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Computerized Counseling for Folate Knowledge and Use:

A Randomized Controlled Trial

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Abstract

Background—Periconception folate supplementation significantly reduces the risk of neural-tube defects, but few U.S. women start folate supplementation before pregnancy, and the amount of clinician time available to counsel patients about folate is limited. This study evaluated whether computer-assisted counseling and the provision of free folate tablets increases women's knowledge and use of folate supplements.

Design—Randomized controlled trial; follow-up began 6 months after enrollment and was completed on average 7 months after enrollment.

Setting/participants—A total of 446 women, aged 18–45 years, were recruited from two urgent care clinics in San Francisco from March to July 2005 (data collection was completed in 2006; data were analyzed in 2007).

Intervention—Participants received a 15-minute computerized educational session and 200 folate tablets.

Main outcome measures—The primary outcome was the knowledge that folate can prevent birth defects; secondary outcomes included the self-reported use of a folate supplement at follow-up.

Results—At follow-up, women in the intervention group were more likely to know that folate prevents birth defects (46% vs 27%, relative risk [RR]=1.72, 95% CI=1.32, 2.23); to know that folate is most important in early pregnancy (36% vs 17%, RR=2.11, 95% CI=1.50, 2.97); and to report the recent use of a folate supplement (32% vs 21%, RR=1.54, 95% CI=1.12, 2.13).

Conclusions—A one-time, brief, computerized counseling session about folate with the provision of free folate tablets increased the knowledge and use of folate supplements among women ≥ 6 months later.

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Trial Registration: NCT00177515.

Introduction

Neural-tube defects, which affect more than 3000 pregnancies in the U.S. each year,¹ can be prevented by the adequate maternal consumption of folate around the time of conception.² Because one half of all U.S. pregnancies are unintended,³ the CDC recommends folic acid supplementation for all women capable of becoming pregnant.⁴ Despite these recommendations, knowledge of the benefits of folate supplementation remains low in the U.S., especially among women who are of lower SES.^{1,5-7} Folate supplementation increases with clinician counseling.⁸⁻¹⁰ Unfortunately, the clinician time available to provide such counseling is limited. This study was designed to evaluate whether computerized counseling about folate can increase the knowledge and use of folate supplements.

Materials and Methods

English-speaking women aged 18-45 years were recruited from the waiting areas of two urgent care clinics in San Francisco between March and July 2005. One of these clinics is affiliated with an academic medical center, the other with a county hospital. A woman was excluded from this study if she was unlikely to become pregnant in the next year because she was currently pregnant, had undergone a hysterectomy or tubal ligation, had an intrauterine device in place, had a partner who had undergone a vasectomy, or was aged >45 years. In addition, women were excluded who did not have a telephone or were relocating. Women who had previously used a folate supplement remained eligible for this study in the hope that the intervention would encourage them to continue folate supplementation. The study was approved by the Committee on Human Research at the University of California San Francisco and by the IRB of the University of Pittsburgh. All participants provided written, informed consent.

At baseline, the women completed a computerized survey while they waited to see a clinician. Audio headphones facilitated the private completion of surveys by subjects with limited literacy. This survey, consisting of 85 items, took approximately 15 minutes to complete, and assessed sociodemographic and reproductive variables as well as the woman's knowledge and use of folate supplements. The use of folate was assessed by asking Have you taken any folate or folic acid supplements in the last few months? The survey was pilot-tested in the study's 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 baseline survey and received the computerized counseling intervention.

Women in the intervention group received computerized counseling about periconception folate supplementation, while women in the control group received computerized counseling about emergency contraception.¹¹ The computer module was administered in a semiprivate space; women wore audio headphones while they watched a short introductory video segment that instructed them how to use the mouse to click on any of nine 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. For women in the intervention group, the video doctor's script addressed questions such as what is folate, why should folate supplements be used, when and how often should folate supplements be used, where can folate supplements be purchased, how much do folate supplements cost, and *why is folate supplementation important*. To complete the module, a participant was required to hear the answers to all of these questions. After completing the computerized counseling session, each subject was

provided with a sample of the medication that had been discussed (folate or emergency contraception). Women in the intervention group received a single bottle that contained 200 tablets (400 mcg) of folate, with written instructions suggesting the ingestion of one tablet daily. Subjects received no additional compensation for participating in this study. Six months later, research assistants who were blinded about the subjects' placement in either the intervention or the control group called all subjects and, using a standardized script, administered a follow-up phone survey. The follow-up survey contained 30 items, all of which had been administered as part of the baseline survey. The primary outcome was the knowledge that folate can prevent birth defects. Secondary outcomes included the use of a folate supplement.

This study was powered to detect significant differences in the knowledge that folate can prevent birth defects between the intervention and control groups. A final sample size of 197 women per treatment group would allow the rejection of a null hypothesis that there is no difference in the knowledge of folate between the intervention and control groups, with 90% power in a two-sided test with $\alpha=0.05$ if the difference between groups was 10% or greater and if 20% of the women in the control group knew that folate can prevent birth defects.¹ As women presenting to urgent care are difficult to follow, the study was designed with the anticipation of losing 10% of the enrolled women, and was planned to enroll a minimum of 217 women in each group.

For the primary outcome, the knowledge that folate supplements can prevent birth defects, an intention-to-treat (ITT) analysis was performed that included all randomized women; in this analysis, women who were lost to follow-up were presumed to have no knowledge or use of folate supplements. In addition, the change in knowledge and the use of folate supplements among the women were examined. Contingency tables and chi-square statistics were used to evaluate the significance of differences between categorical variables; t-tests were used for continuous variables. Finally, a propensity score was created for loss to follow-up and was used to examine the effect of this intervention on the knowledge and use of folate, using propensity-score-weighted models adjusted for sociodemographic variables. Data were analyzed in 2007, using STATA version 9.0.

Results

Five hundred eighty-three women were screened and 446 were randomized at the two study sites (Figure 1). Of the 137 women excluded, most were excluded as they were unlikely to become pregnant in the next year 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 a vasectomy ($n=7$); or were aged >45 years ($n=22$). In addition, 34 women were excluded who planned to relocate or did not have a telephone.

The women randomized had diverse socioeconomic and ethnic backgrounds. While most had some form of health insurance, only one third reported a relationship with a primary care provider. Although few women (4%) stated that they were trying to become pregnant, 14% reported that they wouldn't mind becoming pregnant. However, in the 6 months prior to enrolling, this group of women had experienced considerable risk for unintended pregnancy, as more than half reported one or more episodes of vaginal intercourse with a man without the use of any form of contraception.

At baseline, knowledge of folate was limited in both groups; 26% of the women knew that folate can prevent birth defects, and 9% reported the recent use of a folate supplement. However, 85% of the women were interested in learning about what vitamins they should take, and 70% expressed interest in learning how to prevent birth defects. Immediately after

receiving computerized counseling about folate, 92% of the women reported that they had learned something from the module, 82% reported that they would use the information they received, and another 12% stated they might do so. Most (86%) reported that they would implement the knowledge, and another 10% reported that they might recommend the module to a friend.

Attempts to contact participants were initiated 6 months after enrollment, and were completed an average of 7 months after enrollment. In total, 265 women completed follow-up phone interviews. The number and characteristics of the women who were lost to follow-up were similar between groups. Baseline reproductive histories were similar between women who subsequently did and did not complete follow up. However, women were less likely to complete the follow-up if they were enrolled at the county clinic, had lower incomes, had not completed a college education, and were self-identified as black. At baseline, women who were subsequently lost to follow-up were less likely to know that folate can prevent birth defects (OR=0.43, 95% CI=0.28, 0.67) and less likely to report the recent use of a folate supplement (OR=0.56, 95% CI=0.28, 1.14).

At follow-up, when it was assumed that the women who were lost to follow-up had learned nothing from the intervention, women in the intervention group were almost twice as likely to know that folate can prevent birth defects (relative risk [RR]=1.72, 95% CI=1.32, 2.23). Women in the intervention group were also significantly more likely to report having used a folate supplement in the last few months (RR=1.54, 95% CI=1.12, 2.13). Other outcomes assessed at follow-up are shown in Table 1. In analyses adjusted for age, race, income, insurance, education, and site of enrollment and weighted for propensity for loss to follow-up, women in the intervention group were more likely to know that folate can prevent birth defects (OR=4.19, 95% CI=1.98, 8.85) or to have used a folate supplement (OR=1.55, 95% CI=0.88, 2.72).

In analyses of change from baseline knowledge and the use of folate (that included only subjects who completed follow-up), women in the intervention group were more likely to have learned about folate and to have started folate supplementation (Table 2). A woman's age, race, education, income, marital status, and parity were not associated with whether she learned something about folate from the video doctor.

Discussion

This study found that a one-time, 15-minute computerized counseling intervention with the provision of free folate supplements increased women's knowledge and use of folate 6 or more months later. While two prior studies^{8,9} have shown that counseling by clinicians and the provision of folate can increase folate use, other prior studies^{12,13} in which folate supplements have been distributed without clinician counseling have resulted in only minimal increases in use.

While a conservative ITT analysis showed significant benefit from this intervention, the inclusion in this study of women who had previously used a folate supplement may have biased its findings toward the null. In addition, in settings where women are specifically seeking preconception counseling, such computerized counseling may be even more effective.

However, future studies will need to include more stringent measures of folate use (as the use of any folate supplement in the last few months may not reflect the amount of folate supplementation needed to prevent neural-tube defects) and an assessment of whether computerized counseling (with and without the continued provision of free folate tablets) leads to sustained folate supplementation.

In conclusion, computerized counseling about the benefits of periconception folate supplementation has the potential to decrease neural-tube defects without placing increased demands on clinicians' time. As neural-tube defects continue to affect more than 3000 U.S. pregnancies each year,¹ the refinement of interventions to ensure adequate maternal consumption of folate around the time of conception is needed.

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Figure 1.
Flow of participants through trial

Table 1Intervention effect on knowledge and use of folate supplements among all subjects randomized^a

	Intervention <i>n</i> =227 <i>n</i> (%)	Control <i>n</i> =219 <i>n</i> (%)	<i>p</i> -value
Knows that folate can prevent birth defects	105 (46)	59 (27)	<0.001
Knows that folate is most important in the very first weeks of pregnancy	81 (36)	37 (17)	<0.001
Knows that folate supplements should be taken daily	92 (41)	50 (23)	<0.001
Knows that folate supplements can be purchased without a prescription	99 (44)	54 (25)	<0.001
Took a folate supplement in the last few months	72 (32)	45 (21)	0.007

^a In this analysis, women lost to follow-up were assumed to have no knowledge or use of folate.

Table 2Change in knowledge and use of folate supplements by intervention group^a

	Intervention <i>n</i> =138	Control <i>n</i> =127	<i>p</i> -value
	<i>n</i> (%)	<i>n</i> (%)	
Learned ^b that folate can prevent birth defects	63 (46)	24 (19)	<0.001
Learned that folate is most important in the very first weeks of pregnancy	57 (41)	20 (16)	<0.001
Learned that folate supplements should be taken daily	8 (6)	0 (0)	0.006
Learned that folate supplements can be purchased without a prescription	59 (43)	19 (15)	<0.001
Learned one or more things about folate	93 (67)	58 (46)	<0.001
Started taking a folate supplement	50 (36)	28 (22)	0.01

^aThis analysis includes only women who completed the follow up.

^b*Learned* is used to indicate a positive change in knowledge, meaning that a woman who did not know something at baseline knew the correct answer at follow-up. In this analysis, women who knew that folate can prevent birth defects or were using a supplement at baseline were presumed to have received no benefit from this intervention.