Original Study

A Randomized Controlled Trial to Compare Computer-assisted Motivational Intervention with Didactic Educational Counseling to Reduce Unprotected Sex in Female Adolescents

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A B S T R A C T

Study Objective: To examine a computer-assisted, counselor-guided motivational intervention (CAMI) aimed at reducing the risk of unprotected sexual intercourse.
Design, Setting, Participants, Interventions, and Main Outcome Measures: We conducted a 9-month, longitudinal randomized controlled trial with a multisite recruitment strategy including clinic, university, and social referrals, and compared the CAMI with didactic educational counseling in 572 female adolescents with a mean age of 17 years (SD = 2.2 years; range = 13-21 years; 59% African American) who were at risk for pregnancy and sexually transmitted diseases. The primary outcome was the acceptability of the CAMI according to self-reported rating scales. The secondary outcome was the reduction of pregnancy and sexually transmitted disease risk using a 9-month, self-report timeline follow-back calendar of unprotected sex.
Results: The CAMI was rated easy to use. Compared with the didactic educational counseling, there was a significant effect of the intervention which suggested that the CAMI helped reduce unprotected sex among participants who completed the study. However, because of the high attrition rate, the intent to treat analysis did not demonstrate a significant effect of the CAMI on reducing the rate of unprotected sex.
Conclusion: Among those who completed the intervention, the CAMI reduced unprotected sex among an at-risk, predominantly minority sample of female adolescents. Modification of the CAMI to address methodological issues that contributed to a high drop-out rate are needed to make the intervention more acceptable and feasible for use among sexually active predominantly minority, at-risk, female adolescents.
Key Words: 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 the individuals who acquire an STD each year are younger than 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 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 prevention of 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 assessment of behavior change and design of 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

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patient's readiness to change. Although the 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 the TTM as a framework for interventions that target 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 who were diagnosed with an STD.[15] More recently, an uncontrolled pilot study that assessed 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 that targeted 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]

Although the TTM provides a framework for assessment of readiness to change, motivational interviewing (MI) provides an empirically-supported style for matching counseling to an individual's readiness to change.[18] On the basis of 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 explored 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) on the basis of the conceptual framework of the TTM and use of MI as the counseling strategy compared with 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 with DEC, the CAMI would be more efficacious in decreasing unprotected intercourse among sexually active female adolescents.

Materials and Methods

Study Population

We recruited female adolescents who attended an inner city adolescent medicine and family planning clinic in Pittsburgh, Pennsylvania and 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 a non-English speaker, unable to read at a sixth-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 intrauterine device 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 according to age, race, and sexual history (Fig. 1). Of the 800 adolescents who were telephone-screened for eligibility, 752/800 met eligibility criteria and 572/800 were enrolled. Two hundred 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 because of school, and the remainder cited "time constraints," "transportation," or "none" as the reason for withdrawal.

Study Design

The study was approved by the institutional review board at the Children's Hospital of Pittsburgh and the University of Pittsburgh and was registered at clinicaltrials.gov (NCT00151151). A trained female research assistant screened female adolescents in the clinic or using the telephone. 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 institutional review board 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 (eg, condoms, key rings, water bottles, hand mirrors) and nominal payments for assistance with travel. After enrollment, participants in both groups completed the following assessments: (1) a 90-day timeline follow-back (TLFB) calendar (a well validated and reliable self-report assessment tool)[22] and recorded their sexual, contraceptive, and substance use behaviors; 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 4 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 according to age, race, and sexual history of ever or never sexually active) to 1 of 2 conditions (DEC or CAMI) and immediately received the assigned intervention.

During the 6-month intervention phase, the CAMI group received three 30 to 45-minute sessions of counseling at the enrollment, and 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