Computer-assisted Provision of Emergency Contraception a Randomized Controlled Trial

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BACKGROUND: Emergency contraception (EC) can prevent unintended pregnancy. However, many women continue to lack information needed to use EC effectively and clinician time to counsel women about EC is limited.

OBJECTIVE: To evaluate whether computer-assisted provision of EC can increase knowledge and use of EC among women able to access EC without a prescription.

DESIGN: We conducted a randomized controlled trial in which the intervention group received a 15-minute computerized educational session and 1 pack of EC. The control group received education about periconception folate supplementation, but no information about EC. Participants were contacted 7 months after enrollment.

PARTICIPANTS: Four hundred forty-six women recruited from 2 urgent care clinics in San Francisco in 2005.

MEASUREMENTS: Knowledge of EC, use of EC, and self-reported pregnancy.

RESULTS: At follow-up, women in the intervention group answered an average of 2 more questions about EC correctly than they had at baseline, whereas women in the control group answered only 1 more item correctly (2.0 vs 1.2, $p < .001$). There was a trend toward more use of EC during the study period in the intervention group (10% vs 4% of women followed, $p = .06$; 6% vs 3%, $p = .09$ of women enrolled). Fewer women in the intervention group were pregnant at the time of follow-up (0.8% vs 6.5%, $p = .01$ of women followed; 0.5% vs 4.0%, $p = .01$ of women enrolled).

CONCLUSIONS: Computer-assisted provision of EC in urgent care waiting areas increased knowledge of EC in a state where EC had been available without a prescription for 3 years.

KEY WORDS: women's health; computerized counseling; contraception; emergency contraception.

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INTRODUCTION

Among industrialized countries, the United States has the highest rates of unintended pregnancies.¹ Emergency contraception (EC), a method of preventing pregnancy after an episode of unprotected sex or contraceptive failure, is safe and effective² and may have the potential to reduce rates of abortion.^{3–6} Although misinformation about EC has been widespread, published evidence indicates that EC does not prevent implantation of a fertilized ovum, but rather alters sperm migration, the cervical and uterine environment, and the release of ova such that fertilization does not occur.⁷

Unfortunately, the use of EC in the United States remains far below the use of EC in other industrialized countries. In 1996, 12% of women in the UK reported ever using EC,⁸ but 7 years later in the United States only 6% of women aged 18–49 had ever used EC.⁹ In an attempt to increase the use of EC, in August 2006, the US FDA allowed access to EC without a physician's prescription to individuals older than 18 years.¹⁰ However, even when EC is available “over the counter,” women may lack the information they need to use EC.¹¹ As use of EC increased when women received counseling about EC and a free supply of EC,^{12–15} several medical organizations have recommended counseling women about EC during routine visits.^{16–18} However, in 2001, only 25% of gynecologists and 14% of general practitioners (Internists, family practitioners, and general practice physicians) reported routinely discussing EC.¹⁹

One reason clinicians may not provide counseling about EC is that they lack the time they need to do so. Whereas it is estimated that 11% of clinical time is currently devoted to preventive care, it has been estimated that delivering all recommended preventive care would require 86% of annual clinic time.^{20,21} Clinician time is especially limited in urgent care settings.

As unintended pregnancy is especially common among lower-income women²² who frequently seek medical attention in urgent or emergent care settings,²³ we designed this study to evaluate whether computerized counseling about EC with provision of a free sample of EC can increase knowledge and the use of EC among women seen in an urgent care clinic.

METHODS

English-speaking, adult (18–45 years) women were recruited from the waiting areas of 2 urgent care clinics in San Francisco between March and July 2005. One clinic from which women were recruited for this study is affiliated with an academic medical center; the other is affiliated with a county hospital.

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Women were excluded from this study if they were unlikely to become pregnant in the next year (because they were currently pregnant, had undergone a hysterectomy or tubal ligation, had an intrauterine device in place, had a partner who had undergone vasectomy, were a lesbian, or were over 45 years of age). In addition, we excluded women who planned to relocate or did not have a telephone.

The study was approved by the Committee on Human Research at the University of California, San Francisco, and by the Institutional Review Board of the University of Pittsburgh. All participants provided written informed consent to participate in the evaluation of a computerized educational program. Consent documents made no mention of EC.

At baseline, women were asked to complete a computerized survey while they waited to see a clinician. Audio headphones facilitated private completion of surveys by subjects with limited literacy. This survey consisted of 85 items and was estimated to take 15 minutes to complete. The survey contained questions developed by the Kaiser Family Foundation for a nationwide telephone survey about EC⁹ as well as questions previously used to evaluate contraceptive and pregnancy experiences.¹⁶ The survey assessed women's knowledge of EC, attitudes toward EC, and their ability to access this medication, in addition to standard sociodemographic and reproductive information. To assess women's attitudes toward EC we asked, "Does emergency contraception pose any personal or religious concerns for you?" The survey was pretested in our target population, and ambiguous questions were reworded until consistently interpreted.

After participants completed the baseline survey, they were randomly assigned to the intervention or control group. Randomization was performed by a computer-generated sequence and allocation was concealed from research assistants until after the participant had completed the educational module.

In this study, women in the intervention group received computerized counseling about EC, whereas women in the control group received counseling about preconception folate. Women were provided a semiprivate space in which to use the computer module. When using these educational modules, women wore audio headphones while they watched a short introductory video segment, which instructed them on how to use the mouse to click on any of 9 questions they wanted the "video doctor" to answer. The answers to these questions were provided in the form of short video segments in which the "video doctor" answered the question that had been posed. When appropriate, additional graphics were also displayed. The scripts of the intervention and control counseling modules were constructed in parallel and addressed questions such as: What is EC, when to use EC, what to expect when you use EC, why to use EC, how to use EC, where to get EC, the cost of EC, how does EC work, and why is EC important. To complete the module, a participant was required to hear the answers to all of these questions. After completing the computerized counseling session, the subject was provided with a sample of the medication that had been discussed (EC or folate). Women who received EC received a single package containing two 0.75-mg levonorgestrel pills. Other than these medication samples, subjects received no compensation for participating in this study. Six months later, research assistants who were blinded to whether subjects were in the intervention or control groups called all subjects and administered a follow-up phone survey using a standardized script. The follow-up survey contained 30

items, all of which were administered as part of the baseline survey.

The primary outcome was self-reported use of emergency contraception. Secondary outcomes included knowledge of and attitudes toward EC, use of other contraceptive methods, and self-reported pregnancy.

Our study was powered to detect significant differences in rates of use of EC between the intervention and control groups. We calculated that a final sample size of 197 women per treatment group would allow us to reject our null hypothesis that there is no difference in the rates of use of EC between the intervention and control groups with 90% power in a 2-sided test with an α of .05 if the difference between groups was 15% or greater,¹³ and 20% of women in the control group reported use of EC.¹⁶ Aware that women presenting to urgent care clinics might be difficult to follow, we anticipated losing up to 10% of women we enrolled, and therefore planned to enroll a minimum of 217 women in each group.

For our primary outcome, use of EC, we performed both an intention-to-treat analysis (in which we assumed women who were lost to follow-up never used EC) and an analysis limited to participants who completed follow-up. Similarly, when examining knowledge of EC, we performed a conservative intention-to-treat analysis, in which we assumed that women who were lost to follow-up learned nothing about EC. We then analyzed increases in knowledge among women available for follow-up, assuming that women who were knowledgeable about EC at baseline learned nothing from our intervention. Contingency tables and χ^2 statistics were used to evaluate the significance of differences between categorical variables; *t* tests were used to evaluate the significance of differences between continuous variables. In addition, we used multivariable logistic regression to examine the effect of study group on use of EC after controlling for baseline characteristics (including age, race, education, income, and enrollment site). Similarly, we used multivariable logistic regression to examine the effect of study group on whether a participant learned 1 or more things about EC or became pregnant over the course of follow-up. For all analyses, we used STATA version 8.0 (StataCorp, College Station, TX).

RESULTS

We screened 583 women and enrolled and randomized 446 at the 2 study sites (Fig. 1). Of 137 women excluded, most were excluded because they were unlikely to become pregnant in the next year either because they were currently pregnant ($n = 27$), had undergone a hysterectomy ($n = 7$) or tubal ligation ($n = 18$), had an intrauterine device in place ($n = 22$), had a partner who had undergone vasectomy ($n = 7$), or were over 45 years of age ($n = 22$). In addition, we excluded 34 women who planned to relocate or did not have a telephone.

Sociodemographic and reproductive characteristics of the study sample are shown in Tables 1 and 2. Whereas most women had some form of health insurance, only one third reported a relationship with a primary care provider. In the 6 months before enrolling, this group of women experienced considerable risk for unintended pregnancy; over half of subjects reported 1 or more episodes of vaginal sex with a man without any form of contraception. Prior abortion was reported by 29% of subjects.

Figure 1. Participant flow.

At baseline, functional knowledge of EC was limited in both groups (Table 3). Knowledge of EC was not associated with whether the woman had a relationship with a primary care provider ($p = .45$). Attitudes toward EC were also similar between groups.

A total of 265 women (59%) completed follow-up phone interviews and 181 women did not respond to multiple attempts at contact. Equal proportions of women were lost to

Table 2. Reproductive Characteristics of Study Participants on Enrollment

Characteristic	Total (N=446)	Intervention (N=219)	Control (N=227)
	n (%)	n (%)	n (%)
Reproductive history			
Prior pregnancy	184 (41)	89 (41)	95 (42)
Prior birth	93 (21)	44 (20)	49 (22)
Prior abortion	128 (29)	63 (29)	65 (29)
Frequency of vaginal sex without any form of contraception, in last 6 months			
Always	55 (12)	25 (11)	30 (13)
Most of the time	31 (7)	10 (5)	21 (9)
Some of the time	53 (12)	27 (12)	26 (11)
Rarely	76 (17)	39 (19)	37 (16)
Never	200 (44)	108 (49)	92 (41)
Don't know/not answered	31 (7)	10 (5)	21 (9)
Contraceptive used at last sex			
Condom	204 (46)	105 (48)	99 (44)
Pill [†]	128 (29)	73 (33)	55 (24)
Patch [†]	34 (8)	15 (7)	19 (8)
Ring [†]	8 (2)	5 (2)	3 (1)
Depo-Provera [†]	15 (3)	8 (4)	7 (3)
No Hormonal or Barrier Method	71 (16)	30 (14)	41 (18)

*Data were missing on age for 1 woman, race/ethnicity for 4 women, marital status for 7 women, income for 36 women, prior pregnancy for 9 women, health insurance for 5 women, usual source of care for 11.

[†]29% of pill users, 32% of patch users, and 50% of ring users also reported use of condoms

Table 1. Sociodemographic Characteristics of Study Participants

Characteristic	Total (N=446)	Intervention (N=219)	Control (N=227)
	n (%)	n (%)	n (%)
Age			
18–24 years	117 (26)	56 (26)	60 (27)
25–30 years	157 (35)	87 (40)	70 (31)
31–35 years	106 (24)	49 (22)	57 (25)
36–45 years	65 (15)	43 (20)	38 (17)
Race/ethnicity			
White	195 (44)	95 (43)	100 (44)
Black	53 (12)	24 (11)	29 (13)
Latina	64 (14)	30 (14)	34 (15)
Asian	77 (17)	37 (17)	40 (18)
Other	53 (12)	30 (14)	23 (10)
Marital status			
Never married	234 (52)	114 (52)	120 (53)
Married	64 (14)	32 (15)	32 (14)
Living as married	107 (24)	50 (23)	57 (25)
Separated or divorced	34 (8)	18 (8)	16 (7)
Education			
Less than high school	23 (5)	14 (6)	9 (4)
High school graduate	53 (12)	28 (13)	25 (11)
Vocational school or some college	154 (35)	74 (34)	80 (35)
College degree	139 (31)	61 (28)	78 (34)
Graduate or professional degree	75 (17)	41 (19)	34 (15)
Type of health insurance			
None	118 (26)	59 (27)	59 (26)
Public assistance	81 (18)	39 (18)	42 (19)
Private insurance	240 (54)	116 (53)	124 (55)
Academic clinic site	286 (64)	155 (71)	131 (62)

follow-up from the 2 treatment groups. Women were more likely to be lost to follow-up if they were enrolled at the county clinic, had lower incomes, had not completed a college education, and self-identified as African American/Black. Women who were lost to follow-up were slightly less likely to have used birth control pills at last sex (27% vs 35%, $p = .09$) and slightly more likely to report a prior abortion (33% vs 26%, $p = .09$). However, knowledge of and attitudes toward EC on enrollment were similar between women who subsequently did and did not complete follow up.

At follow-up, approximately one third of women in both groups (33% vs 36%, $p = .20$) reported that since enrolling, they had discussed EC with a physician. However, women in the intervention group were able to answer an average of 2 more items correctly than they had at baseline, whereas women in the control group answered only one more item correctly (2.0 vs 1.2, $p < .001$). When we made the conservative assumption that women who were lost to follow-up learned nothing from the computerized counseling, we still found that women in the intervention group provided more accurate answers to questions about EC than women in the control group ($p = .03$). After adjusting for baseline characteristics including age, race, income, education, and site of enrollment, we found women in the intervention group were more likely to have learned 1 or more things about EC than women in the control group (odds ratio [OR] = 1.96, 95% confidence interval [CI] 1.09–3.51). Women in the intervention group were significantly more likely than women in the control group to have learned that EC is safe, that EC is effective 3–5 days after unprotected sex, that EC will not adversely affect a women's

Table 3. Baseline Knowledge, Attitudes, and Use of Emergency Contraception by Study Group

Characteristic	Intervention (N=219)	Control (N=227)
	n (%)	n (%)*
Knowledge of Emergency Contraception		
Has heard of emergency contraception	198 (90)	209 (92)
Emergency contraception is available in California	147 (67)	156 (69)
Emergency contraception is safe*	138 (63)	156 (69)
Emergency contraception is effective†	159 (73)	171 (75)
Emergency contraception will not adversely affect future fertility	103 (47)	119 (52)
Emergency contraception will not cause birth defects or a miscarriage	38 (17)	46 (20)
Emergency contraception can be used 3–5 days after a condom breaks	76 (35)	97 (43)
Emergency contraception does not provide protection from infection	181 (83)	194 (85)
Menses is expected within 3 weeks of taking emergency contraception	18 (8)	20 (9)
Personal objection to emergency contraception	19 (9)	13 (6)
Had ever used emergency contraception	59 (28)	62 (27)
Had used emergency contraception in last 6 months	11 (5)	15 (7)
Had emergency contraception at home for future use	18 (9)	17 (8)

*n (%) of respondents who provided an affirmative answer

†n (%) who responded that emergency contraception is somewhat safe, safe, very safe, or extremely safe. The mean and standard deviation on the 6-point Likert scale were 2.0 (1.2) and 1.9 (1.3) in the control and intervention groups, respectively, with 0 indicating extremely safe, 1 very safe, 2 safe, 3 somewhat safe, 4 somewhat dangerous, and 5 very dangerous.

‡n (%) who responded that emergency contraception is somewhat effective, effective, very effective, or extremely effective. The mean and standard deviation on the 6-point Likert scale were 1.6 (1.0) and 1.5 (1.0) in the control and intervention groups, respectively, 0 indicating extremely effective, 1 very effective, 2 effective, 3 somewhat effective, 4 somewhat ineffective, and 5 very ineffective.

future fertility, and that EC will not cause birth defects or miscarriage (Table 4).

Less change was seen in women's attitudes toward EC. However, whereas 9% of subjects in the intervention group reported personal or religious concerns about EC before receiving computerized counseling, 97% of women were interested in receiving a free sample of EC after receiving computerized counseling about EC. Among women who completed follow-up who had reported a personal or religious concern about EC at baseline, concerns persisted for only 33% of women in the intervention group compared to 50% of women in the control group.

Women who received computer-assisted provision of EC were no less likely to report using condoms (39% vs 36%, $p = .61$) or hormonal contraception (27% vs 24%, $p = .66$) at follow-up. Rates of sex without any form of contraception were also similar between groups ($p = .61$). However, at follow-up, there was a trend toward more use of EC during the study period in the intervention group (10% vs 4% of women followed, $p = .06$; 6% vs 3%, $p = .09$ of women enrolled). After adjusting for baseline characteristics including age, race, income, education, and site of enrollment, we found women in the intervention group were more likely to have used EC during the study

Table 4. Intervention effect on Knowledge of and Attitudes Toward Emergency Contraception (EC)

Characteristic	Intervention (N=127)	Control (N=138)	p value
	n (%)	n (%)	
Learned 1 or more things about EC	97 (76)	86 (62)	.04
Learned EC is available in CA	31 (24)	25 (18)	.36
Learned EC is safe	33 (26)	16 (12)	<.001
Learned EC is effective	28 (22)	20 (14)	.29
Learned EC will not adversely affect future fertility	47 (37)	27 (20)	.005
Learned EC will not cause birth defects or a miscarriage	43 (34)	19 (14)	<.001
Learned EC can be used 3–5 days after a condom breaks	36 (28)	26 (19)	.005
Learned EC does not provide protection from sexually transmitted infection	14 (11)	8 (6)	.31
Learned a period is expected within 3 weeks of taking EC	25 (20)	19 (14)	.33
Developed a more positive attitude toward EC	10 (8)	6 (4)	.06

period than women in the control group (OR = 7.17, 95% CI 1.38–37.21). In addition, women in the intervention group were more likely to report having a supply of EC pills at home should it be needed in the future (58% vs 11% of women followed; $p < .001$; 34% vs 7% of women enrolled, $p < .001$; Table 5).

Women in the intervention group were less likely to report being pregnant at the time of follow-up (0.8% vs 6.5%, $p = .01$ of women followed; 0.5% vs 4.0%, $p = .01$ of women enrolled) or to have been pregnant since enrollment (4.7% vs 9.4%, $p = .14$ of women followed; 2.7% vs 5.7%, $p = .12$ of women enrolled). There was a trend toward more pregnancies (7% vs 4%, $p = .21$) during the 7 months of follow-up among women enrolled from the county clinic, who were more frequently lost to follow-up. After adjusting for baseline characteristics including age, race, income, education, and site of enrollment, we found that the trend that women in the intervention group were less likely to have become pregnant persisted (OR = 0.41, 95% CI 0.14–1.21), but did not reach statistical significance. Women who became pregnant after enrolling in this study were more likely to have reported at baseline that they had unprotected sex at least "some of the time." However, rates of pregnancy were similar among women who reported at baseline they had used a hormonal method of contraception with last sex (5%) or a condom with last sex (4%).

Table 5. Intervention Effect on Access to and Use of Emergency Contraception (EC) and Rates of Pregnancy

Characteristic	Intervention (N=127)	Control (N=138)	p value
	n (%)	n (%)	
Had EC at home at end of study	74 (58)	15 (11)	<.001
Used EC during the study period	13 (10)	6 (4)	.06
Conceived during the study period	6 (5)	13 (9)	.14
Was pregnant at follow-up	1 (1)	9 (7)	.01

DISCUSSION

We found that a one-time 15-minute computerized counseling intervention with provision of a free sample of EC increased women's knowledge of EC 7 months later. More importantly, we found that women who received computerized counseling about EC and a free sample of EC were less likely to be pregnant when contacted by phone 7 months later. In light of the US FDA's recent decision to allow women access to EC without a physician's prescription,¹⁰ a strength of this study is that it was conducted in a setting in which women had been able to access EC without a physician's prescription for over 3 years.²⁴

This study differs from all prior studies of advance provision of EC, in that standardized counseling was delivered by a computer while subjects waited to see a clinician, placing no additional burden on busy clinicians,²¹ and allowing easy replication of the intervention. Whereas the trend we saw in increased use of EC over the course of the study did not reach statistical significance, the effect size is similar to those reported by studies that have had more power.^{12–15} Similarly, our finding that computerized counseling had no adverse effect on use of condoms or sexual risk-taking is supported by the findings of prior studies.^{12–15}

This study also differs from prior studies of advance provision of EC in that we recruited women who were not actively seeking reproductive health care. In this setting, we found that the large majority (97%) of women were interested in receiving a sample of EC when one was offered. This supports prior work, which found that 96% of people waiting to be seen by an academic emergency department were interested in receiving information about one or more preventive health issues,²⁵ but is in contrast to a study that recruited women from 3 primary care clinics in North Carolina, which reported that 49% of women declined an advance prescription for EC.²⁶ The reason women in our study were more interested in advance EC may reflect differences inherent in the populations studied; alternatively, the counseling about EC that was provided before offering EC may have impacted women's level of interest, or women may have simply felt that a free medication sample had more value than a prescription. Whereas a relatively small fraction of women used the EC they were provided during the 7 months they were followed up as part of this study, the majority (57%) reported having EC at home should it be needed in the future, 7 months after they received the EC. This indicates that more extended follow-up may show a greater effect of this intervention, as having EC at home will likely continue to impact women's ability to use EC when they face a risk of unintended pregnancy.

Strengths of this study include the fact that follow-up interviews were conducted by research assistants who were blinded to which counseling intervention subjects had received. In addition, the women enrolled in this study were diverse from a socioeconomic perspective. Limitations of this study include the fact that all outcomes were self-reported and that the rate of loss to follow-up was higher than anticipated. The fact that loss to follow-up was greatest among women who may be presumed to be at highest risk of unintended pregnancy (as these women reported higher rates of prior abortion, less use of birth control pills, less education, and lower incomes at baseline) implies that our results may underestimate the benefit of computer-assisted provision of

EC in urgent care settings. However, given greater than expected loss to follow-up, which resulted in this study's lack of power in evaluating our primary outcome, the use of EC, future research should confirm using objective measures of pregnancy that computerized counseling about EC can reduce rates of unintended pregnancy when provided in urgent care settings. In addition, it will be important to confirm that these findings can be replicated in populations outside of California, as unintended pregnancy and abortion remain common throughout the United States,²⁷ especially among women in more disadvantaged circumstances.²⁸

In conclusion, computer-assisted provision of EC offers a promising way to provide women the information they need to effectively use EC to reduce the risk of unintended pregnancy. Computerized counseling may be especially useful in urgent care settings where clinicians have limited time to provide preventive counseling.

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Conflict of Interest: Duramed Pharmaceuticals donated samples of emergency contraception for this study, but had no involvement in the study design or drafting of this manuscript. The authors have no other conflicts of interest to report.

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