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Attitude and Behavior Effects in a Randomized Trial of Increased Access to Emergency Contraception

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Abstract

Objective—To explore the effects of providing unrestricted access to emergency contraception in advance of need on various psychosocial outcomes and pregnancy.

Methods—In the trial, women were randomized to either increased access to emergency contraception (two free packs at enrollment with unlimited free re-supply) or standard access. Participants were evaluated for 1 year for pregnancy and other outcomes. Psychosocial data were collected at enrollment and at 6 and 12 months. We applied exploratory factor analysis for data reduction. We compared the resulting psychosocial factors (including factors related to "aversion to pregnancy" and to the perceived "relative benefit" and "accessibility" of emergency contraception), two items directly assessing substitution, and pregnancy between randomization groups over time.

Results—On average, women in the increased access group had significantly stronger perceptions of both the "relative benefit" and "accessibility" of emergency contraception ($p<0.001$ for each). Women in the increased access group were significantly more likely to report that they had ever used emergency contraception because they did not want to use either condoms or another contraceptive method ($p<0.001$). Regarding pregnancy, we noted a significant interaction between randomization group and "aversion to pregnancy" ($p=0.010$): among the least "averse" women, increased access had a protective effect (hazard ratio = 0.64, 95% confidence interval 0.39 to 1.04); among the most "averse" women, increased access had a deleterious effect (hazard ratio = 1.73, 95% confidence interval 1.01 to 2.98).

Conclusion—As a result of having unrestricted access, some women substituted emergency contraception for their usual contraceptive methods.

Clinical Trial Registration—ClinicalTrials.gov, www.clinicaltrials.gov, NCT00060463

INTRODUCTION

Results from at least 14 comparative studies have provided no convincing evidence that increased access to emergency contraception (EC) reduces the risk of unintended pregnancy (1). On the other hand, previous studies also have not found that increased EC access adversely affects self-reported coital or contraceptive use patterns (2) and, in fact, three trials have shown that it does not increase risk of sexually transmitted infection (3-5). Furthermore, most of these

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studies provided evidence that increasing access encourages both more frequent and more prompt use of EC following unprotected intercourse (2). Given these findings, some authors have concluded that providing EC in advance of need is wholly beneficial (6). Recently published international family planning guidelines have advocated universal application of this approach (7). However, based on data from a randomized trial, we recently concluded that some women most likely increased their risk of unintended pregnancy as a direct consequence of having unrestricted access to EC (8).

Here, we describe new findings from this same trial. We conducted these secondary analyses to investigate the effects of providing unrestricted access to EC on women's attitudes and practices regarding reproductive health, use of EC, and use of other contraceptive methods. Our *a priori* null hypothesis was that the randomization groups would not differ, either overall or within any important subgroups, with respect to any of the outcomes being explored.

METHODS

We conducted an unblinded randomized trial in Nevada and North Carolina between October 2002 and June 2005. The protocol was approved by the institutional review boards of the University of California at San Francisco and Family Health International. Details of the trial methods and primary results have been presented previously (5). In brief, we enrolled 1,490 sexually active women aged 14 to 24 years who did not desire pregnancy and who did not plan to use long-acting contraceptive methods within the subsequent year. At the enrollment visit, women completed a computer-assisted self-interview that collected relevant baseline data and that also included a set of 27 reproductive health knowledge and attitude items (Figure 1). These items covered the topics of pregnancy, sexually transmitted infections, condoms, birth control pills, EC, and abortion. To minimize missing data, we programmed the computer to require subjects to answer all questions. Women were then randomized into one of two groups in a one-to-one ratio, stratified by site, using sequentially-numbered, opaque, sealed envelopes. Women assigned to the increased access group received two free packs of EC at enrollment with unlimited free re-supply throughout the study; women assigned to the standard access group were advised about getting EC from the study site at usual charge when needed. The trial sample size was based on the power for comparing the incidence of pregnancy and sexually transmitted infections between groups (5).

During scheduled visits at approximately 6 and 12 months post-randomization, women completed a computer-assisted self-interview that included the same 27 reproductive health items asked at enrollment plus 16 additional items specifically related to EC (Figure 2). This interview also asked two direct questions about whether, since joining the study, the participant had "ever used emergency contraceptive pills because [she] did not want to use" a condom or another contraceptive method. Responses to these two items were scored as 0 = "never," 1 = "once," 2 = "a few times," and 3 = "many times." We also collected data on all pregnancies and each self-reported use of EC throughout the study.

The analyses reported here included all women who contributed data to the primary pregnancy analysis, specifically 724 and 717 women in the increased and standard access groups (5), respectively, except for one woman in the increased access group whose baseline self-interview data were lost due to a computer error. We considered 6- or 12-month visits to be any visit that occurred either between 5 and 7 months or between 12 and 14 month post-randomization, respectively, and we excluded data from any visits that occurred outside of these windows.

We used exploratory factor analysis as a method of data reduction prior to subsequent analyses. Exploratory factor analysis is a statistical method that sorts a large set of questionnaire items into internally-correlated subsets, each of which is assumed to represent an unobserved,

underlying concept, called a "factor." The nature of each factor is subjectively deduced by examining the content of the items in the respective subset. For each participant, one can then estimate a factor score, which signifies her level of congruence with the associated underlying concept. These estimated factor scores can be used as outcomes or predictors in subsequent analyses.

Using only the enrollment data, we first conducted a factor analysis using all 27 reproductive health items (Figure 1). We reverse-scored indicated items so that higher scores always represented a stronger desire or more self-efficacy to prevent either pregnancy or sexually transmitted infection. We used subjective methods (a screen plot of the eigen values (9)) to determine a minimal number of factors that would account for most of the covariation in the original responses. We applied a recommended approach (principal factor analysis followed by an oblique promax rotation (9,10)) to obtain our final solution. We excluded items that either did not sort into any factor or that sorted into more than one factor. As a validation of our solution, we repeated the factor analysis using data from the two follow-up visits separately, but we derived all estimated factor scores for subsequent analyses using the scoring coefficients obtained from the enrollment data.

Similarly, we conducted separate exploratory factor analyses with the 19 EC items (Figure 2) for each treatment group at each follow-up visit. Based on these four analyses, we determined the number of factors and items to be retained; items that were not consistently sorted into a single factor were excluded. Using the reduced item pool, we then fit a factor analysis to the 6-month data for the standard access group alone to eliminate any effects of treatment or time. We used the resulting scoring coefficients to derive estimated factor scores for both groups at both visits. Factor scores were transformed back to the original item scale to aid interpretation.

We investigated the effect of our intervention with respect to the following outcomes: 1) the reproductive health psychosocial factor scores; 2) the EC psychosocial factor scores; 3) the two individual items about substitution of EC for other methods, as well as a combined substitution outcome defined as the maximum response on the two items; and 4) the incidence of pregnancy. To investigate group differences over time while controlling for within-subject correlation, we applied general linear mixed models with unstructured covariance matrices separately for each factor score. We used generalized estimating equation methods with an identity link function and an unstructured working correlation matrix to analyze the combined substitution outcome over time. Each model included terms for visit, treatment, and the visit-by-treatment interaction and was adjusted for all baseline variables listed in Table 1. To explore both the overall effects of increased access as well as any effect modification across important subgroups of women, we first fit a full model that included all of the two-way interactions between the baseline variables and treatment group. We tested the need for all interaction terms simultaneously; if that test was not significant, we used a reduced model without interactions for treatment group comparisons. However, if the overall interaction test was significant, our final model included any interaction terms that were individually significant in the full model.

For the analysis of pregnancy, we used a Cox proportional hazards model, stratified by site, to explore interactions between treatment group and baseline covariates. However, given the relatively small number of pregnancies (67 in the increased access group and 70 in the standard access group), we used a two-step model-building strategy. We first fit a model containing all baseline covariates listed in Table 1, and we used a likelihood ratio test to eliminate non-significant terms. We then tested whether any two-way interactions with treatment group could significantly improve the fit of this reduced model using a second likelihood ratio test. The final model included all significant covariates from the first step and all significant interactions from the second step. We investigated violations to the proportional hazards assumption by adding interactions with time and using a likelihood ratio test. We conducted all tests at the

two-sided 5% significance level. All analyses were performed using SAS, Version 9.1 (SAS Institute, Cary, NC).

RESULTS

In the increased access group, 565 of 723 women in the analysis population (78%) contributed interview data from both follow-up visits, 115 (16%) contributed data from only one visit, and 43 (6%) contributed no interview data. In the standard access group, the corresponding values were 573 of 717 women (80%) with both visits, 117 (16%) with one visit, and 27 (4%) with no interview data.

The factor analysis of the 27 baseline reproductive health items (Figure 1) arranged 14 of the items into four subsets assumed to represent underlying psychosocial factors; the other 13 items were excluded. This four-factor solution accounted for almost 100% of the covariation among the original responses. Based on the content of the items in each subset, we named the factors “perceived contraceptive efficacy,” “aversion to pregnancy,” “access to contraception,” and “stigma.” The results of separate factor analyses with the 6- and 12-month data were almost identical to those for the baseline data, providing some validation of our final solution. For the EC items (Figure 2), factor analyses consistently resulted in a two-factor solution that explained almost 100% of the covariation among the original responses. Six items were consistently arranged into the first factor, seven into the second factor, and six items into neither factor. Based on the item subsets, we named the factors “EC relative benefit” and “EC accessibility.” The estimated scores for these two EC factors were not significantly correlated; however, “EC relative benefit” was significantly correlated with responses to each of the two contraceptive substitution items, with estimated correlations of approximately 0.3.

Enrollment data (Table 1) from the analysis population are similar to those presented previously for the entire randomized population (5). The groups were similar at baseline with respect to the reproductive health psychosocial factors; participants in both groups tended to agree on average with the items (reversed where indicated) in the “perceived contraceptive efficacy,” “aversion to pregnancy,” and “access to contraception” factors, whereas they tended to disagree on average with the items in the “stigma” factor (Figure 1). The groups did not differ significantly with respect to any of the reproductive health factors at either follow-up visit (Table 2), and we found no evidence of treatment effects within any subgroups of the population.

The groups differed significantly in their responses to the two questions about substitution of EC for condoms or other methods (Table 3). At each visit, women in the increased access group were approximately three times as likely as women in the standard access group to report that they had ever substituted. Among women who had data for both follow-up visits and who ever reported substituting, 42% and 45% in the increased and standard access groups, respectively, reported a greater frequency of ever substituting at 12 than at 6 months, suggesting that substitution was not simply an immediate post-randomization occurrence.

For the combined substitution outcome (the maximum response on the two individual substitution questions), we noted a significant interaction ($p<0.001$) between treatment group and contraceptive method used at baseline (hormonal method, consistent condoms, or neither). Consequently, although women in the increased access group were more likely to report substituting with EC at both follow-up visits regardless of contraceptive method used at baseline, the effect was most pronounced among women who neither used a hormonal method nor were consistent condom users at baseline (Table 4).

The groups differed significantly with respect to the “EC relative benefit” factor at both visits; women in the increased access group perceived greater average benefit of EC use (Table 4).

The groups also differed significantly with respect to all six component items of the "EC relative benefit" factor at both visits (all Mantel-Haenszel p-values, controlling for site, were less than 0.01; item means for the 6-month visit are not shown but are similar to those for the 12-month visit presented in Figure 2). Women in the increased access group also had higher "EC accessibility" scores on average than women in the standard access group (Table 4), suggesting that our increased access intervention enhanced women's perceptions of the ease of obtaining and using EC. This effect was significantly more pronounced at the North Carolina site than at the Nevada site, and it was observed in unmarried women but not in the small proportion of married women in our sample.

We conducted some additional analyses to investigate the validity of the substitution questions. The median number of reported EC uses tended to increase with the reported frequency of substitution in both groups (Table 5), as would be expected. In both groups combined, pregnancy rates increased significantly with increasing frequency of substitution (Cochran-Armitage trend test p-value=0.01); however, this result must be interpreted with caution because the order of the reported substitution and pregnancy was impossible to determine in most cases. However, we found evidence that the substitution data may not be entirely valid. Some women in each group reported fewer EC uses than would be implied based on their responses to the substitution items (Table 5). In addition, some women provided inconsistent responses to these items over time, but the relative frequency of these inconsistencies was similar in the two groups: among women who had data for both follow-up visits and who reported any substitution in the first 6 months, 38% and 39% in the increased and standard access groups, respectively, reported more substitution at 6 than at 12 months.

Examining pregnancy incidence, we noted a significant interaction between the "aversion to pregnancy" factor and treatment group (p=0.010): the effect of increased access to EC on pregnancy risk was inversely related to a woman's "aversion to pregnancy." For example, among women with an estimated "aversion to pregnancy" score at the 10^{th} percentile (i.e., the least "averse" women), increased access to EC decreased the risk of pregnancy relative to standard access (hazard ratio = 0.64, 95% confidence interval 0.39 to 1.04). In contrast, among women with an estimated "aversion to pregnancy" score at the 90^{th} percentile (i.e., the most "averse" women), increased access to EC actually increased the risk of pregnancy relative to standard access (hazard ratio = 1.73, 95% confidence interval 1.01 to 2.98). Our model controlled for previous pregnancy, Hispanic ethnicity, and contraceptive method used at baseline. We found no evidence that the proportional hazards assumption was violated for this model.

DISCUSSION

Our results provide a possible explanation for the failure of our EC access intervention to produce a measurable decrease in unintended pregnancies. We found compelling evidence that women who received increased access were more likely than women who received standard access to substitute EC for their usual contraceptive method, even though we were unable to directly measure the extent or nature of that substitution. Substituting EC for a more efficacious contraceptive method, such as regular hormonal contraception or condoms, would increase the risk of unplanned pregnancy. In contrast, use of EC after acts that otherwise would have been either completely or partially unprotected would decrease risk. These two effects could easily have offset each other, thus creating no measurable population-level impact on pregnancy rates.

This conclusion is entirely consistent with that drawn from our previously published analysis from the same study (8). There, we observed that a greater proportion of the pregnancies in the increased access group than in the standard access group were either probably or possibly the result of EC failure. Given this, we reasoned that the women in the increased access group as

a whole likely had more acts for which EC was used in place of a more effective contraceptive method.

Here, we base our conclusion on the totality of our results rather than on any individual finding. Our data do not allow us to identify precisely which participants substituted EC for other contraceptive methods or when they may have done so. Although we refer to the two questions summarized in Table 3 as "EC substitution items," these questions were not pre-tested and participants may not have interpreted them as asking explicitly about substitution, as we had intended. Nevertheless, our data provide consistent evidence to support our conclusion. The items that contributed to the factor we subjectively named "EC relative benefit" (Figure 2) emphasize the utility of EC compared to other contraceptive methods; in fact, two of these items specifically describe substitution scenarios. Thus, an alternative name for the latent concept measured by this subset of items might be "propensity to substitute." The positive correlations between this factor and the direct substitution questions provide some evidence of the validity of this interpretation. Furthermore, because the factor items asked about current attitudes, they were not subject to recall bias, unlike the substitution questions. Indeed, this factor might very well be a more reliable measure of a propensity to substitute than responses to the direct substitution questions.

Although our intervention did not measurably affect pregnancy risk across the entire study population, if it encouraged some women to substitute EC for more effective contraceptive methods, then it caused an increase in pregnancy risk for those acts for those women. The concern that our intervention was hazardous to some women is supported by our analysis of pregnancy. We found that our intervention increased the pregnancy risk among women who were most averse to pregnancy but decreased risk among women who were the least averse. Although our analysis did not specifically link this finding to EC substitution, this finding provides further evidence that the effect of unrestricted access was not uniform across the study population.

Consistent with results from other studies, our primary analysis of this trial found no evidence of a treatment effect on self-reported sexual behavior or use of contraceptive methods other than EC (5). However, one should not infer from those results that unrestricted access to EC had no effect on contraceptive behaviors. First, and most importantly, non-significant statistical tests can never provide persuasive evidence in favor of the null hypothesis. Additionally, self-reported sexual behavior data have been found to be of questionable validity (11). Thus, although the findings presented here are different from those of the primary analyses (5), the two are not necessarily incompatible.

Our analysis has limitations. First, it was not pre-specified and could have been influenced by knowledge of the primary study results. However, we did not selectively present only results that supported our conclusions. Second, we performed many tests of significance without any adjustments for multiplicity. However, the level of evidence provided by almost all of these tests (with p-values typically less than 0.001) would have withstood such adjustment. Third, roughly 8% of all randomized participants contributed no psychosocial data. However, unless the missing standard access participants happened to be much more inclined than the missing increased access participants to have substituted EC for their usual contraceptive method, it seems unlikely that these missing data could have negated our conclusions. Finally, asking the EC psychosocial items in conjunction with providing unlimited access to EC might have persuaded some women to substitute. However, these questions were not asked until the 6-month visit, yet the data provide evidence of substitution prior to this visit, which implies that such an effect could not entirely explain our results.

Our results do not necessarily generalize to other increased access interventions. In particular, providing women with unlimited free supplies of EC in advance of need, as we did, is certainly much more aggressive than making EC available "behind the counter," as is the current policy in the United States. Furthermore, the increased risk that some women experienced as a direct result of our intervention applies to unintended pregnancy only, not necessarily to other undesirable consequences of sex. Specifically, the results from our primary analyses demonstrated convincingly that women with increased access are not at appreciably greater risk for sexually transmitted infections (5). However, although a new international guidance (7; Chapter 3) encourages providers of family planning to, "if possible, give all women who want [emergency contraceptive pills] a supply in advance," our current results do suggest that a policy of providing unrestricted advance access to EC could be detrimental for some women.

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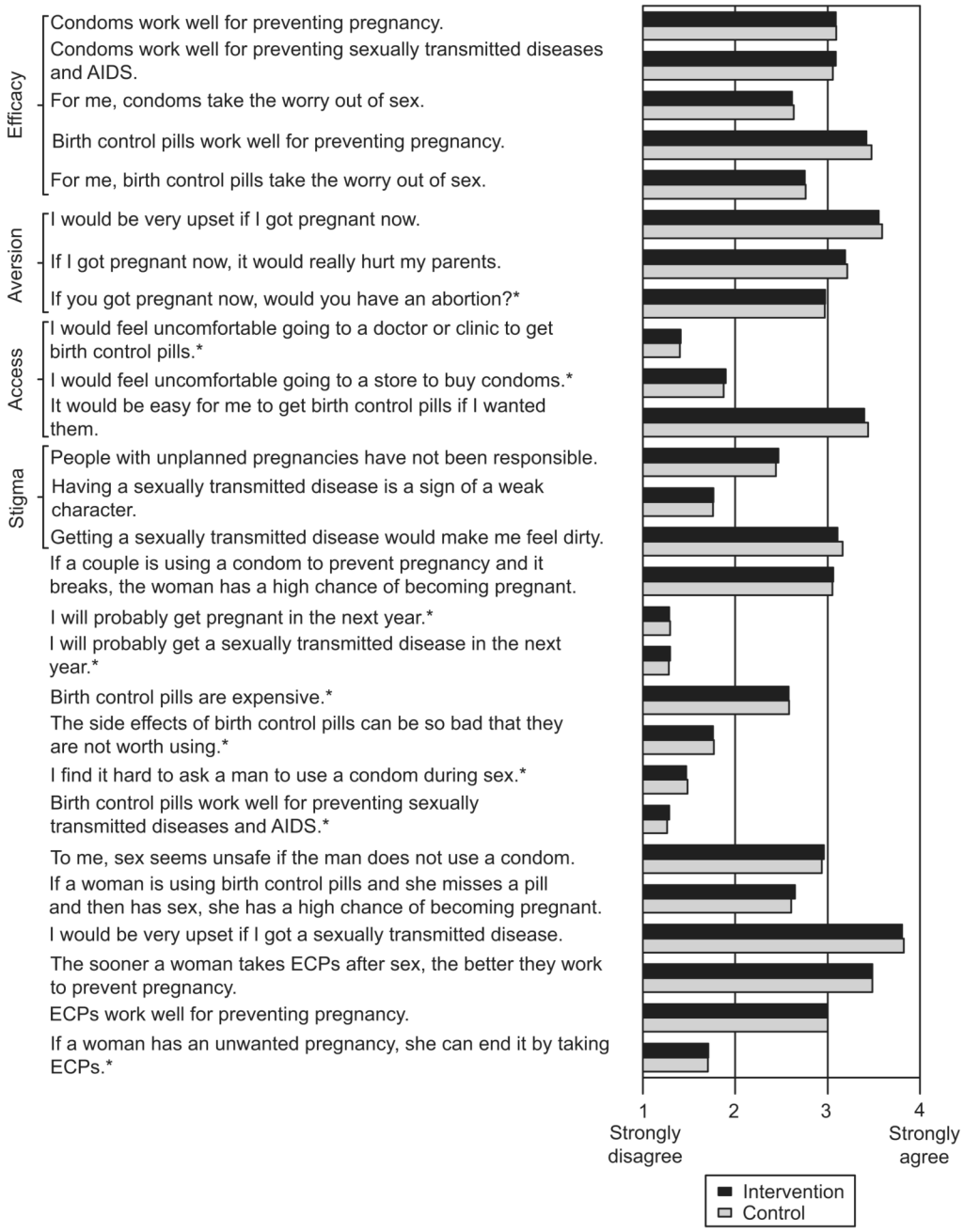

Figure 1.

Reproductive health item means at baseline, grouped by factor. An "*" indicates that the item was reverse-scored prior to factor analysis. ECPs = "emergency contraceptive pills." The item "If you got pregnant now, would you have an abortion?" was scored from 1= "definitely" to 5= "definitely not."

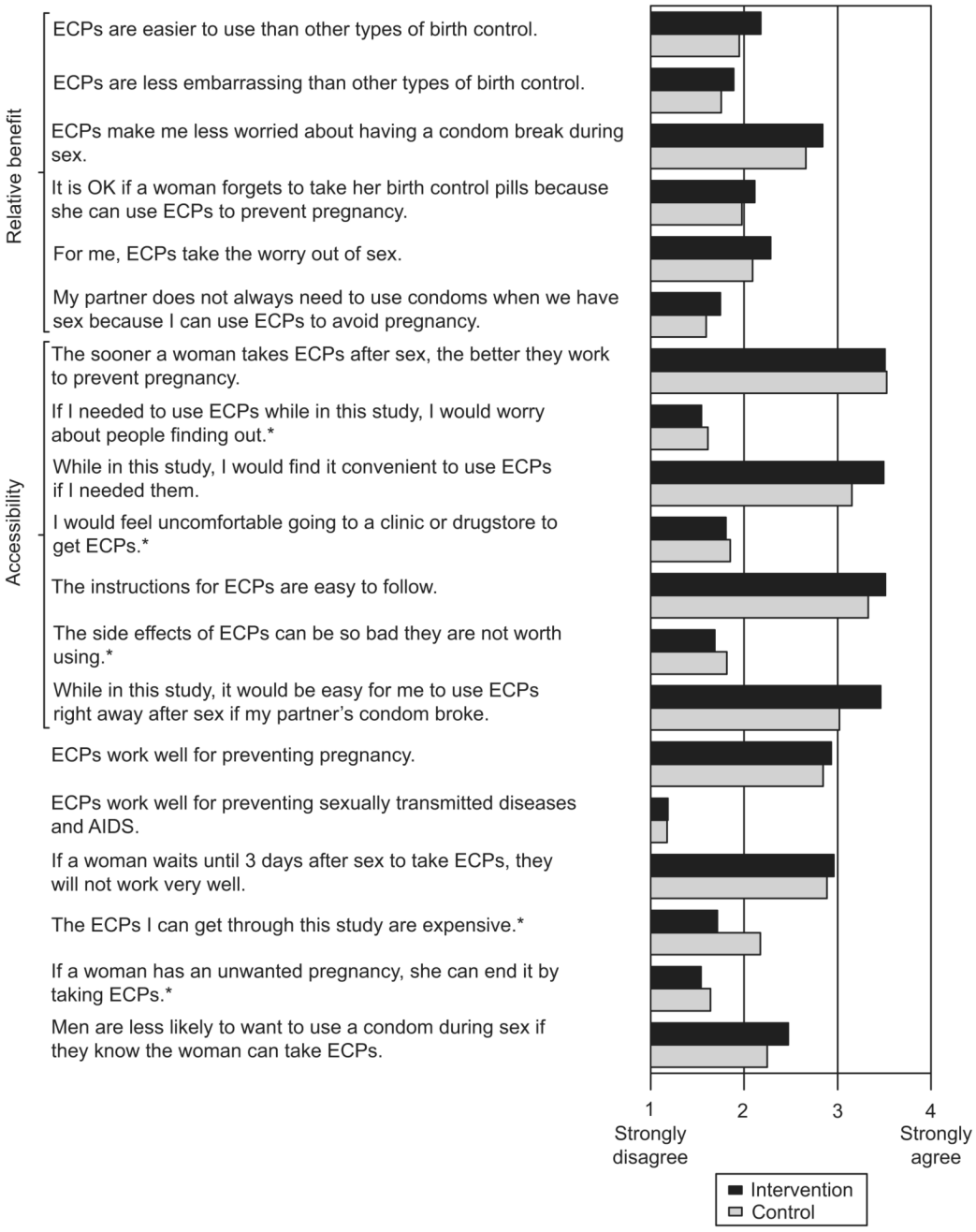

Figure 2.

Emergency contraception item means at the 12-month visit, grouped by factor. An "*" indicates that the item was reverse-scored prior to factor analysis. ECPs = "emergency contraceptive pills."

Table 1

Summary of Baseline Characteristics, by Randomization Group

Characteristic *	Increased Access (N=723)	Standard Access (N=717)
Site		
Nevada	431 (60%)	432 (60%)
North Carolina	292 (40%)	285 (40%)
Age (years)		
14-15	34 (5%)	31 (4%)
16-17	177 (24%)	156 (22%)
18-20	259 (36%)	255 (36%)
21-24	253 (35%)	275 (38%)
Hispanic ethnicity	113 (16%)	80 (11%)
Black race	74 (10%)	75 (10%)
Married	39 (5%)	37 (5%)
High school graduate	465 (64%)	490 (68%)
Any previous pregnancies	150 (21%)	178 (25%)
Had previous abortion	90 (12%)	113 (16%)
Used hormonal contraceptive method in month prior to admission	360 (50%)	347 (48%)
Did not use hormonal method but used condoms consistently in 2 weeks before admission	153 (21%)	144 (20%)
Any previous use of EC	233 (32%)	212 (30%)
Baseline reproductive health psychosocial factors		
“Perceived contraceptive efficacy”	3.0 (0.4)	3.0 (0.4)
“Aversion to pregnancy”	3.5 (0.8)	3.5 (0.7)
“Access to contraception”	3.4 (0.5)	3.4 (0.5)
“Stigma”	2.4 (0.5)	2.4 (0.6)

* Data reported either as frequency (%) or as mean (standard deviation).

Table 2

Model-Estimated Means* for the Reproductive Health Psychosocial Factors, by Visit

Factor	6-Month Visit				12-Month Visit			
	Increased Access (n=621)	Standard Access (n=625)	SE †	P	Increased Access (n=624)	Standard Access (n=638)	SE †	P
"Perceived contraceptive efficacy"	3.03	3.01	0.02	0.38	3.00	3.02	0.02	0.38
"Aversion to pregnancy"	3.35	3.34	0.03	0.62	3.21	3.21	0.04	0.87
"Access to contraception"	3.50	3.51	0.02	0.57	3.52	3.55	0.02	0.18
"Stigma"	2.38	2.36	0.02	0.46	2.33	2.31	0.02	0.53

*Estimated means adjusted for all variables listed in Table 1.

†Standard error of the difference in means.

Table 3

EC Substitution Items, by Group and Visit

Item *	6-Month Visit				12-Month Visit			
	Increased Access		Standard Access		Increased Access		Standard Access	
Response	n	(%)	n	(%)	n	(%)	n	(%)
Provided data	621		625		624		638	
Since joining study, ever used EC because did not want to use condoms?								
Never	427	(69%)	567	(91%)	412	(66%)	561	(88%)
Once	109	(18%)	49	(8 %)	109	(17%)	60	(9%)
A few times	77	(12%)	8	(1%)	91	(15%)	17	(3%)
Many times	8	(1%)	1	(< 1%)	12	(2%)	0	
Since joining study, ever used EC because did not want to use other methods of birth control?								
Never	527	(85%)	595	(95%)	516	(83%)	602	(94%)
Once	37	(6%)	25	(4%)	50	(8%)	26	(4%)
A few times	51	(8%)	3	(< 1%)	46	(7%)	9	(1%)
Many times	6	(1%)	2	(< 1%)	12	(2%)	1	(< 1%)

* Mantel-Haenszel mean score p-values, controlling for site: <0.001 for both items at both visits.

Table 4

Model-Estimated Means* for the Combined Substitution Outcome and the EC Psychosocial Factors, by Visit and in Various Subgroups†

Outcome Visit / Subgroup	Increased Access	Standard Access	SE ‡	P-value
Combined substitution outcome				
6-month visit	0.52	0.14	0.03	<0.001
12-month visit	0.59	0.18	0.04	<0.001
Used hormonal method at baseline	0.40	0.12	0.04	<0.001
Used condoms consistently at baseline	0.50	0.17	0.07	<0.001
Used neither hormonal method nor condoms consistently at baseline	0.84	0.22	0.07	<0.001
"EC relative benefit"				
6-month visit	2.19	2.01	0.03	<0.001
12-month visit	2.16	1.99	0.03	<0.001
"EC accessibility"				
6-month visit	3.40	3.24	0.02	<0.001
12-month visit	3.43	3.26	0.02	<0.001
Nevada	3.41	3.29	0.02	<0.001
North Carolina	3.42	3.19	0.03	<0.001
Married	3.24	3.24	0.07	0.950
Unmarried	3.42	3.25	0.02	<0.001

* Estimated means adjusted for all variables listed in Table 1.

† Includes only subgroups for which the associated interaction term was significant in the model.

‡ Standard error of the difference in means.

Table 5

Summary of Self-Reported EC Use and Pregnancy by Categories of the Combined Substitution Outcome at Each Participant's Final Visit

Ever Substituted EC for either Condoms or Other Birth Control?	Increased Access				Standard Access			
	n	Median EC Uses	Conflicts with Reported EC Use*	Ever Pregnant During the Study	n	Median EC Uses	Conflicts with Reported EC Use*	Ever Pregnant During the Study
Never	426	1	0	28 (7%)	591	0	0	58 (10%)
Once	125	3	3	11 (9%)	74	1	7	4 (5%)
A few times	109	5	7	21 (19%)	22	2	4	2 (9%)
Many times	19	7	2	1 (5%)	3	2	3	1 (33%)

* The number of participants whose data contained inconsistencies between responses to substitution questions and reported EC use. Counts include participants who answered "once" but used 0, answered "a few times" but used fewer than 2, or answered "many times" but used fewer than 3.