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# Intervention to Improve Follow-up for Abnormal Papanicolaou Tests: A Randomized Clinical Trial

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## Abstract

**Objective—**To evaluate the effect of a theory-based, culturally-targeted intervention on adherence to follow-up among low-income and minority women who experience an abnormal Pap test.

**Methods—**5,049 women were enrolled and underwent Pap testing. Of these, 378 had an abnormal result and 341 (90%) were randomized to 1 of 3 groups to receive their results: Intervention (I): culturally-targeted behavioral and normative beliefs + knowledge/skills + salience + environmental constraints/barriers counseling; Active Control (AC): non-targeted behavioral and normative beliefs + knowledge/skills + salience + environmental constraints/barriers counseling; or Standard Care Only (SCO). The primary outcome was attendance at the initial follow-up appointment. Secondary outcomes included delay in care, completion of care at 18 months, state anxiety (STAI Y-6), depressive symptoms (CES-D), and distress (CDDQ). Anxiety was assessed at enrollment, notification of results, and 7–14 days later with the CDDQ and CES-D.

**Results—**299 women were included in intent-to-treat analyses. Adherence rates were 60% (I), 54% (AC), and 58% (SCO), $p$=0.73. Completion rates were 39% (I) and 35% in the AC and SCO

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groups, $p$=0.77. Delay in care (in days) was (M ±*SD*): 58 ±75 (I), 69 ±72 (AC), and 54 ±75 (SCO), $p$=0.75. Adherence was associated with higher anxiety at notification, $p$<0.01 while delay <90 days (vs. 90+) was associated with greater perceived personal responsibility, $p$<0.05. Women not completing their care (vs. those who did) had higher CES-D scores at enrollment, $p$<0.05.

**Conclusions—**A theory-based, culturally-targeted message was not more effective than a non-targeted message or standard care in improving behavior.

## Keywords

cervical dysplasia; intervention; randomized controlled trial; behavior theory; minority

The rate of cervical cancer has not changed in the U.S. since 2003 (ACS, 2011). In the year 2011, the incidence of cervical cancer was 12,710 and over 4,200 women died from a preventable cancer (ACS, 2011). In most cases, regular Papanicolaou (Pap) screening and adherence to treatment or monitoring of precursor lesions can prevent cervical cancer (Lawson, Henson, Bobo, & Kaeser, 2000). Unfortunately, 20–70% of women in the U.S. who experience an abnormal Pap test do not adhere to recommended follow-up (Marcus et al., 1992; Michielutte, Dignan, Bahnson, & Wells, 1994; Paskett, White, Carter, & Chu, 1990; Peterson, Han, & Freund, 2003). Behavioral approaches that improve adherence have been identified as a priority for cervical cancer prevention efforts (NIH, 1998).

Approaches that target low-income and minority women are especially important, as socioeconomically disadvantaged and minority women bear a disproportionate burden of cervical cancer morbidity and mortality (ACS, 2011; Howlader et al., 2011). These disparities appear to reflect more advanced disease upon screening (Downs, Smith, Scarinci, Flowers, & Parham, 2008) and poorer adherence to follow-up (Benard, Lawson, Eheman, Anderson, & Helsel, 2005; Benard, Lee, Piper, & Richardson, 2001) rather than lower screening rates among minorities (National Center for Health Statistics, 2009).

This study evaluated an intervention to improve adherence to follow-up for abnormal Pap test results among minority women and women of lower socioeconomic status. The intervention was a message, delivered verbally to patients at the time of notification of an abnormal Pap test result. The content of the intervention was guided by a unifying theory of behavior (Jaccard, Litardo, & Wan, 1999) which captures the major components of the theory of reasoned action (Fishbein & Ajzen, 1975), planned behavior (Ajzen, 1985), social learning theory (Bandura, 1986), and subjective culture (Triandis, Vassiliou, Vassiliou, Tanaka, & Shanmugam, 1972).

Prior research has described how women represent many of these theoretical constructs when considering follow-up of an abnormal Pap test result (Breitkopf, Catero, Jaccard & Berenson, 2004). Furthermore, several investigations have established relationships between attending follow-up for abnormal Pap test results and constructs such as attitudes, beliefs (Radecki Breitkopf & Pearson, 2009) and knowledge (Breitkopf, Pearson, & Breitkopf, 2005; Stewart, Buchegger, Lickrish, & Sierra, 1994). Importantly, with regard to attending follow-up appointments for abnormal cervical screening tests, the content of the beliefs and their relationship to adherence has been shown to vary by race/ethnicity (Breitkopf, Catero,

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Jaccard, & Berenson, 2004; Radecki Breitkopf & Pearson, 2009). Such variation may underlie observed differences in adherence by race/ethnicity (Carey & Gjerdingen, 1993; Marcus et al., 1998) and should be addressed in interventions designed for minority women through targeted approaches. Finally, literature on implementation intentions and cervical screening (Sheeran & Orbell, 2000) suggests that guiding women toward highly specific intentions to return for follow-up, and including barriers counseling are important components of a behavioral intervention.

The primary objective of the research was to examine whether a theory-based, multi-component intervention that included targeted beliefs for Hispanic, non-Hispanic black and non-Hispanic white women would improve attendance at follow-up among women of lower socioeconomic status who receive abnormal results upon attending cervical cancer screening. Secondary objectives included evaluating the effect of the intervention on time to adherence (delay in care) and whether resolution of the abnormality was achieved (completeness of care), as recommended by Yabroff et al. (2003). Delay in obtaining follow-up care is an important behavioral outcome, as delays can lead to more aggressive treatment at a later date, which can adversely affect patient prognosis (Nelson, Geiger, & Mangione, 2002) or psychological well-being (Lerman, Miller, Scarborough, Hanjani, Nolte, & Smith, 1991). Completeness of care, or continued adherence to recommendations for follow-up until the abnormality has been resolved is also important, yet few studies have followed women long enough to measure this outcome (Ell et al., 2002). In addition to measuring behavioral outcomes, this study considered psychological outcomes of the intervention, as abnormal Pap test results have been associated with depression and anxiety (e.g., Lerman et al., 1991; Rogstad, 2002).

In a multi-site randomized clinical trial, behavioral and psychological outcomes were compared between women notified of an abnormal Pap test result in the context of a message containing information regarding knowledge/skills, importance/salience, environmental constraints, normative influences, and expectancies/beliefs about attending follow-up, as compared to women notified in the context of a non-targeted message (active control group) and passive (standard care only) control group. It was hypothesized that a greater proportion of patients randomized to the intervention would return for their initial follow-up appointment and would complete their care. Among those not attending the initial follow-up appointment, it was hypothesized that delay would be shortest in the intervention group relative to the active and passive control groups, which were not expected to differ. Depressive symptoms and distress regarding the abnormal result were not expected to differ among the study groups whereas women in the intervention group were expected to demonstrate higher anxiety upon receiving an abnormal result than women in the control groups, as the intervention message (described below) was designed to overcome potential complacency, heighten awareness of the importance of follow-up for an abnormal Pap test result, and describe potential negative consequences if left untreated, which may raise anxiety. Consistent with conceptual models of cognitive processing, an acute stressor (such as receiving an abnormal test result) and its associated arousal/anxiety are associated with heightened attention, vigilance, and message encoding (see review by Bourne & Yaroush, 2003). Thus, women who were adherent (versus non-adherent) were hypothesized to have higher levels of anxiety at the time of notification of the abnormal result.

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## Method

### Participants and Setting

Participants were Hispanic and non-Hispanic (black and white) women 18–55 years of age who attended one of the study clinics in southeast Texas between June 1, 2006 and November 30, 2010 for an appointment that included a Pap test. Women were excluded who had a current diagnosis of cervical cancer, or who were pregnant, unable to understand English or Spanish, less than 18 or older than 55 years of age, or did not identify as white, black, or Hispanic. Six Regional and Maternal Child Health Program (RMCHP) clinics were selected as study sites (from a total of 16 RMCHP clinics) based on patient volume and racial/ethnic diversity. The University of Texas Medical Branch (UTMB) RMCHP clinics provide culturally-appropriate care (Anderson, Nelson-Becker, Hannigan, Berenson, & Hankins, 2005) and follow uniform protocols and guidelines for cervical cancer screening and follow-up.

### Recruitment Strategy and Sample Size Determination

Targeted recruitment was conducted by identifying potentially eligible patients from provider lists in the study clinics. Following the September 13, 2008 landfall of Hurricane Ike, recruitment was interrupted for a period ranging from 2 weeks to 6 months. The trial was not resumed in one of the clinics hit hardest by the hurricane. Potentially eligible patients were approached by a trained, bilingual (English/Spanish) research coordinator who assessed the patient's interest in the study and confirmed eligibility.

Enrollment of 3,555 women was expected to result in a sample size of 200 women per group under the following assumptions derived from preliminary work: 13% refusal rate, 20% abnormal Pap rate, and 3% loss to follow-up rate. Based on sample size calculations for the primary outcome variable (initial adherence), a sample size of 200 women per group would provide >95% power to detect an odds ratio of 2.4 between intervention and standard care or intervention and active control groups (i.e., a difference between 55% and 75%), which would represent a moderate effect size. This sample size would yield approximately 85% power to detect an odds ratio of 1.9 (i.e., a difference between 55% and 70%) for attending follow-up within 3 months (delay in care) and approximately 85% power to detect an odds ratio of 1.8 for completeness of care after 18 months (e.g., ability to detect a difference of 35% completing follow-up in the standard care only group compared with 50% in the intervention group).

### Randomization and Blinding

Women were block randomized by race/ethnicity in blocks of six to ensure balance between study groups. A call-in system was used to receive the random assignment. Study group assignment was not disclosed to patients. The study's investigators, statistician, statistical assistant, and research coordinators were blinded until all intent-to-treat (ITT) analyses were performed, at which time the blind was broken.

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## Procedure

The research was approved by the Institutional Review Boards of the Texas Department of State Health Services and UTMB; the study is registered on clinicaltrials.gov (NCT00575510). Data and safety monitoring was performed annually by an independent panel. Written informed consent was obtained and participants completed a self-administered survey in English or Spanish that assessed demographic characteristics and queried attitudes, beliefs, and behaviors surrounding a variety of health topics. Validated Spanish instruments were used when available otherwise translation and back-translation procedures were performed. Women were reimbursed $5 in cash.

Pap test results were obtained from the electronic medical record (EMR) by the research nurse. Patients with normal results were not contacted further. Patients with abnormal results were called by the research nurse once written orders for follow-up were received from the healthcare provider. A script containing the assigned message content and blanks to fill in individualized patient information (specific results, follow-up date, etc.) was used to ensure standard delivery of the intervention and document the interaction. Return of Pap test results by telephone reflected standard care practices in this clinic system at the time of the research. Three failed telephone attempts prompted written, mailed notification.

## Study Group Messages

**Standard Care Only (Passive Control)—**All three groups received standard clinical care, which was to notify women by telephone of their abnormal result, provide general instructions for follow-up, and respond to all patient questions regarding the abnormal test result.

**Intervention—**The intervention message contained information regarding knowledge/skills, importance/salience, environmental constraints, normative influences, and expectancies/beliefs about attending follow-up. The specific content of the message was guided by prior formative data collected via individual qualitative interviews and self-administered surveys among independent samples of women attending the RMCHP clinics (Breitkopf, Catero, Jaccard, & Berenson, 2004; Breitkopf, Pearson, & Breitkopf, 2005; Radecki Breitkopf & Pearson, 2009).

**Knowledge/skills—**The knowledge/skills component involved stating the specific abnormality, providing an indication of its potential seriousness in terms of “high” vs. “low” grade, and outlining the specific procedures and steps to resolve it (e.g., return to the clinic in 2 weeks for a liquid-based Pap test with HPV testing).

**Importance/salience—**The importance/salience component involved statements regarding the importance of returning for follow-up, particularly in the context of a “low grade” abnormality (i.e., “…when I say your abnormality is ‘low-grade’ you should not think ‘low importance’ because it is VERY important to follow-up these abnormalities since right now, we do not know if it is serious or not.”). The appropriateness of the timing of follow-up was also emphasized to assure patients that follow-up appointments may be

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purposefully scheduled to occur several months in the future (to allow transient HPV-related changes to spontaneously resolve).

**Environmental constraints—**Patients were prompted to envision a plan to attend their visit and identify a possible barrier to following-through with their plan (e.g., transportation, lack of child care). The research nurse verbally guided the patient through possible solutions for the identified barrier (barriers counseling).

**Normative influences—**In previous research, normative influences and behavioral beliefs about returning for follow-up differed by racial/ethnic group (Breitkopf, Catero, Jaccard, & Berenson, 2004; Radecki Breitkopf & Pearson, 2009). Among non-Hispanic black women, personal responsibility regarding health has been shown to be prominent whereas family has been shown to be a strong normative influence for Hispanic and non-Hispanic white women. The intervention message included the relevant normative belief for a woman's cultural group, either: "There is only so much other people can do to get you to come back, ultimately, it is up to you –it is your responsibility to take care of your health" or "Your family would probably want you to come back for your follow-up."

**Behavioral beliefs—**Finally, the intervention message incorporated six beliefs about returning for follow-up – 4 common to all women and 2 culturally-targeted beliefs derived from previous work in this same clinic population (Breitkopf, Catero, Jaccard, & Berenson, 2004; Radecki Breitkopf & Pearson, 2009). Beliefs consistently associated with motivation to attend follow-up included negative consequences surrounding not returning for follow-up, specifically that not doing so could lead to infertility, death, future hysterectomy, and hospitalization. The reality of these more severe, long-term consequences (if not an actual diagnosis of cancer) find some support in the literature (Moore, Fetterman, Cox, Poitras, Lorey, Kinney, & Castle, 2010; Solomon, Schiffman, & Tarone, 2001). The belief component for Hispanic women emphasized that avoiding the problem may have bad consequences ("Sometimes women think that if they ignore it, or don't come back to the clinic, that they can avoid dealing with the problem, but this is not true at all. If you fail to come for your follow-up visit, it might be OK for now, but it could develop into a serious health issue in the future") and addressed the feeling of being rushed ("We try to be efficient at the clinic, so that women can get on with their day. I know that sometimes, women think we are *"too quick,"* and they end up feeling rushed through their appointment. If you feel this way, your health care provider and the clinic staff would want to know that, and you should tell them that you'd be more comfortable if things happened more slowly – either what they're saying to you, or what they're doing"). Among non-Hispanic black women, information addressed the likelihood of taking medication or having multiple tests or procedures to resolve the abnormal result and disconfirmed that returning for follow-up would result in being treated with disrespect ("…the clinic staff recognizes that it may not be easy to come in again for another test, and they appreciate it when women show up for their appointments. In fact, our clerks and nurses have a great deal of respect for every patient who is in the clinic, taking care of her health, *especially* when a potential problem has been identified and requires follow-up"). For non-Hispanic white women, the belief component addressed wait times in the clinic ("we do our best to see patients on time in the

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clinic, but I know that sometimes women wait a long time to be seen. If you do have to wait, try to remember that taking care of your health is one of the most important ways you can spend your time") and that discomfort may be associated with some procedures ("If you do not usually find a Pap test to be painful, the colposcopy part of the visit should not be painful. If you do have to have a biopsy, a biopsy has been described as feeling a strong pinch with some cramping. Remember, the nurses are here to help you through your exam in whatever way they can").

**Active Control—**The active control message contained all of the components of the intervention message (knowledge/skills, importance/salience, environmental constraints, normative influences, and expectancies/beliefs about attending follow-up) with the exception of the culturally-targeted beliefs.

## Study Timepoints and Measures

Clinic appointments during which patients presented for Pap testing, were approached by study staff, and entered the study comprised the "initial visit." At this visit, patients provided informed consent, completed a "baseline" survey and underwent Pap testing. The next study timepoint was commensurate with the return of abnormal Pap test results via telephone. This timepoint included the delivery of results within the context of the randomized message group assignment, and measurement of anxiety. The third timepoint comprised the "post-test" in which participants were contacted by telephone (7–14 days following notification of results) and answered questions regarding the intervention, anxiety, depressive symptoms, and distress surrounding the abnormal result. The telephone survey was 20–30 minutes in duration; women received a $15 gift card for their time. A total of 71 women (24%) were unable to be reached to complete the post-test during the designated time period and were considered lost to follow-up. The loss to follow-up rate was 22% in the intervention group, 25% in the active control, and 24% in the standard care group ($\chi^2$=0.14, *df*=2, *p*=0.93, Cramer's V=0.02).

## Behavioral Outcome Measures

**Adherence—**Attendance at the initial follow-up appointment was determined by review of the EMR. For patients who proactively contacted the clinic and rescheduled their appointment in advance, adherence was recorded for the rescheduled visit. Adherence was recorded independently by the research nurse and statistical assistant; no disagreements occurred.

**Delay in Care—**Delay in care reflects the "time to adherence" for each patient. Delay was calculated as the time period, in days, between the originally scheduled follow-up appointment and the date the patient actually attended a follow-up appointment using EMR data. Delay was coded "0" for patients who were adherent. Delay was analyzed as a continuous variable and as a dichotomous variable (<90 *vs.* 90+ days) reflecting evidence-based clinical guidelines (Fung-Kee-Fung, Howlett, Oliver, Murphy, Elit, Strychowsky, et al., 2010).

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**Completeness of Care—**Follow-up appointments related to the abnormal Pap test result were monitored in the EMR for a maximum of 18 months following the abnormal result. Women who attended all scheduled appointments and were advised to return to routine screening were categorized as having completed their care. Follow-up for 4 women extended beyond the study period. These women were counted as completing their care if they had attended all documented appointments related to the abnormal Pap test result up until the study's endpoint, even if they had not yet returned to routine screening. For this outcome variable, initial coding agreement between the research nurse and statistical assistant was 95% ($\kappa$=0.91); disagreements were resolved by re-review of the EMR and corroboration with appointment scheduling records.

## Psychological Outcome Measures

**Distress—**Fifteen items reflecting the two domains of distress within the Cervical Dysplasia Distress Questionnaire (CDDQ) (Shinn et al., 2004) were administered as part of the post-test. The domains included sexual and reproductive consequences (9 items, $\alpha$=0.85), such as "Have you been worried whether having sex will make the problem worse?" and health consequences (6 items, $\alpha$=0.92), such as "Have you worried that you may have cancer?" Items were measured on a 4-point "not at all' (1) to "very much so" (4) rating scale.

**Anxiety—**The 6-item short form Spielberger State Anxiety Inventory (STAI Y-6) was used to assess anxiety (Marteau & Bekker, 1992). The STAI Y-6 was administered at the initial visit as part of the paper-and-pencil survey ($\alpha$=0.83), and by telephone at the conclusion of the notification call ($\alpha$=0.77) and during the post-test ($\alpha$=0.77).

**Depression—**Depressive symptoms were measured using the 20-item Center for Epidemiologic Studies Depression Scale (CES-D) (Radloff, 1977; Soler, Pérez-Sola, Puigdemont, Pérez-Blanco, Figueres, & Alvarez, 1997). The CES-D was included on the survey completed at the initial clinic visit ($\alpha$=0.81) and as part of the post-test ($\alpha$=0.83). Scores can range from 0 to 60, with higher scores indicating greater depressive symptomatology.

## Additional Theory-Based Measures

Items reflecting self-efficacy, perceived importance, and normative influences were included as part of the post-test. Women's perceived ability to return to the clinic (self-efficacy) was measured with the following item: "It would be easy for me to take all the necessary steps to come back to the clinic for follow-up within the recommended time" on a "strongly agree" (1) to "strongly disagree" (6) rating scale. Three additional items queried perceived ability to "attend whatever follow-up is necessary," "overcome last-minute barriers," and "remember the appointment." These were measured on a "cannot do at all" (0) to "certain I can do" (10) scale. Perceived importance was assessed with the following items: "For me, an abnormal Pap test result would not be the most important thing in my life right now" and "Missing one follow-up appointment for an abnormal Pap test just isn't that serious" using a 6-point "strongly agree" (1) to "strongly disagree" (6) rating scale. Additionally, women responded to "Would you say that attending your follow-up for the abnormal Pap test is important or

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unimportant?" using a 6-point rating scale ranging from "extremely important" (1) to "extremely unimportant" (6). Finally, women were asked to rate "How much is coming back for your follow-up really up to you and no one else?" using the options "not at all," (0) "a little," (1) "mostly," (2) and "entirely" (3).

### Contemporaneous Comparison Group

A total of 1,511 women received Pap testing in one of the study clinics, met eligibility criteria, but were not approached ("missed") by study staff during the 4-year recruitment period (Figure 1). Pap test results and attendance at follow-up (for those with abnormal results) was documented using the EMR to provide data (e.g., abnormal Pap rate, racial/ethnic distribution) against which to benchmark study patients. Thus, these women essentially provided a second control group (true standard care) and the ability to examine a "study effect."

### Statistical Analyses

Patient demographics were compared across study groups using chi-square or analysis of variance (ANOVA), as appropriate. Both intent-to-treat (ITT) and per protocol analyses were conducted. ITT analyses included all women randomized into the study and successfully contacted by the research nurse. Per protocol analyses included only women who received the precise content of the message associated with their group assignment. Deviation from the message content occurred as a result of women asking questions that resulted in the delivery of information included in the intervention group (contamination).

Rates of adherence and completion for women randomized to the intervention, active control, and standard care only were compared using the chi-square statistic. Delay in care was evaluated using the chi-square test comparing the proportion of women who delayed initial follow-up <90 days *vs.* those who delayed 90+ days by study group and also by comparing between-group differences in the average delay (in days) using ANOVA. Between-group differences in psychological outcomes including depressive symptoms, anxiety, and distress were evaluated using ANOVA, ANCOVA, or *t* tests as appropriate. For all ITT and per protocol analyses, a $p$ value <0.05 was considered statistically significant. Descriptive data are presented as means ($M$) ±standard deviation, medians ($Mdn$), frequencies ($n$), and proportions (%). Analyses were conducted using SPSS (version 16; SPSS Institute, Chicago, IL).

## Results

A total of 299 minority and low-income women at risk of cervical cancer were included in ITT analyses (Figure 1). Sixty-three percent of the sample ($n$=188) was Hispanic, 27% ($n$=80) was non-Hispanic white, and 10% ($n$=31) was non-Hispanic black. Nine percent of women lived in public/subsidized housing and approximately 50% indicated their income was not sufficient to pay their bills. Nearly all of the abnormal Pap test results were "low grade" (e.g., atypical squamous cells of undetermined significance, low-grade squamous intraepithelial lesion), with 8 results considered to be "high grade." Follow-up procedures generally involved a liquid-based Pap test (58%) or colposcopy/biopsy (39%). Eighty-three

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percent (*n*=249) of the sample was recruited prior to Hurricane Ike. Patient characteristics by study group are shown in Table 1.

In ITT analysis, adherence rates to the initial follow-up appointment did not differ by study group, $\chi^2$=0.63, *p*=0.73, Cramer's V=0.05 (Table 2). Among women who did not attend initial follow-up (42%, *n*=127), delay could be calculated for 80 (63%) women who eventually returned to the clinic. Records for the remaining 47 women indicated that no more appointments were made following 3 missed appointments ("no-shows") (*n*=43), records were sent to an outside provider (*n*=3), and the patient relocated (*n*=1), thus these women were excluded from further analysis of the delay variable. Overall, delay ranged from 1 to 318 days (*M*=60 ±73, *Mdn*=28). Mean number of days delay did not differ by study group, *F*(2,77)=0.29, *p*=0.75, partial $\eta^2$ = 0.007. Of those who delayed care, 79% (*n*=63) of women attended a follow-up appointment within 90 days of the initially scheduled appointment; the proportion of women doing so did not differ by study group, $\chi^2$=1.08, *df*=2, *p*=0.58, Cramer's V=0.12 (Table 2).

Twelve women became pregnant during the 18-month tracking period and were excluded from analysis of the completeness of care outcome. Thus, completeness of care was analyzed for 287 (96%) women. Overall, only 37% (*n*=105) of women completed their care related to the abnormal Pap test result; completion rates did not differ by study group, $\chi^2$=0.51, *df*=2, *p*=0.77, Cramer's V=0.04 (Table 2).

Two women in the intervention group, 6 in the active control, and 62 in the standard care only group received additional information upon request (Figure 1). Excluding these women, a total of 229 or 76% of the ITT sample was available for per protocol analyses. In per protocol analyses, adherence to follow-up was 59% (59/100) in the intervention group, 54% (51/95) in the active control, and 53% (18/34) in the standard care group, $\chi^2$=0.70, *df*=2, *p*=0.70, Cramer's V=0.05. Rates of delay >90 days also did not differ by group, $\chi^2$=1.25, *df*=2, *p*=0.53, Cramer's V=0.11 and were 51% (21/41), 59% (26/44) and 44% (7/16) for the intervention, active control and standard care only groups, respectively. Finally, in per protocol analyses, 39% (38/97) of women in the intervention group, 33% (30/91) in the active control, and 29% (9/31) in the standard care only group completed follow-up care, $\chi^2$=1.39, *df*=2, *p*=0.50, Cramer's V=0.08.

No group differences were observed in STAI-6 scores at the end of the notification call (following delivery of the message group assignment), while controlling for baseline (initial) STAI-6 scores, *F*(2,219)=0.61, *p*=0.94, partial $\eta^2$= 0.001. However, the mean STAI Y-6 score (collapsed across study groups) was highest at the delivery of the abnormal result (*M*=14.7 ±4.5) relative to the baseline assessment when women were awaiting their clinic visit (*M*=11.8 ±4.3) and the post-test (*M*=11.4 ±4.1).

Analysis of post-test data included exploring group differences in distress, anxiety, depressive symptoms, perceived importance of attending follow-up, self-efficacy, behavioral beliefs, and knowledge. Distress specific to an abnormal Pap test result as measured at the post-test by the CDDQ, did not differ by study group, *F*(2,225)=0.23, *p*=0.80, partial $\eta^2$=0.002. Anxiety scores at the post-test showed no group differences, controlling for initial

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scores, $F(2,202)=0.27$, $p=0.77$, partial $\eta^2=0.003$, nor did depressive symptoms, $F(2,222)=0.18$, $p=0.83$, partial $\eta^2=0.002$. Measures of perceived importance were uniformly high at the post-test (means in each of the study groups = 1 on 1–6 scale, with 1 indicating "extremely important") as were items reflecting perceived self-efficacy, including overcoming last minute barriers (means in each of the study groups = 9 on a 0–10 scale, with 10 indicating "certain I can do"). Ceiling effects undermined the ability to assess whether the intervention exerted a measurable effect on these variables. Several behavioral beliefs showed slightly higher values (greater endorsement) among the intervention group but the differences were minimal and should not be interpreted in favor of an intervention effect given the small sample sizes (per-protocol, completed post-test within designated window) contributing to these calculations. Group differences on targeted beliefs were not explored due to even smaller sample sizes and greater instability when further stratifying by race/ethnicity. Post-test knowledge scores were low, with women correctly answering 5/10 items on average, irrespective of study group (data not shown).

Additional analyses were conducted to examine relationships between the theory-based components and behavior, irrespective of group assignment. As anticipated, anxiety was higher among women who were adherent to follow-up as compared to women who were non-adherent, $M=15.3 \pm 4.5$ *vs.* $M=13.7 \pm 4.4$, respectively, $t(243)=-2.85$, $p<0.01$, Cohen's $d=0.36$. With regard to delay, women who returned for follow-up within 90 days believed more strongly that coming back for follow-up was entirely up to her and no one else, $M=3.0 \pm 0.15$ for delay <90 and $M=2.8 \pm 0.44$ for delay >90 days, $t(89)=2.22$, $p<0.05$, Cohen's $d=0.47$. Finally, women who completed their care, relative to those who did not, had fewer depressive symptoms at enrollment, $M=12.7 \pm 9.3$ and $M=15.3 \pm 10.8$, respectively, $t(282)=2.01$, $p<0.05$, Cohen's $d=0.24$.

Data were available for 1,186 women (78%) of those eligible, but not approached to participate during the recruitment period for the study (contemporaneous comparison group, $n=1,511$; Figure 1). Of these, 1,061 women had a normal Pap test result, 90 had an abnormal Pap test result, and 35 did not have a Pap test done. The abnormal rate in the comparison group (90/1151, 7.8%) did not differ from the abnormal rate observed in the study patients (378/5049, 7.5%), $z=0.34$, $p=0.73$. Similar to the characteristics of the study patients with abnormal results, 62% ($n=56$) were Hispanic, 24% ($n=22$) were non-Hispanic white and 13% ($n=12$) were non-Hispanic black. The mean age was 28 years ±9 ($Mdn=26$, range 18–53). Adherence to initial follow-up could be ascertained for 81 out of 90 women (90%) with abnormal results in the comparison group and was 62% (50/81). This rate did not differ from the rate observed in the standard care only study group (58%, 56/96), $z=0.54$, $p=0.59$.

## Discussion

This study evaluated a theory-driven intervention designed to improve adherence to follow-up among minorities and women of lower socioeconomic strata who received an abnormal cervical screening result. The results of this trial failed to show a significant effect of the intervention on attendance at initial follow-up, time to attendance (delay), and completing the recommended course of care. Results showing that only around half of women attended their initial follow-up appointment, 1 in 5 failed to attend follow-up within 3 months, and

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only about one-third of women completed the recommended course of clinical care, suggest that much work remains if disparities in cervical cancer morbidity and mortality are to be reduced.

The evidence surrounding the applicability of social-cognitive frameworks to minority populations has been conflicting, with some studies finding support (Champion & Collins, 2012; Martin et al., 2008) and others failing to find support (Trost, Pate, Dowda, Ward, Felton, & Saunders, 2002; Vega, Sallis, Patterson, Rupp, Morris, & Nader, 1988). The theory-based intervention tested in this study was designed from preliminary work conducted in similar populations in which the theoretical components were operationalized and shown to be predictive of behavioral intentions (Radecki Breitkopf & Pearson, 2009). Specific behavioral and normative beliefs about attending follow-up that were more prominent within a particular racial/ethnic group (Hispanic, non-Hispanic black, non-Hispanic white) in this qualitative preliminary work were included as part of the targeted message to each racial/ethnic group in the intervention message. While these beliefs were empirically-derived and provided some guidance for tailoring, they do represent the investigators' interpretation of the qualitative data and what is normative in these groups. It is plausible that the investigator's interpretation was flawed or biased, leading to a negative trial. It is also the case that the targeted beliefs incorporated into the intervention may not be relevant to every individual within a specific racial/ethnic group nor can they be considered representative of an entire cultural belief system. Thus, while there are limitations associated with the culturally-targeted intervention, it is unlikely that the intervention content was irrelevant or inappropriate to the patients, and resulted in a negative trial. Instead, the results raise the possibility that additional factors not included in the intervention influenced behavior, or that a single message, delivered at what was believed to be "a teachable moment" (when results were returned), was simply not able to impact behavior occurring some time later. The absence of group differences on several key constructs measured at the post-test raises the additional possibility that receiving news of an abnormal Pap test result may have led to interference of information processing rather than creating a teachable moment.

Corresponding to standard practice in this clinic system for delivery of abnormal test results, the intervention was delivered verbally, over the telephone, with no "booster" messages or follow-up written material. Automated telephone appointment reminder recordings ("teleminders") were available to all patients who wished to receive them, but contained only appointment date and time information. The intervention may simply not have been strong enough, without reinforcement, to exert a lasting influence on behavior, particularly for a long-term outcome such as completion of care. Appropriate "boosters" may have increased the intervention's effectiveness, but this is speculative, and further work would be needed to ascertain the modality (another telephone call, follow-up mailing) and content of the boosters.

An important finding in this study is that women who were adherent reported greater levels of anxiety immediately after hearing their results than women who were not adherent. This is somewhat inconsistent with recommendations regarding return of abnormal Pap results, where efforts to quell anxiety are often emphasized. Instead, the findings regarding anxiety

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and adherence are reminiscent of the “Yerkes-Dodson Law” in which behavioral performance is typically worst at the lowest and highest levels of anxiety or arousal (Yerkes & Dodson, 1908). Particularly in younger, otherwise healthy individuals, an acute stress response or heightened anxiety associated with an abnormal test result may be adaptive, particularly with appropriate cognitive appraisal and coping (Lazarus & Folkman, 1984; Schneiderman, Ironson, & Siegal, 2005). The challenge becomes identifying the appropriate (and motivating) level of anxiety for this context through sensitivity analyses, exploring individual differences and designing interventions that achieve optimal levels of anxiety/arousal. The data provided in this study at enrollment, notification, and post-test using a well-established measure of anxiety are a promising start.

Another important finding relates to the role of personal responsibility. Women who returned for follow-up within 90 days believed more strongly than women who delayed longer that attending follow-up was entirely up to them. Within the context of the theoretical framework, this finding suggests that emphasis on the normative influences of others may be better directed toward messages of personal responsibility and toward increasing self-efficacy. It is possible that lower socioeconomic status heightens this sense of self-reliance.

Among the strengths of this investigation is the inclusion of vulnerable groups including women of lower socioeconomic status who are less likely to attend screening and women of racial/ethnic minorities who experience greater mortality due to cervical cancer. In addition, the assessment of multiple behavioral outcomes, including delay in attending initial follow-up and continued attendance until resolution within an 18-month period was informative and innovative. Finally, the ability to examine a contemporaneous comparison group provided confidence that the abnormal rate observed in the study (which was lower than anticipated) was not reflecting selection bias and moreover, that the adherence rates seen in the standard care only study group (notified by the research nurse) did not differ from the adherence rate observed in the comparison group (notified by clinic nurses), lessening concern over a potential “study effect.”

Limitations of this research include the failure to achieve statistical power given the discrepancy in the estimated and observed abnormal rate and the small effect size that can realistically be achieved in a single telephone intervention. Post-hoc power calculations suggest that over 10,000 women per group would be needed to detect an odds ratio of 1.01, which corresponds to increasing adherence from 58% to 60%. This magnitude of difference may not be clinically meaningful given the small proportion of abnormal results that progress to cancer and that progression from pre-invasive cervical dysplasia to cervical carcinoma may take 8–10 years. Conclusions from this study cannot be generalized to women with high-grade abnormalities, as 97% of those randomized had low-grade abnormal results. Further investigation of women with high-grade abnormalities is needed, as they are at particular risk of progression to cancer. Finally, enrollment of African American women was lower than anticipated and reduced the ability to draw conclusions about this group. Lower enrollment is partly attributable to the fact that the clinic that was not re-opened to the study after the hurricane served the highest proportion of African American patients.

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The barriers to eliminating cervical cancer are largely behavioral. This study examined only behaviors related to secondary prevention of cervical cancer. As guidelines change and screening intervals lengthen, the importance of adherence may increase (Ashok, Berkowitz, Hawkins, Tangka, & Saraiya, 2012; U.S. Preventive Services Task Force, 2012). Further efforts are needed to develop and test targeted interventions to improve adherence in populations particularly vulnerable to cervical cancer.

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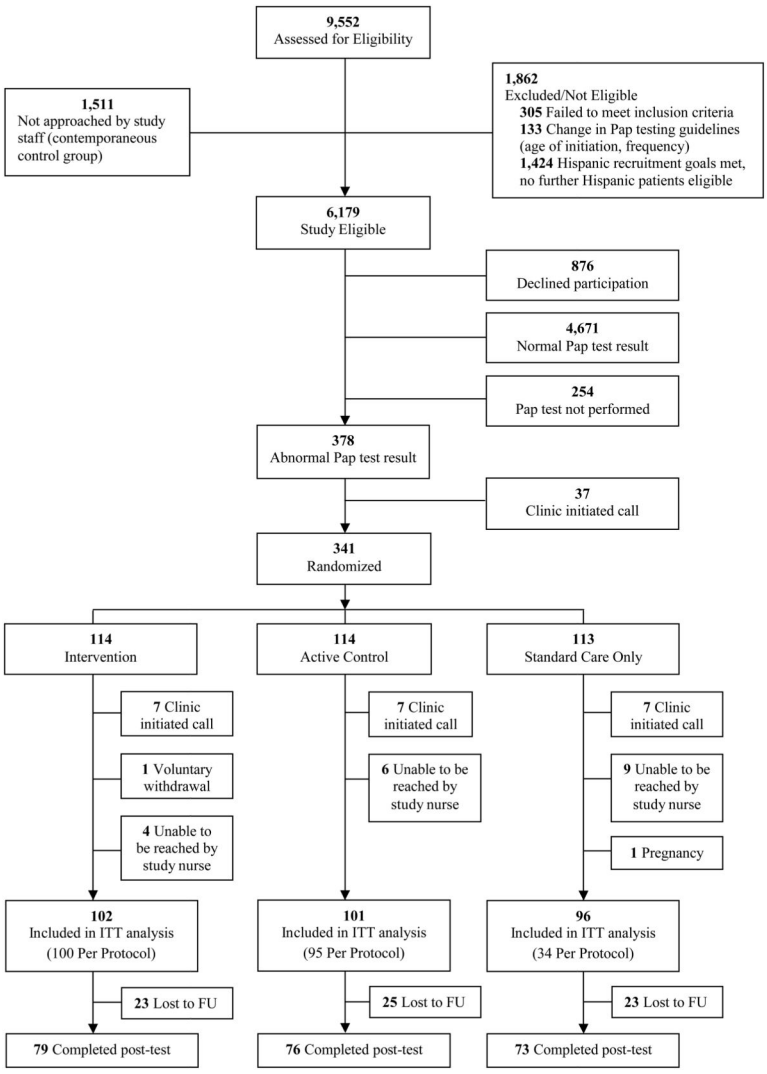


**Figure 1.**
Flow of Patients through the Study

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## Table 1

Patient Characteristics by Study Group

| | Study Group | | | |
|---|---|---|---|---|
| **Characteristic** | **Intervention (*n*=102)** | **Active Control (*n*=101)** | **Standard Care Only (*n*=96)** | ***p*** |
| Ethnicity/Race, *n* (%) | | | | 0.99 |
| Hispanic | 64 (63) | 62 (61) | 62 (65) | |
| Non-Hispanic white | 28 (27) | 28 (28) | 24 (25) | |
| Non-Hispanic black | 10 (9) | 11 (11) | 10 (10) | |
| Age (y), *M* ±*SD* | 26.78 ±7.3 | 28.25 ±8.2 | 28.65 ±8.4 | 0.22 |
| Marital status: unmarried,† *n* (%) | 82 (81) | 76 (78) | 74 (78) | 0.83 |
| Highest education, *n* (%) | | | | 0.66 |
| <High school | 30 (30) | 32 (32) | 39 (41) | |
| High school/GED | 37 (37) | 31 (31) | 25 (26) | |
| Vocational training/some college | 29 (29) | 29 (29) | 27 (28) | |
| College degree (2- or 4-year) | 5 (5) | 7 (7) | 5 (5) | |
| Annual income ($USD), *n* (%) | | | | 0.26 |
| <10,000 | 46 (53) | 28 (33) | 35 (43) | |
| 10,000–24,999 | 29 (34) | 40 (47) | 34 (41) | |
| 25,000–49,999 | 9 (10) | 15 (18) | 11 (13) | |
| 50,000+ | 2 (2) | 2 (2) | 2 (2) | |
| Language: English, *n* (%) | 76 (74) | 75 (74) | 69 (72) | 0.90 |

† Includes single/never married (*n*=164), divorced (*n*=30), widowed (*n*=4), separated (*n*=34).

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## Table 2

Adherence, Delay in Care, and Completion of Care by Study Group, Intent to Treat Analyses

| | Study Group (*n*) | | | |
|---|---|---|---|---|
| | **Intervention** | **Active Control** | **Standard Care** | ***p*** |
| Adherence (N=299) | 60% (102) | 54% (101) | 58% (96) | 0.73 |
| Delay in Care <90 days (N=80)* | 80% (25) | 72% (25) | 83% (30) | 0.58 |
| Completion of Care (N=287)** | 39% (99) | 35% (97) | 35% (91) | 0.77 |

* Of the 127 women who did not attend their initial follow-up appointment, delay could be calculated for 80 women who eventually returned to the clinic.

** 12 women became pregnant during the 18-month follow-up period and were excluded from this analysis.