The researchers conducted the first clinical trial, the Fluoride Varnish Randomized Controlled Trial (FVRCT), in San Francisco. They subsequently conducted two more studies, the Mothers and Youth Access (MAYA) Trial and the Glass Ionomer Sealant and Fluoride Varnish Trial (GIFVT), in San Diego County.

For FVRCT, the researchers randomized the mothers with their children to one of two groups: either the children received fluoride varnish and their mothers received parental counseling or only the mothers received parental counseling. For MAYA, the researchers enrolled pregnant women. When the women’s infants were 4 months old, the researchers randomized the mothers with their infants to either a group in which the infants received fluoride varnish at the first sign they were losing tooth enamel or a group in which the infants received preventive fluoride varnish and the mothers received chlorhexidine mouth rinse. For GIFVT, the researchers randomly assigned children to receive fluoride varnish only or fluoride varnish plus glass ionomer sealants on their back primary (baby) teeth.

Target Population

In FVRCT, almost all children were from either Latino or Chinese backgrounds. In the MAYA and GIFVT studies, most of the participants were Latino.
Recruitment Approach

- For FVRCT, the researchers recruited participants primarily through two health centers that had dental clinics. One health center had primarily a Latino population and the other center had mostly a Chinese population. The researchers recruited mothers with young children from either the dental clinic or the general health center through bilingual flyers. Depending on the health center, the flyers were either in English and Spanish or in English and Chinese.

- For the MAYA and GIFVT studies, the researchers employed a two-pronged approach that included a dedicated outreach worker who went to community health fairs and other community events to talk about the study. The participating health center in each of these two studies viewed this recruitment approach as beneficial because it brought in new potential patients, who would then see the comprehensive services that the health center offered in health promotion, disease prevention, and health care and treatment.

Primary Barriers

Time and transportation were major barriers for participation.

Successful Recruitment Strategies

- The researchers recruited participants through health center staff and at community health fairs and other events. They also advertised in community newspapers and posted flyers.

- Staff members who are familiar with the culture of potential participants are effective at recruiting because they naturally interact in a culturally appropriate way.

For example, with Latino participants, a culturally appropriate interaction would include expressing interest in the participants’ families and lives in ways that might seem prying to a person from another culture. These relationships are also important in retention.

- To reach pregnant women for the MAYA study, an outreach representative gave presentations about the trial at prenatal orientation classes; meetings of the Special Supplemental Nutrition Program for Women, Infants, and Children; and Medicaid orientations. The presentations included information about oral health and about the study. The research staff also connected with the staff of the obstetrics and gynecology (OB/GYN) department at the health center where the study was being conducted; the OB/GYN staff then told women who came to their clinic about the study.

- MAYA also held baby showers as recruitment events. The baby showers included free breakfast and prizes, such as diapers and baby bottles. Contrary to widespread belief among researchers, NIH funding can be used to purchase food, but it must be well justified in the budget. In Hispanic culture, especially, providing food is seen as a sign of welcome and hospitality.

Retention Strategies

- For FVRT, recruitment was relatively easy, but retention was more challenging. The problem may have been that mothers agreed to take part in the study without being really committed to or engaged in it.

- For MAYA and GIFVT, the researchers tried to make sure that women were more engaged in the project and understood the time commitment before they enrolled.
• MAYA also delayed randomization to increase the chance that participants would stay in the study. Pregnant women were enrolled in their second trimester. One of the obstacles to retention in the Latino community is that some women return to Mexico after giving birth because of the need for social support from extended family members there. The researchers waited to randomize participants until the infants were 4 months old to increase the chances that the randomized participants would stay in the area until the study was completed.

• The MAYA baby showers were originally held monthly as recruitment events. The showers were popular, and women who enrolled in the study asked to attend later showers. Excluding them would have been culturally inappropriate. The parties increased costs but proved to be an important retention tool, creating social cohesion among the participants and staff as well as a safe place for the women to discuss health issues. The parties even led to some women being connected with care for postpartum depression, an important mental health issue that the women might otherwise not have mentioned. The baby showers were so useful that eventually they evolved into first-birthday parties for the infants which again enhanced retention and cohesion. The study continued until the infants were 3 years old.

• The researchers increased retention through the practical step of asking each participant for two or three different phone numbers, including the contact information of family members or neighbors who would know how to find the participant if she moved or changed phones.

Lessons Learned

• Women want to participate in studies or projects if they believe that they are getting something out of it, such as monetary compensation, social support, or the feeling that they are contributing to something that will help their children, their family, or their community.

• The MAYA monthly baby showers, originally intended as a recruitment event, evolved into a powerful tool for retention. The parties worked so well that a research staff member from the community developed the idea of continuing the monthly event as first-birthday parties for the infants after all of them were born.

“Part of recruitment is how to make the experience compelling. It’s not only about money. Are they getting support? Are they feeling like they are contributing to something that is actually going to help their children or their younger sisters or cousins? Is this an opportunity to help their community with a health issue?”

–Stuart Gansky, Dr.P.H., M.S.,
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