#### What is ACCORDS?

Adult and Child Center for Outcomes Research and Delivery Science

#### ACCORDS is a 'one-stop shop' for pragmatic research:

- A multi-disciplinary, collaborative research environment to catalyze innovative and impactful research
- Strong methodological cores and programs, led by national experts
- Consultations & team-building for grant proposals
- Mentorship, training & support for junior faculty
- Extensive educational offerings, both locally and nationally





### ACCORDS Upcoming Events – mark your calendars!

January	<ul> <li>January 12 – ACCORDS Grand Rounds, Bethany-Rose Daubman, MD</li> <li>January 15 – D&amp;I Science Graduate Certificate application launch</li> <li>January 28 – ACCORDS/CCTSI Community Engagement Forum</li> </ul>			
March	March 9 – ACCORDS Highlights, Megan Abbott, MD			
April	<ul> <li>April 8 &amp; 9 – D&amp;I Science for Researchers Workshop</li> <li>April 13 – ACCORDS Grand Rounds</li> <li>April 24 – ACCORDS/CCTSI Community Engagement Showcase</li> </ul>			
May 20-21, 2026	20-21, 2026 Colorado Pragmatic Research in Health Conference Pragmatic Research: Methods, Tools, and Technology for Rapidly Chang Contexts			

Full list of events and dates are available on ACCORDS Education website





## Studies from the Prevention Research Center for Family and Child Health



Mandy Allison, MAEd, MD, MSPH
Professor of Pediatrics, Director of the Prevention
Research Center for Family and Child Health,
University of Colorado School of Medicine



Andrea Jimenez-Zambrano, PhD, MPH
Assistant Professor, Department of Pediatrics,
University of Colorado School of Medicine









# Maternal and Child Health at the Prevention Research Center for Family and Child Health (PRC): Insights from NFPx and ENRICH

Mandy A Allison, MD MSPH

Andrea Jimenez-Zambrano, PhD MPH

and team members at the

Prevention Research Center for Family and Child Health

(<a href="https://medschool.cuanschutz.edu/accords/cores-and-programs/prevention-research-center-for-family-child-health">https://medschool.cuanschutz.edu/accords/cores-and-programs/prevention-research-center-for-family-child-health</a>)







# Prevention Research Center for Family and Child Health

We are devoted to fostering healthier and more equitable communities for children and families to flourish through evidence-based interventions, programs, and policies focused early in life.











# Multi-Disciplinary Team

**Pediatrics** 

Caregiver-child interactions and child development

Developmental Psychology

Maternal and early childhood home-visiting

Maternal perinatal health

Community engagement

Cross-Sector collaboration

Evidence-informed policy

Mixed methods, pragmatic trials, implementation science







#### Caregiver-child relationships

DANCE

• PUPPETalk

#### Perinatal health

Pregnancy and Parenting Partners (P3)

Perinatal workforce (School of Nursing partners)

#### Cross-sector collaboration

- Early Intervention, primary care, and home-visiting
- Primary care redesign
- Systems for Action

Nurse Family Partnership (NFP)

- Original randomized clinical trials
- Global replication
- NFP expansion (NFPx)

# Current NFP implementation and effectiveness

- Black mother's experience in NFP
- Child welfare
- NFP client and nurse retention

Home-visiting innovations

- Addressing IPV
- ENRICH (cardiovascular health)
- Addressing mental health and substance use





ADULT AND CHILD CENTER FOR OUTCOMES RESEARCH AND DELIVERY SCIENCE

UNIVERSITY OF COLORADO CHILDREN'S HOSPITAL COLORADO



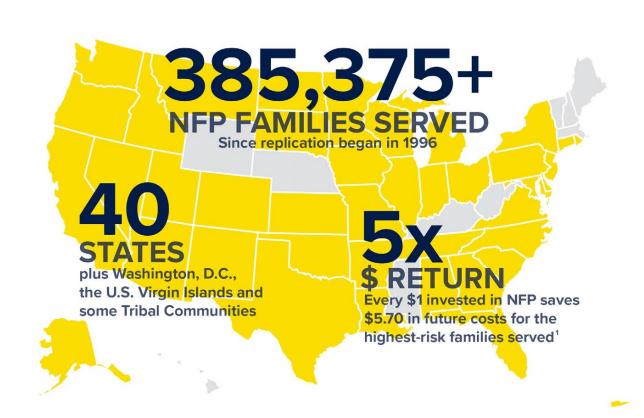






# Nurse-Family Partnership (NFP)

- Prenatal and early childhood home visiting by nurses
- Pregnant individuals
  - No previous live births
  - Enrolled prior to 28 weeks gestation
- Overlapping adversities or risks for poor health outcomes
  - Poverty
  - Low education
  - Young age
  - Chronic illness (mental and physical health)









# NFP's Three Goals







Improve pregnancy outcomes

Improve child health and development

Improve maternal health and life-course







# US Randomized Clinical Trials of NFP Program

Elmira, NY 1977



N = 400

Memphis, TN 1987



N = 1,138 and N=742

**Denver, CO 1994** 



N = 735







# NFP Expanded Eligibility Initiative or NFPx





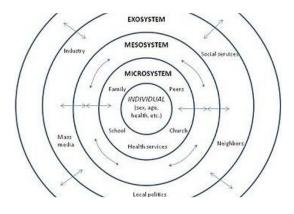








# Behavioral and biological reasons why NFP may be different for people with previous live births



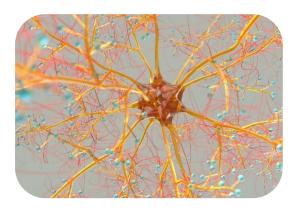
**Human Ecology Theory** 



**Attachment Theory** 



Social Cognitive/ Self Efficacy Theory



Biology (Neuroendocrine changes)







# NFP Model for Innovation Development

Understand program challenges

Formative development of innovation

Pilot innovation

Rigorous testing of innovation Translate learning into practice

Olds, Donelan-McCall, O'Brien, MacMillan, Jack, Jenkins, Dunlap, O'Fallon, Yost, Thorland, Pinto, Gasbarro, Baca, Melnick & Beeber (2013). Improving the Nurse-Family Partnership in Community Practice. *Pediatrics*, 132, S110









# Formative Study (2017-2021)

- 35 teams in 28 sites in 15 states
- Feasibility
- Acceptability
- Requirements for serving people with previous live births (multiparous or 'multips')

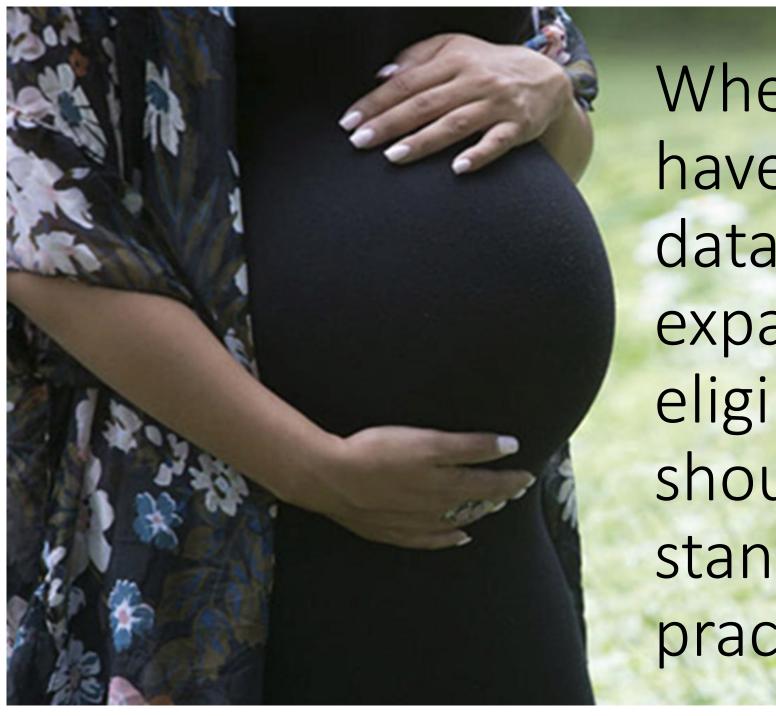
Quasi-Experimental Design Pilot Study (2020-2022)

- Compared multip NFP clients to similar multips covered by Medicaid
- NFP sites successfully enrolled multips with risk factors for poor outcomes
- NFP did not appear to improve birth outcomes
- Participation in NFP was associated with increased receipt of postpartum visit and recommended well child care

Florida Pilot focused on 'late' referrals and enrollments (2020-2023)

- Late referrals were more likely to be multiparous, receive late prenatal care, report smoking, be an immigrant
- Late registrants had fewer visits during pregnancy, better retention at 12 months, similar or better rates of screening
- Program outcomes were similar for late registrants and those enrolled prior to 28 weeks





When do we have enough data to decide if expanded eligibility for NFP should become standard of practice?





# NFP Model for Innovation Development

Understand program challenges

Formative development of innovation

Pilot innovation

Rigorous testing of innovation Translate learning into practice

Olds, Donelan-McCall, O'Brien, MacMillan, Jack, Jenkins, Dunlap, O'Fallon, Yost, Thorland, Pinto, Gasbarro, Baca, Melnick & Beeber (2013). Improving the Nurse-Family Partnership in Community Practice. *Pediatrics*, 132, S110









#### What do we know now that we did not know in 2017?

- NFPx meets community need and reaches those at risk for poor health outcomes
- Serving multips and late registrants is feasible and acceptable
- Requirements for serving multips and late registrants
- NFP is associated with increased receipt of preventive care for multips
- NFPx does not appear to affect 'standard' NFP delivery

#### What are the research gaps?

- Impact of NFP for people with previous live births on:
  - Maternal stress/maternal flourishing
  - Birthing and postpartum experience
  - Tobacco and other substance use
  - Parenting and home environment
  - Injury prevention for index child
  - Behavior and development of index child
- Effect of home-visiting on siblings in the home
- Return on investment







# Randomized Clinical Trial of NFP Impact in Ohio

Recruiting 500 pregnant people with previous live births (multips) experiencing risk factors for poor maternal-child health outcomes

Brighter Futures NFP, Dayton, OH

Center for Family Safety and Healing NFP,
Columbus, OH/ Nationwide Children's Hospital

Parent Advisory Board

Help Me Grow—Coordinated Intake and Referral System



250 Multips referred to NFP

250 Multips receive 'usual care' including referrals to other community resources (comparison group)



Data collection visits: baseline, 36 weeks pregnancy, postpartum, 6 months, 12 months, 18 months, 24 months
Outcomes: gestational hypertension, birth outcomes, breastfeeding, maternal tobacco and other substance use, maternal stress, quality of home environment, parent-child interaction, child's development, child ED visits and hospitalizations, sibling's cognitive development





# Randomized

Brighter Futures NFP, Daytor OH

250 Multips

gestational hypertension, birth of home environment, pare

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Parent Advis

Help Me Grow—Coordinated Intake and Referral System

250 Multi<sub>k</sub> care' including referrals

ity

mparison group)

abstance use, maternal stress, quality visits and hospitalizations, sibling's







Challenges to individual randomization and lower than expected enrollment in NFP

Roll out design? Cluster design? Quasi-experimental design

Challenges to recruitment

Increase number of recruitment sites by switching to remote data collection

Time required to measure child development outcomes for intervention starting in pregnancy

Shift primary focus to caregiver-child interaction measures

Expense

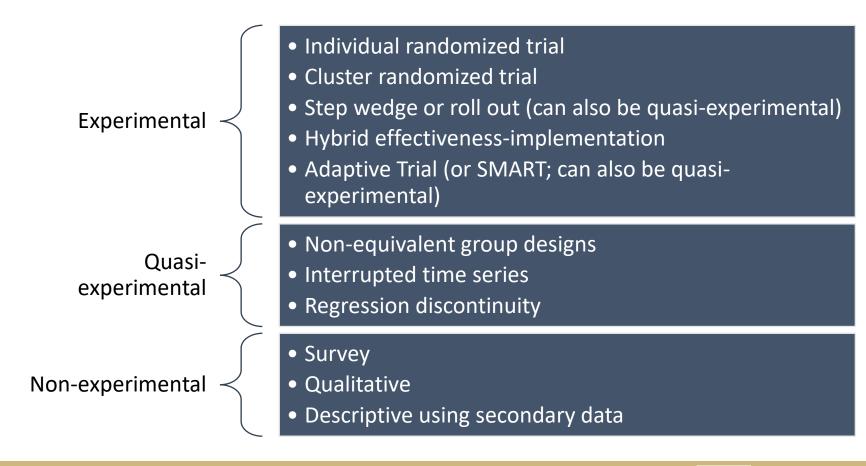
Smaller sample size (different primary outcomes)
Shorter timeline and fewer data collection visits
Less expensive measures (less staff time)







### Research Methods







## Revised Trial of NFP for People with Previous Live Births

Recruiting 250 pregnant people with previous live births (multips) experiencing risk factors for poor maternal-child health outcomes

7 existing NFPx sites around the country (with additional pending) and 'matched' community partner such as centralized intake and referral, WIC, community health center serving pregnant women



125 Multips enrolled in NFP are recruited soon after NFP enrollment 125 Multips receiving 'usual care' including referrals to other community resources (comparison group)



Data collection visits: baseline, postpartum, 6 months, 9 months

Primary Outcomes: appropriate gestational weight gain, birth experience, breastfeeding, caregiver-child interaction, sibling behavior and socio-emotional development







# Design aspects to increase validity of quasi-experimental design



Ensure that program and comparison groups are highly similar in observable pre-program characteristics

Recruiting participants from 'matched' geographic areas

Use of baseline covariates

Some outcomes measured before and after intervention delivered



Study design and primary analysis pre-specified



Outcome data collected in the same way for both groups



Follow the same practices that a well-conducted randomized controlled trial follows to produce valid results (other than the actual random assignment)

Prevent attrition

Intent-to-treat analyses







# Next steps





# The ENRICH Study

Early Intervention to Promote Cardiovascular Health of Mothers and Children

MPIs: Mandy Allison, MD, MSPH and Kate Sauder, PhD

ESI: Andrea Jimenez-Zambrano, PhD, MPH



# What is ENRICH?

#### **Evidence-Based Home Visiting**









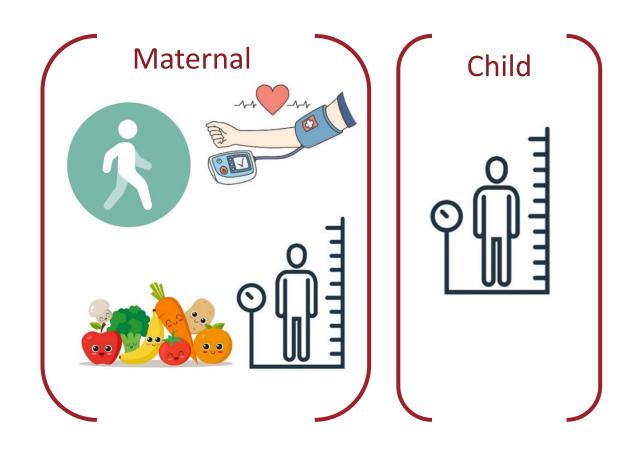
# Who is participating in the study?





# **Primary Study Aims**

- Evaluate <u>CVH among adults</u> who receive HV enriched with CVH promotion content in the prenatal and postpartum periods compared to adults with HV without enriched content.
  - MEPA diet quality score
  - Time spent in moderate and vigorous physical activity
  - BMI
  - Blood Pressure (BP) at 12 months postpartum (primary endpoint)
- Evaluate <u>CVH among children</u> who receive HV enriched with CVH promotion content in the postpartum period compared to children with HV without enriched content.
  - BMI z-scores at 24 months postpartum (secondary endpoint)





# Implementation Study

- What intervention components and how much of the intervention (dose) did participants receive as part of ENRICHed HV?
- What was the context of the HV agency and service delivery system?
- To what extent did supervisors and HVers adopt (deliver) ENRICHed HV?

Construct	# Items	Measure	Participant	Timepoint	
				Baseline	12m
Implementation (	Outcomes	(RE-AIM)			
Reach	TBD	Aggregate level site/model data	N/A	Final year of ENRICH	
Adoption	15	Evidence-Based Practice Attitude Scale <sup>271</sup>	HVer, S	Х	Х
	3	Organizational Readiness to Change Assessment <sup>272</sup>	HVer, S	X*	Χ*
Implementation	N/A	ENRICHed HV Content Visit Log	HVer	Every home visit	
	N/A	Length of HV Enrollment	HV admin data	Final year of ENRICH	
Maintenance	40	Program Sustainability Assessment Tool <sup>273</sup>	HVer, S	Final year of ENRICH	
Implementation (	Context (F	PRISM)			
Intervention					
Participant	TBD	Satisfaction with ENRICHed HV Intervention	ENRICH	At 24 mo or	utcomes da
Perspectives			participant	colle	ection
Organizational	4	Mission Alignment <sup>274</sup>	HVer, S	X*	Χ*
Perspectives	12	Innovation <sup>275</sup>	HVer, S	X*	Χ*
	4	CFIR Inner Setting Measure: Implementation Climate <sup>276</sup>	HVer, S		Х
	9	Organizational Readiness for Implementing Change (ORIC) <sup>277</sup>	HVer, S	X*	Х*
Recipient Charac	teristics				
Participant	N/A	Participant level demographics, SDOH, and psychosocial measures collected as part of main trial, as detailed in Section 9.1, Table 9.1	ENRICH participant	N/A	N/A
HV Agency Staff	13	Staff demographics (e.g., race, ethnicity, educ, time in role, height and weight)	HVer, S	Х	
	3	Self-Efficacy <sup>274</sup>	HVer, S	X*	Χ*
	9	Maslach Burnout Inventory – General Survey – Short Form <sup>278,279</sup>	HVer, S	Х	Х
	24	CFIR Inner Setting Measure: Culture; Learning Climate; Leadership Engagement; Available Resources <sup>275</sup>	HVer, S	х	
HV Agency	7	HV Agency Characteristics	Lead	Х	
Implementation 5	Strategies	(Section 7, Figure 7.1)			
Training	N/A	Interactive Training Content Checklist	ENRICH Trainers	Every Interactive Training	
	N/A	HV Model-Specific Community of Practice (CoP) Session Attendance	ENRICH Trainers; HVer, S	Every model-specific CoP session	

HV: Home Visiting; HVer: Home Visitor; S: Supervisor; Lead: HV Agency Leadership; 12m = 12 Months Following Completion of Training

<sup>\*</sup>For ENRICHed HV Staff only. Not applicable for Usual HV staff

# Study Design

# UG3: planning and pilot study Years 1 & 2

- Develop new ENRICH-specific intervention materials and integrate with HV intervention
- Evaluate recruitment and data collection procedures
- Gather feedback from participants and local partners
- Work alongside coordinating center and clinical sites to develop common protocol and harmonize intervention

#### **UH3:** full trial

#### Years 3-7

- Enrollment and baseline data collection prior to 34 weeks gestation
- Randomization to ENRICHed HV or standard HV
- Program delivery prenatally through 24months postpartum
- Outcomes data collection at 12 and 24 months postpartum



#### **ENRICH Intervention Timeline: Enrollment < 28 Weeks ENRICH** Start Here Start with Metabolic Health and Child Modules Either Physical Activity OR Healthy Eating & Weight can go first based on the postpartum, then work in additional parent-focused modules with the child modules based on client's needs client's preference Healthy Eating & Weight: **Physical Activity:** Metabolic Health: **Child Modules:** Healthy Weight During **Know your Health Getting Active** 1 month **Know Your Health** Pregnancy Postpartum Consider **During Pregnancy** subbing in ENRICH child Portion Sizes for a materials in **Focus on Your Fitbit** Then prioritize the key 3 months place of NFP (incentive!) **Healthy Weight** BP Check Month 1 ysical Activity and Healthy monthly memos Eating & Weight Modules. (dark pink) you would Plus an additional 9 typically use! My Healthy Eating 6 months modules to choose **Plate BP Check Month 3** Other Topics: from! 6 sleep health modules Select among The client's choice 9 months to choose from! Sugar Sweetened between 4 topics Beverages, Fried Foods, Ultra-Processed Foods. Plus an additional 20 12 months 15 months Smoking and Tobacco or Restaurant modules to choose **Use During Pregnancy** Eating from! 4 mental health & 18 months stress modules Tip: Between 12-18 months postpartum may be another opportunity to discuss maternal cardiovascular health topics! NFP enrollment Birth of baby 6 months 12 months 18 months NFP -4-6 wks - - - 2-4 mos - - 5-6 mos - - 7-10 mos - 1-113 mos - 14-17 mos - 18-21 mos - 18-21 mos - - 18-21 mos - 18 Prioritize 'Know Your Graduation



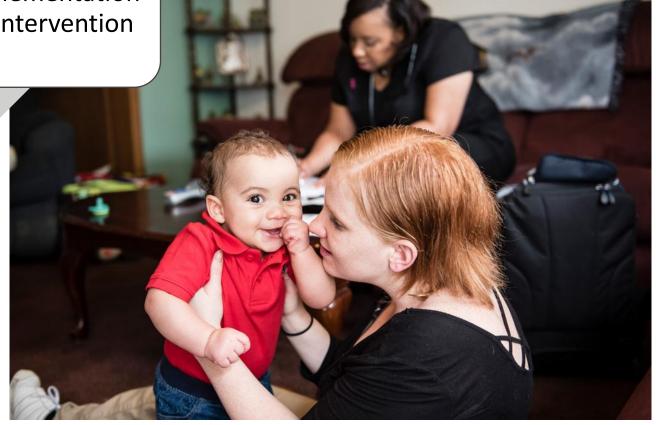
Health During Pregnancy' then key Physical Activity

and Healthy Eating and Weight modules (dark pink) Each hashmark on the timeline represents 1 NFP visit.

# Current Status

Recruitment N=140 Baseline Data Collection N=127

Implementation of Intervention





# Ancillary Study

# Understanding Social Drivers of Cardiovascular Health in the ENRICH Trial Population



# Background

- •Promoting and maintaining cardiovascular health (CVH) from pregnancy onward is essential to reducing the intergenerational burden of cardiovascular disease.
- •Children born to women with gestational diabetes or other indicators of poor CVH show higher rates of obesity and hypertension at increasingly younger ages, suggesting that risk trajectories begin early in life.
- •Social drivers of health—including social support, cultural norms, healthcare access, nutritious food availability, and safe environments for physical activity—strongly influence CVH.
- •Although addressing unmet social needs in chronic disease management improves outcomes, current CVH guidelines do not adequately emphasize tailoring interventions to meet these needs.

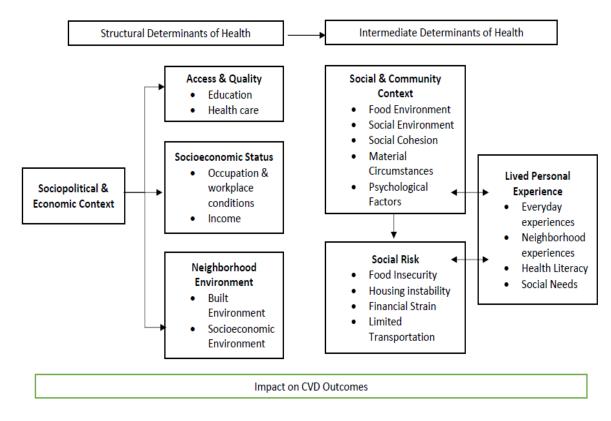


#### Aims

- 1. Characterize the social drivers of health and unmet social needs that may influence NFP clients' ability to engage in CVH promoting behaviors including diet, physical activity, and sleep.
- 2. Deepen understanding of how social drivers of health and unmet social needs affect NFP clients' ability to engage in CVH promoting behaviors.



**Critical Framework of Social Determinants of Health (CFSDH)** 



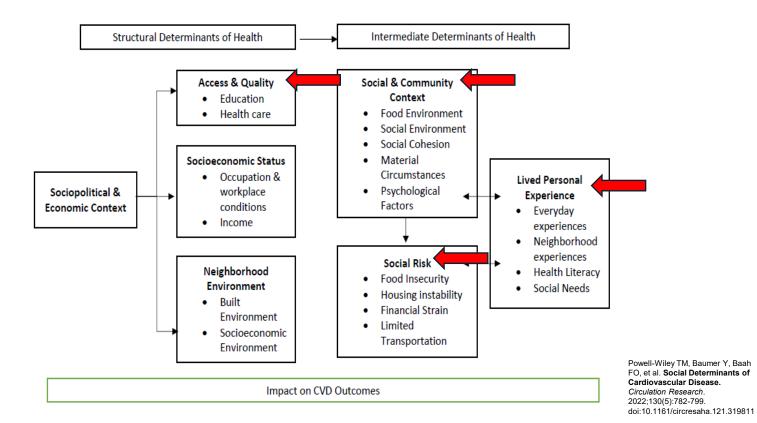


Powell-Wiley TM, Baumer Y, Baah FO, et al. Social Determinants of Cardiovascular Disease.

Circulation Research.

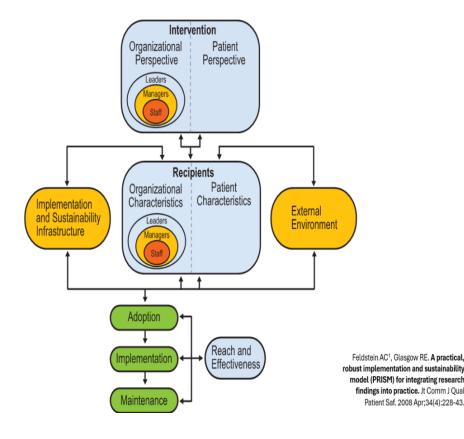
2022;130(5):782-799. doi:10.1161/circresaha.121.319811

**Critical Framework of Social Determinants of Health (CFSDH)** 



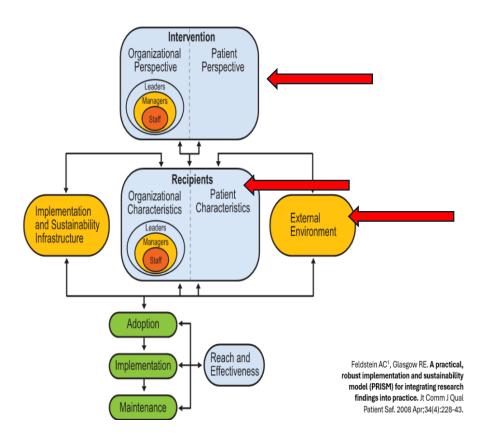


Practical, Robust implementation and Sustainability Model (PRISM)



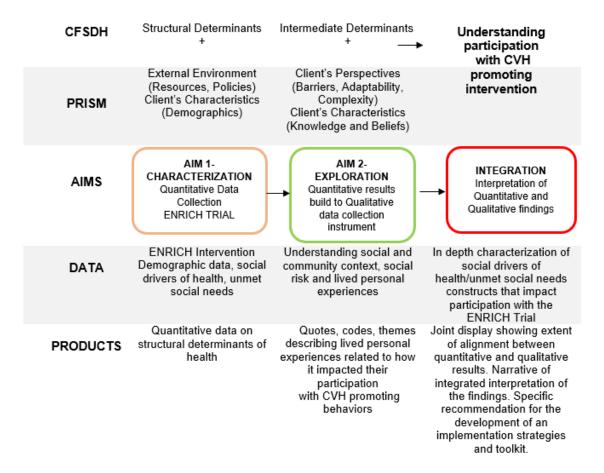


Practical, Robust implementation and Sustainability Model (PRISM)





### Experimental Design + Methods





### Aim 1- Quantitative Data Collection

#### **Social Drivers of Health Drivers**

- Food Insecurity: Household Food Security Scale
- Nutrition Security: Nutrition Security Survey
- Discriminatory Experiences: Everyday Discrimination Scale
- Childhood experiences: *Adverse* childhood event
- Socioecological Factors: Social Vulnerability Index

#### **Baseline survey variables**

- Education
- Income
- Health insurance
- Living situation
- Household composition
- Marital status





### Aim 2-Qualitative Data Collection

- Conduct semi-structured interviews
  - Participants who have been enrolled in ENRICH for over a year.
  - Participants who are ≥18
  - Either speak English or Spanish





### Aim 2-Qualitative Data Collection





### Next Steps

Dec 25

• Quantitative Data Analysis

• Interview guide development based on quantitative data

Jan 26

- Recruitment of interview participants
- Start collecting Qualitative Data
- Continue to refine Specific Aims Page for R01 Implementation Grant

May 26

Qualitative Data Analysis

June 26 • Submission of R01 Implementation Grant



# Thank you!

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303-724-1083





### Secondary Study Aims

- Evaluate if <u>adults</u> receiving ENRICHed HV, compared to those receiving usual HV, have differences in:
  - Primary outcomes at 24 months
  - $\circ$  A composite score of CVH using the American Heart Association's Life's Essential 8 (LE8)
  - Individual health behaviors and factors at 12 and 24 months postpartum (i.e., 281 MEPA diet quality score, time spent in moderate and vigorous physical activity, 282 sleep, tobacco use, BMI, BP, blood glucose, and blood lipids)
- Evaluate if <u>children</u> receiving ENRICHed HV, compared to those receiving usual HV, have differences in:
  - A composite score of CVH using modified LE8 scoring criteria for children to include sleep, diet, and physical activity/screen time at 24 months
  - Growth trajectories as measured using BMI z-scores over the first 24 months of age
  - Assess implementation outcomes of ENRICH and the context in which ENRICH is implemented (Implementation study).

# **ENRICH Training for Home Visitors**



At your next visit, you check in on the SMART goal she created on page 3. She states she hasn't been able to make much progress with this goal and you perceive she is feeling discouraged about getting more active.

Let's pick up the scenario at this home visit and listen in on the conversation between Rachelle and the home visitor:

HV: It sounds like you are feeling a bit discouraged with your goal to do an online workout video.

Rachelle: Yeah, I've been feeling extra tired lately and I don't really have much time to do one

HV: It sounds like you are having a hard time finding the energy to try something new and fit it in to your schedule.

Rachelle: Exactly. I know it's important to exercise but don't know what to do when I just want to sleep when I am not at work.

HV: Well, maybe we should start with something simpler. I noticed on page 3 of Getting Active During Pregnancy you checked "Walking the dog" as an activity you do regularly. Can you tell me more about that?

Rachelle: Oh yeah, I walk my roommate's dog before I head into work around noon, since my roommate works full time and I work part time. We usually just go around down the street and back.

HV: How is that for you?

Rachelle: Not bad... Peanut (the dog) is cute and I guess it's nice to get some fresh air before going to work inside for 4 hours.

- 1. What would you say next to continue this conversation with Rachelle?
- 2. What did the home visitor do to support Rachelle during this discussion?
- 3. What techniques (Motivational Interviewing, etc.) might you use to incorporate Rachelle's motivations and overcome barriers in support of her goal?
- 4. What would you do differently to discuss Rachelle's barriers and motivation for change?
- 5. Write an example of a SMART goal Rachelle may create at the end of this visit.