

Overcoming the Hope-Evidence Gaps in Behavioral Health Research

What do remote clinical trial methods enable?

Eric Hekler, PhD

Professor, & Interim Associate Dean, Community Partners, Herbert Wertheim School of Public Health and Human Longevity Sciences

Director, Center for Wireless and Population Health Systems (CWPHS)

Design Lab

University of California, San Diego USA

@ehekler and ehekler@ucsd.edu

Acknowledgements

- Core Colleagues: Pedja Klasnja, Susan Murphy, Job Godino, Daniel Rivera, Olga Perski, Guillaume Chevance, mc Schraefel,
- Prior students: Sayali Phatak, Cesar Martin, Mohammad Freighoun, Elizabeth Korinek, John Harlow
- Key colleagues who informed this line of thinking
 - Dana Lewis, Donna Spruijt-Metz, Richard Kravitz, Deborah Estrin, Misha Pavel, Ben Marlin, Camille Nebeker, Cinnamon Bloss, Stephen Schueller, Kathy Kim, Erik Johnston, Guillaume Chevance, Ida Sim
- Funders
 - R01CA24477 (PI: Hekler);
 - T32MH122376 (MPIs: Ohno-Machado, Hekler, Wells, Politis)
 - NSF IIS-1449751 (PI: Hekler)
 - RWJF: 71995 (PI: Hekler) & 74610 (PI: Lewis)
 - NLM: R01LM013107 (PI: Hekler)
 - NHLBI: R01HL125440 (PI: Klasnja)
 - NCI U01CA229445 (PI: Spruijt-Metz)

Take-Aways

Hope-evidence gaps exist with behavioral health interventions

- | | | |
|-------------------------|--|---------------------|
| 1. Desired effects | | long-term results |
| 2. Real-world support | | low adherence |
| 3. just-in-time support | | disruptive/shut off |
| 4. Evidence-based | | poor implementation |
| 5. Rapid scaling | | poor evidence |

What to do?

Rely less on summative RCTs (studying things) & instead study process

Use appropriate methods to iteratively optimize in real-world contexts

Foster more robust partnerships with researchers working within real-world contexts

Behavioral health's research goal

- Real-world success advancing behavioral health
- How?
 - Improved understanding of behavioral processes
 - Improved capacity to reliably produce desired behavioral changes

Success stories

CDC Centers for Disease Control and Prevention
CDC 24/7: Saving Lives. Protecting People™

Search

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National Diabetes Prevention Program

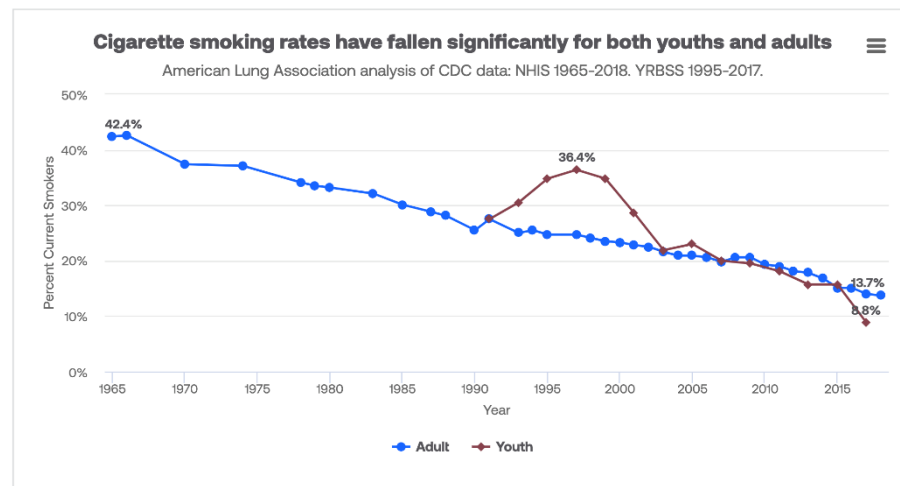
[Español \(Spanish\)](#)

NATIONAL DIABETES PREVENTION PROGRAM

Working Together to Prevent Type 2 Diabetes

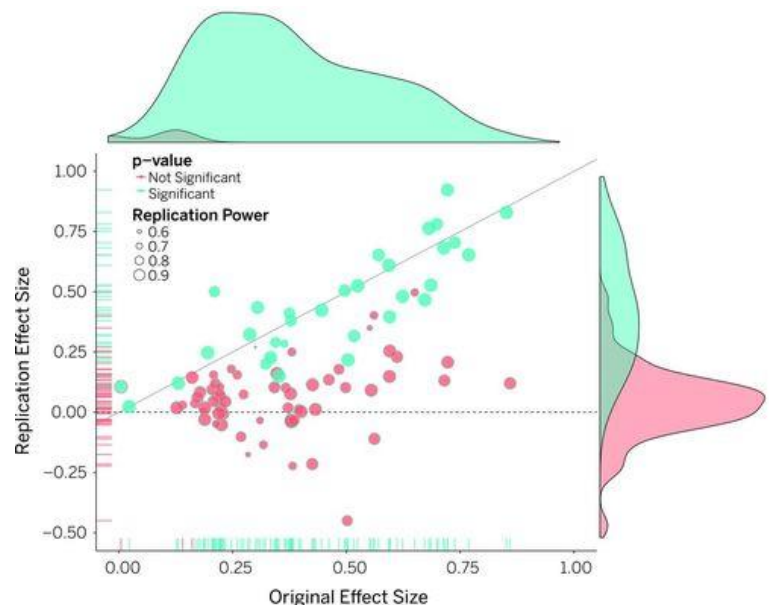
The National Diabetes Prevention Program (National DPP) is a partnership of public and private organizations working to prevent or delay type 2 diabetes. Partners make it easier for people at risk for type 2 diabetes to participate in evidence-based lifestyle change programs to reduce their risk of type 2 diabetes.

Trends in Cigarette Smoking Rates



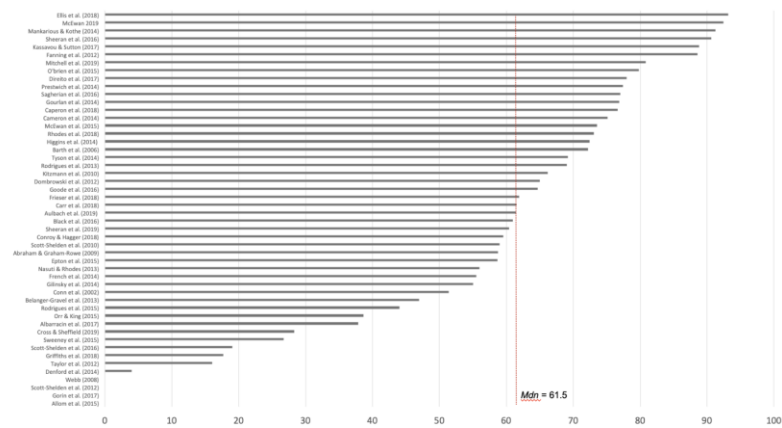
How are we doing?

Our predictions aren't replicating



Our treatments aren't reliably producing change

Figure 1
Heterogeneity in Interventions to Change Health Behaviors: Distribution of F values in 46 Meta-Analyses



Rothman, A. J., & Sheeran, P. (in press). The Operating Conditions Framework: Integrating mechanisms and moderators in health behavior interventions. *Health Psychology*

Hope-Evidence Gaps

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Why do the gaps exist?

- Mismatch – between inherent complexity of target phenomena and appropriate methods.

Mismatch of complexity

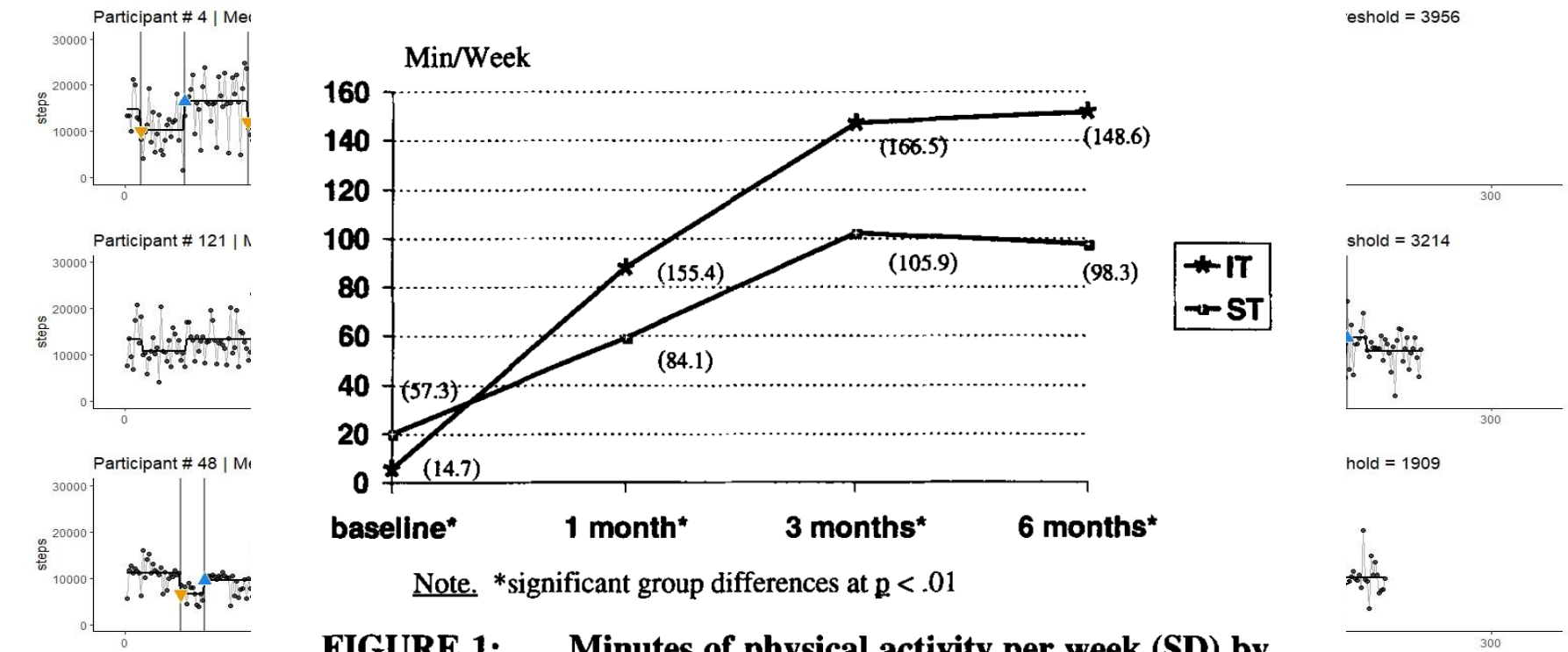
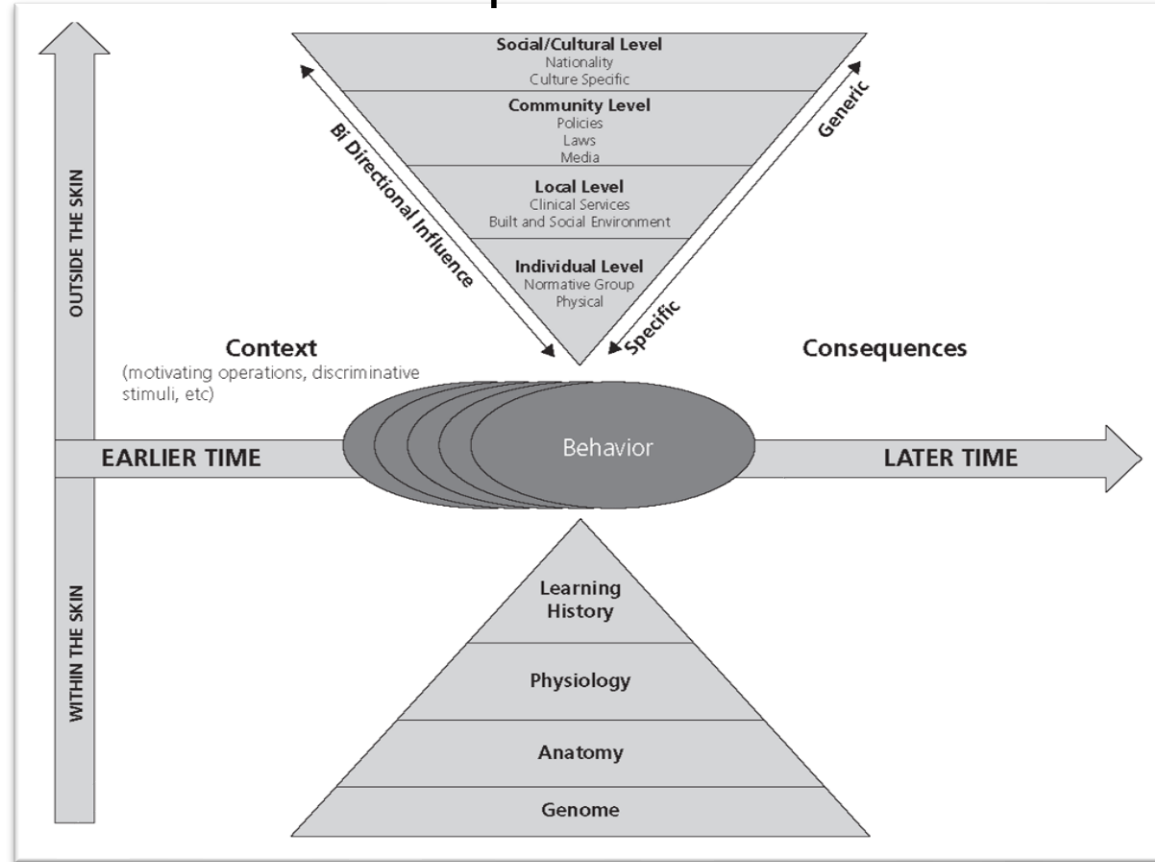


FIGURE 1: Minutes of physical activity per week (SD) by treatment condition.

Chevance, G, Baretta, D Heino, M, Perski, O, Hekler, E, Klasnja, P, Godino, J. (2020) Non-linear, day-to-day fluctuations in walking behavior: An Ideographic modelling approach, *Manuscript submitted for publication*

Marcus et al (1998.) *Ann Behav Med* 20(3): 174-180

Human behavior is complex.



Context matters. History/time matters. People adapt to context (difference).

Hovell M, Wahlgren D, Adams M. *Emerging theories in health promotion practice and research*. 2009;2:347-85.

Mismatch (part 2)

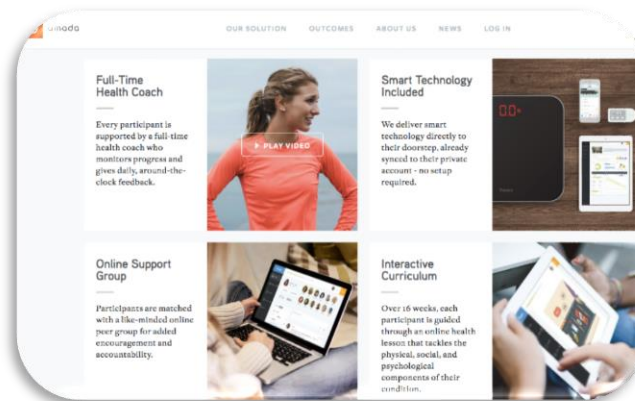
- Complexity is simplified by studying dynamic processes in context.
- Our methods largely study things
 - Studying things is useful when the causal model is simple and linear, not true with greater complexity

RCTs study things...

Pharmaceuticals



Complex behavioral interventions

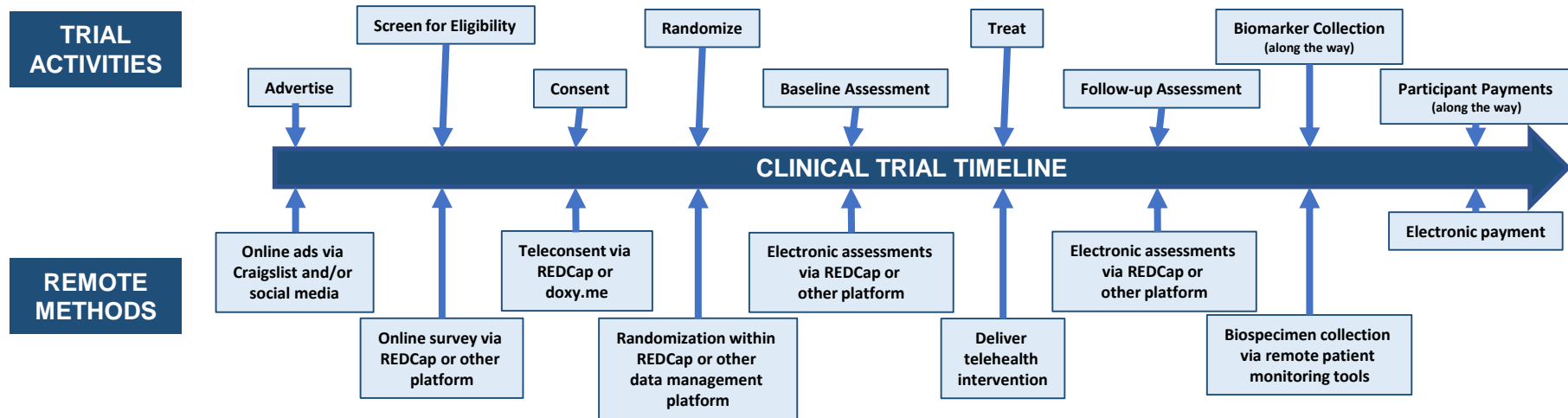


Hope-Evidence Gaps

What to do?

- Only use an RCT when:
 - Simple causally (linear causation assumption justified)
 - If complex, the “thing” should be:
 - stable
 - can be implemented and will be used in context
 - Likely to produce benefits over risks & costs
- Otherwise, study processes in context

Remote clinical trial tools enable us to study processes in context, not things



Slide courtesy of Jennifer Dahne, MUSC

How to study processes in context?

- Study how the elements of a complex intervention works
- Use optimization trials, particularly taking advantage of time series data
- Build within existing contexts and resources (e.g., within clinic resources, using robust digital platforms, et)

Processes can be understood better when studying components

Goal-setting
Tool

Walking
Reminder
Tool

Glucose
Monitoring
Tool

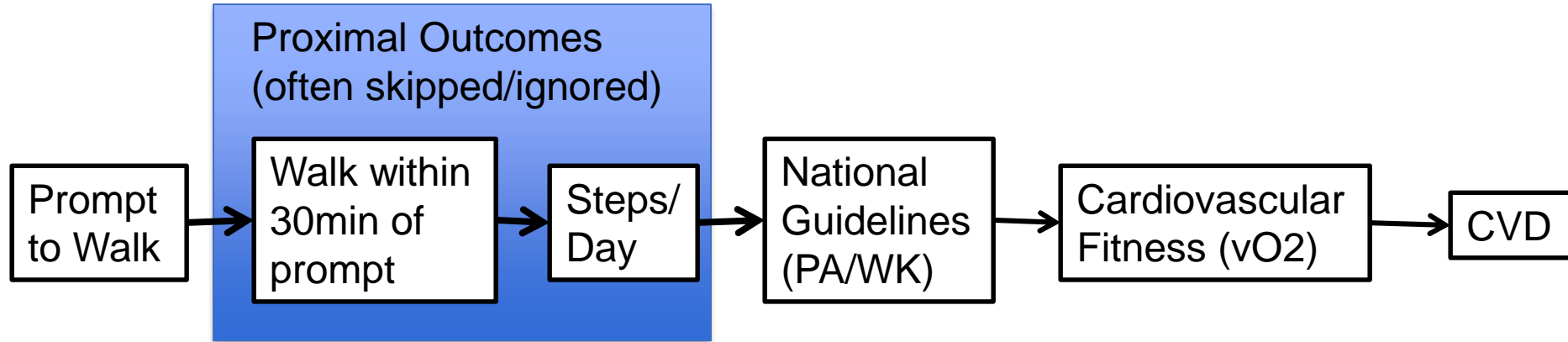
Pain
Reduction
Tool

Social
Support Tool

Insulin
Dosage Tool

Proximal outcomes of the module

Shortest timescale for measuring a meaningful effect



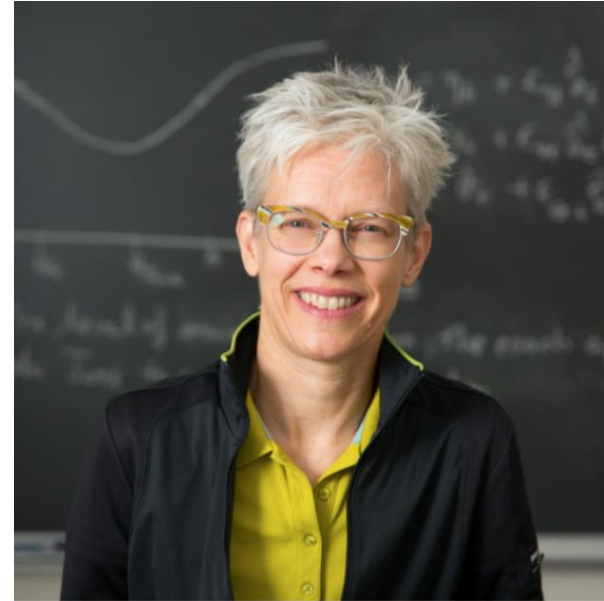
Efficient study designs

Optimization trials

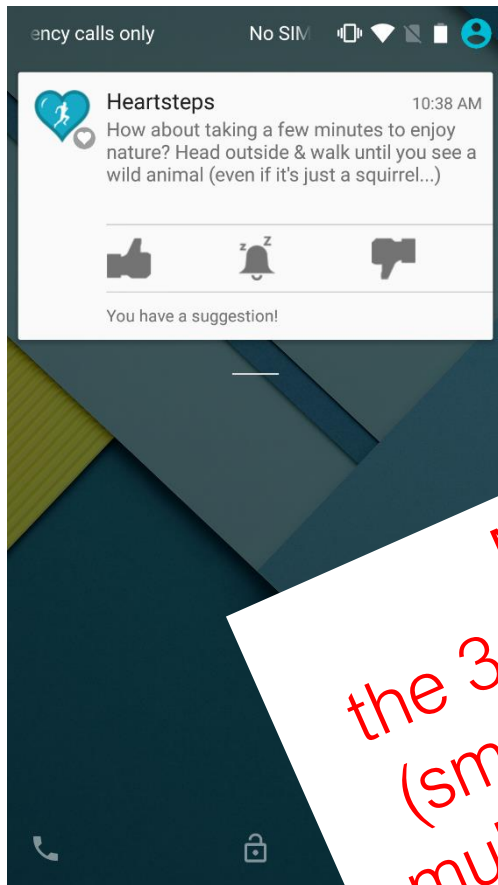
- Factorial trials (Collins)
 - Enables testing of intervention components and their interactions
- Others
 - Sequential Multiple Assignment Randomized Trial (SMART; Murphy) “N-of-1” study designs (Hekler ’19); Control Optimization Trial (COT; Hekler 18’),
- Micro-randomization trials (Murphy & Klasnja)
 - Same as factorial trials + enables testing the contexts when components help vs. not

Micro-randomized trials

- Sequential, full factorial designs
- Randomize each intervention component
- Each time we *might* deliver component
- Multiple components can be randomized
- Randomized 100s or 1000s of times



Klasnja, Hekler, Shiffman, Boruvka, Almirall, Tewari, Murphy, Health Psych, 2015



Suggestions

Suggestions tailored

- time

to interrupt sitting

What

What learned?

MRTs can be used to fill the 3 hope-evidence gaps efficiently (smaller samples, shorter trials, with multiple components tested at once).

from?

Does it work?

—varying moderating effects

- In what states/contexts does it work? For whom?

Questions:

Klas, , Smith, S., Seewald, N. J., Lee, A., Hall, K., Luers, B., **Hekler, E. B.**, & Murphy, S. A. (2019). Efficacy of Contextually Tailored Suggestions for Physical Activity: A Micro-randomized Optimization Trial of HeartSteps. *Annals of behavioral medicine : a publication of the Society of Behavioral Medicine*, 53(6), 573–582. <https://doi.org/10.1093/abm/kay067>

Family Health Centers of San Diego

Site PI: Job Godino, PhD

Co-Investigators: Jie Liu, MD; Charles Smoot, MD; Luis Rodriguez, MD;
Noe Crespo, PhD, Elva Arredondo, PhD; John Elder, PhD



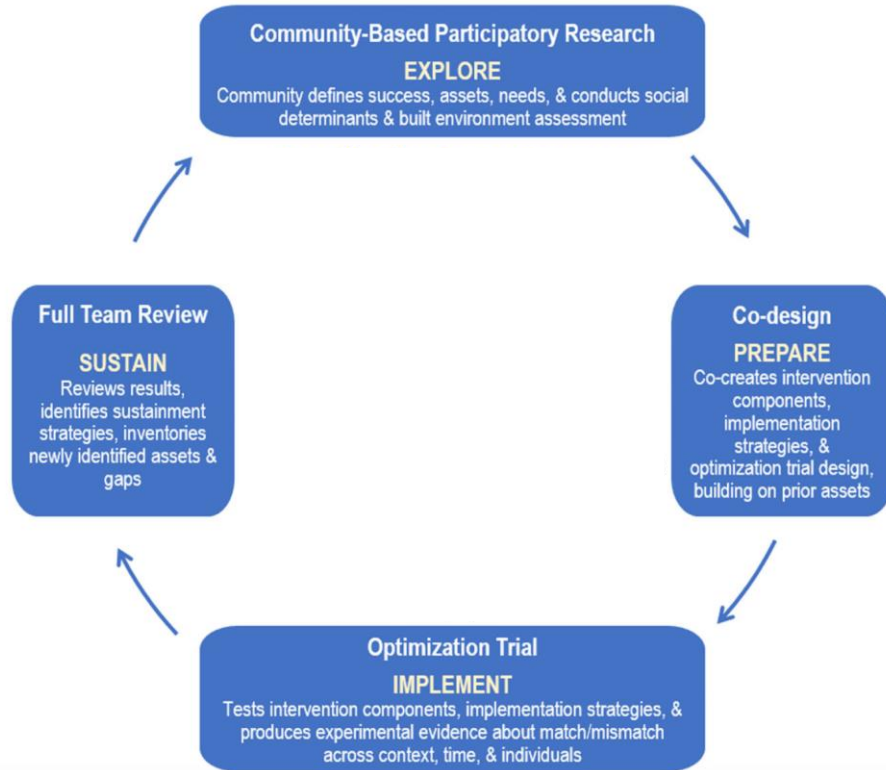
- Federally Qualified Health Center
- More than 64,000 patients with hypertension
 - 14% Black and 46% Latino
- Since 2019, 57% presented with systolic blood pressure ≥ 130
 - 61% Black and 56% Latino



Goals

(1) Integrate a digital therapeutic for hypertension self-management education and support into the health system; (2) Equitably deliver in a multicultural and multilingual context; and (3) Create evidence that generalizes to Federally Qualified Health Centers.

Robust real-world evidence about processes in context



- Sample

- Patients diagnosed with pre-hypertension/hypertension
- N=118, 85% power; effect size=0.122, 15% attrition

Conditions

- Telehealth coaching vs. not
 - (randomized weekly, proximal outcome=systolic blood pressures averaged across week)
- Medication adherence reminders sent or not
 - (randomized daily, proximal outcome=% Medication Adherence)

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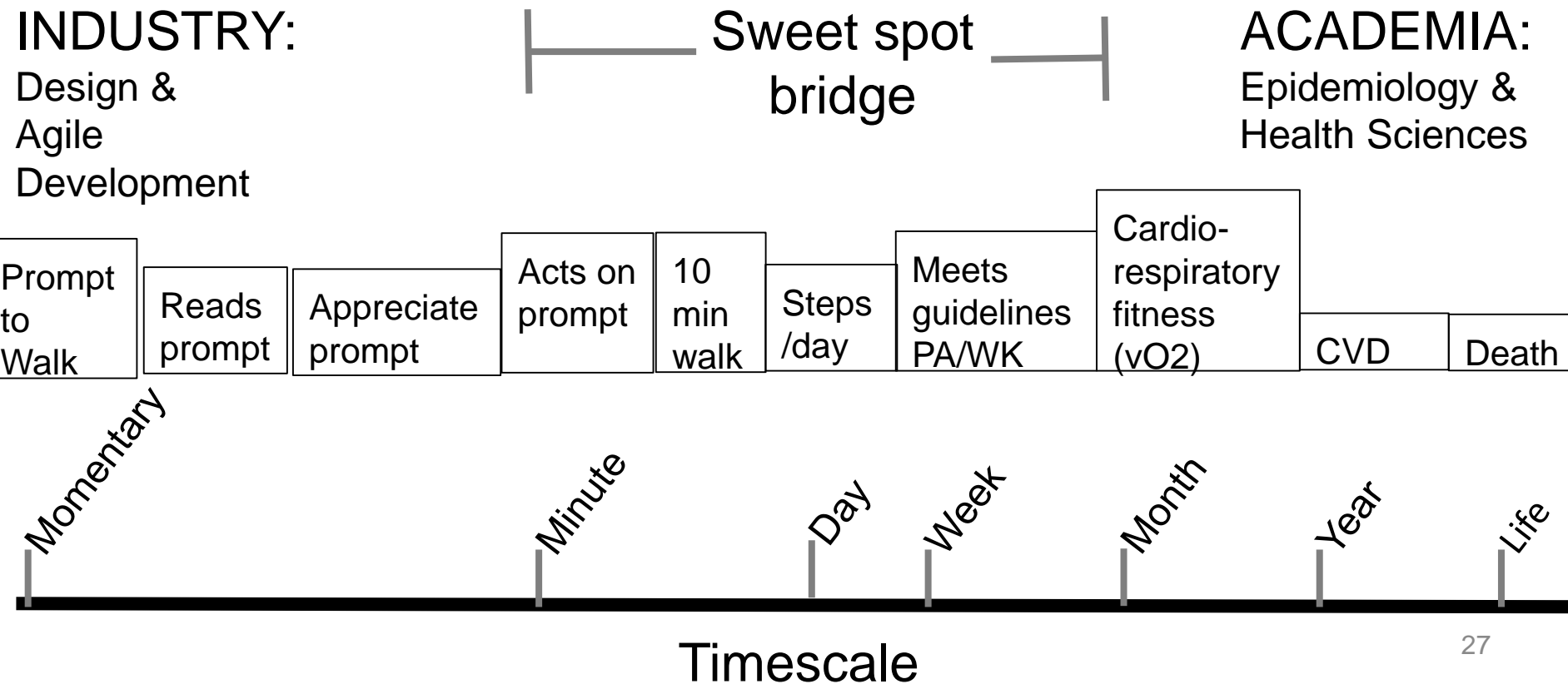
University of California, San Diego USA

@ehekler and ehekler@ucsd.edu

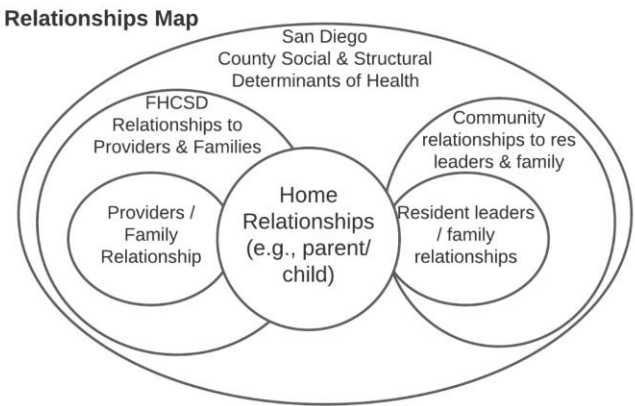
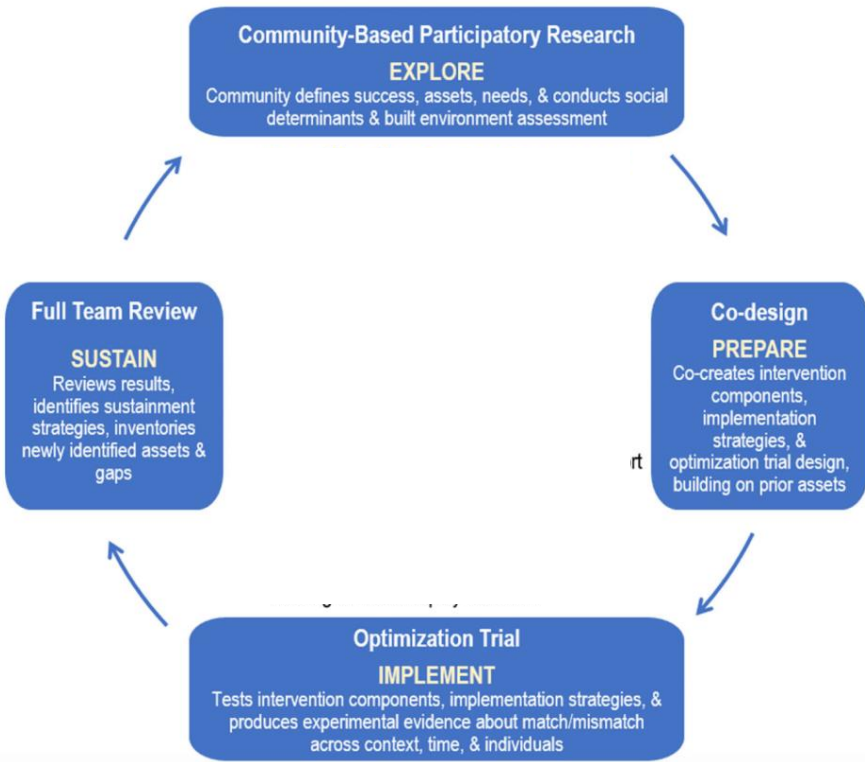
Extra Slides

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Measurement timescale is key

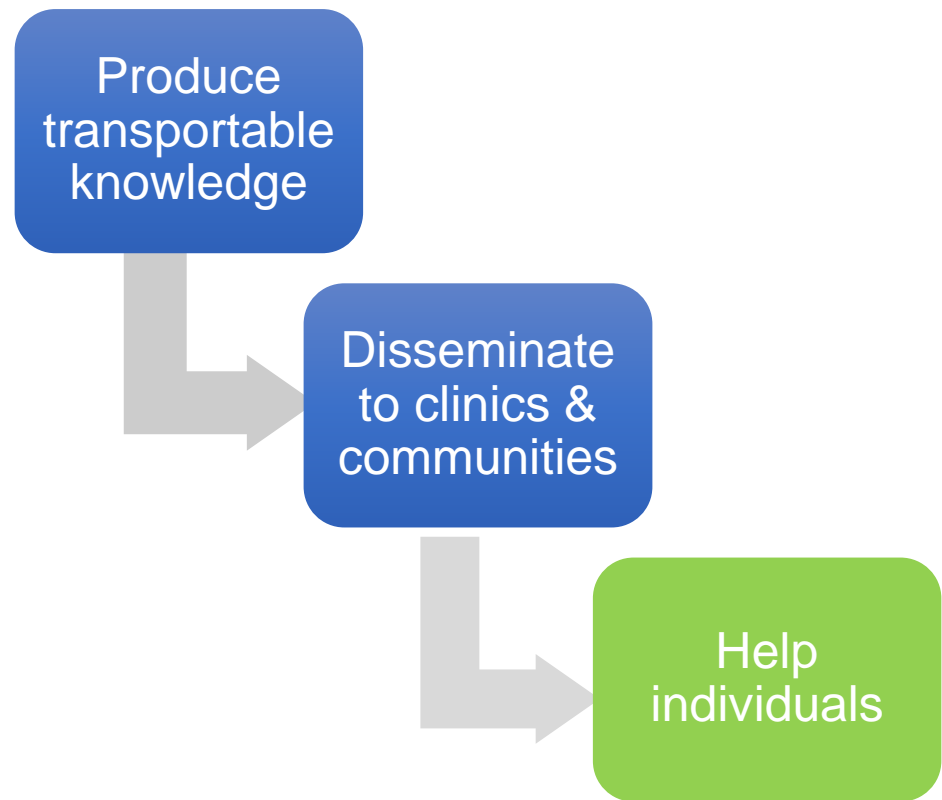


EXAMPLE: Precision Population Health Approach to ACEs to Reduce Health Disparities

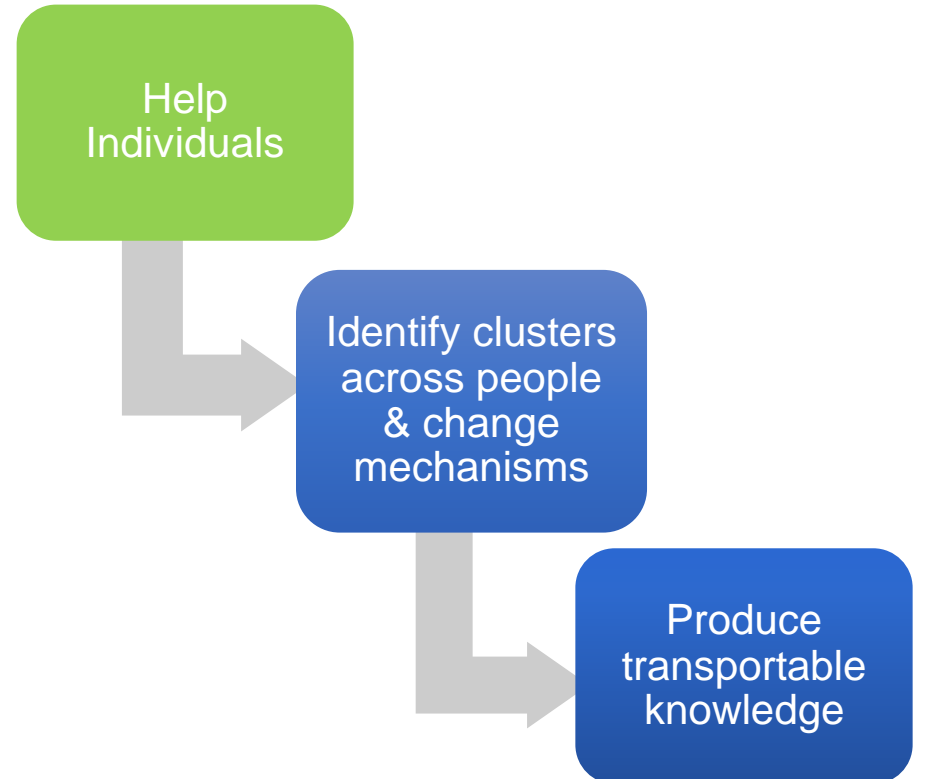


FHCS	Promotores	County (via SDCOI)	Resident Leaders	Streetwyze
prevention, treatment, and surveillance resources for ACES / trauma-types & advancing trauma-responsive relationships between FHCS & all providers, including promotores	emphasis on supporting trauma-responsive relationships & navigation within FHC & county for families	prevention, treatment, and surveillance resources for ACES / trauma types & supporting trauma-responsive relationships between families and County	emphasis on social and structural determinants of health and family relationships with community	detection of real-time risk factors of social and structural determinants of health for ACES / trauma types & as a social network for families to share what's working and what's not on referrals

Big Data Paradigm



Small Data Paradigm



How small data might help

- Success criteria defined by and for an individual
- Including the individual is uniquely valuable for studying phenomena that manifest idiosyncratically
- Dynamic support tools can be built around meaningful decision points
- Including the individual can help to rule out some variables

How do you measure mechanisms of action?

coleman.ucsd.edu/research/

cws.ucsd.edu

Center for Wearable Sensors brochure (PDF)

Neural Interaction Lab

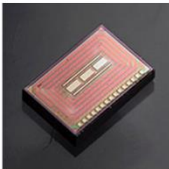
Todd P. Coleman | UCSD Bioengineering

Electrical Digestive Engineering



APRIL 19, 2018 Clinical Trial Tests Tattoo Sensor as Needleless Glucose Monitor for Diabetes Patients

A temporary tattoo for glucose monitoring developed by engineers at UC San Diego is being tested in a phase I clinical trial. The study will test the tattoo sensor's accuracy at detecting glucose levels compared to a traditional glucometer. The clinical trial is enrolling 50 adults, ages 18 to 75, with either type 1 or 2 diabetes or diabetes due to other causes. [Full Story](#)



APRIL 10, 2018 Tiny injectable sensor could provide unobtrusive, long-term alcohol monitoring

Engineers have developed a tiny, ultra-low power chip that could be injected just under the surface of the skin for continuous, long-term alcohol monitoring. The chip is powered wirelessly by a wearable device such as a smartwatch or patch. The goal of this work is to develop a convenient, routine monitoring device for patients in substance abuse treatment programs. [Full Story](#)

www.nalshurafa.com/portfolio.html#prettyPhoto



Body Image Myrror

Introducing Myrror, the device that seeks to revolutionize the prevention of eating disorders and over-exercising.



Speed Eating

Hand to mouth gesture detection.



How do you measure mechanisms of action?

Secure | <https://md2k.org/research-agenda/biomarkers>



Advancing biomedical discovery and improving health through mobile sensor Big Data

ABOUT RESEARCH SOFTWARE TRAINING DEPLOYMENTS EVENTS MHEALTHHUB RELATED PROJECTS



October 3, 2017

Digital Phenotyping Technology for a New Science of Behavior

Thomas R. Insel, MD¹

» Author Affiliations

JAMA. 2017;318(13):1215-1216. doi:10.1001/jama.2017.11295

BiliCam

An alternative for detecting newborn jaundice – which can lead to brain damage and death – using a smartphone's camera and flash. Instead of looking for "yellowness" in the skin, the camera and flash together measure the amount of bilirubin in the blood by examining wavelengths of light absorbed by the skin. In the U.S., this app will enable parents and general practitioners to screen before involving a specialist. In many parts of the world, midwives and traveling nurses more commonly deliver babies. Currently they have no screening tool for jaundice; this app will provide them with one.

HemaApp

A means of measuring total hemoglobin in the blood using a smartphone's camera and flash. Many health conditions – such as anemia, malnutrition and pulmonary illnesses – impact hemoglobin levels. This app is not only a disease screening tool but it can also help medical professionals assess the nutritional well-being of individuals and communities. Current monitoring requires blood samples or expensive equipment. By eliminating the need for blood draws, HemaApp alleviates concerns about sample contamination or infection.

SpiroSmart

Hundreds of millions of people worldwide suffer from chronic respiratory diseases, and millions die each year. SpiroSmart measures lung function by having the patient blow into a phone's microphone, replacing an expensive dedicated spirometer for diagnosing and managing asthma, cystic fibrosis and other pulmonary diseases. SpiroCall is a related project that is particularly useful in low resource settings where smartphone access is limited. It turns any ordinary phone into a spirometer through a toll free calling service.

BPSense

Measures blood pressure by using Pulse Transit Time (PTT) analysis, the time taken for a pressure pulse to travel through the arteries. One method uses a phone's dual camera to measure a person's pulse at his/her fingertip and ear simultaneously. A second method uses a phone's microphone and camera to listen to the patient's heart beat and measure pulse at his/her fingertip. In addition to tracking, BPSense can also remind individuals to check their blood pressure at various times throughout the day.

CoughSense

Coughing is the number one symptom individuals report when experiencing an illness. Currently, to assess coughing, patients are asked to self-monitor or wear specialized equipment. CoughSense uses the phone's microphone to monitor cough frequency for a single person or, when networked, to track trends across an entire population. In this way, it will be an important tool in monitoring the spread of diseases such as influenza or tuberculosis through pattern recognition in high-density areas. Further analyzing the cough signal could uncover the cause of certain symptoms.

health @ ubicomplab
UNIVERSITY OF WASHINGTON

Enabling smart care through smartphones

<http://ubicomplab.cs.washington.edu>

Ubiquitous Computing Lab
University of Washington
Professor Shwetak N. Patel