

Lessons from GRACE: A US Study Focused on Women Living with HIV

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Table of Contents

- [The Need for Studies of Women Living with HIV](#)
- [Why Have There Been so Few Women Participating in Trials?](#)
- [Enter GRACE](#)
- [Successful Recruitment, but High Dropout](#)
- [Results](#)

The Need for Studies of Women Living with HIV

The proportion of women living with HIV in the US rose from seven percent in 1985 to 23 percent at the end of 2014. That means that nearly one in four Americans living with HIV is a woman. The good news

is that the number of women newly diagnosed with HIV dropped 40 percent from 2005 to 2014. Nevertheless, rates of HIV remain [especially high among women of color](#) – almost eight out of ten women living with HIV in the US are African American or Latina.

Globally, the World Health Organization reported that women made up just over half of all people living with HIV in 2017. In some areas, particularly in sub-Saharan Africa, almost six out of ten new cases of HIV are among women.

Despite this, studies of HIV prevention and treatment ([clinical trials](#)) have traditionally included very small numbers of women. It is not uncommon for HIV studies to have women represent less than one in every five people being studied. As a result, most information on the effectiveness and safety of HIV drugs is based on research done in men.

Because HIV and some HIV drugs may act differently in women's bodies, there is a strong need to conduct studies that are specifically designed to answer questions for women. More information is needed on specific drug doses for women, possible differences in lab tests (such as [CD4 cells](#) and [viral load](#)), how infections and [gynecological conditions](#) affect women living with HIV, and what [side effects](#) are likely to affect women. The only way to find out this information is for more women living with HIV to participate in clinical trials.

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Why Have There Been so Few Women Participating in Trials?

For many years, community advocates, including Dawn Averitt, the founder of The Well Project, have been calling for trials to include more women and people of color. There are many reasons why this has been hard to do.

Historically, women were kept out of many types of clinical trials (not just HIV studies). This was out of concern that they might become pregnant while on a trial of an experimental drug that could turn out to harm the baby. In 1993, US regulations were changed and women were encouraged to participate in clinical trials, but progress has been very slow and the number of women in HIV studies has remained low.

There are many reasons women have not participated in clinical trials. Some are concerned that a trial may be unsafe or that they will not be allowed to drop out if it is not right for them. In some African-American and Latino communities, there may be distrust of the medical establishment in general and/or clinical researchers in particular because of trials that were conducted before the US government established strong guidelines to protect people who participate in clinical trials.

In addition, [stigma](#), lack of support, lack of child care, lack of information about the studies, and lack of transportation often prevent women and people of color from participating in HIV trials.

Enter GRACE

An HIV clinical trial needed to be designed in a way that could overcome some of the barriers for women and people of color. In order to do this, health care providers and community advocates worked with Tibotec (now Janssen), the company that makes the protease inhibitor Prezista (darunavir).

The result was the GRACE study. GRACE stands for **G**ender, **R**ace, **A**nd **C**linical **E**xperience. The study was designed to see if there were differences in drug effectiveness, safety, and side effects between men and women who took Prezista for 48 weeks.

GRACE began in 2006. It was the largest treatment trial to focus on women living with HIV in the US and the first to focus on women who had experience taking HIV drugs. GRACE was specifically designed to enroll women and people of color.

Successful Recruitment, but High Dropout

GRACE created a lot of excitement in the HIV community. Advocates watched closely to see if the trial would be able to overcome barriers to having women participate. GRACE was successful.

GRACE was able to reach its goals for recruiting participants on schedule. GRACE enrolled 67 percent women and 84 percent people of color, showing that it is possible to recruit large numbers of women, African Americans, and Latinos into clinical trials.

Some of the new strategies were selecting study sites (such as clinics and medical centers) that were accessible to women and people of color, raising awareness among the people they hoped to enroll, and providing support for the participants and the study sites. Specific strategies included:

Site selection

- Finding sites where women living with HIV received care, including sites that had not participated in clinical trials before
- Selecting sites in areas where there were high numbers of HIV cases among women and people of color
- Requiring sites to enroll three women before enrolling the first man

Outreach

- Awareness campaigns in the minority media
- Community advisors and advocates working on getting the word out
- GRACE logo and materials that study sites and participants both liked
- Community events and articles in HIV community newsletters

Participant and site support

- Providing other HIV drugs free of charge to study participants (in addition to Prezista)
- Increased flexibility and availability of health care providers at study sites
- Funds for child care and travel for participants
- Study kits for both sites and participants with materials to support study participation
- Continuous involvement, including regular site visits and support meetings, through all phases of the study

According to Dawn Averitt, “A whole lot of what worked in GRACE was just about the sense of being a part of something bigger than yourself, being really valued, appreciated, and respected in an environment where, frankly, a lot of people are dealing with shame and [stigma](#).”

Despite the fact that GRACE successfully enrolled women, nearly one quarter of the women dropped out of the study by week 24. In comparison, only nine percent of male study participants dropped out. Most of the women did not drop out because the drugs did not work or because of side effects. The most common reason for women to drop out was “lost to follow up.” This refers to study participants whom the study can no longer reach or track. People become ‘lost to follow up’ for several reasons: they move away, they decide not to participate in the study and do not tell the study managers, or they become ill or die.

From June 2010 to June 2011, GRACE researchers asked participants to complete a survey about their

experience of being in the study. While many participants said that access to HIV treatment was a major reason for joining the study, many others chose to participate because they felt good knowing that what they were doing would help others. Several others also said that participating in a study of women and people of color was important to them.

The high dropout rate among women may be a sign of the difficulties in treating low-resource populations or working with sites that are not used to conducting research studies. The dropout rate in GRACE may also reflect the obstacles women of color who are living with HIV in the US face in remaining in care. Almost one quarter of those who completed the survey said that getting to the testing site was the worst part of their study experience. The higher dropout rate among women shows the need for more strategies to keep participants from minority groups in future trials.

Results

GRACE compared the effectiveness, safety, and side effects of Prezista on men and women. At 48 weeks, there were no major differences in response to treatment between women and men taking Prezista. In addition, there were no major differences in safety or side effects.

This information is very valuable. It gives women peace of mind that a drug they are taking has been studied in bodies similar to their own.

It is important for more women to get involved in HIV clinical trials and for more trials to be designed with women and people of color in mind. There are many women's health issues that still need to be studied in women living with HIV. You can help by getting involved and participating. If you are interested in learning about or enrolling in clinical trials, see our fact sheet about [clinical trials](#).

Additional Resources

Select the links below for additional material related to the GRACE study.

- [Women Under-Represented in HIV Clinical Trials \(AIDSmap\)](#)
- [What Helps and What Hinders Participation in HIV Clinical Trials? \(TheBodyPRO\)](#)
- [GRACE: New HIV Study Shows that Large Numbers of Women and People of Color can ...](#)
- [Insights on GRACE \(Gender, Race, and Clinical Experience\) from the Patient's Pe...](#)
- [An Interview With Debbie Hagins, MD, Clinical Director of a Ryan White Clinic i...](#)
- [Dropout Rate in Study of US Minority Women Near 25% at 24 Weeks \(NATAP\)](#)
- [Treatment Access Biggest Trial Plus in Survey of Women/Minority GRACE Study \(NA...](#)
- [Large Numbers of Women and People of Color Can Be Successfully Enrolled in HIV ...](#)
- [FDA Research, Policy, and Workshops on Women in Clinical Trials \(FDA\)](#)
- [Including Women and Minorities in Clinical Research \(NIH Office of Research on ...](#)

