

# Recruiting for a multisite pragmatic clinical trial during COVID-19

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## Abstract

### Abstract

Three HCSRN sites (Kaiser Washington (KPWA), N. California (KPNC) and Sutter Health (SH)) and the Institute for Family Health (IFH) in New York, partnered to conduct an NIH-sponsored pragmatic trial of acupuncture v. usual care among at least 807 older adults with chronic low back pain.

### Methods

KPWA (the coordinating center), KPNC, SH, and IFH were responsible for recruiting 185, 288, 210, and 124 participants, respectively. We describe here some of our key challenges, opportunities, and successful solutions for conducting a multisite pragmatic trial in a high-risk population during COVID-19

### Results

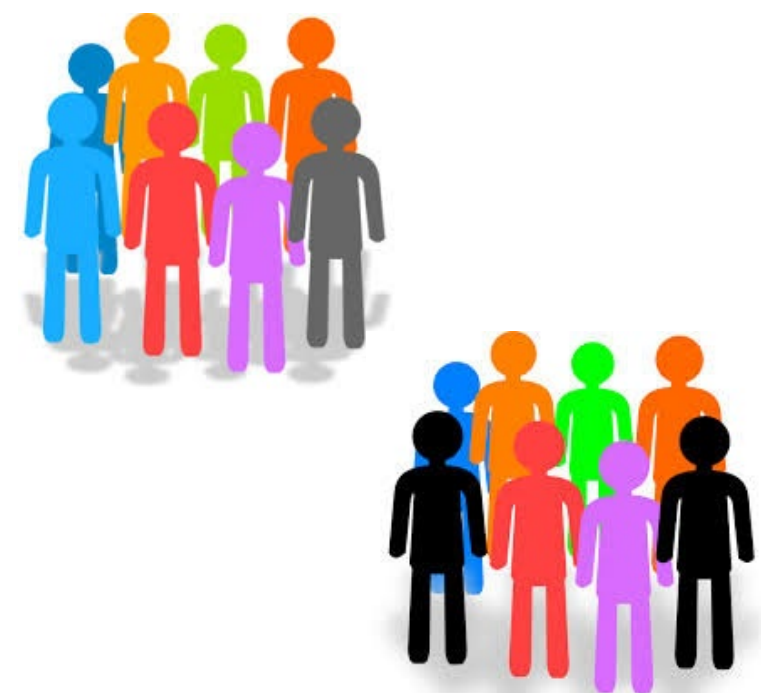
The pandemic delayed recruitment initiation (scheduled for Jan 2021) for all sites. In 2021, actual recruitment began at KPWA and IFH in July, SH in Oct, and KPNC in Dec. Periodically, recruitment was halted by individual research departments, staffing issues emerged, and both patients and acupuncturists expressed COVID-19-related concerns. In response, we conducted infection-control assessments with our practitioners, adjusted study timelines, and monitored local infection patterns. Because this was a multi-site study and the pandemic flared at different times in the different geographies, recruitment overall was able to continue uninterrupted.

### Conclusions

COVID-19 affected each center at different times during recruitment; therefore, the study team was able to leverage these differences to meet target recruitment goals throughout the study and surpass final study recruitment goals and on schedule.

## Aim

BackInAction (BIA) is a multi-site, pragmatic trial of acupuncture treatment for at least 807 adults aged 65 and older that faced delays and disruptions, but also saw unexpected benefits



## Methods

### This study faced challenges unique to the trial intervention and population

Target population of adults age 65+ is particularly vulnerable to COVID-19 infection and risks.

- To address this challenge, the trial delayed recruitment until vaccines were widely available, ultimately resulting in an abbreviated recruitment timeline, and one site paused recruitment during the Delta spike

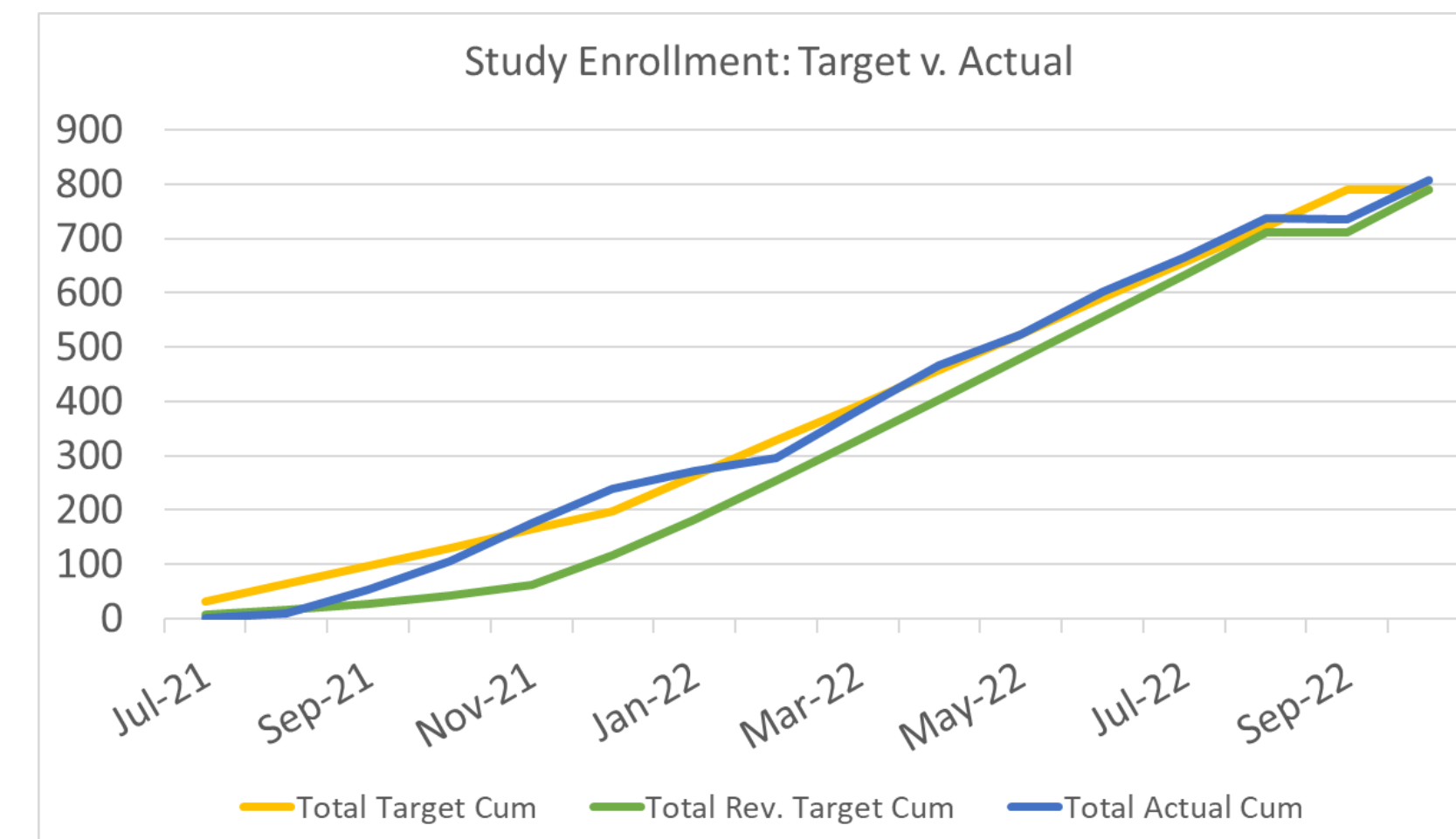
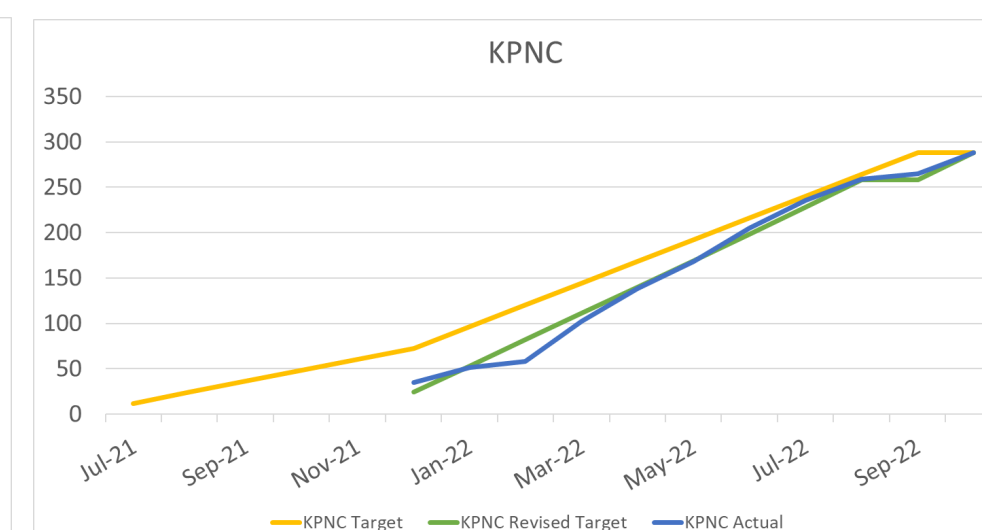
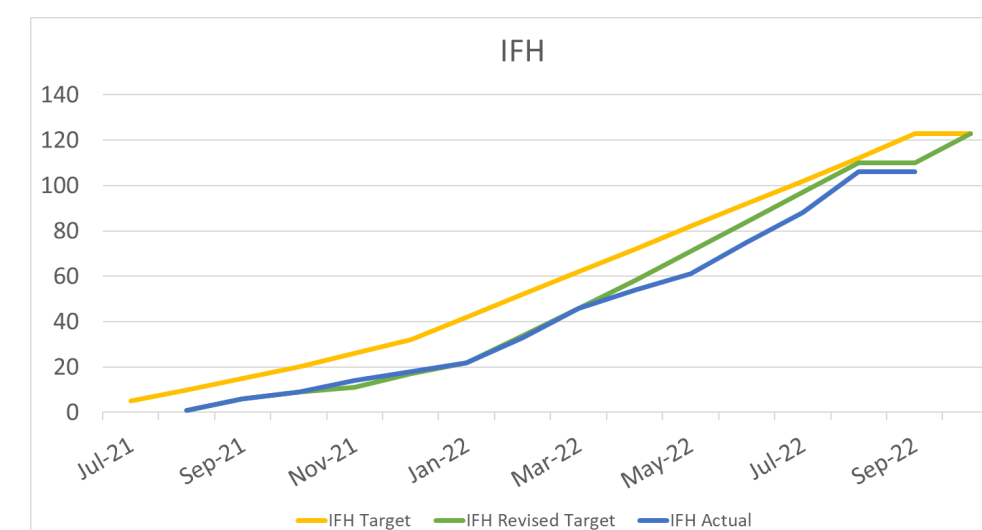
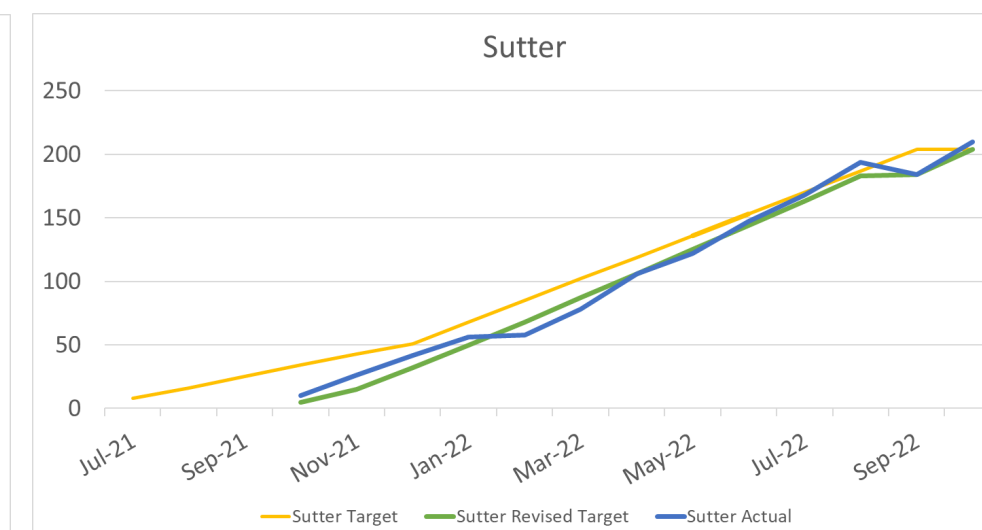
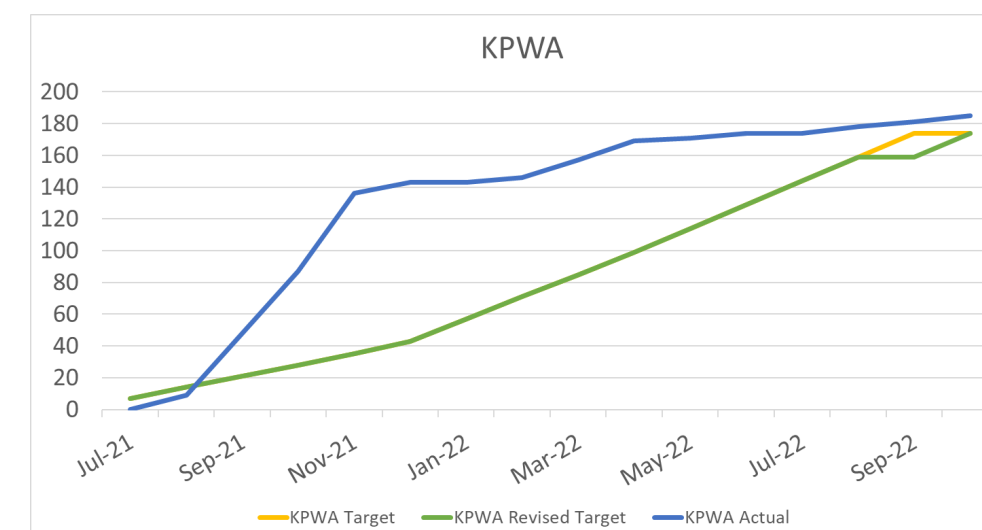
Acupuncture is an in-person intervention requiring additional safety measures, such as verification of vaccination by participants and acupuncturists and restricted clinic hours.

- In response, acupuncturists increased their safety measures, study teams throttled recruitment at sites with decreased clinic capacity, and the study team collected data on study acupuncturists safety practices, intervening when necessary.

BIA trial had an ambitiously short initial timeframe imposed by NIH to allow timely feedback to assist CMS' expected acupuncture coverage decision; CMS' decided in January 2020 to cover acupuncture yet the study timeline remained unchanged.

- While an administrative supplement was submitted and funding largely based on COVID-related delays, this change in context contributed to ability to extend the grant an additional year.

## Recruitment Trajectories

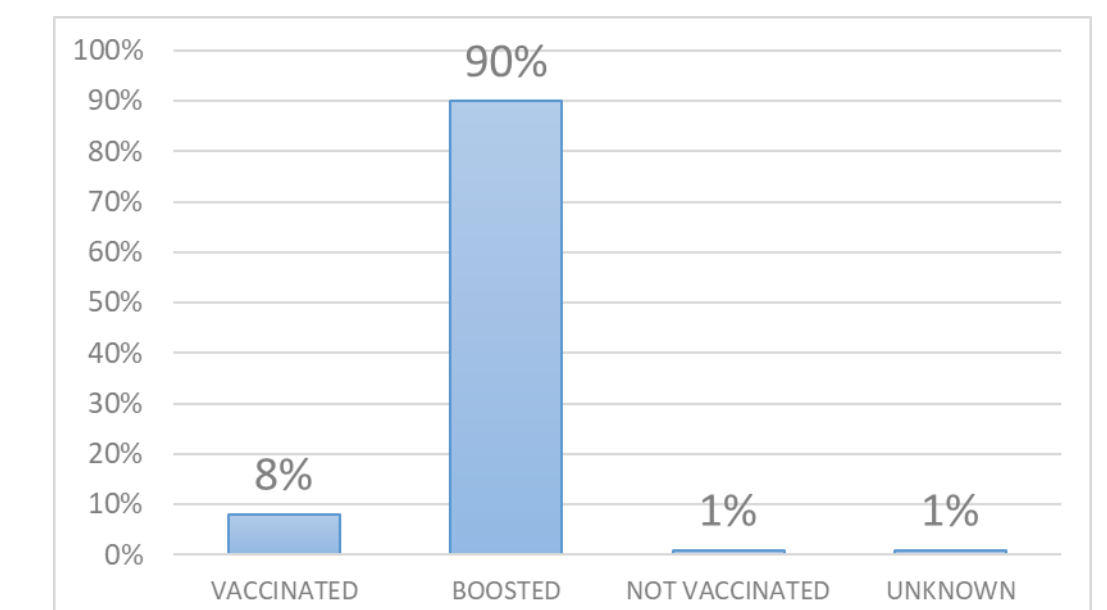


- ❖ Overall
- ❖ All sites met recruitment goals



## Sutter Vaccination Results

### Vaccination Status of Sutter Health BIA Participants (Counts)



## Conclusions

- ❖ COVID-19 affected each site at different times during recruitment; therefore, the study team was able to leverage these differences to meet target recruitment goals throughout the study and surpass final study recruitment goals and on schedule.