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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 or oral levonorgestrel 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 the method of contact was text messaging, e-mail or any (62/68; 91% contacted) and worst for the 18 who had a landline phone (only 7 contacted; 39%). After controlling for age, having an e-mail address, text messaging, language preference, type of EC chosen and insurance, preferred contact other than phone increased the likelihood of follow-up by 10% [risk ratio (RR) 1.1 95% confidence interval (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 1 year, while women who preferred e-mail 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

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1. 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 maximize internal validity and allow 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 that 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 e-mail, 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 e-mails 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 1 year of follow-up.

2. 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 1 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 e-mail 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 e-mail 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 e-mail 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 ($p \leq .2$) in the univariable regression were adjusted for potential confounders in a modified Poisson regression [6].

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

3. 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 Fig. 1). The majority of women in this study reported having a cell