



Increasing Marginalized Voices In Clinical Trials

Toluwalase Ajayi MD





Working Towards Healthier Pregnancies – and Healthier Babies.



PowerMom
Scripps Research
Digital Trials Center

Join our community of pregnant people collecting and contributing important pregnancy-related health information through app-based surveys and wearable sensors. Together, we are working to reduce health disparities and learning more about what leads to healthy pregnancies and healthy babies for every pregnant person.

[Join Us](#)



Scripps Research

The background features a network of circular icons connected by lines, radiating from a central point. The icons include a heart with an ECG line and a clock, a brain, a clipboard with a checkmark, and a speech bubble. On the right side, there are silhouettes of a person's head and a hand holding a smartphone. The overall color palette is muted, with shades of blue, teal, and brown.

OUR GOAL

Build the largest, most diverse, pregnancy-related research community, in order to inform and support pregnant people across the country and improve maternal and fetal outcomes.



PowerMom

SOLVING A NATIONAL HEALTH CRISIS



Among developed countries, U.S. is ranked **1st in maternal mortality**

↑ 200%

Cases of severe maternal morbidity (SMM) have dramatically increased in the last 20 years



20.1 deaths per 100,000 live births



Only developed country to not guarantee access for home visits

Pregnant women of **color at highest risk**

3 X

Black women more likely to die giving birth compared to white women in the U.S.

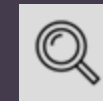
↑ 19%

Since 2018, Hispanic women seeing the highest increase in SMM rates



Black and Hispanic women are more likely to have risk factors for SMM

Lack of research and Missing Voices



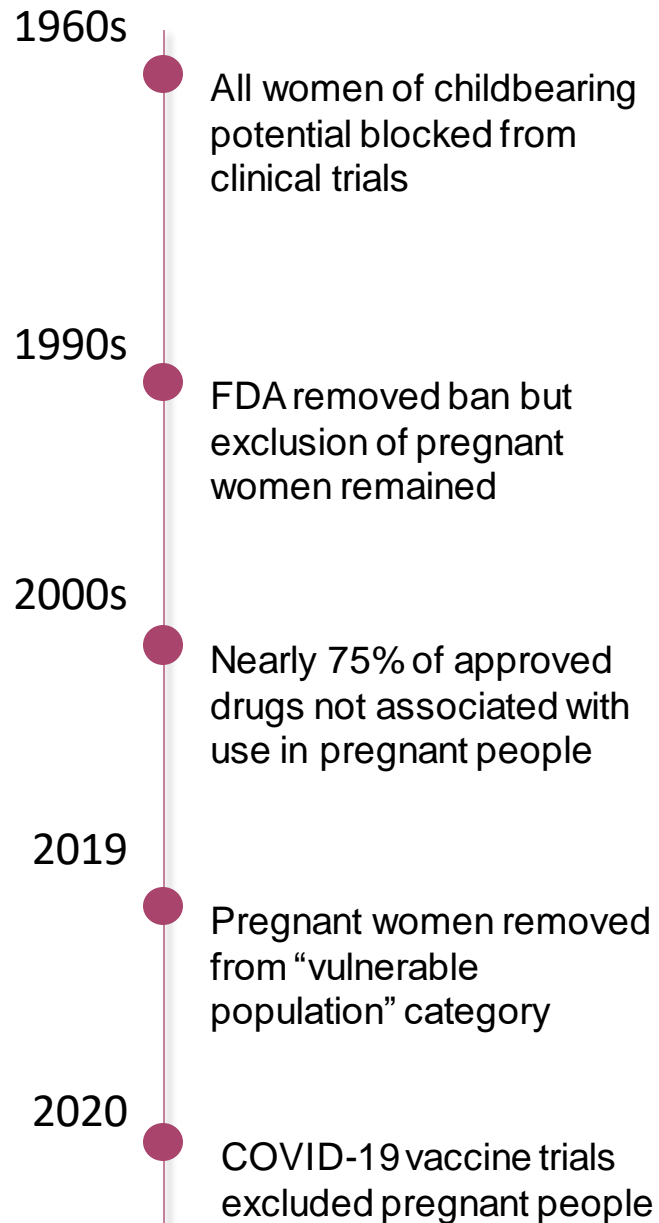
Pregnant woman excluded from medical research



Disparities in representation



Variations in care creates adverse outcomes and higher costs



A medical intervention doesn't just show up out of nowhere; it takes decades of research, clinical trials, and investment—and that's a great thing, but not a great thing when half the population is basically left out.

Natasha Bonhomme, Genetic Alliance

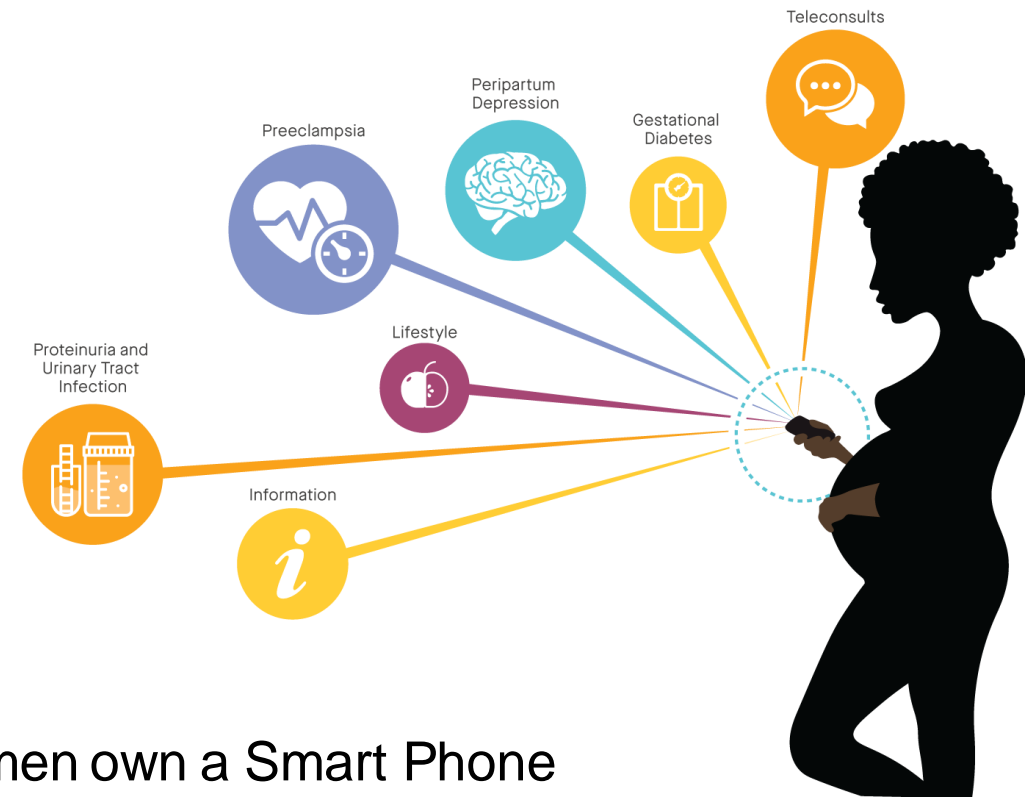
Women Were Left Out of Clinical Trials Until the '90s—This Is How It's Impacted Our Health

Well + Good, July 6, 2020

Multi-modal Data

Wearables and other sensors
Self-reported surveys
Demographic information
Electronic health records
Claims data

Empowering and engaging pregnant people with their own data



- 90% of Women own a Smart Phone
- 83% of Black Americans own a Smart Phone
- 76% of Americans with Incomes 30K or less

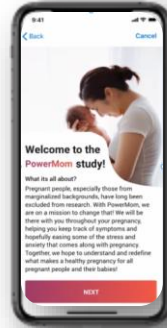
Proof-of-concept

PowerMom pilot research study (2017)

Voluntary collection through surveys and sensors

Smartphone enabled direct-to-participant research

Collecting detailed data on a frequent basis without in-person clinic visits



npj | Digital Medicine

www.nature.com/npjdigitalmed

ARTICLE OPEN
The Healthy Pregnancy Research Program: transforming pregnancy research through a ResearchKit app

Jennifer M. Radin^{1,2}, Steven R. Steinhubl^{1,2}, Andrew I. Su¹, Hansa Bhargava³, Benjamin Greenberg³, Brian M. Bor⁴, Megan Doerr⁴ and Eric J. Topol^{1,2}

Enrolled 3.5k participants

15% rural zip codes
25% non-white
50% overweight or obese
4% over 40 years old

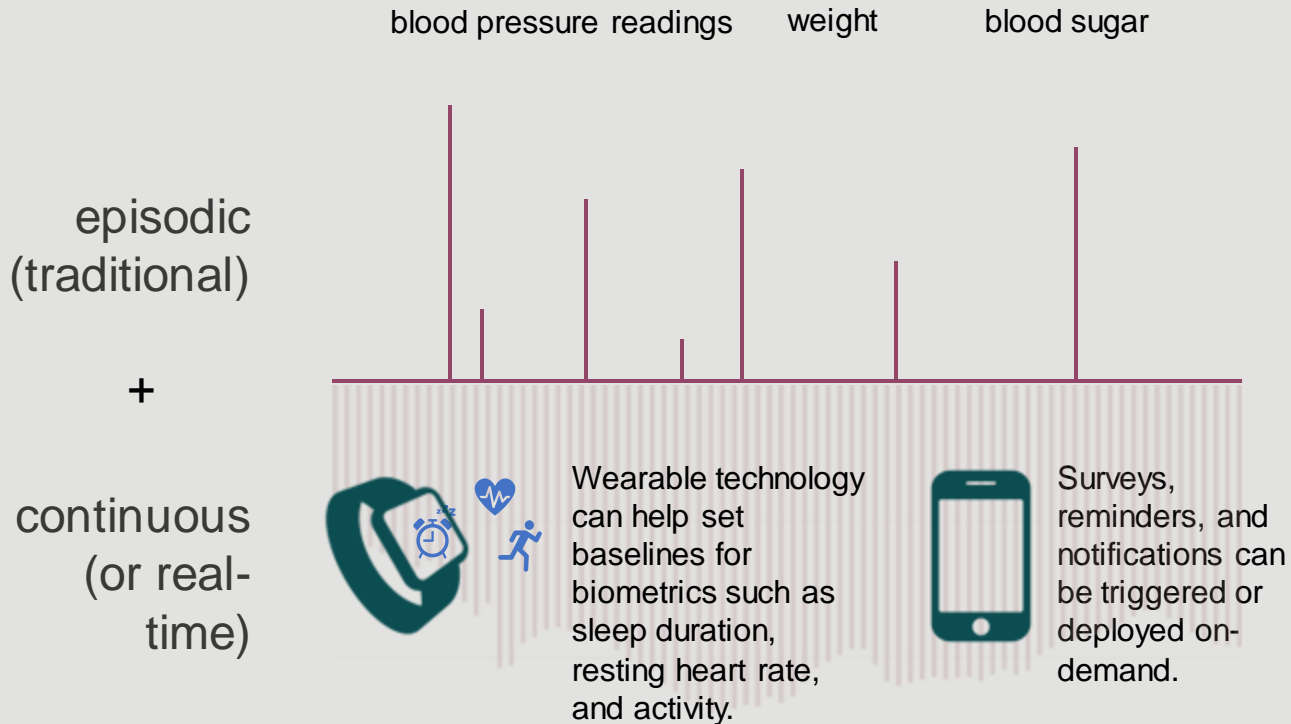
14,000 unique physiologic data points

Participants actively engaged in the study for an average of 59 days

Potential to fill in knowledge gaps

Ranging from individualized weight gain to earlier identification of preeclampsia, gestational diabetes, peripartum (postpartum) depression, and other complications

Broadening the research landscape

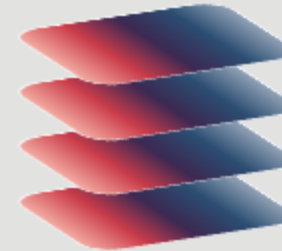


Lightweight, foundational protocol



Baseline biometrics
Bi-weekly surveys
Demographics
Birth outcomes
EHR data (optional)




Layered, targeted sub-studies



PowerMom-FIRST
Post partum depression
Nutrition tracking
At-home blood pressure monitoring

Expanding traditional monitoring and leveraging the insights gleaned from remote, continuous monitoring can inform new guidelines that set that stage for a new maternal health care paradigm.

PowerMom

2:42   

[Cancel](#)

Consent To Participate In Research

POWERMOM
Healthy Pregnancy Research Program

Principal Investigator Toluwalase (Lase) Ajayi, MD
tajayi@scripps.edu
Scripps Translational Science Institute
3344 N. Torrey Pines Court, Plaza Level
La Jolla, CA 92037




Contact Person Lauren Ariniello
[858.784.2253](tel:858.784.2253)
powermom@scripps.edu

Institutional Review Scripps Office for the Protection of Research Subjects Board (IRB)
[858.678.6402](tel:858.678.6402)

Research Site(s) PowerMom Study in MyDataHelps app
Sponsor: The Scripps Research Institute (Scripps)

You are being invited to participate in the PowerMom: Healthy Pregnancy Research Community 2.0 (PowerMom). This is an observational study. There is no treatment or intervention. It is a voluntary study. You do not have to take part.

This form tells you about PowerMom so you can decide if you would like to participate. Please




2:50   

[Cancel](#)

PowerMom Intake Survey


This survey asks questions about your health and current pregnancy, and should only take a few minutes of your time to complete.

[GET STARTED](#)


3:24   

Welcome to PowerMom!

Tasks

Health History Survey 
⌚ 10-15 minutes

Featured Article










Exercise during pregnancy

Is it okay to exercise during your pregnancy? What types of exercise can you do and how will they benefit you and your little one.

⌚ 8 minutes

Share Digital Health Data

 Dashboard  My Data  Resources  Settings


3:18   


Exercise during pregnancy


Is it okay to exercise during your pregnancy? What types of exercise can you do and how will they benefit you and your little one.


⌚ 8 minutes


Resources


During Pregnancy 





Post Partum 

Sleep 

Lactation & Breastfeeding 

Birth Control 

Other 

 Dashboard  My Data  Resources  Settings

Data Collection

HealthKit & Google Fit

- Activity
 - Steps
 - Distance
- Sleep
- Blood Pressure
- Heart Rate
- Weight

Short Intake	Health History	Biweekly	Gestation	Outcome
At time of enrollment	At time of enrollment	Every two weeks	Every two months	6-8 weeks after delivery
Due date	Mom's pregnancy history	Medications, vaccination	Support during and after pregnancy	Date of pregnancy
Demographic Information	Baby's second parent history	Symptoms	Plans to feed the baby	Mode of Delivery, Baby Delivery information
Zip code, access to care	Medications	Weight, BP, pulse	Contraception plans	Postpartum survey

Flexible Platform!

Can easily add or change questions

Privacy Guardrails

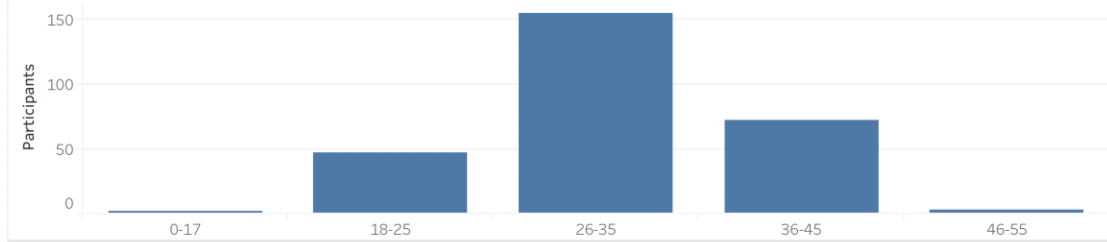
- **All items are are IRB approved through Scripps**
 - Any cobranding materials
 - Expediated IRB approval for new materials
- **NIH Certificate of Confidentiality**
 - Authority to operate
- **Deidentified data even when linking participants**



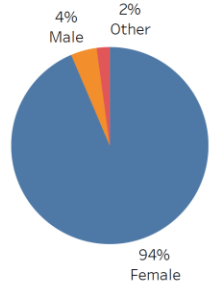
Enrollment

	Participants	Last 7 days	Last 14 days	Last 21 days	Last 28 days
PowerMom	811	7	17	23	33

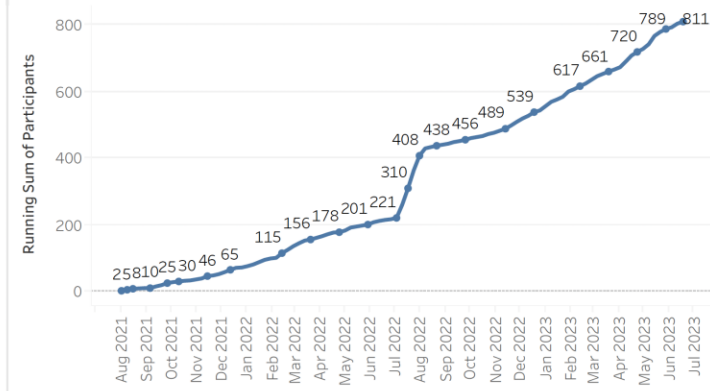
Age Distribution



Gender Distribution

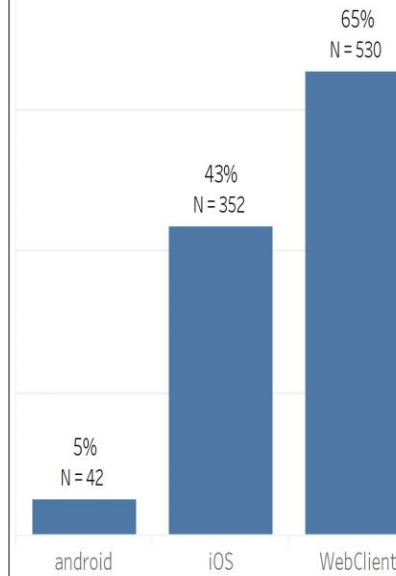


Cumulative Enrollment by Day

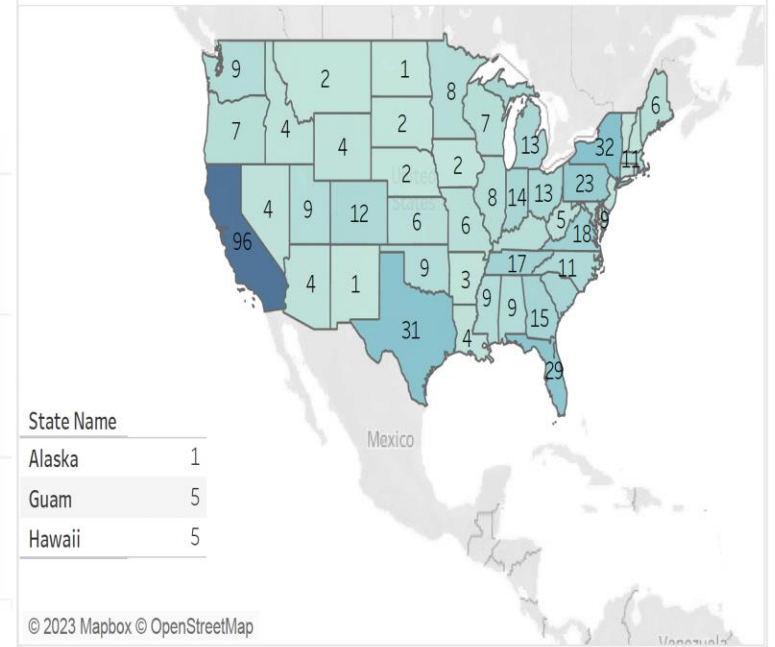


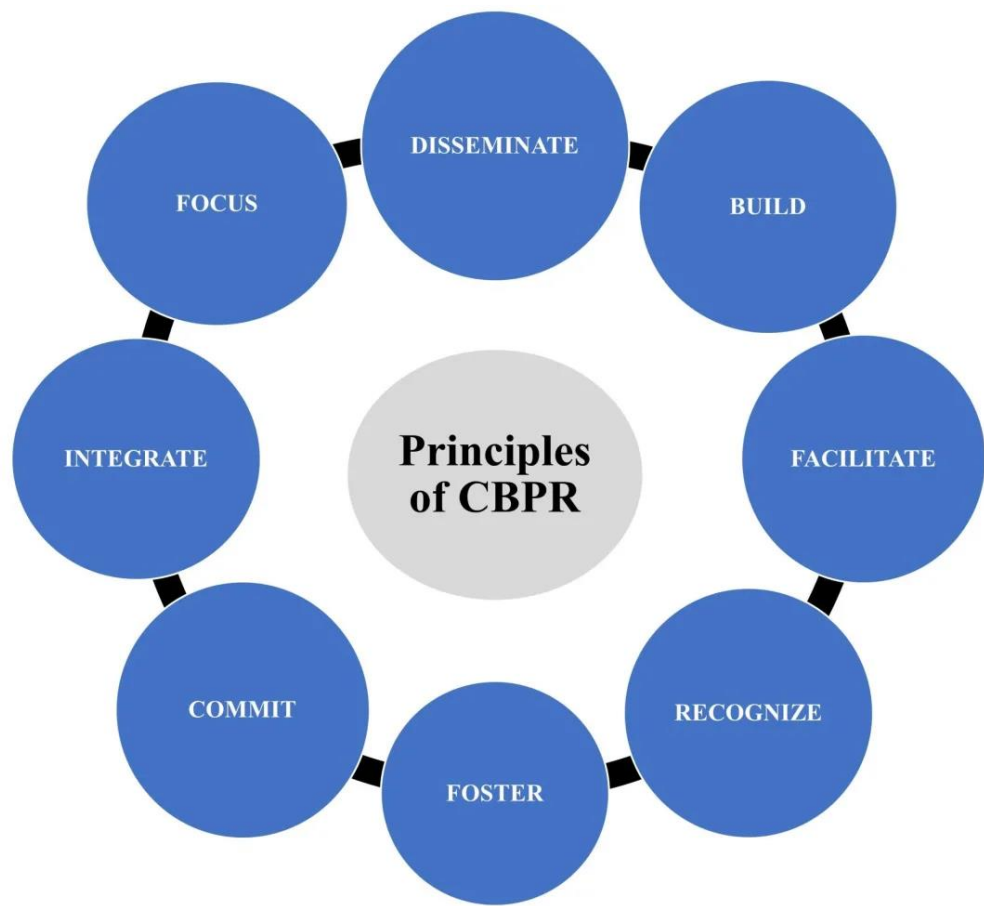
Consumers by Device

*Includes Coordinator completed surveys



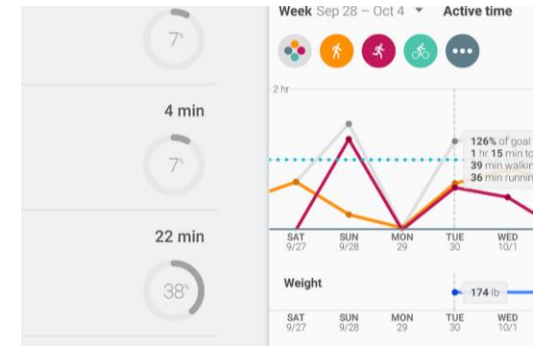
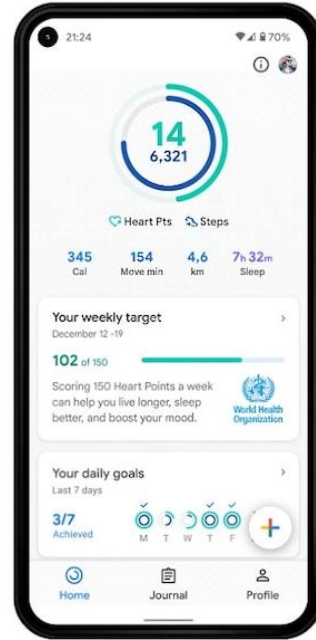
Participant by zip



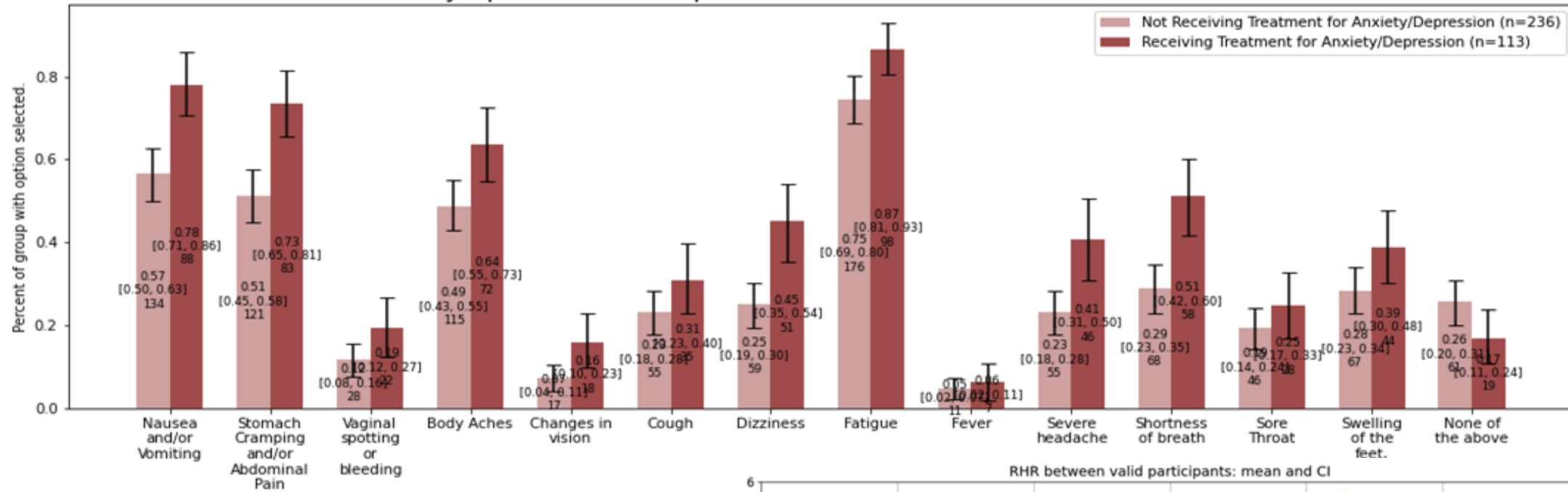


Data Streams

- Continuous Glucose Monitoring
- Nutrition
- Sleep
- Single-lead ECG
- Body Temp (infections)
- Activity (Type and Intensity)
- Mood Disorders
- Breastfeeding



During the past 2 weeks, did you experience any of the following symptoms? (Participants that answered Yes at least once)



Resting heart rate

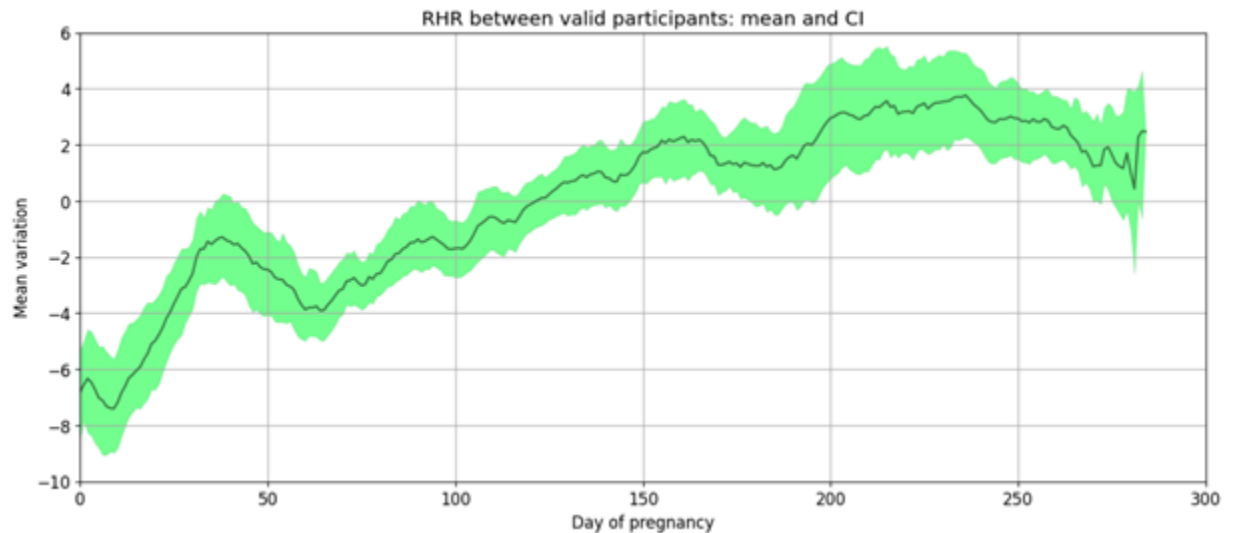
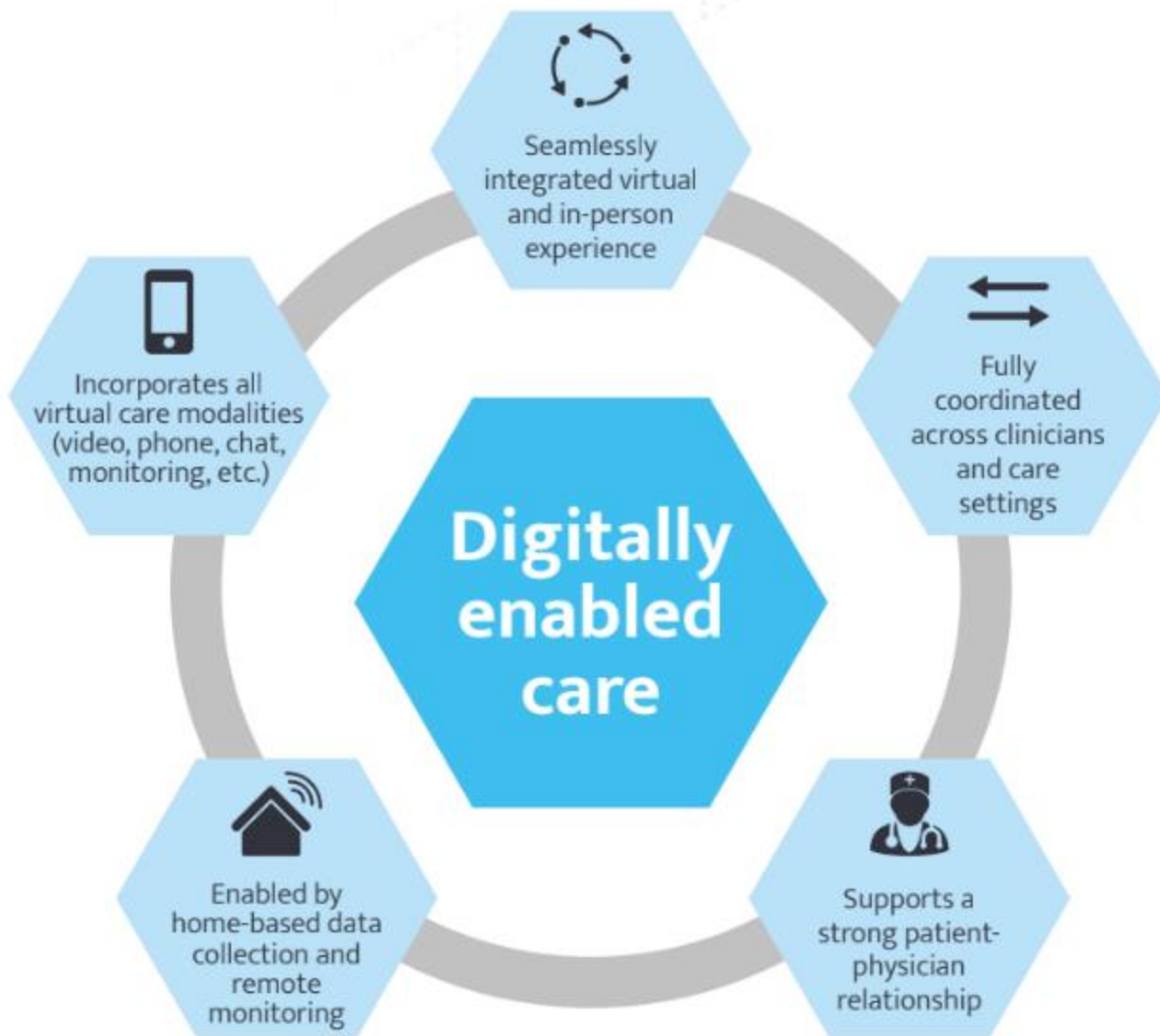


FIGURE 2. Digitally enabled care



COMMUNITY BASED PARTNERSHIPS

1. Perceptions on digital health technology and remote monitoring
2. Barriers to use
3. Facilitators to use and adherence



PowerMom CONSORTIUM



Press release

New research consortium to tackle maternal health disparities with digital technologies

Mobile app-based research platform aims to engage and empower researchers and participants across the country...

December 7, 2021



African American Wellness
Center for Children & Families



Learn more and join us at PowerMom.scripps.edu