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SHORT COMMUNICATION

Delivery of home-based post-partum contraception in rural Guatemalan women: feasibility, recruitment and retention in a cluster-randomized trial

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Background: Few cluster-randomized trials have been performed in rural Guatemala. Our objective was to describe the feasibility, recruitment and retention in our cluster-randomized trial.

Methods: In our cluster-randomized trial, a range of contraceptives were brought to mothers' homes in rural Guatemala.

Results: Of 173 women approached, 33 were excluded. Of the 140 eligible women, 127 (91%) consented to participate. Of the 87 women who should have been assessed for the primary outcome, three were lost to follow-up, which represents a retention rate of 97%.

Conclusions: Nurses who are both clinical providers and study staff can feasibly conduct research, which leads to high enrollment and retention rates.

Keywords: community-based programming, contraceptive implant, Guatemala, long-acting reversible contraceptives, post-partum contraception

Introduction

Performing clinical trials is a challenging process that can be made more challenging when they occur in settings that are constrained by various resources.[1,2] ClinicalTrials.gov currently boasts registration of more than 300 000 trials. Eleven registered cluster-randomized trials have been published from Guatemala and five were performed by the same experienced research group in the same region.[3] This study design has not yet been used in the southwest Trifinio region of Guatemala, which is a geographically isolated and underserved region that supports 25 000 migrant workers of low socio-economic status.[4] Given the relative lack of experience in this region with cluster-randomized trials, the purpose of this article is to report on the feasibility of conducting such a study in a very-low-income setting and to present early recruitment and retention rates.

Regarding the setting, in partnership with the Center for Global Health at the University of Colorado, a local agricultural company founded a health service organization in the southwest Trifinio community called the Center for Human Development. This organization supports a clinic and community-based maternal and child healthcare programs in Trifinio. The maternal program, called Madres Sanas, provides four home-based antenatal care visits and two home-based post-partum visits delivered by community nurses.[4]

Post-partum contraception, per the WHO, is essential to preventing unintended pregnancies through the first 12 mo post-partum. Our study, which studies post-partum contraception, is a prospective cluster-randomized trial in this community that leverages the Madres Sanas program to enrol women in a geographically isolated and underserved community.[4] This

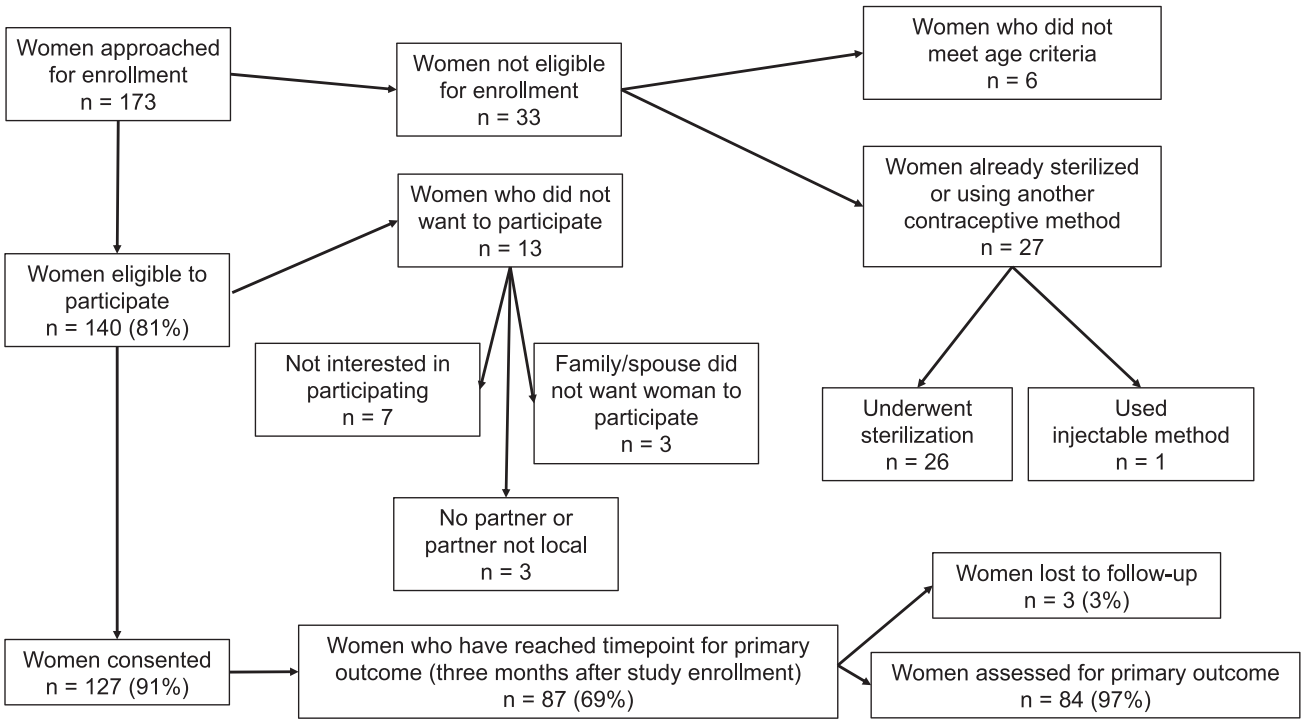

Figure 1. Recruitment and retention of study subjects since study initiation.

information may be useful for other investigators as they plan similar trials in similar communities.

Materials and methods

Our trial was registered at ClinicalTrials.gov (NCT04005391) as of 1 July 2019.[5] Our protocol has been submitted for review (5 July 2019) to the journal *Trials*. We have approval from both the Colorado Multiple Institutional Review Board (COMIRB 17-1314) and the Instituto de Nurtición de Centro América y Panamá (CIE-REV-076/2018) to conduct this trial. The initial patient was enrolled in our study on 23 October 2018.

Study activities

The Madres Sanas program at the Center for Human Development is delivered by community health nurses, many of whom live in the communities they serve.[4] The nurses are assigned in teams of two to serve specific communities. They travel by motorcycle tuk-tuks to the communities 5 d a week to perform their visits. At the post-partum visit after routine clinical care is complete, the nurses screen their patients and offer enrollment in our cluster-randomized trial.

Prior to study initiation, we not only conducted clinical capacity building in terms of training nurses on implant placement, but we also provided research training in good clinical practice and research on human subjects and conducted both site initiation visits for training and subsequent interim site visits to ensure adherence to study protocols. For the randomization process, we combined 12 communities into eight clusters that were matched for the expected number of post-partum visits over the study time frame. Then we used SAS software to randomize the eight clusters into intervention and control groups stratified by the three nursing units, ensuring that each unit had an intervention cluster and a control cluster.

In intervention clusters, the nurses offer women condoms Mejvida (Vive Amor), pills PSI paraguay (Segura Plus), an injection Concept Foundation (Cyclofem) or an implant Merck (Jadelle) in their homes. The objective of the trial is to observe the association of delivery of post-partum contraceptive methods in women's homes during their final (40 d) post-partum visit with the use of a contraceptive implant 3 mo after enrollment (our primary outcome). Control clusters receive routine care, which includes post-partum contraceptive counselling, but no home-based provision of post-partum birth control methods. All women are surveyed at 3 and 12 mo post-enrollment about their contraceptive usage, continuation, satisfaction and pregnancy status.

Results

The currently enrolled study population has a mean age of 22 y, the majority (60%) has between 1 and 6 y of education, 82% are married or live with their partner and 38% were parity 3 at the time of enrollment (14% primiparous, 29% parity 2, 19% parity $\geq$4). As shown in Figure 1, of the 173 women approached regarding participation in the study, 33 were excluded. Six were excluded by age criteria, 26 had already undergone surgical sterilization and one had already received a medroxyprogesterone injection. Of the remaining 140 eligible women, 127 (91%) consented to participate in the study. Of the 87 women who

should have been assessed for the primary outcome at the time this article was written, which is a survey to assess implant use at 3 mo, three have been lost to follow-up, which represents a retention rate of 97% (Table 1).

Discussion

This article demonstrates that a cluster-randomized trial to deliver post-partum contraception in the home, including the implant, by community nurses is feasible. We have a 91% enrollment rate and a 97% retention rate in a rural, geographically isolated community in a lower middle-income country. We did initially face barriers to study execution during the ethical review process, which took 13 mo to complete. The initial reviewing body did not want to provide approval for a contraception-related study, which they declined to continue reviewing 6 mo into the process.

We attribute our success with enrollment and retention in our cluster-randomized trial to the trust and partnership cultivated by the University of Colorado with the communities served through the Center for Human Development.[4] This previously described model is unique in its healthcare delivery model, but now we assert that it is also unique in its model for the research infrastructure it has established.[5] A facilitator of our research success is a trial design that leverages clinical providers to collect study data in communities in which they are deeply integrated as community providers, members and leaders. Of note, we are following enrollees until 12 mo, so our retention numbers will likely change by that later time point. Our Madres Sanas program, which serves as both a healthcare delivery mechanism and a research infrastructure, is a model worth disseminating; other investigators should consider adding a research component to established clinical infrastructure.

Authors' contributions: SB-M, CR, AJ-Z and AB are currently executing the study. GH, EA, SB and JS assisted with study design and perform study oversight. SS and EJ-C assigned randomization of the clusters and developed the analytical plan. MSH conceived of the study with JS and EA, is the principal investigator on the study and wrote the manuscript with feedback and edits from all the authors.

Acknowledgements: We wish to acknowledge the Madres Sanas community nurses for the high-quality work they do in southwest Trifinio that significantly impacts the lives of the women and children they serve. Now, through the dissemination of research they have conducted, they have the potential to impact women and children beyond the southwest Trifinio community.

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Competing interests: The authors do not have any competing interests to declare.

Ethical approval: The study protocol, the data collection forms and the consent form were approved by both the Colorado Multiple Institutional Review Board and their International Research Advisory Committee (COMIRB 17-1314) in the USA and by the Instituto de Nurtición de Centro América y Panamá (INCAP) in Guatemala (CIE-REV 076/2018), as well as by the Community Advisory Board. Both ethics review committees are providing ongoing review of the study as it is being conducted.

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