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We Should Really Keep In Touch: Predictors of the Ability to Maintain Contact With Contraception Clinical Trial Participants Over 12 Months

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Abstract

Objectives—This study assesses the ability to maintain contact with participants enrolled in an emergency contraception (EC) trial with 12 months of follow-up based on the modes of contact they provided at enrollment.

Study Design—Data came from a clinical trial offering women the copper intrauterine device (IUD) or oral levonorgestrel (LNG) for EC. A modified Poisson regression was used to assess predictors associated with the ability to contact study participants 12 months after enrollment.

Results—Data were available for 542 participants; 443 (82%) could be contacted at 12 months. Contact at 12 months was greatest for those whose preferred method of contact was text messaging, email, or any (62/68 91% contacted) and worst for the 18 who had a landline phone

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(only 7 contacted, 39%). After controlling for age, having an email address, text messaging, language preference, type of EC chosen, and insurance, preferred contact other than phone increased the likelihood of follow-up by 10% (RR 1.1 95% CI 1.0-1.2), while having a landline reduced a woman's likelihood of being contacted at 12 months by 50% compared to women with a contract cell (RR 0.5; 95% CI 0.3-1.0).

Conclusion—The few women with a landline for contact had poor follow-up at one year while women who preferred email or text had the highest rate of follow-up.

Implications—Understanding how best to reduce loss to follow-up is an essential component of conducting a contraceptive clinical trial. Improved participant retention maximizes internal validity and allows for important clinical outcomes, such as pregnancy, to be assessed.

Keywords

participant retention; emergency contraception; IUD; levonorgestrel

Introduction

One of the most challenging aspects of conducting clinical trials is minimizing loss to follow-up (LTF). Improved participant retention and long-term follow-up in clinical trials maximizes internal validity and allows for important clinical outcomes to be assessed. In contraceptive trials, LTF may be related to an outcome of interest such as pregnancy. Study results may be altered after vigorous efforts to contact participants are made in order to analyze this outcome. For example, if additional efforts to contact participants revealed additional pregnancies among participants that had moved away, this would increase the pregnancy rate. This hypothesis is supported by a recent review that reported pregnancy rates may increase when final outcomes are identified for participants initially lost to follow-up [1]. This also demonstrates the importance of preventing LTF in order to report accurate and unbiased data.

The literature on emergency contraception (EC) demonstrates substantial issues with losing participants during follow-up periods [2, 3]. Increased mobility can often mean decreased connectivity; participants may change their home address, their email, or cell phone number without notifying contacts, let alone study coordinators. Follow-up success may be a combination of convenience and access to reliable methods of communication. Some individuals may prefer brief contact via social media or text messaging rather than lengthy emails or telephone conversations. Early work has begun on evaluating use of the Internet versus in-person and telephone follow-up among study participants [4]. It is important that researchers attempt to better understand participant contact preferences to minimize LTF. This is especially true for outcomes that are most meaningful to reproductive health professionals such as unplanned pregnancy, contraceptive method continuation, and method satisfaction that require long follow-up periods. This study aims to identify characteristics that predict a contraceptive trial participant's ability to maintain contact for one year of follow-up.

Materials and Methods

Women aged 18-30 years presenting for EC at two family planning clinics in Salt Lake City, Utah (November 2009 to July 2010) were offered participation in a prospective observational study comparing oral levonorgestrel (LNG) to the copper intrauterine device (IUD) for EC. Participants were provided their desired method of EC at no cost and were followed for one year to assess pregnancy rates. The methods and results of the main study are published in this journal [5]. At the time of enrollment, participants were asked to provide a telephone number, home address, and three additional personal contacts. If available, text messaging capability and email addresses were also obtained for participants and designated contacts. Potential participants were excluded if unable to provide a phone number.

Baseline demographics, current method of contraception, obstetric history, history of sexually transmitted infection, reasons for EC need, and time from unprotected intercourse were collected at the time of enrollment. Prior to the participant leaving the clinic, study staff scheduled a 4-week follow-up contact.

Participants were contacted by phone, text, or email to complete follow-up questionnaires at 1, 3, 6, 9, and 12 months. If participants were unreachable by these methods, clinical records were queried for updated contact information. If participants were still unreachable, a certified letter was sent to the most current mailing address. The protocol did not specify *a priori* number of contact attempts prior to searching by clinical records or sending a certified letter. Research staff determined on an individual basis that a subject was “unreachable”, but in no case did that occur prior to having made fewer than three attempts using each method available to contact a participant.

The primary outcome of this secondary data analysis was successful contact with study participants 12 months after enrollment. Sociodemographic differences between women who were contacted at 12 months and those who were not were compared using chi-square test and student's t-tests. We employed a modified Poisson regression to identify independent predictors of the ability to follow participants over the 12-month time period [6]. The following variables were assessed: provision of an email address for contact, provision of a phone number, phone type (landline, long-term contract cell phone, monthly prepaid cell phone), age, race/ethnicity, English or Spanish language, insurance status, income level, preferred method of contact, and type of EC selected.

Predictors with potential associations ($p \leq 0.2$) in the univariable regression were adjusted for potential confounders in a modified Poisson regression [6].

Data analysis was performed utilizing *Stata 13 statistical software* (College Station, TX, StataCorp LP). This study was approved by the Institutional Review Board of the University of Utah and Planned Parenthood Federation of America Medical Affairs Department.

Results

Data were available for 542 participants, 443 (81.7%) of whom could be contacted 12 months after enrollment which occurred from November, 2009 to July 2010. Participants had a mean age of 22.4 ± 3.4 years and white race was predominantly reported (65.7%). Participant demographics by follow-up status are listed in Table 1. Of the 542 participants, 215 (39.7%) chose the copper IUD and 327 (60.3%) chose oral LNG. The primary analysis in the main outcomes paper describes participants who were excluded or who withdrew over the course of the study in greater detail [5]. The remaining participants were included in this secondary analysis and assessed for follow-up (see Figure 1). The majority of women in this study reported having a cell phone 521/542 (96%) or email address 497/542 (92%) with 537/542 (99%) of participants reporting either of these modes of communication, while 514/542 (95%) had both email and a cell phone. Only 18 participants (3%) provided a landline phone number; however, less than half (7) were contacted at 12 months. After removing 9 women who withdrew from the study 533 women remained in the analysis. Of the 465 participants who preferred to be contacted by phone 381 (82%) were contacted at 12 months. While 62 of the 68 participants who preferred either text messaging, email, or any method of contact provided (91%) were contacted at 12 months. Figure 2 depicts the percentage of participants followed over 12 months by their mode of contact. Most women could be contacted at 1 and 3 months regardless of their chosen contact method; however, women with a landline were significantly less likely in the simple regression to have follow-up at 6 months and after.

A modified Poisson regression was used to examine factors associated with successful follow-up at 12 months [6]. The analyses are shown in Table 2. In the univariable analysis, being older than 25, providing an email address, having a prepaid or contract cell phone, having text-messaging capabilities, indicating English language preference, self-identifying as Non-Hispanic/White, selecting the IUD as EC, a preferred contact other than phone, and having private insurance were each found to be associated with successful contact at the 12-month follow-up time point ($p < 0.05$). Both ethnicity and Spanish language were deemed to be potentially significant in follow-up ($p < 0.2$); however, because Spanish language serves as a proxy for Hispanic ethnicity only language was included in the final model.

After adjusting for age, having an email address, text messaging, language, type of EC chosen, insurance, and preferred method of contact, having a landline reduced a woman's likelihood of being contacted at 12 months by 50% compared to women with a contract cell (RR 0.5; 95% CI 0.3-1.0). Additionally, women who reported that their preferred contact method was email, text, or anything rather than just phone were 10% more likely to be contacted at follow-up (RR 1.1 95% CI 1.0, 1.2). Women who were 25 years or older (RR 1.1; 95% CI 1.0-1.2), had private insurance (RR 1.1; 95% CI 1.1-1.2), and women who chose the IUD as EC (RR 1.1; 95% CI 1.0-1.2) were also more likely to be contacted at 12 months in the adjusted model.

Discussion

Nearly all women in this study reported having either a cell phone or email address (96%) and 9 of 10 participants had both email and a cell phone. While only 3% of women provided a landline number, these women made up a disproportionate number of participants who were unable to be contacted after one year. Women who report using a landline were less likely to complete follow-up than women with either a prepay or a contract cell. The difference between the individuals who could be contacted at one year and those who could not suggests that having a landline compared to either a contract cell phone or an email address was a negative predictor of successful follow-up. This may be due to a population of women who were switching to mobile phones over the course of the year, or perhaps the lack of a cellular phone is indicative of lower socioeconomic status which may not be apparent in the income or educational characteristics as these younger women may still be dependent and not yet finished with schooling. Additionally, women who indicated that their preferred method of contact was email, text, or anything rather than just phone were also more likely to be contacted at 12 months. The fact that close to all of these women could be contacted may be due to a higher level of comfort with computer and mobile technologies in general among these women. Women who were older and those having private insurance were also more likely to be followed up. These women may be more stable and have ongoing employment, which may make maintaining contact easier for them.

The follow-up in this study is higher compared to other EC studies' LTF rates of 30-60% at 1 year [2, 3]. One EC study demonstrated remarkably low attrition rates with less than 10% LTF, however, the study period was only 6 months [7]. In a trial assessing tobacco treatment, Kim et al used similar follow up points to the current study [8]. They were able to improve their follow-up rates of high-risk participants from 83% at 3 months to 93% at 12 months using proactive measures. Techniques used by Kim et al included dedicated staff, using multiple contact methods including email, text messaging, and social networking as well as conducting field outreach. This study, although not related to contraception, is a good example of how time from enrollment should not necessarily affect attrition if active follow-up and best practices are used to contact study participants.

In a contraceptive trial of adolescents and young women a 93% follow-up rate was obtained with intensive efforts to maintain contact with study participants [9]. While extensive follow-up may improve participant retention, it can also be time consuming, costly, and may contribute bias. A time and cost analysis of participant retention efforts by Rdesinski et al showed spending approximately 1.2 hours and \$39.14 per participant was required for a 90% retention rate in a population of young women of lower socioeconomic status and level of education [10]. In a contraceptive clinical trial, Macaluso et al found that attrition in their study biased results regarding health-related behaviors [11]. Their protocol involved close follow-up for correct and consistent use of the female condom with a clinic visit every 4 weeks. Active follow-up may lead to altered or "better" behavior on the part of the participant and, while helpful in participant retention, may not accurately reflect what happens in the real world.

This prospective assessment of the ability to follow-up hundreds of participants in an EC study provides investigators with important considerations as they try to keep in touch with participants in clinic settings. A significant limitation of this work is that the most potent predictor of poor follow-up, use of a landline, was used by only 3% of study participants. Because this marker was rare it significantly limits the application of this finding for future work. Additional limitations exist in that the number of women approached for participation and reasons for exclusion were not documented. Furthermore, the mode of contact was not recorded when the successful follow-up occurred. Documenting the screening process and whether participants were contacted by their preferred method and which method of contact was ultimately successful (text, cell phone, or email) would have strengthened the findings. Additionally, online data collection may have reduced LTF as electronic reminders for individuals who provided an email address would have been possible and may have improved overall follow-up. However, many women reported having an email but few identified this as their preferred method of contact. This study utilized a consistent follow-up protocol that did not include additional proactive measures for harder-to-reach individuals.

It is important for researchers to continue to improve follow-up methods and incorporate new technology. With most young adults reporting use of social networking sites and over 80% of cell phone users reporting that they have their cellular device within arms reach all or most of the time, we should explore additional ways to stay connected [12]. Encouraging results from research involving technologies such as text messaging have shown some improvement of contraception knowledge and education in adolescents [13]. This technology may be applied to improving continued contact with clinical trial participants. However, there is also the potential for increased call screening by the participant. For example, a study which added the study personnel as a “contact” on participant's cell phones actually showed a decline in responses from participants [14]. It may be useful to conduct a test call to make sure the cell phone number is correct before the patient leaves the clinic or to assess participant preferred contact method with additional options such as calls, text, email, Facebook™, Twitter™, and other modalities. Spanish-speaking participants may be more likely to respond if contact is initiated in Spanish. It is important to flag participants' preferred language prior to first follow-up and to have all contact materials available in multiple languages.

Ultimately, it is critical for researchers to take a participant-centered approach and develop strategies to improve communication with study participants including sensitivity to social and cultural identity. Enhanced understanding of best practices for participant retention in contraceptive research is needed. Future research focusing on the preferred methods of contact by participants and broadening the use of new technologies for follow-up will improve follow up rates and the quality of contraceptive research.

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References

1. Trussell J, Portman D. The creeping pearl: why has the rate of contraceptive failure increased in clinical trials of combined hormonal contraceptive pills? *Contraception*. 2013
2. Walsh TL, Freziers RG. Patterns of emergency contraception use by age and ethnicity from a randomized trial comparing advance provision and information only. *Contraception*. 2006; 74:110–7. [PubMed: 16860048]
3. Glasier A, Baird D. The effects of self-administering emergency contraception. *The New England journal of medicine*. 1998; 339:1–4. [PubMed: 9647872]
4. Haider S, Dodge LE, Brown BA, Hacker MR, Raine TR. Evaluation of e-mail contact to conduct follow-up among adolescent women participating in a longitudinal cohort study of contraceptive use. *Contraception*. 2013; 88:18–23. [PubMed: 23290427]
5. Turok D, Jacobson J, Dermish A, et al. Emergency contraception with a Copper IUD or oral levonorgestrel: an observational study of 1-year pregnancy rates. *Contraception*. 2013
6. Zou G. A modified poisson regression approach to prospective studies with binary data. *American journal of epidemiology*. 2004; 159:702–6. [PubMed: 15033648]
7. Raine TR, Harper CC, Rocca CH, et al. Direct access to emergency contraception through pharmacies and effect on unintended pregnancy and STIs: a randomized controlled trial. *JAMA : the journal of the American Medical Association*. 2005; 293:54–62.
8. Kim R, Hickman N, Gali K, Orozco N, Prochaska JJ. Maximizing Retention With High Risk Participants in a Clinical Trial. *American journal of health promotion : AJHP*. 2013
9. Raine TR, Foster-Rosales A, Upadhyay UD, et al. One-year contraceptive continuation and pregnancy in adolescent girls and women initiating hormonal contraceptives. *Obstetrics and gynecology*. 2011; 117:363–71. [PubMed: 21252751]
10. Rdesinski RE, Melnick AL, Creach ED, Cozzens J, Carney PA. The costs of recruitment and retention of women from community-based programs into a randomized controlled contraceptive study. *Journal of health care for the poor and underserved*. 2008; 19:639–51. [PubMed: 18469433]
11. Macaluso M, Wang X, Brill I, et al. Participation and retention in a study of female condom use among women at high STD risk. *Annals of epidemiology*. 2005; 15:105–11. [PubMed: 15652715]
12. Charts M. Half of Mobile Phone Owners Always Have Their Device Within Arm's Length. 2013
13. Hall KS, Westhoff CL, Castano PM. The impact of an educational text message intervention on young urban women's knowledge of oral contraception. *Contraception*. 2013; 87:449–54. [PubMed: 23062523]
14. Sheeder J. Personal Communication. 2013

Figure 1. Flow chart of loss to follow-up (LTF) by type of emergency contraception (EC) chosen

Successful Follow-up by Contact Method

Figure 2. Percentage of participants contacted at each follow-up interval by contact method provided*

Table 1

Participant characteristics by ability to be contacted at 12 months.

	All Participants n (% total) n = 542 [§]	Able to contact at 12 months n (%) n = 443 [§]	Unable to contact at 12 months n (%) n = 90 [§]	p-value
Mean age (±SD)	22.4 (±3.4)	22.6 (±3.4)	21.7 (±3.1)	0.02
Race/Ethnicity				
White	356 (65.7)	307 (69.3)	43 (47.8)	<0.01
Hispanic/Latina	104 (19.2)	75 (16.9)	29 (32.2)	
Other	82 (15.1)	61 (13.8)	18 (20.0)	
Income				
\$20,000	341 (62.9)	272 (63.0)	61 (68.5)	0.6
>\$20,000- \$44,000	143 (26.4)	122 (28.4)	21 (23.6)	
>\$40,000	46 (8.5)	38 (8.8)	7 (7.9)	
Insurance				
Private	202 (38.0)	182 (42.0)	17 (19.5)	<0.01
Medicaid	56 (10.6)	46 (10.6)	9 (10.3)	
None	273 (51.4)	207 (47.6)	61 (70.1)	
Prior Pregnancy				
No	299 (55.7)	251 (57.0)	40 (45.5)	0.05
Yes	238 (43.9)	189 (43.0)	48 (54.6)	
Prior Abortion				
No	460 (84.9)	375 (84.7)	76 (84.4)	0.9
Yes	82 (15.1)	68 (15.4)	14 (15.6)	
Spanish Language				
No	529 (97.6)	436 (98.4)	84 (93.3)	<0.01
Yes	13 (2.4)	7 (1.6)	6 (6.7)	
Have Email				
No	42 (7.8)	27 (6.1)	13 (14.4)	<0.01
Yes	499 (92.2)	415 (93.9)	77 (85.6)	
Text Messaging				
No	30 (5.6)	16 (3.6)	14 (15.7)	<0.01
Yes	510 (94.4)	426 (96.4)	75 (84.3)	
Phone Type				
Contract Cell	464 (86.0)	388 (88.0)	67 (75.3)	<0.01
Prepaid Cell	57 (10.6)	46 (10.4)	11 (12.4)	
Landline	18 (3.3)	7 (1.6)	11 (12.4)	
Length of time with same phone number				0.03
<1 year	99 (24.3)	74 (22.0)	22 (34.4)	
1 year or more	309 (75.7)	263 (78.0)	42 (65.6)	
Preferred Phone				
Phone	473 (89.9)	381 (86.0)	84 (93.3)	0.06
Email, Text, Any	69 (12.7)	62 (14.0)	6 (6.7)	

	All Participants n (% total) ¶ n = 542 [§]	Able to contact at 12 months n (%)¶ n = 443 [§]	Unable to contact at 12 months n (%)¶ n = 90 [§]	p-value
EC Chosen				
IUD	215 (39.7)	180 (40.6)	29 (32.2)	0.1
Oral LNG	327 (60.3)	263 (59.4)	61 (67.8)	

¶ Percentages may not equal 100 due to rounding;

§ Rows and columns may not add up to total n due to incomplete survey data and 9 participants withdrew over the course of the study

Table 2

Modified Poisson Regression models for predicting ability to contact study participants at 12 months.

	Crude RR (95% CI)	<i>p</i> -value	Adjusted RR ^a (95% CI)	<i>p</i> -value
Age				
<25 years	Referent		Referent	
25+ years	1.1 (1.0, 1.2)	0.1	1.1 (1.0, 1.2)	0.17
Email				
No Email	Referent		Referent	
Had Email	1.2 (1.0, 1.6)	0.05	1.2 (1.0, 1.5)	0.08
Phone Type				
Contract Cell	Referent		Referent	
Prepaid Cell	0.9 (0.8, 1.1)	0.41	1.0 (0.8, 1.1)	0.61
Landline	0.5 (0.3, 0.8)	<0.01	0.5 (0.3, 1.0)	0.05
Text Messaging				
No	Referent		Referent	
Yes	1.6 (1.1, 2.2)	<0.01	1.1 (0.8, 1.5)	0.64
Race/Ethnicity				
White	Referent			
Hispanic Latina	0.8 (0.7, 0.9)	<0.01		
Other	0.9 (0.8, 1.0)	0.05		
Spanish Language				
Yes	Referent		Referent	
No	1.6 (0.9, 2.6)	0.08	1.4 (0.8, 2.4)	0.23
EC Chosen				
Oral LNG	Referent		Referent	
IUD	1.1 (1.0, 1.1)	0.13	1.1 (1.1, 1.2)	0.04
Insurance				
None	Referent		Referent	
Medicaid	1.1 (0.9, 1.2)	0.24	1.1 (1.0, 1.3)	0.09
Private	1.2 (1.1, 1.3)	<0.01	1.1 (1.1, 1.2)	<0.01
Preferred Method of Contact				
Phone	Referent		Referent	
Email, Text or Any	1.1 (1.0, 1.2)		1.1 (1.0, 1.2)	0.03
Income Level				
\$20,000	Referent			
>\$20,000- \$40,000	1.0 (1.0, 1.1)	0.32		
>\$40,000	1.0 (0.9, 1.2)	0.63		

^a Adjusted model included 518 participants with non-missing data for all variables.