2016

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Citation/Publisher Attribution

Gold, M. A., Tzilos, G. K., Stein, L.A.R., Anderson, B. J., Stein, M. D., Ryan, C. M., Zuckoff, A., & DiClemente, C. (2016). A Randomized Controlled Trial to Compare Computer-assisted Motivational Intervention with Didactic Educational Counseling to Reduce Unprotected Sex in Female Adolescents. *Journal of Pediatric and Adolescent Gynecology, 29*(1), 26-32. doi: 10.1016/j.jpag.2015.06.001
Available at: https://doi.org/10.1016/j.jpag.2015.06.001

HHS Public Access

Author manuscript

J Pediatr Adolesc Gynecol. Author manuscript; available in PMC 2017 February 01.

Published in final edited form as:

J Pediatr Adolesc Gynecol. 2016 February ; 29(1): 26–32. doi:10.1016/j.jpag.2015.06.001.

A Randomized Controlled Trial Comparing Computer-Assisted Motivational Intervention to Didactic Educational Counseling to Reduce Unprotected Sex in Female Adolescents

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Abstract

Study Objective—To examine a computer-assisted, counselor-guided motivational intervention (CAMI) aimed at reducing the risk of unprotected sexual intercourse.

Design—We conducted a 9-month, longitudinal randomized controlled trial with a multi-site recruitment strategy including clinic, university, and social referrals, comparing the CAMI to didactic educational counseling (DEC) with 572 female adolescents (mean age = 17; SD = 2.2

years old, (range 13–21 years); 59% African Americans) who were at risk for pregnancy and STDs. The primary outcome was the acceptability of the CAMI by self-reported rating scales. The secondary outcome was the reduction of pregnancy and STD risk using a 9-month, self-report Timeline follow-back calendar of unprotected sex.

Results—The CAMI was rated easy to use. Compared to the DEC, there was a significant effect of the intervention suggesting that the CAMI helped reduce unprotected sex among participants who completed the study. However, due to the high attrition rate, the intent-to-treat analysis did not demonstrate a significant effect of the CAMI on reducing unprotected sex.

Conclusions—Among those who completed the intervention, the CAMI reduced unprotected sex among an at-risk, predominantly minority sample of female adolescents. Modifying the CAMI to address methodological issues that contributed to high drop-out rates are needed to make the intervention more acceptable and feasible among sexually active predominantly minority, at risk, female adolescents.

Keywords

adolescents; sexually transmitted diseases (STDs); HIV; computer intervention; contraception; pregnancy prevention; condom; Motivational Interviewing (MI); Transtheoretical Model (TTM)

Introduction

Sexually transmitted diseases (STDs), including HIV, remain epidemic in the United States among female adolescents, aged 15 to 19 years, who experience over 3 million STDs per year. The reported rates of gonorrhea and chlamydia are highest among females in this age group [1, 2]; Further, it is estimated that up to half of individuals who acquire an STD each year are under the age of 25 years, and minority female adolescents are disproportionately affected[3]. In response to the high rates of STDs, the Healthy People 2020 Sexually Transmitted Diseases[4] objectives set a goal to increase the proportion of sexually active adolescents who use contraception that both effectively prevents pregnancy *and* provides barrier protection against disease[5], and to reduce the proportion of adolescents diagnosed with STDs. Although the Institute of Medicine proposed that behavioral interventions represent the most promising approach to preventing STDs[6], the methodological limitations of most studies to date have restricted their effectiveness in improving health outcomes[7].

The Transtheoretical Model (TTM) has been proposed as a comprehensive framework for assessing behavior change and designing interventions[8-12]. The core constructs of the model include stages of change, decisional balance, situational self-efficacy, and the processes of change[12]. These constructs have been validated with many behaviors across a variety of populations. The model proposes a stage-matched approach to behavioral counseling in which the provider matches the counseling technique to the patient's readiness to change.

Although TTM has been used predominantly to assess adult behavior change, this framework has also begun to be used to address adolescent health behaviors including increasing condom use[13]. The Guidelines for Adolescent Preventive Services specifically advocate using the TTM as a conceptual framework for working with adolescents because the stages of readiness to change represent temporal, motivational, and constancy aspects of

change[14]. However, few studies to date have used TTM as a framework for interventions targeting the sexual risk behaviors of female adolescents. Shrier and colleagues reported on a small sample size (N = 123 randomized at baseline; 64 at follow-up) which limited the power to detect treatment effects at 12 months in their assessment of a safer sex intervention for female adolescents diagnosed with an STD[15]. More recently, an uncontrolled pilot study assessing a single-session, computer-delivered TTM intervention to increase condom use found that this technology was acceptable and feasible in a group of high-risk female adolescents[16]. A randomized controlled trial that delivered a TTM-tailored intervention with computer-based tailored feedback targeting dual-method contraception use among 542 women (median age of participants was 22 years old), did not find an effect for incident STD outcomes[17].

While the TTM provides a framework for assessing readiness to change, motivational interviewing (MI) provides an empirically-supported style for matching counseling to an individual's readiness to change[18]. Based on the principles of motivational psychology, and client-centered therapy, MI represents a general and practical approach for changing behaviors by enhancing and facilitating a patient's own internally motivated change process. A number of publications explore the use of brief motivational interventions to change adolescent behaviors including alcohol use[19], smoking cessation and diet[20], and contraceptive decision-making[21].

The primary aim of this study was to examine the acceptability and feasibility, and the secondary aim was to examine the efficacy of a Computer-Assisted Motivational Intervention (CAMI) based on the conceptual framework of the TTM and using MI as the counseling strategy as compared to Didactic Educational Counseling (DEC) to reduce STD and pregnancy risk behaviors among female adolescents. We hypothesized that participants would find the CAMI to be an acceptable and feasible intervention, and that, compared to the DEC, the CAMI would be more efficacious in decreasing unprotected intercourse among sexually active female adolescents.

Methods

Study Population

We recruited female adolescents who attended an inner city adolescent medicine and family planning clinic in Pittsburgh, Pennsylvania as well as those recruited from acquaintance referral, relatives, and local universities between February, 2003 and September, 2006. Inclusion criteria included being a female adolescent between the ages of 13 and 21 years, having access to a telephone, and being able to sign informed consent. Exclusion criteria included being non-English speaking, unable to read at a 6th grade level, blind or visually impaired, deaf or hearing impaired, or having another communication barrier, living in a group or foster home, currently or trying to get pregnant, engaging in exclusively same-gender sexual behavior, having an IUD or contraceptive implant in place, and being sterile (surgically or medically). Of the 800 female adolescents who were assessed for eligibility, 572 were randomized to either the CAMI (n = 286) or DEC (n = 286) condition stratified by age, race, and sexual history (see Figure 1). Of the 800 adolescents who were telephone screened for eligibility, 94% met eligibility criteria and 72% were enrolled. Two hundred

and twenty eight were excluded (48 did not meet inclusion criteria). The most common reasons for exclusion were pregnancy or the desire to get pregnant, and placement in foster care. Participants withdrew from the study for the following reasons: 1 death, 10 moved away, 5 due to school, and the remainder cited "time constraints," "transportation," or "none" as the reason for withdrawing.

Study Design

The study was approved by the institutional review board (IRB) at the Children's Hospital of Pittsburgh and the University of Pittsburgh and was registered at clinicaltrials.gov (NCT00151151). A trained female research assistant (RA) screened female adolescents in the clinic or by telephone. Those adolescents who agreed to participate reviewed and signed a consent form in person at the research office. A waiver of parental consent was approved by the IRB because adolescents are allowed to consent to clinical contraceptive counseling services without parental consent and participation in the study was of minimal risk. Participants were offered nonmonetary incentives for participating (e.g., condoms, key rings, water bottles, hand mirrors) as well as nominal payments for assistance with travel. After enrollment, participants in both groups completed the following assessments: 1) a 90-day Timeline Follow-back calendar (a well-validated and reliable self-report assessment tool)[22] recording their sexual, contraceptive, and substance use behaviors (TLFB), and 2) a computerized assessment to collect demographic information, sexual, contraceptive, pregnancy and STD history, psychological assessments of mood, substance use, abuse history, and measurement of the four TTM constructs of stage, decisional balance, self-efficacy, and processes of change for condom use and other contraceptive use. After completing the baseline assessment, participants were randomized (stratified by age, race, and by sexual history of ever or never sexually active) to one of two conditions (DEC or CAMI) and immediately received the assigned intervention.

During the six-month intervention phase, the CAMI group received three, 30-minute sessions of counseling at the enrollment, 3- and 6-month visits consisting of one-on-one brief counseling using MI with an interventionist who was guided by computer-generated feedback. The structure of the CAMI included the fundamental principles of expressing empathy, developing discrepancy, rolling with resistance, and supporting self-efficacy. Guided by the participant's computer assessment, her TLFB calendar, and her pregnancy and STD risk assessments, the CAMI sessions focused on preventing acquisition of STDs, planning pregnancies, motivating adolescents to be sexually abstinent or use condoms consistently, and initiating or maintaining contraceptive or abstinent behaviors. The counselor and participant together discussed the feedback and how her current behavior fit into her future goals, collaborating to compose a specific SAFE (**S**ex, **A**bstinence, **F**eedback, and **E**ducation) Plan on the computer. The SAFE Plan is a behavior worksheet adapted from previous work in Motivational Interviewing (see Miller & Rollnick)[23, 24], and included a specific plan, reasons for the plan, specific steps of the plan, potential barriers to completing the plan with possible solutions, as well as who was going to help the participant with her plan and how they would assist her. The SAFE Plan was a typed and printed contract that was signed by the participant to demonstrate her commitment and co-signed by the counselor to demonstrate the counselor's support for the plan.

The DEC (Didactic Educational Counseling) group participants received three, 30-minute sessions of didactic counseling at the enrollment, 3- and 6-month visits. The DEC curriculum was created using standard family planning curricula, matched for time and attention, and contained three modules of didactic information on contraception, STDs and their prevention, and abstinence. Participants were allowed to choose the order in which they completed each of the three modules but they were required to complete all three modules by the end of the 6-month intervention phase of the study[25]. At the completion of each DEC session, participants were given pamphlets that corresponded to the content of each counseling session (e.g., contraception, STDs and their prevention, abstinence). The counselor, a layperson with a bachelor's level training, did not provide any personalized feedback on participants' STD or pregnancy risk or their TLFB calendar, and they did not create a collaborative SAFE plan. Participants in both conditions had identical assessment and intervention schedules, and returned to the study office to complete a TLFB and computerized assessment every three months (at 3 and 6 months, immediately prior to the intervention session, and at 9 months from enrollment, which was three months post-intervention) to assess changes in sexual behaviors across time.

Analytical Methods

Descriptive statistics are presented to summarize the characteristics of the cohort (see Results). We used t-tests and χ^2-tests to compare intervention arms with respect to background characteristics and follow-up assessment rates. Conditional fixed-effects logistic regression models for panel data were estimated to evaluate the effect of intervention on unprotected sexual intercourse (dichotomized to contrast any sexual intercourse without a condom versus none) at each follow-up assessment. The fixed-effects estimator controls for all time-invariant between-subject heterogeneity (observable or unobservable) and focuses only on within-subject changes over time[26]. Between-subject variation is controlled through randomization and fixed effects methods may be more efficient because the error term has a smaller variance[26].

In a fixed effects model, the intervention is estimated as the first-order treatment-by-time interaction. We present both an as-treated analysis using the observed data, and an intent-to-treat analysis; for the latter analysis, we used multiple imputation by chained equations (MICE) as implemented in Stata 12.1 (StataCorp) to generate and analyze 20 imputed data sets. MICE is a principled and flexible method[27] for analyzing multivariate data with missing values. Variables used in the imputation model included age, race/ethnicity, and treatment condition, baseline frequency of unprotected sex, and the dichotomous outcomes at 3-, 6-, and 9-months. Random effects logistic regression was used to examine predictors of attrition at 3-, 6-, and 9-months. Evaluated predictors included age, race/ethnicity, educational attainment, religiosity[28], frequency of marijuana use, frequency of alcohol use, and baseline condom use.

Results

Participants mean age was 17.4 (± 2.2) years; 337 (59.0%) were African-American, 183 (32.1%) were Caucasian, and 51 (8.9%) were of other ethnic or racial origins; 381 (67.3%)

were enrolled in or completed high school (Table 1). On average, participants reported having unprotected sex 2.01 (± 10.1, Median = 0) times in the 90 days prior to baseline. Consistent with effective randomization, the intervention arms did not differ significantly with respect to age, race/ethnicity, educational attainment, frequency of alcohol use, frequency of marijuana use, or frequency of pre-baseline unprotected sexual intercourse (Table 1).

Table 1 reports the rates of assessments completed at each follow-up point, and the overall rate of participants observed at 1 or more follow-up assessments. Overall rates were 78.0%, 67.5%, and 60.8% at 3-. 6-, and 9-months respectively; 482 (84.3%) participants were observed at 1 or more follow-up assessments. While randomization appeared successful, there is evidence of differential participant attrition. Compared to the DEC arm, follow-up rates for participants randomized to CAMI were approximately 10% lower at each assessment (Table 1).

The primary outcome was the acceptability of the CAMI by self-reported rating scales. Regarding acceptability of the computerized assessment, many participants (69.8%) reported having a high level of experience using computers; only 8 (1.4%) reported this was their first time using a computer. Most participants (93.5%) liked how the assessment looked and 97.7% rated it as easy to understand. There were no significant differences between CAMI and DEC groups in any of these areas. Over half of participants (56.3%) reported that the 60 to 90-minute computer assessment was “too long” or “much too long;” participants randomized to CAMI (62.9%) were significantly ($\chi 2 = 10.26$, $p = .001$) more likely than participants randomized to DEC (49.7%) to describe the assessment as “too long.” However, participants who perceived the assessment as being “too long” were not significantly (OR = 1.13, z = 0.54, $p = .589$) more likely to be lost to follow-up than those who did not feel the assessment was too long. A majority of participants reported they were mostly or completely comfortable entering their sexual history (70.8%), alcohol and drug use history (74.5%), and history of sexual, physical, or emotional abuse (70.2%) into the computer.

The secondary outcome was the reduction of pregnancy and STD risk using a 9-month, self-report Timeline follow-back calendar of unprotected sex. Among participants who had unprotected sex at baseline, the observed risk of pregnancy and STI was 0.68 ($\chi^2 = 3.11$, $p = 0.08$) at 3 months, 0.79 ($\chi^2 = 0.96$, $p = 0.33$) at 6 months, and 0.54 ($\chi^2 = 5.88$, $p = 0.12$) at 9 months. In Table 2, the reference category is DEC at baseline. Coefficients for time give the estimated difference in the odds of any unprotected sex at 3-, 6-, and 9-months among participants randomized to DEC. The coefficients for the treatment-by-time interaction give the difference in expected odds of any unprotected sex for CAMI compared to DEC at each time point. In the as-treated analysis (Table 2), a statistically significant intervention effect was observed at 9-months (OR = 0.34, 95% CI 0.14; 0.85, $p < .05$). At 9-months, the expected odds of engaging in unprotected sex for participants randomized to CAMI was only about 34% as large as for those randomized to DEC. Treatment effects at 3-months (OR = 0.46, 95% CI 0.20; 1.06, $p > .05$) and 6-months (OR = 0.74, 95% CI 0.30; 1.80, $p > .05$) were directionally consistent with the research hypothesis but were not statistically significant. Additionally, treating time as a linear effect, we found a statistically significant treatment by linear time interaction effect (OR = 0.89, 95% CI 0.80; 0.98, $p < .05$). In the

intent-to-treat analysis, the coefficients contrasting CAMI to DEC, while directionally consistent with the research hypothesis, were not statistically significant at 3-months (OR = 0.53, 95% CI 0.23; 1.25, $p > .05$), 6-months (OR = 0.81, 95%CI 0.35; 1.90, $p > .05$), or 9-months (0R = 0.49, 95% CI 0.19; 1.24, $p > .05$). Additionally, we found the treatment-by-linear time effect was also not statistically significant (OR = 0.94, 95% CI 0.85; 1.03, $p > .05$).

We examined predictors of loss to follow-up, estimated by random effects with month entered as a categorical covariate and analysis limited to months 3, 6, and 9. Race/ethnicity differences in dropout became stronger as the study progressed; by 9-month unadjusted dropout rates were 40% (Caucasians), 30% (African Americans), and 24% (other ethnic minorities). Participants who were Caucasian and older were significantly more likely, compared to younger participants of other ethnicities, to drop out by the 9-month follow up. Loss to follow-up was not associated significantly with religiosity, educational attainment, frequency of alcohol use, frequency of marijuana use, or baseline use of condoms.

Discussion

This randomized controlled trial assessed the efficacy of a computer-assisted, counselor-guided motivational intervention using MI and constructs from the Transtheoretical Model, compared to a didactic pregnancy and STD preventive counseling, on female adolescents' sexual behaviors. The assessment was rated as easy to understand and most participants felt comfortable disclosing information. Our findings indicate that for those participants who completed the study, the CAMI intervention, compared to the didactic counseling, significantly increased the likelihood of fully condom-protected sex in this population.

Attrition rates were higher than anticipated and consistently higher among participants randomized to CAMI. While the intervention arms did not vary with respect to demographic characteristics or rates of unprotected sex prior to baseline, we found predictors in participant attrition: participants who were Caucasian and older in age were more likely to drop out over time. It is possible that the CAMI was less acceptable to older compared to younger female adolescents and this may reflect preferences or concerns about sustained interest in the content or delivery of the intervention. With regard to race/ethnicity, it is possible that this could reflect personal preferences and perceptions of the counselor/participant match. For example, some studies have found that participant race/ethnicity moderated preferences, perceptions and treatment outcomes[29]. Interestingly, the current finding that Caucasian participants were more likely to drop out of the study is in contrast with studies that demonstrate higher attrition rates for minorities[30]. We offer additional speculation. It is possible that the participants in the CAMI group may have had higher attrition rates because they may have made commitments to behavior change that they later found to be more difficult to make or sustain than they anticipated. Moreover, it is possible that participants may not have returned to complete the study for fear of disappointing their counselor or the staff for lack of behavior change, despite counselors verbally reinforcing at the end of each CAMI visit that behavior change is challenging.

More than two-thirds of participants reported having a high level of experience using computers, and nearly all liked how the assessment looked and found it easy to understand, and this did not vary by group. Still, loss to follow-up is a particular challenge among high-risk groups, and differential attrition among groups is a common limitation with respect to recruitment and retention[31]. A review of behavioral intervention studies targeting reduction of HIV, STD, and pregnancy among adolescents reported that the average attrition rate was 14.7% among the studies that conducted 6-month follow-up, and an additional 13.1% among follow-ups between 6 to 12 months[31]. Acceptability data here revealed that over half (56.3%) of participants felt the 60 to 90-minute computer assessment was "too long" or much "too long," with a significant difference between the two groups (62.9% CAMI vs. 49.7% DEC, $\chi 2 = 10.26$, $p = .001$). This difference may be reflective of the additional 10-minutes of questions administered to the CAMI group that were used to create the feedback printout, and suggests that shortening the computerized assessment may enhance acceptability in future studies.

The significant effect of the intervention observed in the as-treated analysis suggests the CAMI intervention can help reduce unprotected sexual intercourse among participants who completed the study. However, the differential attrition suggests that the intervention needs to be modified if it is to be used in the future. Predictors of age and race/ethnicity can also assist in modification of the CAMI to make it more acceptable. Furthermore, providing enhanced incentives for participant time and the utilization of mobile devices to aid in follow up may help increase retention.

The study design includes several strengths. First, the CAMI provided, with participant permission, education about STDs including HIV as well as ways to prevent pregnancy including abstinence, and also included risk factors that are relevant during this vulnerable time in adolescence. For example, incorporating social factors including interpersonal relationships with boyfriends and friends, and substance use behavior, has been recommended for preventive interventions targeting vulnerable populations that are disproportionately at higher risk for HIV/STDs[32]. Acceptability of the current intervention design therefore could provide future direction for counseling guidelines for health interventions that effectively reduce STDs and unintended pregnancy. Second, the study included reliable and valid measures of the outcome variables including the use of the Timeline follow-back. Third, our study included an ethnically and socioeconomically diverse, community-based cohort.

The study also had limitations. First, while diverse, the sample was predominantly African American (59%) and findings may not be generalizable to other populations of adolescents or young adult women. Second, there was a significantly greater loss to follow-up among participants randomized to CAMI. Third, we did not have biological measures of pregnancies or STDs, so the results rest on self-reported behaviors as well as self-reported history of pregnancy and STD acquisition.

Future studies are recommended to modify the CAMI, including shortening the length of the assessment and intervention as recommended by study participants, to reduce attrition, and learn if the as-treated findings can be replicated with a heterogeneous sample of sexually

active high-risk young women. Given the staggering rates of STD acquisition and unintended pregnancies among female adolescents, preventive interventions that are acceptable and effective in targeting sexual risk behaviors and reducing incidence of HIV/STDs and unintended pregnancy in this vulnerable population are needed.

Acknowledgements

Dr. Gold and the study from which these data were compiled were supported by a grant from the National Institute of Child Health and Human Development (R01-HD41058). We would like to thank the incredible research staff, without whom this work would have been impossible including: Jacqueline Simpronio, Karen Derzic, Rita Labbett, Terri Angiolieri, Anya Sheftel, Amy Benson, Kym Smith, Susan Smola, LaToya Warren, Shana Rush, Aimee Hong, Lauren Hartz, and Nicole Boback. We would especially like to thank all the young women who participated in this study; they were always our teachers and our inspiration.

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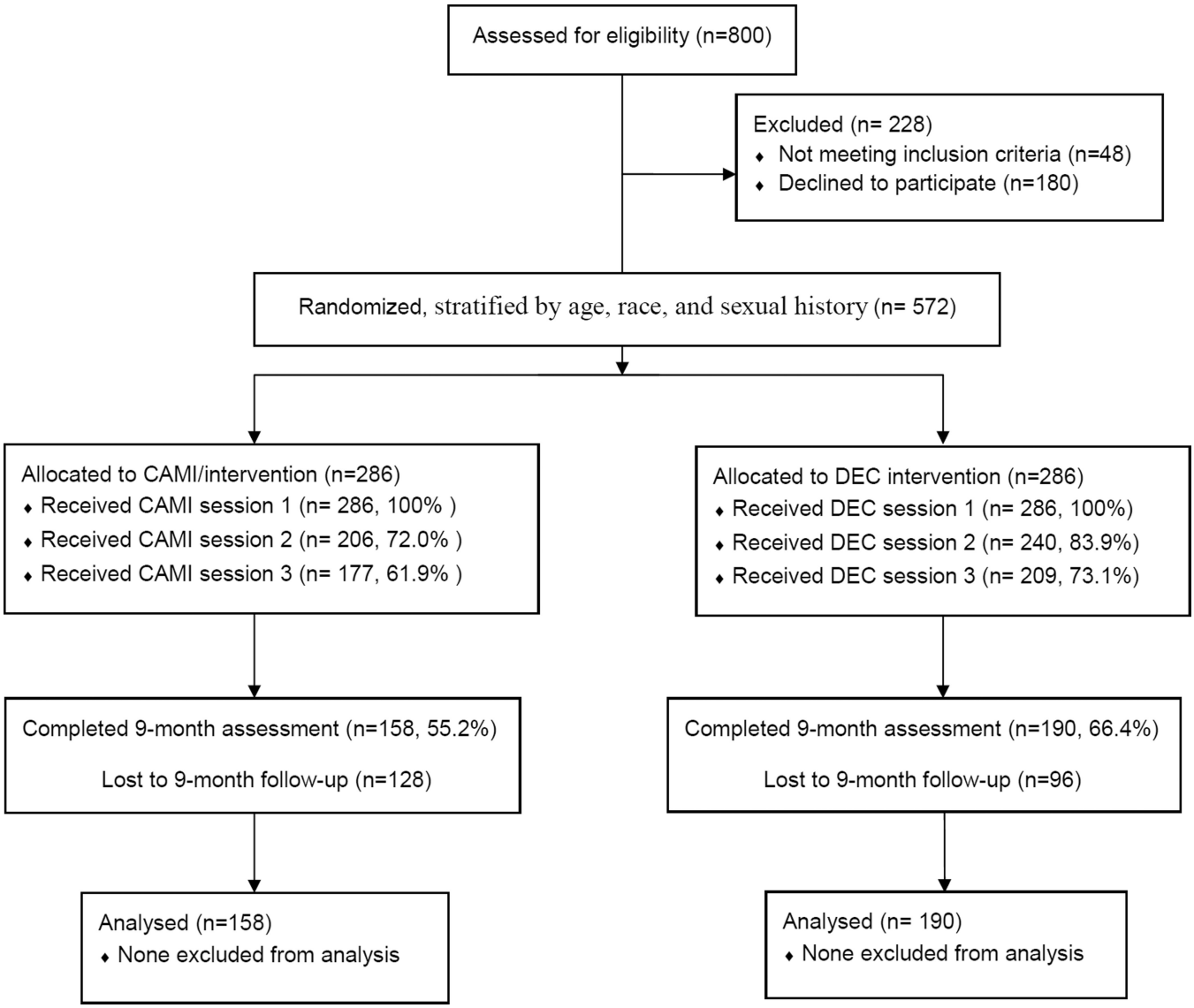

Figure 1.
Participant Flow

Table 1

Background Characteristics by Intervention Arm

	Cohort (n = 572)	DEC (n = 286)	CAMI (n = 286)	t (p =) or χ^2 (p =)
Age in Years	17.4 (± 2.2)	17.3 (± 2.2)	17.4 (± 2.2)	−1.02 (.308)
Race/Ethnicity				
Caucasian	183 (32.1%)	91 (31.8%)	92 (32.3%)	
African-American	337 (59.0%)	168 (58.7%)	169 (59.3%)	0.18 (0.912)
Other	51 (8.9%)	21 (9.4%)	24 (8.4%)	
In College (Yes)	185 (32.7%)	96 (33.9%)	89 (31.5%)	0.39 (.530)
Religiosity[a]	4.6 (± 3.1)	4.8 (± 3.1)	4.3 (± 3.21)	1.59 (.112)
Times Had Unprotected Sex	2.0 (± 10.1)	2.6 (± 13.3)	1.5 (± 5.1)	−1.31 (.191)
Frequency of Alcohol Use	2.3 (± 3.9)	2.4 (± 4.0)	2.2 (± 3.8)	0.46 (.645)
Frequency of Marijuana Use	0.07 (± 0.93)	0.01 (± 0.12)	0.13 (± 1.30)	−1.50 (.135)
Follow-Up Rates				
at 3-Months	446 (78.0%)	240 (83.9%)	206 (72.0%)	11.77 (.001)
at 6-Months	386 (67.5%)	209 (73.1%)	177 (61.9%)	8.16 (.004)
at 9-Months	348 (60.8%)	190 (66.4%)	158 (55.2%)	7.51 (.006)
1+ Follow-ups	482 (84.3%)	254 (88.8%)	228 (79.7%)	8.91 (.003)

[a]Religiosity Index included the summation of values from responses on four items: (1) religious affiliation; (2) frequency of attendance at religious services; (3) the influence of religious beliefs on decisions about having sex; and (4) the influence of religious beliefs on using something to prevent pregnancy. Item responses included: (1) affiliation (none = 1, any = 2), (2) frequency of attendance (never = 1 to daily = 7), and two items on the impact of religious beliefs on decisions about (3) sex and (4) contraception (not at all = 1 to completely = 4), resulting in an index with a range of 4 to 17. We then categorized scores into low, medium, and high religiosity groups by tertiles. The religiosity index showed good internal consistency (Cronbach's alpha = 0.65); see Gold et al., 2010[28] for full description.

Table 2

Conditional Fixed-Effects Logistic Regression Models Estimating the Effect of Intervention on the Odds of Unprotected Sexual Intercourse at Follow-Up.

	Intent-To-Treat[a] OR (95%CI)	As-Treated[b] OR (95%CI)
DEC at Baseline [REF]	1.0	1.0
Time at Follow Up		
Month 3	0.60 (0.33; 1.11)	0.91 (0.51; 1.60)
Month 6	0.48* (0.24; 0.95)	0.67 (0.37; 1.26)
Month 9	1.12 (0.37; 3.36)	1.26 (0.69; 2.29)
Intervention by Time		
>Month 3	0.53 (0.23; 1.25)	0.46 (0.20; 1.06)
>Month 6	0.81(0.35; 1.90)	0.74 (0.30; 1.80)
>Month 9	0.49 (0.19; 1.24)	0.34* (0.14; 0.85)

[a] Analysis of 20 complete data sets generated by multiple imputation by chained equations. Only participants who vary across time contribute to the likelihood in the conditional fixed-effects models; the number of participants estimated to have within subject variation ranged from 282 to 369 across the 20-imputed data sets.

[b] In the as-treated data set, 158 participants contributed within participant variation to the conditional fixed-effects model.

DEC = Didactic Educational Counseling

CAMI = Computer Assisted Motivational Intervention