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Randomized trial of a physician-based intervention to increase the use of folic acid supplements among women

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Objective: Fewer than one third of American women take folic acid daily, although many women report that they would take folic acid if their physicians advised them to do so. This study determined the impact of a physician intervention during routine gynecologic visits on folic acid supplementation.

Study design: Patients were assigned randomly to receive brief folic acid counseling, a reminder phone call, and 30 folic acid tablets (n = 162 women; intervention group) or to receive counseling about other preventive health behaviors and a folic acid informational pamphlet (n = 160 women; control group). Self-reported folic acid use was compared at baseline and at 2 months.

Results: Of the 279 patients who completed the study, weekly folic acid intake increased in the intervention group by 68%, compared with 20% in the control group ($P = .008$). No significant differences were found in daily intake. The women who were most influenced by the intervention were black and lower income and not planning pregnancies.

Conclusion: With little effort expended to encourage folic acid use, gynecologists could potentially reduce the risk of folate-preventable birth defects among their patients by as much as 11%.

Folic acid supplementation at 0.4 mg daily, beginning before conception, has been shown to reduce the risk of neural tube defects (NTDs) by 50% to 70%.[1,2] The Centers for Disease Control and Prevention, the March of Dimes, and other national and professional organizations recommend that all women who are capable of becoming pregnant consume at least 0.4 mg of folic acid daily.[3] Although more women are becoming aware of these recommendations,[4] great discrepancy remains between the awareness level and the intake of folic acid.[5] Less than one third of reproductive-aged women take folic acid supplements daily.[4]

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The individuals who are most influential to a woman's preventive health practices (ie, health care providers) have not incorporated the folic acid message into their routine practices. According to a March of Dimes survey, 89% of women report that they would be more likely to take folic acid if advised to do so by a health care provider.[4] Among women who are aware of folic acid, only 30% cite health care providers as the source of the information.[4]

Health care providers may be reluctant to incorporate folic acid advice into an already busy clinic appointment, unless they are shown that a briefly delivered message can have a significant impact on their patients' behavior. This randomized controlled trial was designed to determine the impact of a very brief physician-based intervention during routine gynecologic visits on women's folic acid intake.

Material and methods

Subjects

Eligible women between the ages of 18 and 45 years were enrolled at 1 of 4 clinics during a routine gynecologic visit. Two clinics were affiliated with a medical school, and 2 clinics were private practices. Women were excluded if they were currently pregnant, were visiting for preconception or nonroutine care, were unable to speak and understand English, or had had a hysterectomy or tubal ligation or a previous pregnancy that was affected by an NTD. Before this study, clinic staff did not routinely discuss the benefits of folic acid with their patients as part of the gynecologic examination. The protocol and procedures for informed consent were approved by the Institutional Review Board of the University of Arkansas for Medical Sciences before subject enrollment.

Intervention

Women were assigned randomly into either the folic acid (intervention) group or control group. Randomization occurred at the patient level. Participating physicians saw patients in both the intervention group and the control group. Women in the intervention group received brief (30- to 60-second) counseling and a starter bottle of 30 folic acid tablets from the gynecologist, a booster phone call from a research nurse 1 to 2 weeks after the clinic visit, and a pamphlet produced by the Centers for Disease Control and Prevention addressing the benefits of folic acid. The counseling session covered the documented benefits of folic acid and the need for all women to take a folic acid supplement. A script that included 5 evidence-based folic acid talking points (Appendix) was available to the gynecologist. The booster phone call reminded women of the importance of folic acid taken before pregnancy in reducing the risk of having a child with a birth defect.

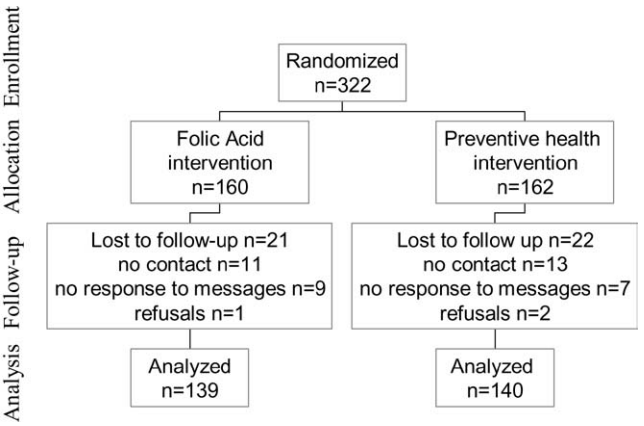

Figure Flow diagram of progress through the phases of a randomized trial.

Women in the control group received brief (30- to 60-second) physician counseling on 1 of 3 preventive health behaviors: breast self-examination, seat belt use, or sunscreen use. Scripts were provided that summarized statements of the American College of Obstetrics and Gynecology on the value of each behavior.[6] Physicians were not prohibited from including folic acid in their advice to control patients.

Women in the control group also received the folic acid informational pamphlet, a coupon for a free bottle of 30 folic acid tablets, and a stamped addressed envelope to mail the coupon. On receiving a coupon, we immediately sent a bottle to the patient. Although folic acid is known to reduce the risk of NTDs,[1,2] the benefits of physician counseling in increasing folic acid intake have not been established. Therefore, no treatments that are known to be beneficial were withheld from the control group.

Measures

Outcomes

Women were contacted by telephone 2 months after the clinic visit to assess the frequency of the folic acid intake, as adapted from questions in the 2000 March of Dimes Gallup survey[7]: "In the past month, how often, if at all, have you taken multivitamins or prenatal vitamins?" "To your knowledge, does this multivitamin or prenatal vitamin contain at least 400 μg (0.4 mg) of folic acid?" and "In the past month, how often, if at all, have you taken folic acid supplement pills?" Daily use was defined as 7 days per week, and weekly use as at least 1 day per week.

Fidelity to intervention

Two sources of information were used to determine appropriate implementation. Physicians and nurses