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Contraception 85 (2012) 263–269

Contraception

Original research article

No sex for science? Formative research on the acceptability and feasibility of a true contraceptive efficacy clinical trial☆

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Received 22 January 2011; revised 18 May 2011; accepted 6 July 2011

Abstract

Background: Recruitment challenges and restrictions on intercourse frequency and timing have stymied previous attempts to implement true contraceptive efficacy clinical trials.
Study Design: Qualitative research was conducted in Madagascar, South Africa, and the United States to explore the acceptability of three potential true contraceptive efficacy study designs and the feasibility of recruitment for such trials, including characteristics of potential participants who may be willing to join.
Results: Participants preferred the study design with the least restrictive sex criteria: participants have sex with assigned contraceptive method/no method on days around ovulation and use condoms on other days. Participants suggested that condom adherence would be low. Differences were noted across sites on whether female participants should be actively seeking pregnancy or not actively seeking pregnancy but willing to accept a pregnancy. Recruitment of participants was expected to be difficult.
Conclusions: Data suggest that a true contraceptive efficacy clinical trial may not be feasible at this time in these settings.

Keywords: True efficacy; Contraceptives; Qualitative research; Acceptability; Recruitment; Feasibility

1. Introduction

True contraceptive efficacy clinical trials measure the inherent protection of a contraceptive method by controlling for the frequency and timing of intercourse, adherence and ability to conceive and by restricting the frequency and timing of intercourse to one act of vaginal intercourse on the day of ovulation [1]. Participants use their assigned contraceptive method or no method on that day and have no intercourse on any other day in their menstrual cycle or they have intercourse only during the 5 days after the day of ovulation. Such placebo-controlled trials are possible because women who enroll desire pregnancy but are willing to delay conception for 1 month. The design is attractive to researchers because it allows the true efficacy of a contraceptive method to be measured prospectively and compared to a control group using no contraceptive method.

Previous attempts to implement true contraceptive efficacy clinical trials have faced several difficulties. While a pilot study in the United States demonstrated the feasibility of the approach [2], implementation of the subsequent true

☆ This work was completed with support from the US Agency for International Development to FHI under cooperative agreement #GPO-A-00-05-00022-00. The views expressed in this paper, however, are solely those of the named authors.

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doi:10.1016/j.contraception.2011.07.004

contraceptive efficacy clinical trial in the United States was unsuccessful. A high participant exclusion rate led to the premature closure of the study [3]. This was primarily due to multiple enrolled participants feigning being new participants as a result of having a limited amount of contact with study staff. Another attempt followed after incorporating lessons learned, but that trial was terminated early due to slow recruitment and few pregnancy outcomes (Markus Steiner, personal communication, January 26, 2006). Recruitment of the most appropriate participants and the need to restrict intercourse have been the major challenges of these study designs (Markus Steiner, personal communication, January 26, 2006).

In light of these challenges, we carried out a formative research study to determine the perceived acceptability of multiple true contraceptive efficacy study designs among reproductive health experts, key informants and potential participants. We also explored the feasibility of recruiting for such trials including the characteristics of individuals who may be willing to participate in a future trial, potential recruitment sites, how to focus recruitment efforts, incentives, and suggested recruitment strategies and messages. Here we report on data related to (a) study design, focusing on acceptability of potential study designs, and (b) recruitment, focusing on participant pregnancy intentions and whom to target during recruitment. The study was carried out in Antananarivo, Madagascar; Durban, South Africa; and Chapel Hill/Durham, NC, USA.

2. Materials and methods

2.1. Study design, study population and recruitment

An iterative study design was used, starting with in-depth interviews (IDIs) with reproductive health experts and key informants, followed by focus group discussions (FGDs) with potential participants. Experts were scientists or program planners in the field of reproductive health and family planning, while key informants were generally staff from local community groups and health care organizations. Participants were selected using purposeful sampling techniques [4], including a snowballing approach for identifying experts and key informants (i.e., participants identified other experts and key informants for study staff to invite for an interview). During the IDIs, experts and key informants described the characteristics of participants who might be likely to participate in a future true contraceptive efficacy trial and where such individuals could be recruited. Individuals from these sites as well as from other similar sites were included in the subsequent FGDs.

To be eligible to participate in an FGD, women and men had to be within reproductive age (18–35 years for women and 18–45 years for men; in South Africa, a wider range was used for reproductive age: 18–49 years for women and 18 years to no upper age limit for men) and were either planning to get pregnant at some time in the future or willing to accept pregnancy in the near future (in the next 5 years for the US site). In the United States, participants must have also considered themselves to be in a steady sexual relationship for the past 6 months. To ensure an adequate FGD sample, a broader definition of pregnancy intentions was used for the FGD eligibility criteria from that suggested for a true contraceptive efficacy trial.

Based on investigator discussions and informed by previous research, two international study sites were chosen for their perceived potential of implementing a successful true contraceptive efficacy trial. The US site was chosen to explore solutions to the barriers faced by the previous US-based true contraceptive efficacy trials.

2.2. IDI and FGD topics

During both the IDIs and FGDs, participants were asked to discuss the feasibility of recruiting trial participants who actively desire pregnancy but are willing to delay conception for 1 month and of recruiting trial participants who are willing to accept pregnancy but are not necessarily actively trying to conceive. Participants also discussed the acceptability and ability to adhere to three true contraceptive efficacy study designs. Vignettes were used to discuss the designs with key informants and FGD participants. The three study designs were as follows: (a) study design 1: intercourse at least one time during a 2- to 3-day period around the day of ovulation using an assigned method or no method; intercourse can occur on any other day using a condom; (b) study design 2: intercourse at least one time during a 2- to 3-day period around the day of ovulation using an assigned method or no method; no intercourse on any other day; and (c) study design 3: intercourse one time on the day of ovulation using an assigned method or no method; no intercourse on any other day.

2.3. Analysis

All IDIs and FGDs were audiotaped and conducted in either Malagasy or French in Madagascar, in either Zulu or English in South Africa and in either Spanish or English in the United States. In Madagascar and South Africa, all IDIs and FGDs were transcribed verbatim in the language in which they were conducted and then translated into English if conducted in the local language. Translation was verified by bilingual study staff. In the United States, simultaneous transcription and verbatim translation into English by the bilingual interviewer were used for the FGDs conducted in Spanish. A priori codes related to recruitment and study design were applied to the data by analysts working in pairs using NVivo 7 software. Intercoder reliability procedures were used until the two analysts reached approximately 90% agreement. Once all transcripts were coded, textual coding reports were produced, followed by data display tables. Data reduction summaries were created to identify the most salient information to answer the study's objectives. All steps were completed with data from each site. Summaries were then