls will be monitored for quality assurance purposes. Feedback will be provided to the interviewers to correct performance weaknesses.

**3.8 Medical Record Review (MRR)**

Participants will be asked to sign and return a MRR form to the study office after the baseline interview. The signed release will remain valid for the duration of the study. Dates and results of completed BC, CC, and CRC screening tests and confirmation of participant date of birth (DOB) will be requested from health care providers named by participants during the baseline and 12-month interviews. We are confirming DOB to ensure that records are obtained for the correct woman. The MRR form signed by the participant along with a request from our research office will be presented to the medical facility (secure fax, phone, secure email, or in- person) where the cancer screening tests were ordered or performed. This request will inform the clinic/facility staff about the study and request information from the medical record about the participant's cancer screening history to be sent to a secure fax or mailed to the study office at OSU. Women who report never being screened and/or cannot produce provider names or locations will be asked to complete MRR forms in order to contact locations that they may visit for screenings during the study period. Non-responders will be contacted again, if necessary, to obtain this information. We anticipate that at least 85% of the participants will return a signed MRR form, and 95% of clinics will respond to our request for information (based on our prior studies).[16]

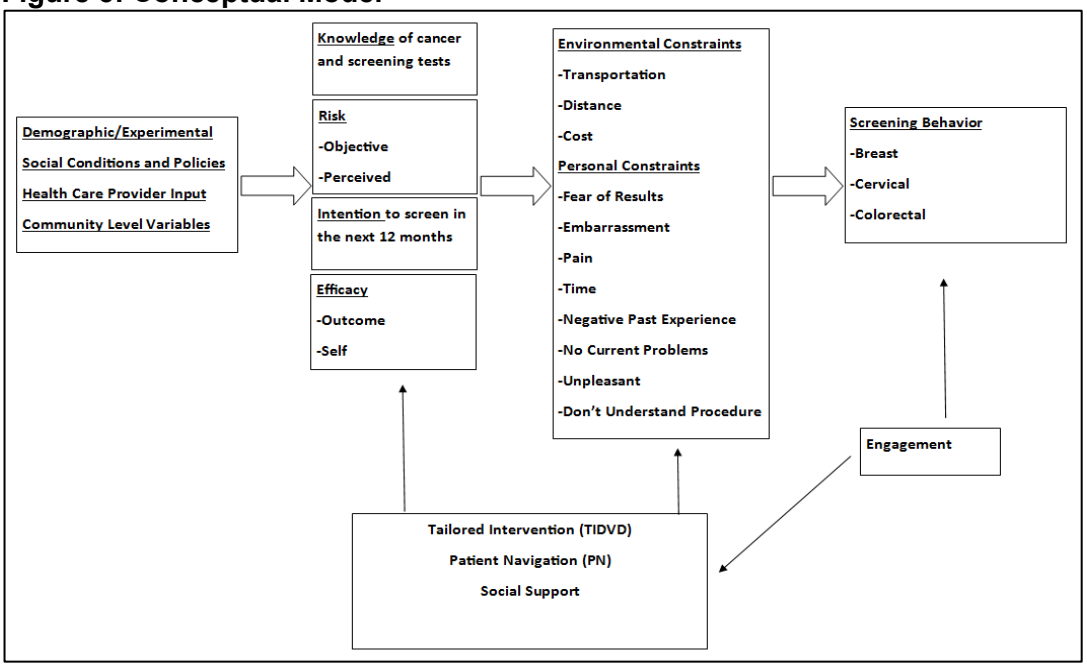
**4.0 Interventions**

**4.1 Conceptual Model for the Intervention**

A multiple health behavior change intervention is especially appealing when addressing behaviors that are conceptually similar, such as cancer screening behaviors. Cancer screening behaviors have many commonalities and have been found to be correlated with common variables predicting screening for all 3 tests.[17] For example, the theoretical principles used to make behavior change for each cancer screening test include self-efficacy, and the use of change processes that move an individual through stages of change.[18-20] The interventions proposed will focus on the needed cancer screening tests concurrently

and teach principles of behavioral change (e.g. self-efficacy). Several studies have found that interventions targeting multiple behavior change (but none have focused on 3 screening test behaviors) have been effective in simultaneously changing up to five behaviors. In 2005, a randomized controlled trial was effective in helping CRC patients change multiple behaviors.[21] More recently, researchers found that an intervention targeting multiple behaviors was successful in decreasing sedentary behavior in CRC survivors.[22] Johnson coined the word coaction to reflect the synergistic effect one behavior can have on another.[23] He concluded that regardless of study design or other variability, coaction was consistently found in multiple behavior studies.

**Figure 5: Conceptual Model**




The conceptual model (Figure 5) uses constructs from the Theory of Reasoned Action, Theory of Planned Behavior, as well as other well-established behavioral theories.[24-27] This model will build on previous work by identifying an individual's beliefs about variables known to predict behavior change.[24,28,29] These variables will have intervention messages tailored to each women's input. Our goal is to provide a unified intervention that supports adherence to all 3 cancer screening tests, depending on individual screening needs. Responses are tailored to specific tests needed by the individual. Ability to carry out tests will vary based on which test is being discussed and the program will tailor messages appropriate to the test(s) needed.[28-30] Variables that may affect beliefs directly or indirectly such as demographics, health care provider input, and social conditions and policies are identified in Figure 4. This model will be used to identify intervention effects and to test model development. Intervention "engagement" has been identified by researchers and theorists as a critical component of intervention effectiveness and will be measured and included in the analyses.[31]

This study will test two interventions (TIDVD and PN) in comparison to UC. The following sections describe the two interventions separately as well as the intervention pre-testing. Overall, both interventions (TIDVD and PN) will address any combination of screening tests needed by an individual woman. Women will be categorized into one of seven groups based on baseline adherence status for each of the three screening tests. The ability of either the intervention arm to simultaneously address any combination of the three screening tests (BC, CC, or CRC) represents a holistic approach to preventive care that may be cost effective. For example, for women who need both mammography and CRC screening, both the TIDVD and PN interventions will provide messaging about common benefits of BC and CRC screening, and, if appropriate, build on the success of CC screening (Table 4). If a woman indicates abnormal signs or symptoms at any time, she will be referred to her health care provide or a health care clinic. We will identify any abnormal screening tests that occur in the follow-up surveys and a PN will contact women (in any study arm) to assure they are able to follow-up with further testing. Since this will be done after the intervention is concluded and outcome data (screening adherence) are collected, this action will not interfere with the study results. The two interventions, TIDVD and PN, are described in detail below.

**Table 4. Sample TIDVD Messages Tailored to Screening Adherence at Baseline**

| | | |
|---|---|---|
| **Needs only CRC screening** You already understand the benefit of mammography and Pap tests but might not know that CRC starts as a single cell which can grow and divide for a long time before you would be aware you had cancer. Just like BC or CC, if CRC isn't found early, it can spread to other parts of your body making it hard to treat and may cost you your life. The good news is that all cancers can be found early – before they spread; when almost all women are completely cured. | **Needs BC and CRC screening** You already understand the benefit of having Pap tests but might not know that BC and CRC start as a single cell which can grow and divide for a long time before you would be aware you had these cancers. If BC or CRC isn't found early, it can spread to other parts of your body making it hard to treat and may cost you your life. The good news is that these cancers can be found early – before they spread and when almost all women are completely cured. | **Needs BC, CRC, and CC** Many women don't realize that BC, CRC and CC all start as a single cell which can grow and divide for a long time before you would be aware you had cancer. If this cancer isn't found early, it can spread to other parts of your body may cost you your life. The good news is that these cancers can be found early – before they spread and when almost all women are completely cured. |

### 4.2 Tailored DVD

The TIDVD will include a CC screening component and barriers unique to rural women that are identified during focus groups. The TIDVD will be mailed to a participant and played on a regular DVD player, Blu-ray player, or computer. The participant interacts in real time with the DVD by answering questions posed by the DVD program and using arrow keys on the remote to highlight and enter their response. All possible tailored messages and videos are included in the TIDVD program with algorithms that provide individualized messages and videos tailored to individual data. The TIDVD format was selected for three reasons. *First*, the majority of women in rural areas have a DVD player. *Secondly*, the DVD can be programmed such that women can answer questions using the remote control allowing delivery of tailored messages in real time. We can program a DVD to deliver health messages with visual aids such as graphs, video clips, and storytelling. Once data are obtained from the individual, the program delivers a message developed specifically to the data provided in real time. For example, a message about the barrier of embarrassment with CRC screening would be delivered only if the participant indicated she was embarrassed about the test. We are tailoring on multiple barriers, as well as age and rural residence.[32-34] *Third,* DVD can be duplicated quickly with minimal expense and mailed to participants. The tailored program begins with a generic introduction that explains the use of arrow keys on the remote control to enter responses and asks a few basic questions to determine adherence to each of the 3 screening tests, as well as age (in decade), race, and family history. Responses to questions are stored in memory and integrated into responses (obtained throughout the program) to queries about belief constructs (perceived risk, benefits, and self-efficacy). Throughout the TIDVD program, women will receive programmed tailored messaging bundled to their screening status on BC, CC, and CRC (Table 6). Risk messages are tailored to both perceived and objective risks. For barriers, a list of potential barriers will be presented and women will indicate up to three barriers for the relevant test. The DVD program ends with the narrator encouraging viewers to make an appointment for any of the screenings needed. Screens will be narrated along with the critical information appearing as written text, allowing women with low literacy to use the program. On average, our previous interactive CRC DVD program required 10 minutes to complete, so we anticipate this TIDVD program covering BC, CC, and CRC screening information to take no longer than 30 minutes to complete if the participant chooses to watch all components of all three screening sections. Program coding will be done using DVD Studio Pro.

### 4.3 Tailored DVD + PN

The second intervention group will receive a TIDVD intervention followed by a telephone call from a PN.

#### 4.3.1 PN Intervention

PNs will attempt to contact participants by telephone within 1 week after mailing the DVD. PNs will make at least 10 attempts at different times and on different days, including weekends, if needed. This timeframe will allow women to have received the DVD and watched it. If not viewed, the PN will encourage women to view the DVD and will assist to facilitate this. The PN will reinforce the DVD message and address barriers to receiving needed screening tests, including those not mentioned in the DVD. PNs will complete electronic encounter forms during each participant contact and have a file for each navigated participant. The encounter forms will include: 1) days/times of contact attempts; 2) a summary of the telephone call with documented cancer screening barriers; 3) navigator actions to address screening barriers; and 4) time spent on the call. PNs will track any other actions taken to assist participants (e.g. arrange transportation)

and track the time taken to complete those actions. PN information will be directly submitted to a database that will alert them when a follow-up action needs to be placed for a participant (e.g. an alert will be sent to the PN to call the participant to remind them of a cancer screening appointment). PNs will make as many contacts as needed to assist participants to complete screening tests.

**4.3.2 PN Qualifications and Training**

The success of a PN intervention is dependent upon the navigator's ability to communicate with a wide range of people and in the culturally accepted vernacular. Personal skills such as the ability to be empathetic, patient, and caring are important when it comes to helping participants understand and comply with cancer screening tests. PNs will be trained by Dr. Katz and Ms. Tatum, and will include information about cancer screening, treatment, and ways to overcome barriers to health care. Navigators will be trained jointly by OSU and IU staff, and training will include an explanation of the PN role as serving as a link between the participants and the health care system to guide participants to complete needed cancer screening tests. The following criteria will be assessed prior to allowing the PN to begin: 1) ability to communicate; 2) knowledge/understanding of cancer screening; and 3) understanding of the community and cultural setting.

**4.3.3 Community Resources/Referral Network for the PN Intervention**

In Year 1, a listing of community resources needed to address barriers and needs of participants with no primary care provider, no regular source for screening tests, abnormal test results and cancer will be assembled by the project staff and PNs. We will involve local and state American Cancer Society (ACS) offices as well as our State Agricultural Extension Offices located in each county in this effort. This listing will include medical resources, financial resources, transportation, local agencies, etc. For example, if a participant needs transportation, the PN will only query the data base for local transportation systems. Under the direction of Dr. Katz, low literacy educational resources will also be identified so that PNs can provide appropriate materials (e.g. from NCI, ACS, etc.). Most importantly, after outcome assessment, the PN will contact any women who received an abnormal screening test, regardless of study arm, to assure proper follow-up has occurred with her provider.

**4.4 Intervention Pretesting**

Usability testing will occur using both individual user feedback and CAB member discussions. The CAB will be actively involved in development and evaluation of the PN and TIDVD interventions to ensure clarity, relevance and sensitivity. Usability will be evaluated by assessing ease of use, content (leveling and appropriateness), aesthetic appeal, and cultural relevance. We will present prototypes to members of the target population either individually or in group sessions as components are designed. The information gathered during testing sessions will be used to revise both interventions as needed.

**4.5 Usual Care (UC)**

Women randomized to UC will receive brochures developed by the research team using national guidelines and/or existing, current brochures developed by those organizations that explain and provide encouragement for BC, CC, and CRC screening. Women will receive these after the active intervention phase is complete.

**4.6 Potential Risks**

No risks are anticipated from baseline or follow-up surveys. Risks anticipated with receiving the intervention materials (brochures, DVD, PN call(s)) or encouraging participants to obtain BC, CC, and/or CRC screening exams are minimal, e.g., embarrassment or unnecessary fear of cancer.

**4.7 Protection against Potential Risks**

We anticipate no risks. Only persons directly involved with the study will have access to data identifying individuals. Records and forms will be kept in locked file cabinets when not in use. No names will be stored on computer files for data analysis, and no individuals will be identified in the results of this study. Access to computer-stored information will require simultaneous knowledge of the data format, computer language, file name and password. Participants will be told that they do not have to answer any questions they do not want to answer.

**4.8 Potential Benefits**

The participants may not benefit directly from the study, however, benefits to the subjects may come in the form of increased awareness and use of cancer screening tests for the detection of BC, CC, and/or CRC. The subjects and society in general will benefit through the knowledge gained in promoting knowledge about cancer control with the future benefits of lower mortality from cancer. The benefits far outweigh the risks of this study, since even the possible risks, mainly unnecessary fear of cancer, might prompt participation in screening, which is in itself of benefit to the subject.

## 5.0 Data Handling and Analyses

### 5.1 Statistical Analysis

#### 5.1.1 Sample Size

Estimates of effect size (Table 5) for the intervention at 12 months is based on our experience in projects promoting screening among underserved populations. We estimate 10% attrition at 12 months, when our primary outcome will be assessed. Attrition of 10% is conservative because we will have medical record data on most of the persons who drop out which will reduce the effect of drop out on the primary outcomes. We based power calculations on 2-sided tests when comparing the two intervention arms (TIDVD vs. TIDVD+PN) because we could not be certain which group would perform better. Because of the overwhelming evidence in the literature[35,36] that the UC arm does not have better screening rates than tailored DVD or PN interventions, we based the power calculations on 1-sided tests for comparisons to the control group (TIDVD vs. UC; TIDVD+PN vs. UC). The planned statistical analyses are consistent with these power calculations. Specifically, we will use two sided tests for TIDVD vs. TIDVD+PN, and the 1-sided tests for comparing interventions to the UC arm, using the 1-sided p-value from the Z statistic in contingency table analysis and from the likelihood ratio test in logistic regression analysis. To achieve 80% power for the contingency table analyses, and the likelihood ratio tests of logistic regression for the primary outcome of adherence to all needed screening tests at 12 months by MRR, a sample size of 356 per each intervention group and 180 in the UC group will be needed, which will require 396 per intervention group and 200 in the UC group at baseline to account for attrition. For 80% power for the secondary outcome of adherence to any needed (BC or CC or CRC) test, regardless of the number of screening tests needed, a sample size of 376 per each intervention group and 200 in the UC group will be required at 12 months. We will require 418 per intervention group and 222 in the UC group at baseline to account for attrition and to achieve at least 80% power for both outcomes. The total sample size is 1058 participants enrolled with 418 randomized to each intervention arm and 222 randomized to the UC arm.

**Table 5. Sample Size***

| Effect sizes for screening at 12 months | Control (UC) 12 Months | TIDVD 12 months | TIDVD+ PN 12 months | N needed per TIDVD and TIDVD+PN at baseline for 80% power at 12 months | N needed in control arm (UC) at baseline for 80% power at 12 months | Projected N per TIDVD and TIDVD+PN intervention arms at 12 months | Projected N in control arm (UC) at 12 months | Power TIDVD vs. TIDVD+ PN | Power TIDVD vs. control (UC) | Power TIDVD+ PN vs. Control (UC) |
|---|---|---|---|---|---|---|---|---|---|---|
| **Cervical** | 35% | 50% | 70% | NA | NA | NA | NA | NA | NA | NA |
| **Breast** | 35% | 45% | 65% | NA | NA | NA | NA | NA | NA | NA |
| **Colon** | 30% | 40% | 55% | NA | NA | NA | NA | NA | NA | NA |
| **All needed screenings (primary outcome)** | 10% | 20% | 30% | 396 | 200 | 356 | 180 | 82% | 83% | 99% |
| **Any (at least 1) needed screening (secondary outcome)** | 25% | 35% | 45% | 418 | 222 | 376 | 200 | 80% | 80% | 99% |

*Estimates of effect sizes for the secondary outcome (at least 1 needed test adhered to by 12 months) was based on the most conservative single test (i.e., colon cancer screening). Effect sizes for the primary outcome were based on an estimated reduction of 5% in the number of participants who would adhere to all needed tests compared to only one of the needed tests. Power columns are based on the most stringent required sample size, i.e., when N=418 per each intervention arm and N=222 controls at baseline and projected 376 per each intervention arm and 200 controls at 12 months.

#### 5.1.2 Primary Outcome

The primary outcome of adherence to screening guidelines at 12 months for Hypotheses 1 and 2 will combine MRR and self-report by using MRR when available and self-report otherwise. We anticipate obtaining MRR and verification on screening tests at the 12-month survey. Participants will be asked to provide contact information on both their primary care physician and any specialist who provided a screening test, reducing the chance of missing a test that was conducted but not reported to the primary care physician. For those who are lost to follow-up, a signed MRR form will enable us to obtain the adherence outcome for those participants. Thus, we anticipate adherence for the overwhelming majority of patients will be based on MRR. Dr. Monahan will supervise these analyses with assistance from Mr. Young.

For hypotheses 1 and 2, the differences in binary adherence (Hypothesis 1, all needed screenings; Hypothesis 2, any needed screening) across the three randomized arms will be tested initially with pair-wise chi-square tests. Binary logistic regression analysis will be used to compare the two interventions

and the UC group on the binary dependent variable (adherence), while adjusting for any potentially confounding covariates. The models will be controlled for any demographic covariate (e.g., age, education) for which the randomized groups differ significantly at baseline using a liberal significance level of 0.20 to achieve conservative adjustment. As a sensitivity analysis, multiple imputation will be used to impute the adherence outcome for participants who are lost to follow-up and did not sign a MRR. We plan to include screening history as a covariate in our analysis by using the total number of past screenings for each test since the participant turned 50. All variables in the logistic regression models will be tested using the likelihood ratio test.[37] Adjusted odds ratios (ORs) and profile-likelihood-estimated 95% confidence intervals for those ORs will be provided. Our proposed theoretical model includes only variables that can be measured and used in modeling. The conceptual model (Figure 2) uses constructs from the Theory of Reasoned Action, and Theory of Planned Behavior, as well as other well-established behavioral theories.[25-28] Our model has taken these theories into consideration and added important constructs such as engagement. Therefore, we will perform theoretical modeling using structural equation modeling using the MPLUS software, as described in the next section. We have labeled this section as exploratory analyses because it is not part of the primary aims; however, the results will provide insightful findings about the context of the intervention effects including how all the theoretical variables interact with each other, both in terms of mediation and moderation effects.

### 5.1.3 Exploratory Aims

Associations between theoretical variables (community, social, and individual) and the binary screening outcomes will be identified with non-linear mixed models, accounting for two levels of assessment. The first level includes variables measured at the person level such as individual demographic and screening history variables, as well as beliefs which are measured for each participant in this study. The second level includes community variables measured at the county level such as number of providers, number of screening facilities, deprivation index, and median income level. Moderators of intervention effects on adherence will be identified by testing interaction terms in the model. The theoretical model in Figure 4 , including mediation effects, will be tested with structural equation models using the MPLUS software.[38]

Most recently recorded height and weight will be collected from any medical providers an individual provides to us to contact for cancer screening history. Height and weight will be used to calculate body mass index (BMI) to compare the association of BMI status and the concordance of self-report and medical record review as it relates to screening adherence for breast, cervical and colorectal cancers. Demographic and behavioral factors (such as age and smoking status) may modify associations between BMI and concordance of self-report and medical record review-confirmed cancer screening adherence; relationships between those variables and BMI and cancer screening adherence will be investigated.

### 5.2 Evaluation of Cost-Effectiveness

Dr. Eric Seiber will assume responsibility for the cost-effectiveness analyses. The proposed economic evaluation of interventions can be seen as addressing three questions:

1) what are the full costs associated with the implementation of the interventions (cost-identification analysis);
2) what are the net costs associated with the interventions (is each intervention actually cost-saving?); and
3) what is the cost-effectiveness of each intervention?

### 5.2.1 Cost of the Interventions

The first question is answered by a careful accounting of the operational costs of the interventions, excluding those costs that are purely attributable to the research. Some of these are fixed costs associated with hiring and training PN's (which may recur if there is turnover in the position), and others are ongoing costs associated with the delivery of services. In the model implemented in this study, the PN's spend full time in that activity. Thus, the costs of implementation are straightforward and obtainable. Even though the PN is full-time, we will want to collect data concerning at least the broad categories of time use, so that we can estimate the cost of specific components (e.g., arranging transportation) more accurately. The best way to do this will be a structured time log. We will use a developed Participant Encounter Form and a Tracking Log of Direct Participant Contacts that will provide the majority of this information. The procedures outlined above will establish the aggregate cost of implementation. However, it will also be useful to measure cost on a per-unit basis. This will be done by calculating average cost per active participant per month and average cost per participant for cancer screening completion, for each test, type of test, and

all needed tests.

### 5.2.2 Cost Savings

The second question is whether each intervention is actually cost-saving, and is essentially an attempt to calculate the numerator in a typical cost-effectiveness analysis:[39] the change in cost attributable to each intervention. Using the terminology of Gold et al., a full assessment would require measuring the changes in use of health care resources, changes in use of non-health care resources, changes in use of informal caregiver time, and changes in use of participant time for cancer screening.[39] In order to avoid distortions in the measured impact of an intervention due to pricing differences, all cancer screening tests will be assigned cost based on their Medicare allowable payment, regardless of how the service was actually paid for. Medicare payments are often used as a proxy for cost in cancer studies.[40,41] While this is not a pure cost measure, it is comparable and avoids other potential distortions like differences in cost to charge ratio for different payors.

### 5.2.3 Cost Effectiveness

The third question, the cost-effectiveness of each intervention, will be the most difficult to address. Because of the nature of the interventions and the limited time for observation, it is not likely that the interventions will have a significant impact on standard measures of effectiveness used in cost-effectiveness analysis, such as quality-adjusted life years (QALYs). Cost-effectiveness analysis (CEA) implies a comparison of whether the cost per unit of outcome in one situation exceeds that in another. Unless the outcome measures are comparable, this is not possible. We will be able to examine outcomes of the interventions and the UC group (completed cancer screening tests). Our analysis will emphasize the first two questions (cost of the intervention itself, calculation of net cost). CEA will consist of measuring the incremental cost of achieving the observed incremental outcomes, but not a cost-effectiveness ratio in standard terms. Cost Utility: From our cost effectiveness estimates, we will conduct a QALY-based (Quality Adjusted Life Year) cost utility analysis. Calculating QALYs will require both utility (quality) weights and estimates of the life years saved. Both utility weights and the life years saved from the health outcomes will be drawn from the published literature. The Markov modeling will be conducted in TreeAge. Dr. Xu will conduct these analyses.

## 5.3 Process Evaluation

Dr. Mira Katz will conduct the process evaluation for the study using a mix of quantitative and qualitative methods focusing on the following 3 areas.

### 5.3.1 TIDVD Intervention

The process evaluation will include such key components as reasons for viewing/not viewing the TIDVD; participant satisfaction with the TIDVD and engagement with the intervention. The data collected on the 2 month survey will be used for this evaluation.

### 5.3.2 PN Intervention

The PN data collection form documents each participant's encounter(s) and lists the potential barriers and actions so the PN can easily document each participant-reported barrier and the associated PN actions. Analysis will be primarily descriptive but can address not only the frequencies of each barrier, but their clustering within individuals and distribution by geographic and demographic characteristics. Little is known about the range of barriers faced by rural women and the effective actions which can be taken to address cancer screening barriers. This data collection activity will provide rich descriptive data on these issues. Reports will include the number of participants reached with the content of the conversation, calls or contacts scheduled or rescheduled, and those who refused.

## 5.4 Quality Assurance for Intervention Fidelity

Evaluation of intervention processes is needed to ensure consistency of intervention delivery. Modifications will be made as necessary and recorded to ensure appropriate intervention delivery and maintenance of protocol integrity. Evaluation questions will assess user experience/satisfaction with the intervention. A random sample of participants per month will be called by the project manager to confirm receipt of the DVD and PN calls. The 2-month process evaluation survey will contain questions about the DVD or DVD+PN to serve as a rough manipulation check allowing us to document whether participants viewed the DVD or spoke to navigators. The BMSR will provide quality checks on 10% of the PN calls to document that the telephone

call was made, if cancer screening barriers were reported, and the actions discussed match the PN document.

### 5.5 Data Management

We will use REDCap as our data entry system. It will be used to complete the baseline and follow-up questionnaires, will work directly with the OSU CCTS Research Informatics Services Core and will be used as a central location for data processing and management. Vanderbilt University, with collaboration from a consortium of institutional partners (including OSU) and the NIH National Center for Research Resources, has developed a software toolset and workflow methodology for electronic collection and management of research and clinical trial data. REDCap data collection projects rely on a thorough study-specific data dictionary defined in an iterative self-documenting process by all members of the research team with planning assistance from the CCTS Research Informatics Services Core. As part of the data dictionary development process, individual fields can be denoted as "identifiers". When exporting a de-identified dataset, these variables are omitted. Additionally, the data export tool also allows shifting of dates for a limited data set export. REDCap provides a secure, web-based application that is flexible enough to be used for a variety of types of research, provides an intuitive interface for users to enter data and has real time validation rules (with automated data type and range checks) at the time of entry. It offers easy data manipulation with audit trails and ad hoc reporting functionality for reporting, monitoring and querying patient records, and an automated export mechanism to common statistical packages (SPSS, SAS, Stata, R/S-Plus). REDCap is 21 CRF Part 11 capable. Currently, REDCap installations support electronic signatures by positively identifying the user through a unique username and password combination. The provisioning of accounts and user access to specific database(s) is integrated with the OSU Medical Center LDAP authentication service, and the provisioning of access and specific user rights are managed by CCTS staff.

Each participant will be assigned a unique participant identification code (PID) when first recruited that will follow their electronic information in REDCap, throughout the study. Each participant will have their own folder that will contain a copy of their consent documentation form, Patient Data Sheet, Medical Records Release form, and any letters sent to the participant. The folders will be stored in locked filing cabinets in a locked office. No information about a study participant will be given to third parties unless that subject has given written or witnessed consent to do so.

All paper forms will be scanned into the system where optical character recognition (OCR) software interprets each data item and exports the data to a Microsoft SQL Server database maintained by the OSU CCTS. Teleform performs basic range checks and data edits immediately following OCR. Records with data not meeting pre-specified edit checks or failing to be recognized by the OCR engine will be placed in a suspended file for verification by quality control staff. The CCTS SQL Server database is maintained on striped and mirrored disks to insure data integrity and undergoes incremental backups to tape daily. The system resides inside the OSUWMC firewall and is protected in a locked and secured room.

Information will be obtained and maintained on all individuals screened for this study. If available we will keep demographic data on those individual who are ineligible and eligible but refuse. The data will be used to ensure that we do not contact individuals who are ineligible for the study or who have told us they do not want to participate in the study. The data will also be used to characterize/compare this group individual to those who are eligible and agree to participate; it is important to determine if those who are ineligible and especially those who refuse to participate, are in way inherently different from the women who participate in the study.

### 5.6 Record Retention

All research records (including identifying information) will be maintained until data analysis and all manuscripts have been completed, or for the length of time designated by the institutional requirements (OSU, IU) and the NCI. Paper records will be maintained in a secured storage facility and electronic data will be stored in a password protected database until is appropriate to destroy the data. The IRBs at OSU and IU and the NCI will be notified of our intent to destroy the data. Data will be sent to Indiana University (IU) as necessary for the purpose of conducting data analyses for the study. The data will be sent in a secure manner to IU (using OSU secure container or similar software) by Mr. Young. If required by NCI, de-identified data may be shared with the NCI and their data repositories.

### 5.7 Management Plan

Overall study responsibility belongs to Drs. Paskett and Champion, Co-PIs of the study. Dr. Paskett and her staff will be responsible for day-to-day study oversight including obtaining human subjects approval,

drawing/recruiting the sample, conducting interviews and the PN intervention, and data management activities. Dr. Champion and her staff will be responsible for the refining and troubleshooting the TIDVD and supervising the data analyses. Dr. Katz will assist in training the PNs and overseeing the process evaluation. Dr. Rawl will assist with refinement of the DVD program and study measures. Dr. Grever will serve as the team clinician to advise about medical-related issues and to provide expertise related to clinical environments which serve these women. Dr. Seiber will lead the cost analysis with assistance from Dr. Xu, and Dr. Monahan will lead data analysis with assistance from Mr. Young.

## 6.0 Ethical and Regulatory Considerations

### 6.1 Regulatory Approval

Prior to initiating the research project and conducting any research project activities the PIs will obtain written approval to conduct the research project from the appropriate institutional regulatory bodies. Should changes to the research project protocol become necessary, the PIs will submit protocol amendments in writing to the IRBs for approval prior to implementation.

### 6.2 Informed Consent

As noted in section 3.2.3, consent will be sought and obtained via phone and verbal consent process completed prior to initiating any research project procedures. Each element of the consent will be verbally explained to the potential participant. The woman will be given an opportunity to ask questions and have the questions answered to her satisfaction. Once the individual understands each element of the verbal consent, including the purpose, requirements, benefits, risks, confidentiality, right to withdraw, and contact person, then and only then will it will be documented that the individual consented to participate in the study.

### 6.3 Data and Safety Monitoring Plan

We have developed a Data and Safety Monitoring Plan for this study. The purpose of the data and safety monitoring plan is to ensure the safety of participants, the validity and integrity of data, and the appropriate termination of studies for which significant benefits or risks have been uncovered or when it appears that the study cannot be concluded successfully. Risks associated with participation in research must be minimized to the extent practical and the method and degree of monitoring should be commensurate with risk. The essential elements of the Data and Safety Monitoring Plan include:

1. Monitoring the progress of the study and the safety of participants
2. Plans for assuring compliance with requirements regarding the reporting of adverse events (AE)
3. Plans for assuring that any action resulting in a temporary or permanent suspension of the study is reported to the appropriate agencies
4. Plans for assuring data accuracy and protocol compliance.

Prior to the initiation of the project, all project staff will receive standardized training to ensure that the activities of the study are conducted in a uniform, safe, confidential and secure manner. A tracking system will be put in place to document data collection activities, and reports will be generated on a weekly and monthly basis to monitor the study activities. Conference call meetings of the research team will take place on a monthly basis to monitor the activities of the project and to continually reassess the progress of the project including assessments of data quality, timeliness, participant recruitment, accrual, retention and monitoring of the risk versus benefits throughout the study period. In addition, face to face meetings among the local institutional study staff will take place once per week to discuss the activities of the project.

All AEs will be reported according to the policy outlined by the Institutional Review Board (IRB) at the OSU and IU. The appropriate forms will be completed and sent in accordance to the timeline set forth by the IRBs. All AEs will be reported to and reviewed by the study team. The research project manager will conduct a10% eligibility verification. If a violation is noted, the research manager will document the violation and inform the research project and OSU and IU investigators of the matter. The appropriate action will be taken to rectify the violation and to determine what or if any corrective actions need to take place. All protocol violations will be documented and reported to the IRBs. Also, any privacy violations will be reported to the IRBs and the institutional privacy offices. All privacy violations, adverse events, and protocol violations will be reported to and reviewed by the principal investigators (Drs. Electra Paskett and Victoria Champion) and the research team, who will be responsible for reporting to the appropriate regulatory bodies at OSU and IU.

The IRB will be provided feedback more frequently if there should be any adverse events or other recommendations. The investigators are responsible for reporting to the NIH project director any action resulting in temporary or permanent suspension of the research project at OSU. These actions will be reported to the NCI program director within 72 hours of notification. All documents or correspondence that are generated in the course of correcting or appealing the suspension status must also be forwarded to the program director

within 72 hours of it being presented to the institutional body that put for the directive to temporarily or permanently suspend the research project. During this time no research project activities can occur.
The principal investigators are responsible for submitting reports; annual reports will be sent to the OSU and IU IRBs, and as required by the NIH project office. Information included in the reports will include the number of individuals enrolled in the study, dropout rates and any protocol deviations.

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