Controversial Comparators in Behavioral Trials

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Invited Session #1
Controversial Issues in Behavioral Trial Methodology
May 20, 2024

2024 BOSTON

SCT | 45TH ANNUAL MEETING

Disclosures

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  The Foundation for Barnes-Jewish Hospital

- Consulting Relationships: None
- Stock Equity: None
- Speaker's Bureaus: None

Overview

- Comparators for medical trials
- Comparators for behavioral trials
  - Complexities
  - Controversies
  - Guidance
- Conclusions and recommendations

Comparators for Medical Trials

- The comparator is a given in most medical trials.
  - And reviewers usually accept it without any pushback.
- Nevertheless, there are some controversies surrounding medical trial comparators.
- Examples:
  - Standard-of-care controls in pivotal cancer trials
  - Inappropriate placebo and sham controls

Standard-of-Care Controls in Pivotal Cancer Trials

- New cancer drugs are often compared to standard-of-care therapies (not placebos).

- Hilal et al. (2019) examined 97 oncological RCTs with SOC controls (2013-2018).
  - 95 led to FDA approvals.
  - **16/95 (17%) had suboptimal SOC control conditions.**
    - Control participants received "straw man" comparators instead of the current standard of care.
  - These trials led to the approval of drugs that may not have been superior to the standard of care.

Hilal et al. *JAMA Oncology* 2019;5(6):887-892.

Inappropriate Placebo or Sham Controls in Medical Trials

- *Perfect resemblance* is the goal when designing placebo or sham controls.
  - The placebo or sham should be completely indistinguishable from the active treatment, if possible.
  - Perfect resemblance is often achievable, but not always.
  - Sometimes attempts to achieve it can backfire.
- E.g., a bitter ingredient was added to the placebo in trials of Tamiflu (oseltamivir), an antiviral used to treat influenza A and B, to mimic the taste of the drug.
  - But the additive was also known to cause G.I. symptoms.
  - This biased the drug-placebo comparison for adverse G.I. effects.
  - Result: potential harms were underestimated.

Webster et al. *Eur J Clin Invest* 2019;49(11):e13169

Choosing Comparators for Behavioral Trials

- Despite these controversies, comparators are usually easy to choose in medical trials.

- It can be much harder to choose the comparator for a behavioral trial.

  - There are many possibilities.
  - Some are controversial.
  - Uncertainty among investigators & reviewers is common.
  - No explicit rules and little guidance until recently.

Example: "Attention Controls"

- So-called "attention control" or "attention-placebo control" conditions are both popular and problematic in behavioral intervention research.
- Many researchers believe that behavioral trials can't be internally valid or rigorous if they do not control for attention and/or placebo effects.
- I strongly disagree, for several reasons.
- Two of the most serious drawbacks concern:
  - Design failures.
  - Mismatches between trial aims and comparator choices.

The Origins of Attention Control Mythology

- In the early years of psychotherapy research, treatments were often compared to wait-list or no-treatment controls.
  - Common criticisms:
    - You're merely showing that psychotherapy is better than nothing. We're not impressed.
    - You're setting a lower bar for efficacy than drugs are held to (drug trials control for placebo).
- These criticisms cast a pall over psychotherapy research.
- This led to pressure to use more stringent control conditions in behavioral trials.
- Misguided solution: Let's emulate drug trials.

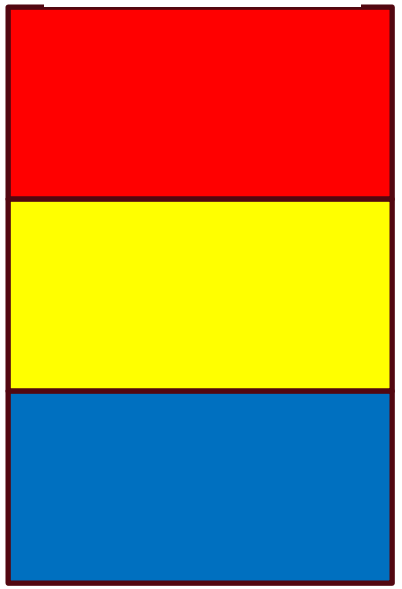
Placebo Controls in Drug Trials Are Not Like Attention Controls in Behavioral Trials

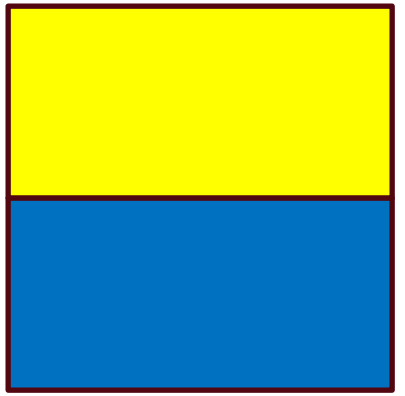
- Thanks to double-blinding and superficially identical pill-like objects…
  - …it's possible to extract the active ingredient from a pill and leave only its placebo value behind.
  - …all patients can also be given standardized *clinical attention* that does not differ qualitatively or quantitatively between the drug and placebo arms.

- Clinical management in drug trials focuses on adherence, symptoms, etc.
  - It's medically necessary and makes sense to patients and clinicians.
  - It provides meaningful clinical attention.

- In a typical drug trial, (1) the active ingredient, (2) the pill's placebo value, and (3) clinical attention are *dissociable.*

Typical Drug Trial





Active Ingredient (Chemical)

Placebo

Clinical Attention

Drug Arm

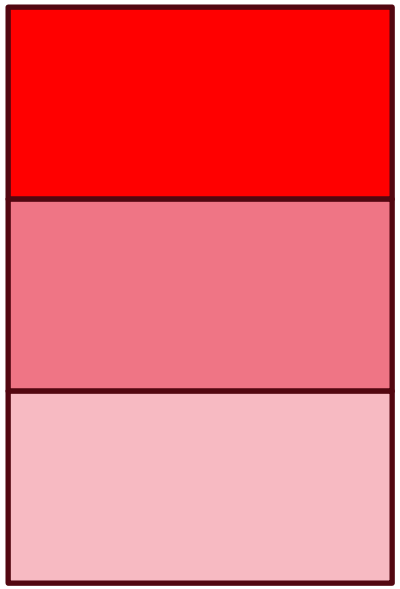
Placebo Arm

Placebo Controls in Drug Trials Are Not Like Attention Controls in Behavioral Trials

- Thanks to *single*-blinding and the interpersonal aspects of behavioral interventions,
  - …it's *impossible* to extract the active ingredients from a behavioral intervention and leave only the placebo value behind.
  - …the clinical attention and placebo effects are entangled with the delivery of the active ingredients.
- Clinical attention in behavioral intervention arms combines nonspecific factors (e.g., emotional support) with active ingredients (e.g., delivery of therapeutic content).
- Clinical attention in "attention control" arms inevitably combines attention with some *other* intervention – usually one designed to fail and fool the participants.
  - Clinical attention cannot be delivered "naked;" it has to be cloaked in "therapeutic" activities.
- For these reasons, (1) the active ingredients, (2) the placebo value, and (3) clinical attention are usually *not* dissociable in behavioral trials.

Typical Behavioral Trial

There are *genuine* active ingredients in the intervention arm,
pseudo-active ingredients in the control arm,
and *different* placebo ingredients and attention between arms.

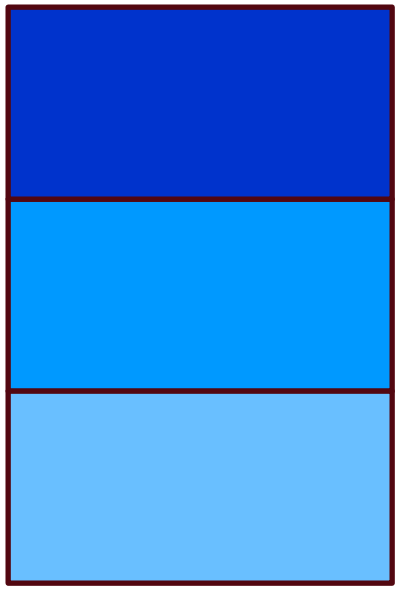


Intervention Arm

"Active Ingredients"

Placebo

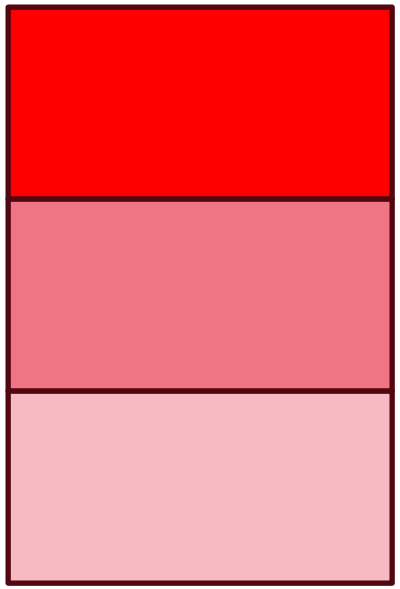
Clinical Attention



Attention Arm

Typical Behavioral Trial

This is not equivalent to a placebo-controlled drug trial.
It's essentially a comparative trial of a real vs. a bogus intervention.

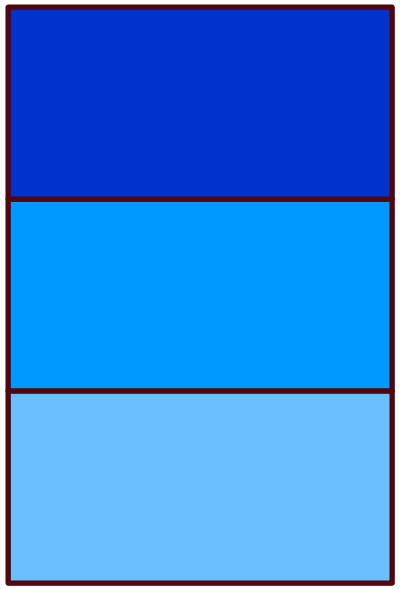


Intervention Arm

"Active Ingredients"

Placebo

Clinical Attention



Attention Arm

Misalignment Between Aims and Trial Design

- This design conundrum is one issue.
- Misalignment is arguably an even more important issue.
- Primary purpose of a placebo-controlled drug trial:
  - ISOLATE THE EFFECT OF THE PHARMACEUTICAL CHEMICAL.
  - The trial design matches the purpose of the trial.
- Primary purpose of an attention-controlled behavioral trial:
  - ISOLATE THE EFFECT OF THE THERAPY'S ACTIVE INGREDIENTS.
  - The design does not fit this purpose.
  - The purpose itself is misguided.

Rethinking the Purpose of Behavioral Efficacy Trials

- Nonspecific ingredients (e.g., empathy, active listening, etc.) are an *integral* part of complex, human-delivered behavioral interventions.
  - Isolation of the active ingredient effect is not very informative.
- Better approach:
  - Maximize the quality of the nonspecific ingredients.
  - Concentrate on optimizing the active / specific ingredients.
  - Evaluate the efficacy of the optimized intervention relative to a *clinically meaningful* comparator, even if this results in nonspecific differences (e.g., contact time) between groups. e.g.
    - Usual care, standard of care, or best available, evidence-based intervention
  - Results indicate whether the intervention is superior to genuine existing practices rather than to an artificial "attention-control" intervention.

Changing Beliefs

- Controlling for attention seems sensible.
  - Balancing attention between groups seems aesthetically pleasing.
  - But it doesn't make sense, and it's counterproductive.
  - It's the most common problem in the selection of comparators for behavioral trials.
  - But it's not the only one.

- What's the alternative to basing control group choices on obsolete traditions?
  - Make use of one or more of the contemporary guidance frameworks for comparator choices in behavioral trials.

Recommended Guidance Papers

Freedland KE, et al.; NIH Office of Behavioral and Social Sciences Research Expert Panel on Comparator Selection inBehavioral and Social Science Clinical Trials.
The selection of comparators for randomized controlled trials of health-related behavioral interventions: recommendations of an NIH expert panel. J Clin Epidemiol. 2019 Jun;110:74-81.

Freedland KE. **Purpose-guided trial design in health-related behavioral intervention research.** Health Psychol. 2020 Jun;39(6):539-548.

Gold SM, Enck P, Hasselmann H, Friede T, Hegerl U, Mohr DC, Otte C. **Control conditions for randomised trials of behavioural interventions in psychiatry: a decision framework.** Lancet Psychiatry. 2017 Sep;4(9):725-732.

Conclusions

- The comparator should fit the purpose of a behavioral trial.
- Attention control conditions often seem intuitively appropriate.
  - But they seldom fit the purpose of the trial.
  - They’re often used when investigators (and reviewers) lack clarity about the purpose of a trial.
- Guidance frameworks have been published to promote more rational decision-making about comparators in behavioral trials.
  - Please make use of them.

Thank you for your attention.

It was very therapeutic.

I feel much better now.

Equipoise in Single-Blind Trials

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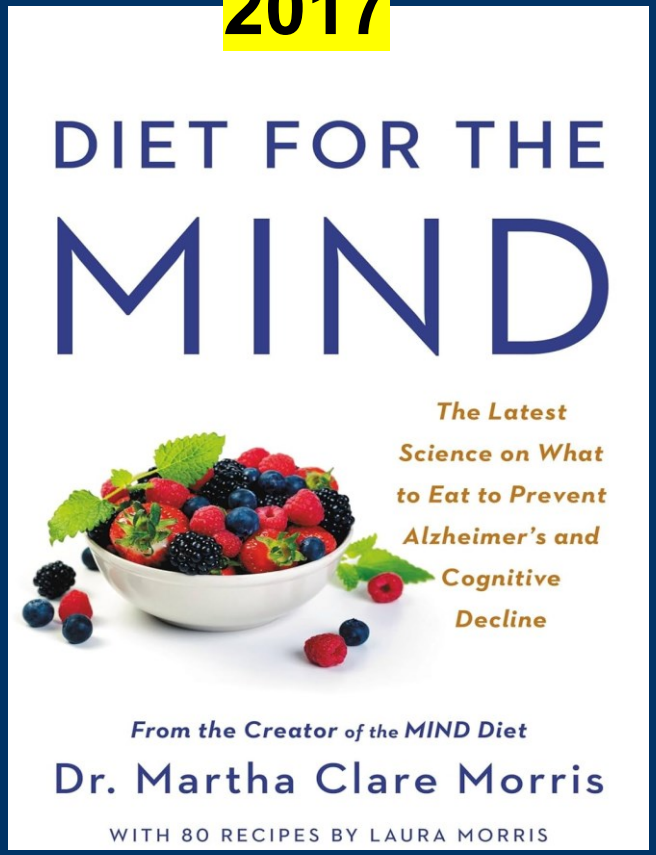
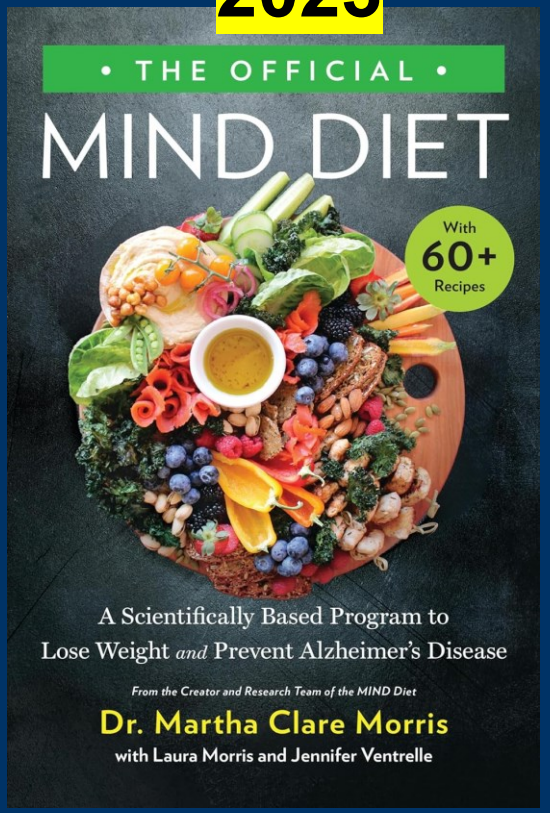
MIND Diet for prevention of cognitive decline

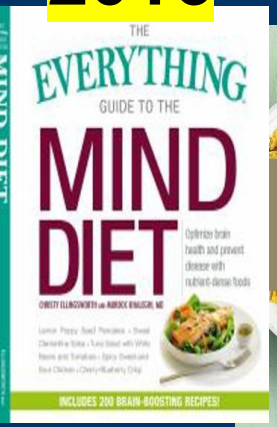
2017



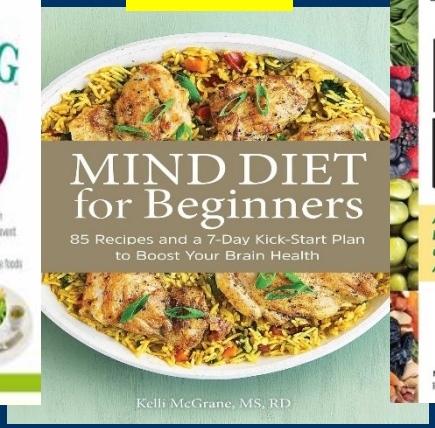
2023



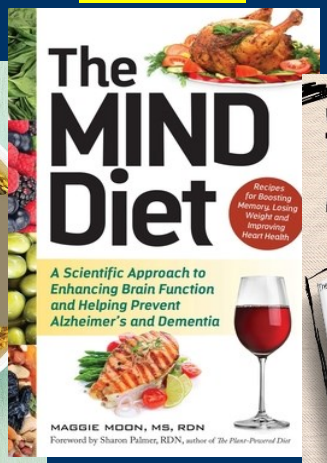
2016



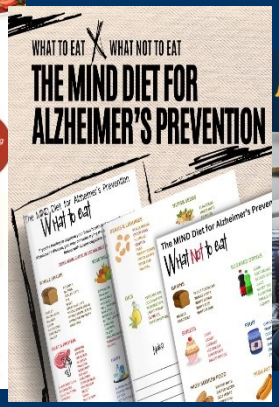
2017



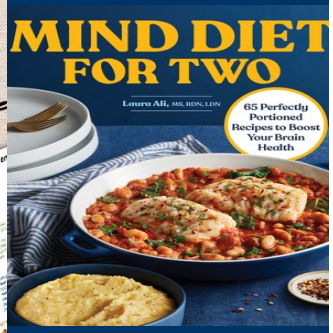
2021



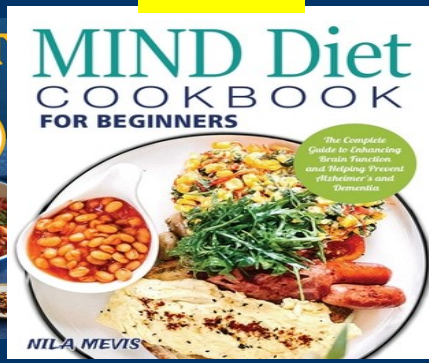
2021



2022



2022



Trial of the MIND Diet for Prevention of Cognitive Decline in Older Persons

Barnes . . . Morris. *NEJM* **2023**

DESIGN

--604 older adults with family history of dementia

--Enrolled in the trial in **2017-2018**

--Randomized to:

MIND diet

Standard Caloric Restriction

RESULTS

--Null trial.

--Both groups improved at 3 years:

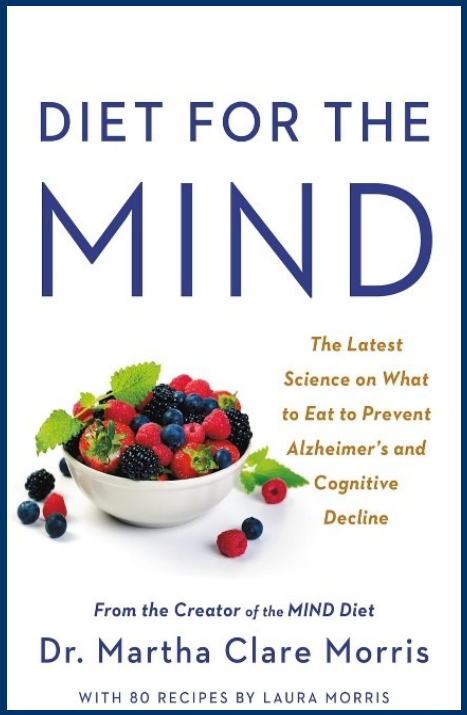
--Global cognition

--Structural changes in brain from MRI

--Reduction in weight

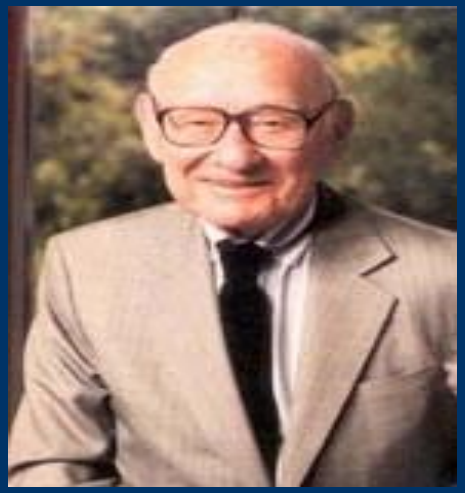
--Improvement in the Mind Diet Score

2017

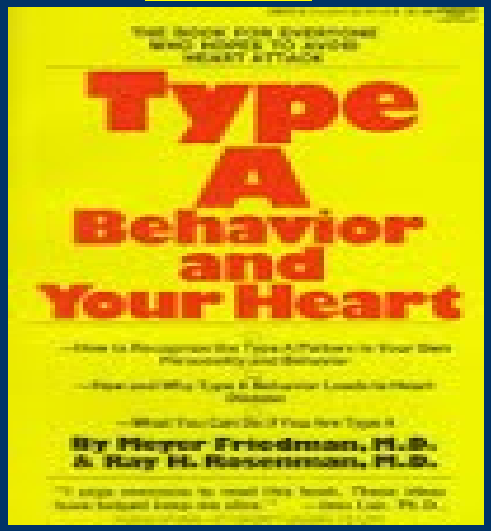


The Recurrent Coronary Prevention Project

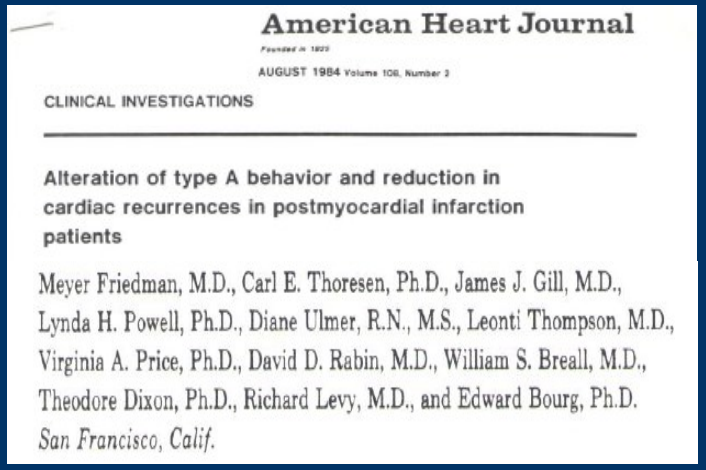
Meyer Friedman, MD



1974



1984


American Heart Journal

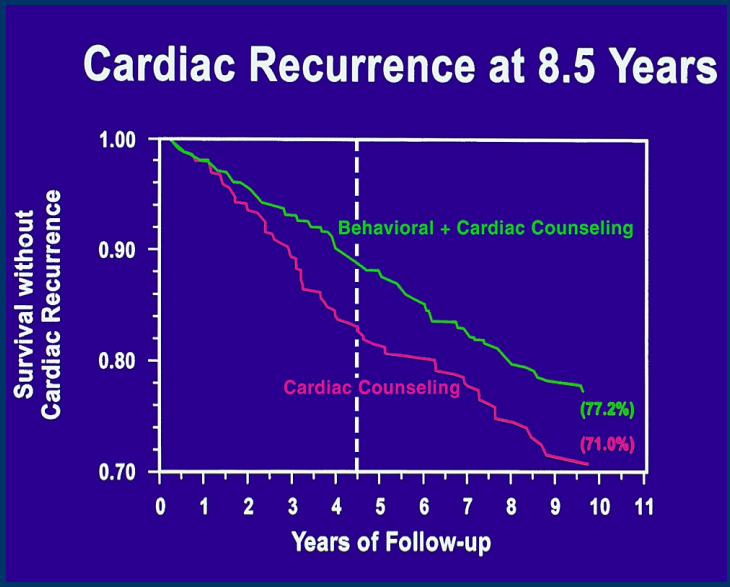
AUGUST 1984 Volume 108, Number 2

CLINICAL INVESTIGATIONS

Alteration of type A behavior and reduction in cardiac recurrences in postmyocardial infarction patients

Meyer Friedman, M.D., Carl E. Thoresen, Ph.D., James J. Gill, M.D., Lynda H. Powell, Ph.D., Diane Ulmer, R.N., M.S., Leonti Thompson, M.D., Virginia A. Price, Ph.D., David D. Rabin, M.D., William S. Breall, M.D., Theodore Dixon, Ph.D., Richard Levy, M.D., and Edward Bourg, Ph.D.

San Francisco, Calif.



REPUTATION INFLUENCES:

--Acceptance rates for publication in journals

--Critique of methods

(Okike et al., 2016)

Lack of Equipoise and Preference for a Trial Result Bias Single-Blind Clinical Trials

EQUIPOISE

"A state of genuine uncertainty on the part of the investigator regarding the comparative therapeutic merits of each arm in the trial."

Freedman *NEJM* 1987

PREFERENCES

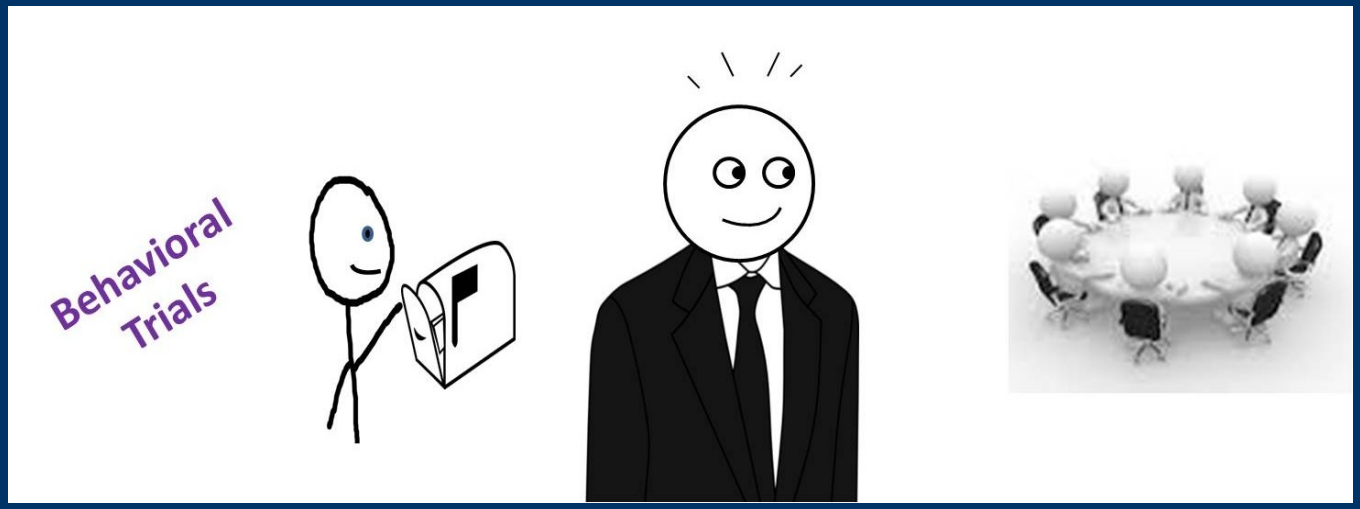
Investigator is not objective. Has a clear preference for a particular trial result

Sackett *J Chron Dis* 1979
Chalmers & Matthews *Lancet* 2006

Single-Blind Behavioral Trials Lack Design Control Achieved with Double-Blind

DOUBLE-BLIND
(Subjects, Staff, Investigators Blinded)

SINGLE-BLIND
(Outcomes assessors blinded; Staff, Investigators Unblinded)



Single-Blind Behavioral Trials Receive Lower Clinical Trial Quality Ratings

Trial Evaluation System	Maximum Score	Relevant Item	Maximum Score Behavioral Trial
Jadad, 1996	7 points	Double-Blind?	6 points
Delphi, 1998	8 points	Patient Blinded?	7 points
CONSORT, 2010	22 points	Patients, Providers Interventionists Blinded?	21 points
Cochrane, 2003	10 points	Patient Blinded?	8 points
		Provider Blinded?	

Berger & Alperson, *Rev Recent Clin Trials* 2009

Consequences of Single-Blind

PLACEBO RESPONSE

Belief in treatment can improve outcome, inflate effect size, risk type 1 error, and provide an alternative explanation for results

SURGERY FOR KNEE PAIN: Real vs. Sham Surgery (Moseley *NEJM* 2002)

Decrease in pain	No difference (33% in both)
Improvement in physical function	No difference
Benefits of Sham sustained over 2 years	

ACUPUNCTURE FOR BACK PAIN: Real Acupuncture vs. Sham vs. No Treatment (NCCIH Review, 2000)

Acupuncture vs. Sham	No difference
Sham vs. No Treatment	Significant difference

IRRITABLE BOWL SYNDROME: Open Placebo vs. No Treatment (Kaptchuck et al., 2010)

Symptom Severity	Significant difference
Quality of Life	Significant difference

Consequences of Single-Blind

POST-RANDOMIZATION BIAS

Differential value placed on specific arms can threaten equality produced at the time of random

Co-Intervention Bias	Compensatory “Underdog” adjustment where providers prescribe differential medications, therapies, or programs
Treatment Crossover	Participants seek favored treatment on their own.
Ascertainment Bias	Differential outcome assessment based upon based differential outcomes expectations
Differential Drop-Out	Expectation of benefit influences enthusiasm for continuation

Symptoms of Bias

INFECT ETHOS OF CLINICAL TRIAL TEAM

CONVERSATIONS *"I am going to prove this hypothesis."*

"Poor Mr. Smith got into the control group."

TRIAL DESIGN *"If I use a usual care comparator, participants will get something or nothing"*

Use of many primary outcomes to control "spin"

REPUTATION Principal Investigator seen as a "*True Believer*"

Recommendation

ONGOING MONITORING

Ongoing assessment of differential by arm:

- treatment crossovers
- co-interventions
- attrition
- adherence

Evaluate Risk of Bias: Higgins et al. Cochrane Risk of Bias Scale, BMJ 2011

Independent monitoring of quality and adherence

Recommendation

EXTEND THE BLIND

BLINDING OPTIONS	PLAYERS
Assessment of Outcomes	Outcomes Assessors
Treatment Assignment	Statistician
Trial Hypotheses	Principal Investigator
Trial Aims	All
Labels for Trial Arms	All
Details of the Intervention	Research Assistants
Passion for the Intervention	Interventionists
Descriptions of Trial Design	Data and Safety Monitoring Board
	IRB
	Grant Reviewers

Recommendation

EXTEND THE BLIND

Blind to Hypotheses, Not to Aims

"*We are comparing two treatments.*

Treatment A requires attendance at weekly group meetings.

Treatment B requires reading educational tip sheets sent weekly in the mail.

We do not know if either of these treatments is effective for your condition."

Recommendation

EXTEND THE BLIND

Table 1. **Extending the blinding in a behavioral trial**

	BLINDING OPTIONS					
PLAYERS	**Trial Hypotheses**	**Trial Aims**	**Subject Treatment Assignment**	**Outcomes**	**Implementation**	**Details of the Intervention**
Principal Investigator	U	U	B	B	U	U
Co-Investigators	B/U	U	B	B	U	B/U
Statistician	U	U	U	U	U	B
Project Director	B	U	B	B	U	U
Interventionists	B	U	U*	B	U*	U*
Research Assistants	B	U	B	B	U	B
Subjects	B	U	U*	B	U*	U*
Subject's Physicians	B	U	B	B	B	B
Outcome Assessors	B	B	B	B	B	B
IRB	U**	U	B	B	B	U
Data Safety & Monitoring Committee	U	U	U***	U	U	U

U = Unblinded; B = Blinded
** Unblinded only within own arm*
***IRB Protocol unblinded; consent form blinded*
****Unblinded in the aggregate only; not for individual subjects*

Recommendation

SCIENTIFIC MINDSET

Equipoise is Grounded in Reality

Odds of a Positive Clinical Trial:

1 in 5

- NHLBI big budget clinical trials conducted after 2000 observed a significant benefit in only **8-16%** trials (Kaplan 2015; Gordon 2013).
- When limited to big budget behavioral trials, a significant benefit was observed in only **18%** (Irwin, 2016).

Recommendation

SCIENTIFIC MINDSET

Interim Reports

RESIST TEMPTATION TO:

--examine interim results

--publish interim reports

--risk participant reactivity to early results

INTERIM REPORTS

--are common in behavioral trials and industry-sponsored drug trials

--should be pre-specified, justified, and approved by the independent Data and Safety Monitoring Board.

Recommendation

SCIENTIFIC MINDSET

Passion For the Question;
Not the Answer

"So many scientists suffer from prejudices. Independence from prejudices is the mark of distinction between:

a mere artisan
and
a real seeker after truth."

Albert Einstein, 1944

Recommendation

SCIENTIFIC MINDSET

Keep Preferences Private

LANGUAGE

"We are going to <u>prove</u> this hypothesis."

↓

"We are going to <u>test</u> this hypothesis."

"TRUE BELIEVERS"

Lead the behavioral intervention

Do not lead the clinical trial

Recommendation

SCIENTIFIC MINDSET

Discipline

HOPE

PASSION

EQUIPOISE

Summary

Are you a seeker after truth?

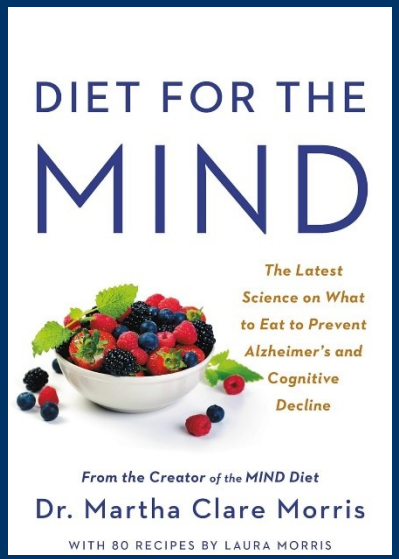
SEEKERS:

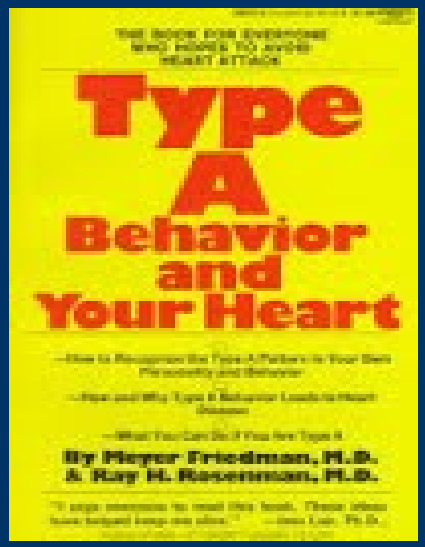
Scientific mindset

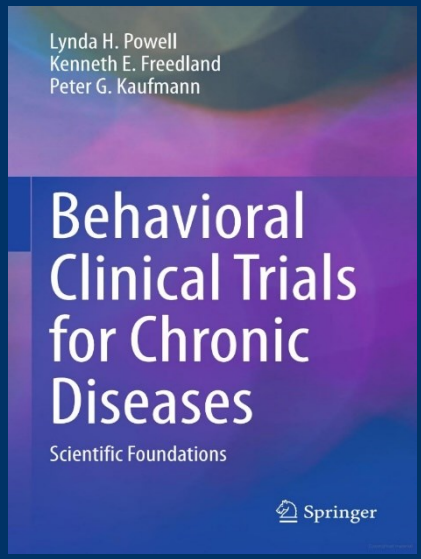
Passion for the question but uncertainty about the answer

Discipline to keep preferences to self

Extend this discipline to all participants, staff, investigators, and operations in a clinical trial







Chapter 10
Preferences, Equipoise, and Blinding

Racial and Ethnic Diversity in Behavioral Clinical Trials

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May 20, 2024

2024 BOSTON

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Disclosures

NO RELEVANT DISCLOSURES

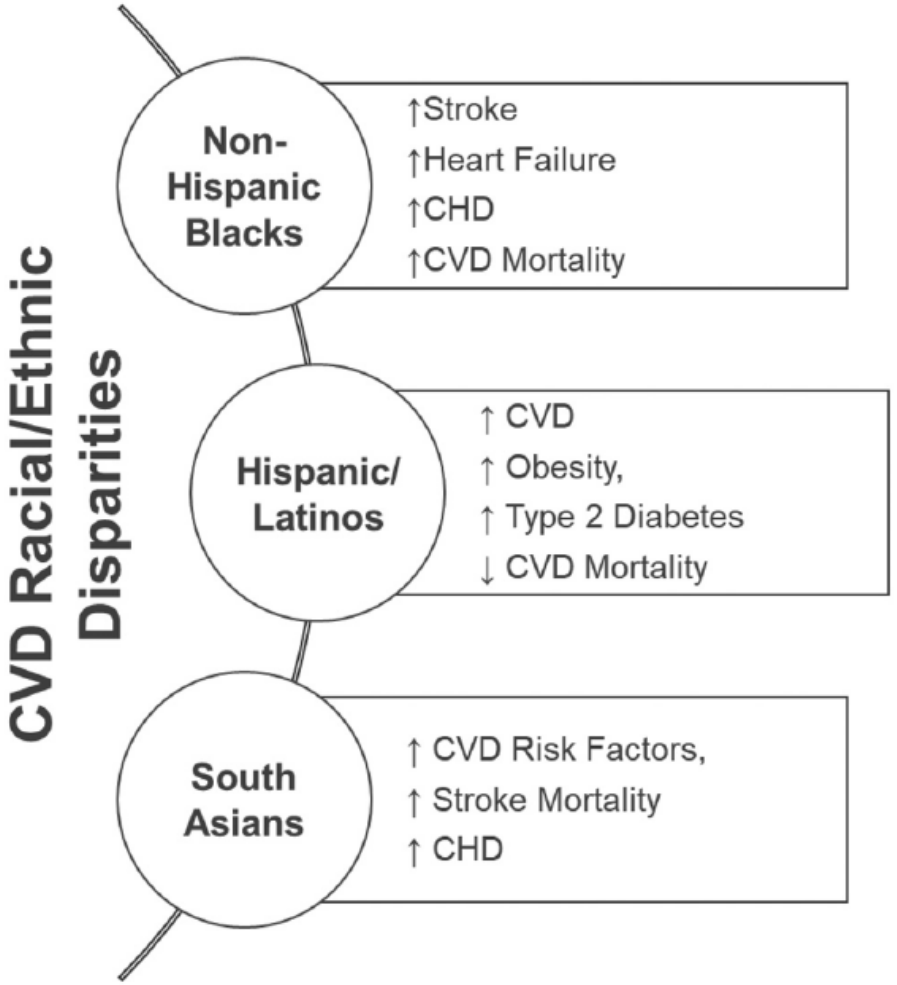
Outline

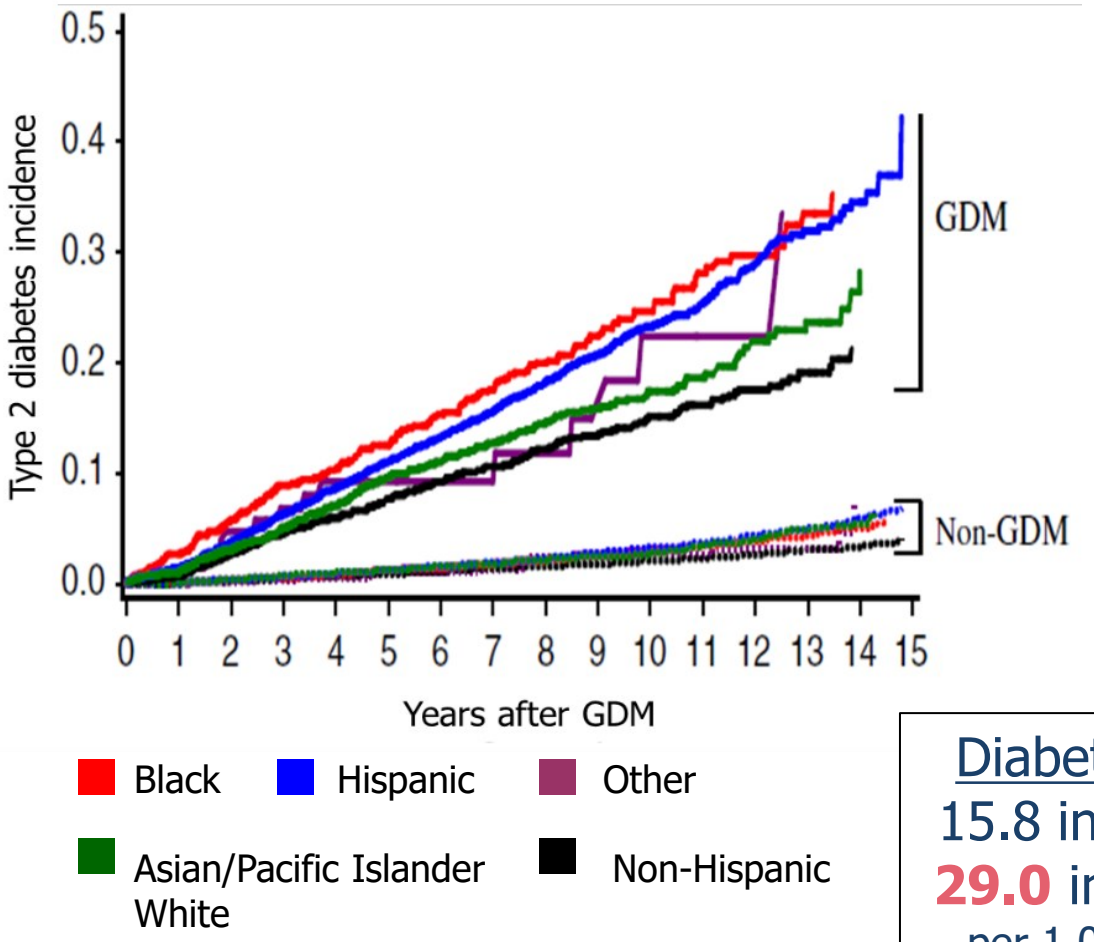
Background and rationale

Participant-Centered Inclusion in Behavioral Clinical Trials

Summary and resources

Racial/ethnic disparities in cardiovascular disease (CVD) & diabetes

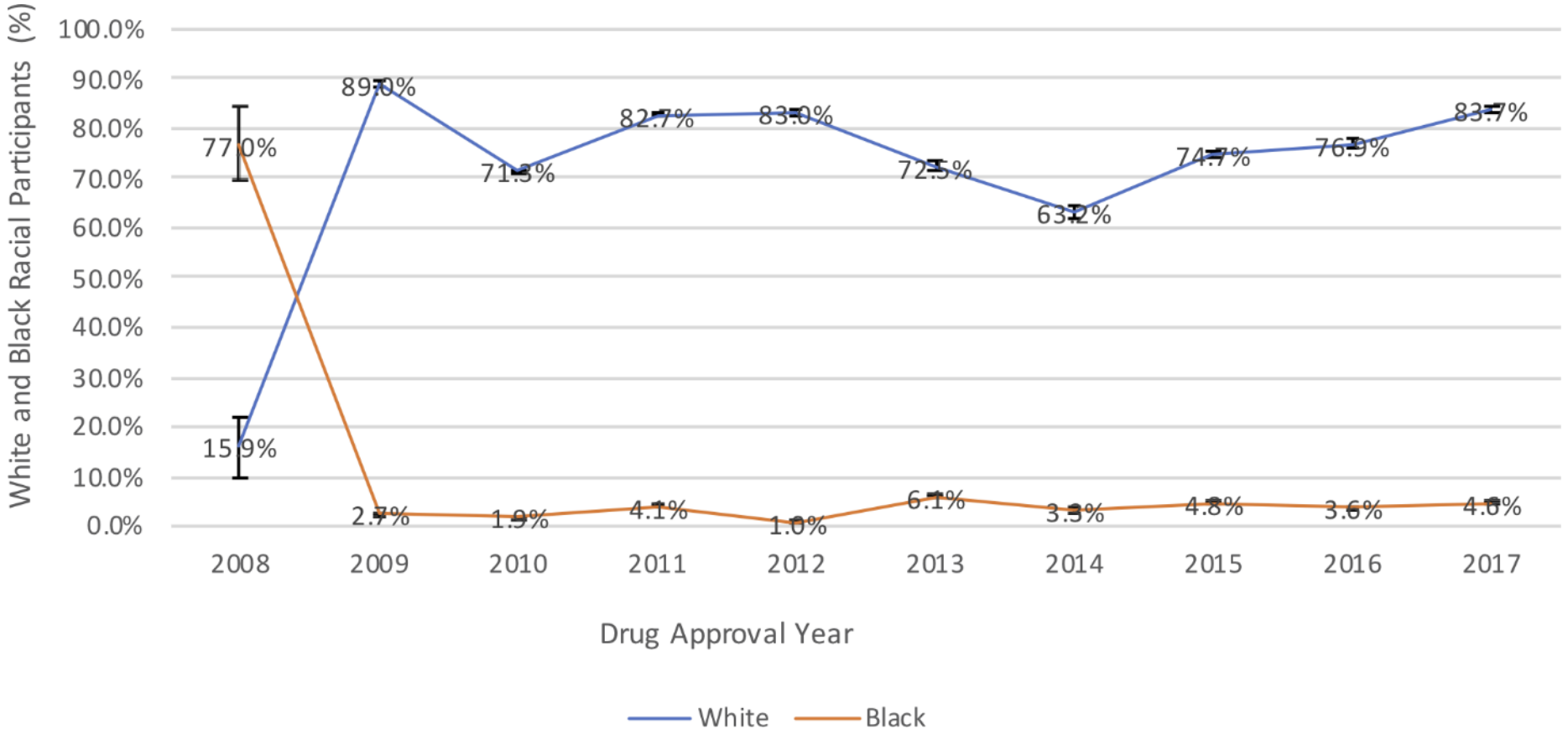




Diabetes incidence:
15.8 in white women
29.0 in black women
per 1,000 person-years

Chirinos et al. 2022. *Health Psy*
Xiang et al. 2011 *Diabetologia*

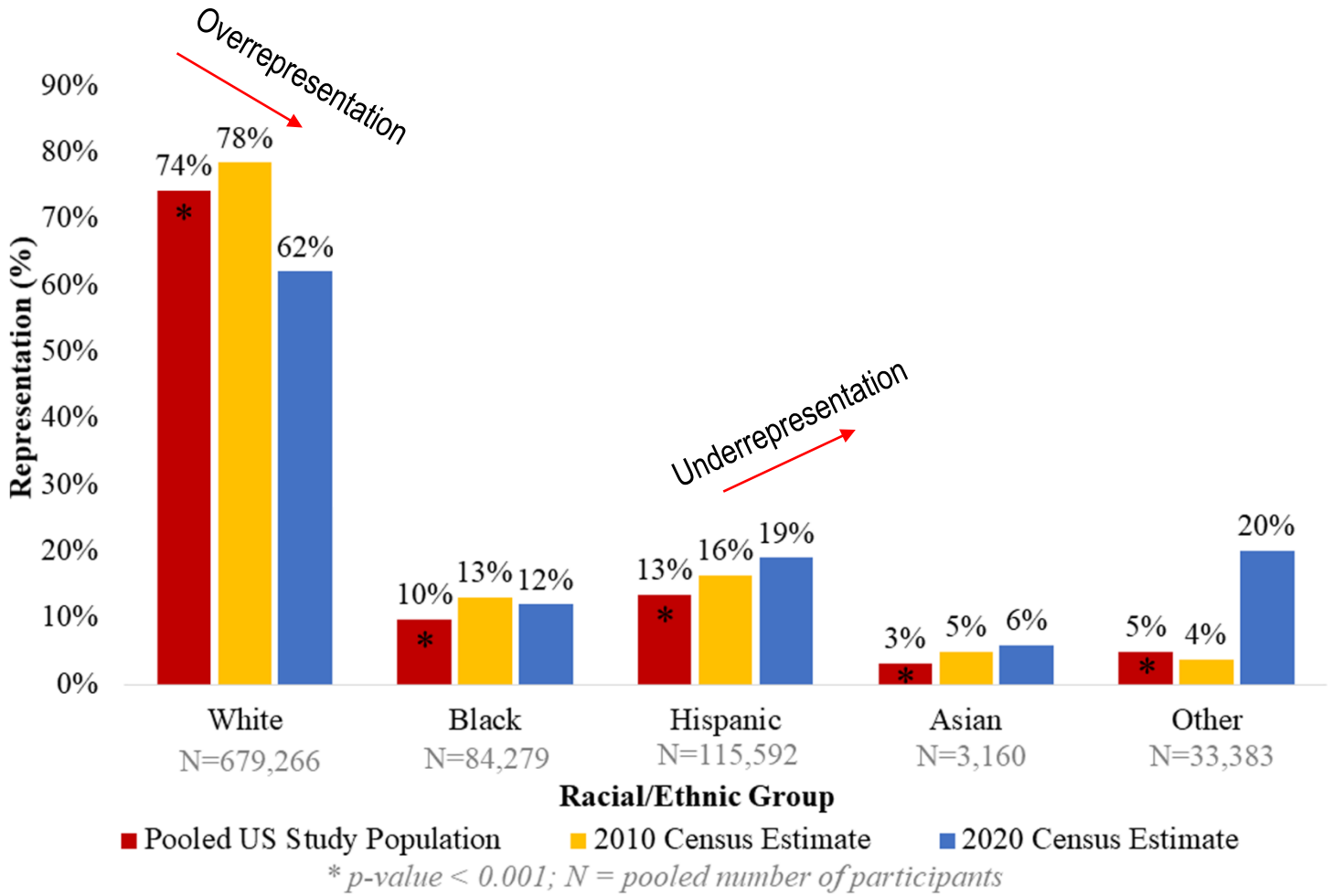
Racial/ethnic underrepresentation in pivotal CVD and diabetes trials



Comparison of overall percentage of white and black people enrolled in pivotal cardiovascular and diabetes drug trials by year of FDA approval

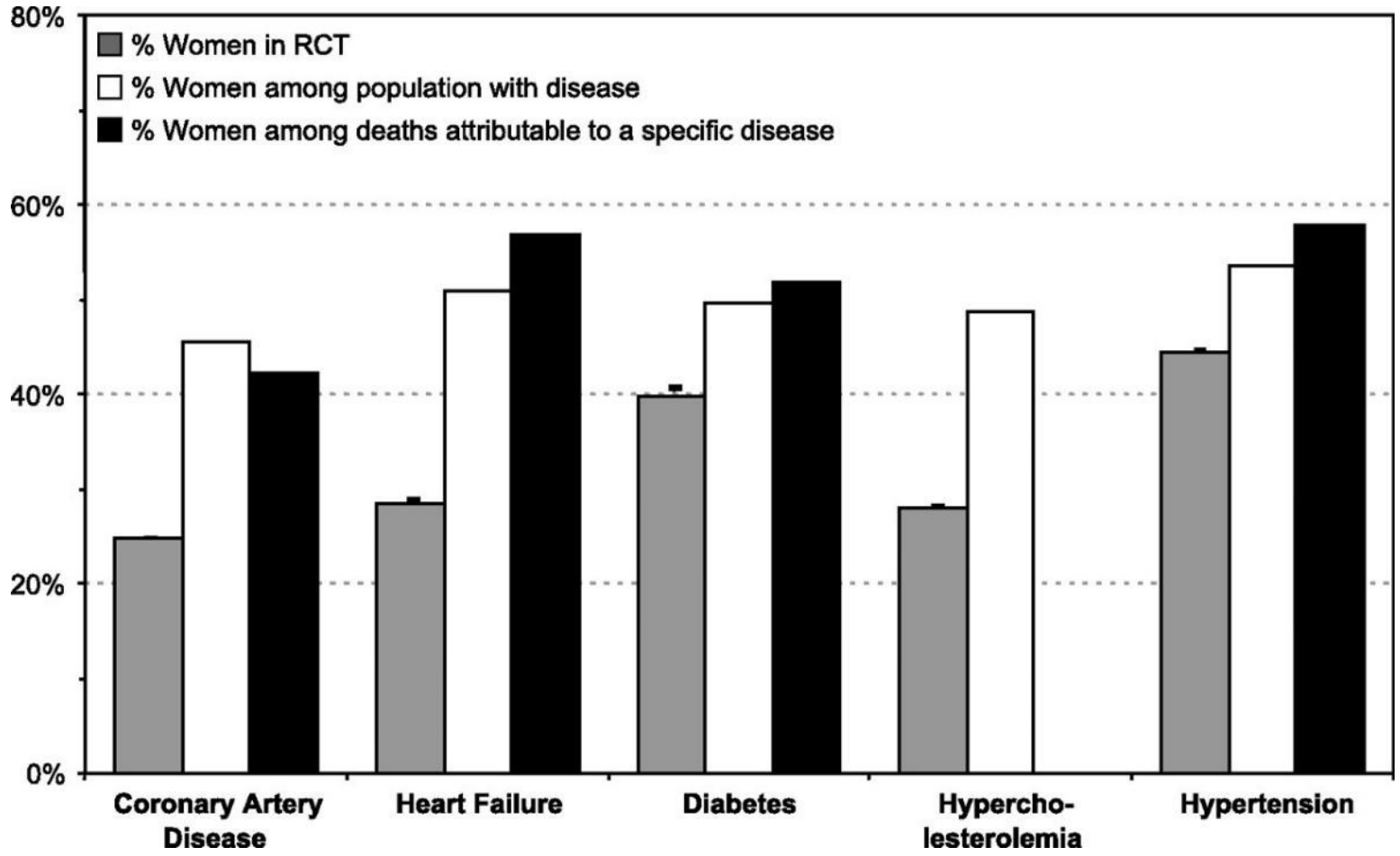
Khan et al. 2020. Ten-Year Trends in Enrollment of Women and Minorities in Pivotal Trials Supporting Recent US FDA Approval of Novel Cardiometabolic Drugs. *J Am Heart Assoc*.

Racial/ethnic underrepresentation in adverse pregnancy outcomes research



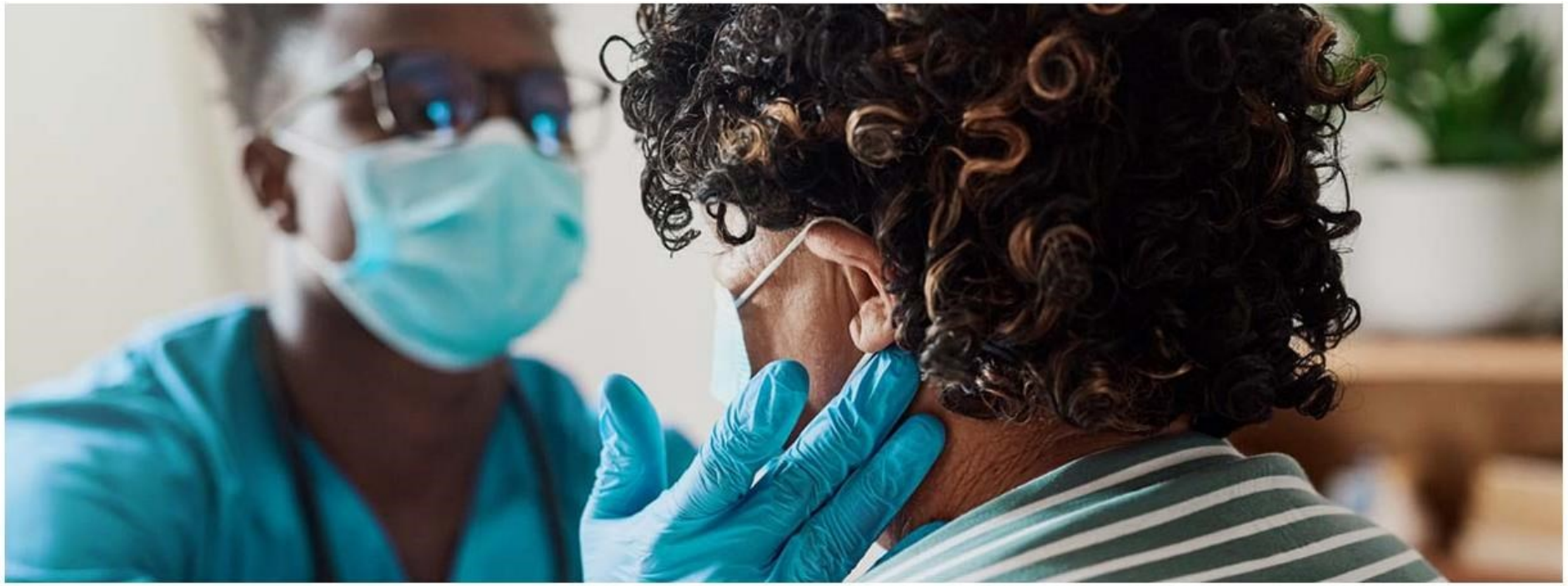
Gomez 2022. Racial and Ethnic Group Underrepresentation in Studies of Adverse Pregnancy Outcomes and Cardiovascular Risk. *J Am Heart Assoc.*

RCTs of CVD prevention: Underrepresentation of women given disease burden



Melloni 2010. Representation of Women in Randomized Clinical Trials of Cardiovascular Disease Prevention. *J Am Heart Assoc.*

National Academies report



SHARE

Lack of Equitable Representation in Clinical Trials Compounds Disparities in Health and Will Cost U.S. Hundreds of Billions of Dollars; Urgent Actions Needed by NIH, FDA, Others to Boost Representation

https://nap.nationalacademies.org/catalog/26479/improving-representation-in-clinical-trials-and-research-building-research-equity

National Academies report

Lack of representation:

Compounds health disparities in populations underrepresented and excluded in clinical trials

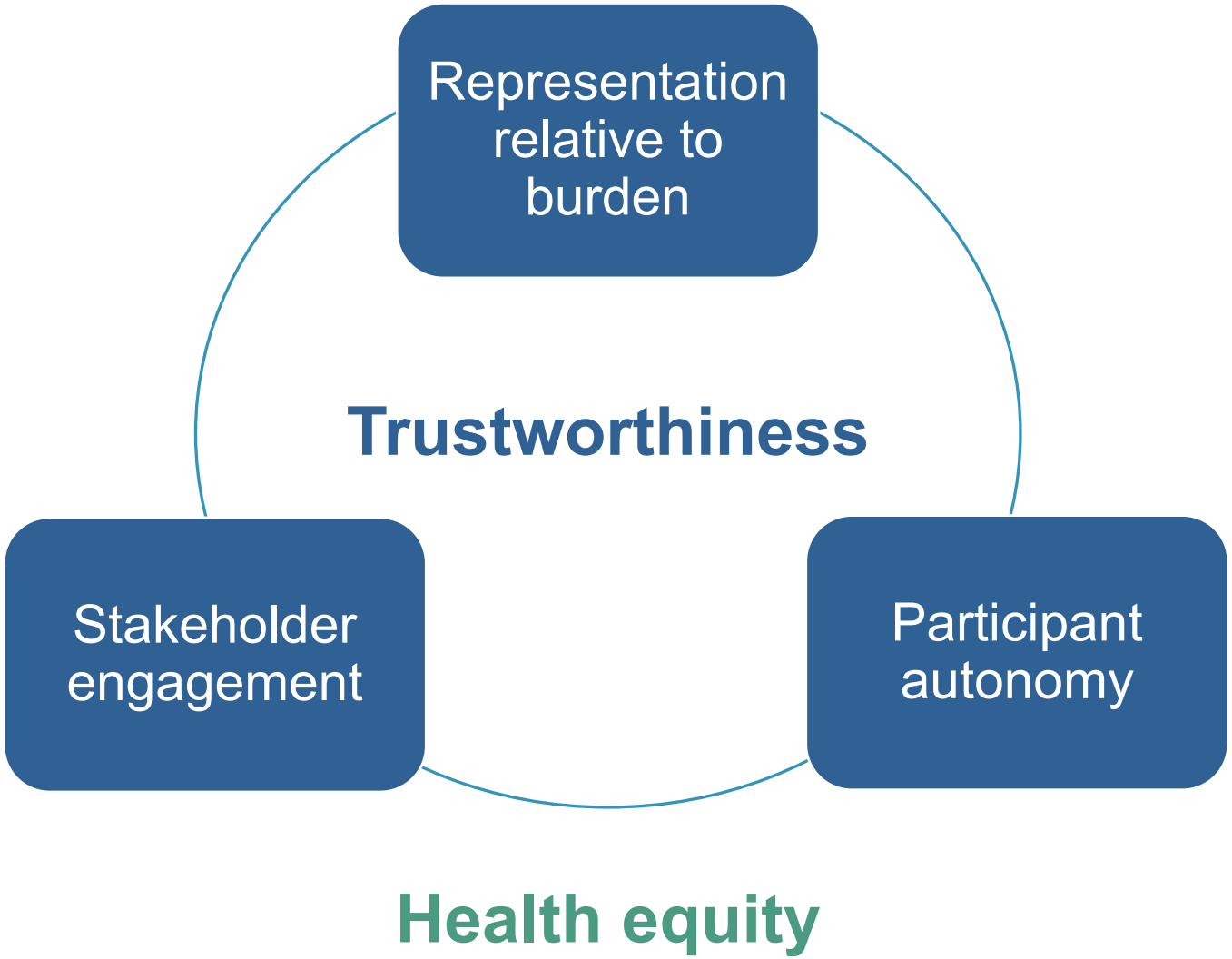
May lead to lack of access to effective medical interventions

Costs hundreds of billions of dollars

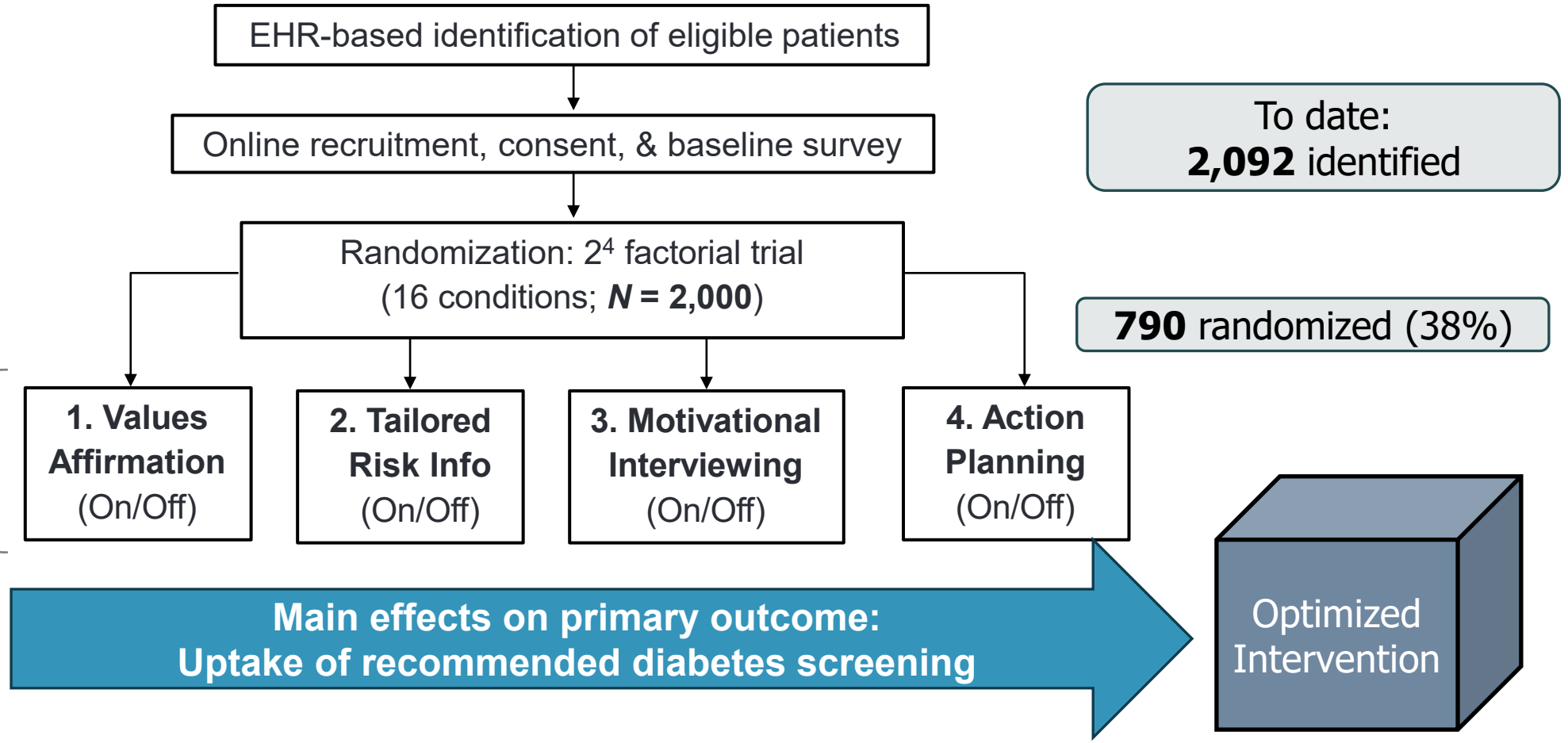
https://nap.nationalacademies.org/catalog/26479/improving-representation-in-clinical-trials-and-research-building-research-equity

Drive equitable behavioral clinical trials using multi-faceted approach to diversity and inclusion

Participant-Centered Inclusion in Behavioral Clinical Trials



SUNRISE Trial



R01 DK122087. Optimization trial: Maximizing postpartum screening after GDM. Brown & Ferrara, MPIs

[1]Brown et al., 2024 *PEC Innovation*

As of 4/4/24

Participant-Centered Inclusion in Behavioral Clinical Trials

Systematic quality improvement

Pre-define goals

Monitor progress

Innovate solutions

Enhance Communication

Team Building

Add Value & Respect Participant Contributions

Listen to Participant & Stakeholder Voices

Build the Science of Inclusive Recruitment & Retention

Example strategies

Brown et al. 2024. International Behavioural Trials Network Conference. *Ann Behav Med* (abstract in press)

Enhance Communication

Minority recruitment techniques

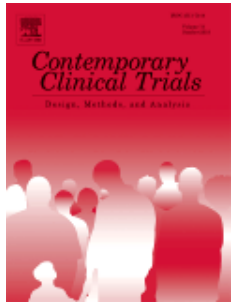
Health disparities statement in recruitment letters

Minority recruitment into clinical trials: Experimental findings and practical implications

Susan D. Brown [a,*], Katherine Lee [a,1], Danielle E. Schoffman [a,2], Abby C. King [a,b], LaVera M. Crawley [c], Michaela Kiernan [a]

[a] Stanford Prevention Research Center, Department of Medicine, Stanford School of Medicine, Stanford, CA, United States

Contemporary Clinical Trials 33 (2012)



Recruitment and Retention

Outreach to diversify clinical trial participation: A randomized recruitment study

Susan D Brown[1], Paula N Partee[1], Juanran Feng[1], Charles P Quesenberry[1], Monique M Hedderson[1], Samantha F Ehrlich[1], Michaela Kiernan[2] and Assiamira Ferrara[1]

Enhance Communication

Orientation Sessions

Promoting trial retention & fully informed consent

American Journal of
Preventive Medicine

RESEARCH METHODS

Methods-Motivational Interviewing Approach for Enhanced Retention and Attendance

Danielle E. Jake-Schoffman, PhD,[1] Susan D. Brown, PhD,[2,3] Michael Baiocchi, PhD,[4] Jessica L. Bibeau, MA, PMP,[5] Jennifer Daubenmier, PhD,[6] Assiamira Ferrara, MD, PhD,[2] Maren N. Galarce, MPH,[2] Wendy Hartogensis, MPH, PhD,[7] Frederick M. Hecht, MD,[7] Monique M. Hedderson, PhD,[2] Patricia J. Moran, PhD,[7] Sherry L. Pagoto, PhD,[5] Ai-Lin Tsai, MA, MS,[2] Molly E. Waring, PhD,[5] Michaela Kiernan, PhD[8]

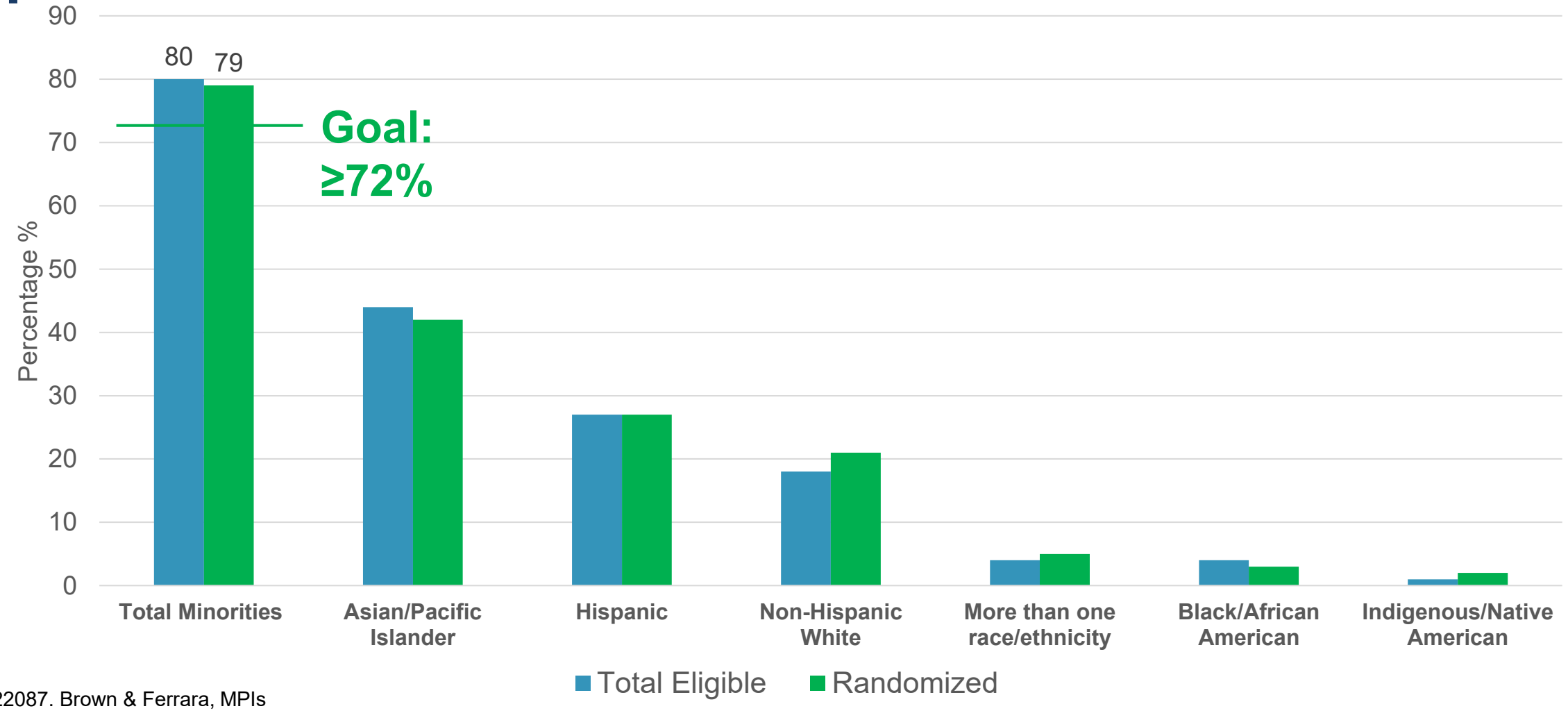
Introduction: Suboptimal and differential participant engagement in randomized trials—including retention at primary outcome assessments and attendance at intervention sessions—undermines rigor, internal validity, and trial conclusions.

Methods: First, this study describes Methods-Motivational Interviewing approach and strategies

Before vs. after implementing orientation sessions:

- Higher retention & intervention attendance across 3 behavioral trials
- No reduction in % randomized
- *No difference in racial /ethnic distribution of those randomized*

SUNRISE Trial: Preliminary Representation by Race/Ethnicity



R01 DK122087. Brown & Ferrara, MPIs

Brown et al. 2024. International Behavioural Trials Network Conference. *Ann Behav Med* (abstract in press)

Missing: Eligible, 2%; randomized, 0%. *8/31/23*

Team Building

Faster Together (Coursera)

Kusnoor *et al. BMC Medical Research Methodology* (2021) 21:44
https://doi.org/10.1186/s12874-021-01240-x

BMC Medical Research Methodology

RESEARCH ARTICLE Open Access

Design and implementation of a massive open online course on enhancing the recruitment of minorities in clinical trials – Faster Together

Sheila V. Kusnoor[1*], Victoria Villalta-Gil[2], Margo Michaels[3,4], Yvonne Joosten[5,6], Tiffany L. Israel[6], Marcia I. Epelbaum[1], Patricia Lee[1], Elizabeth T. Frakes[1], Jennifer Cunningham-Erves[7], Stephanie A. Mayer Sarah C. Stallings[2], Nunzia B. Giuse[1,9], Paul A. Harris[8,9] and Consuelo H. Wilkins[2,7,8,10,11]

Kusnoor et al. 2021

Listen to Participant & Stakeholder Voices

Monitor satisfaction via actionable items

SUNRISE Trial
Preliminary Data

Question	Response	
Did the informed consent form **prepare you** for what to expect during this study? [1]	Completely or Mostly Yes	74%
Did the research team treat you with **courtesy and respect**? [1]	Always or Usually	86%
Would you **recommend joining a research study** to your family and friends? [1]	Definitely or Probably Yes	86%

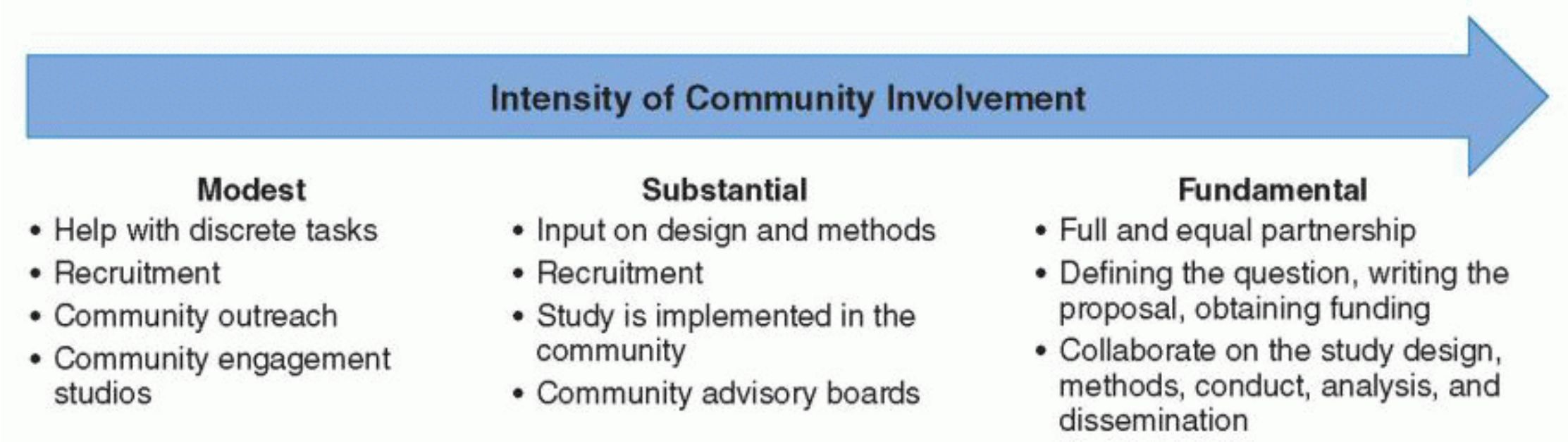
"*What next*" trial timeline

R01 DK122087. Brown & Ferrara, MPIs

[1]Kost et al. 2014, 2018. Research Participant Perception Survey (RPPS)

Listen to Participant & Stakeholder Voices

Convene Advisory Boards



Kanaya 2023. In *Designing Clinical Research. 5th Edition*, Browner WS. et al.

Summary

Equitably testing behavioral interventions for diverse populations requires an intentional focus on clinical trial inclusion

- Involve entire team
- Define goals, monitor progress
- Leverage empirical research & new resources

Resources

AAMC CENTER FOR HEALTH JUSTICE

AAMC Toolkits

- Trustworthiness
- Community engagement

https://www.aamchealthjustice.org/

Vanderbilt establishes Recruitment Innovation Center to increase enrollment of minorities, women and older adults in clinical trials

Many clinical trials are stopped prematurely because they fail to recruit enough study participants. Vanderbilt University Medical

RIC TEMPLATES FOR SHARING STUDY RESULTS

REFERRING PROVIDERS: AN OUTREACH GUIDE

COMMUNITY OUTREACH GUIDE

FASTER TOGETHER, ENHANCING THE RECRUITMENT OF MINORITIES

RECRUITMENT AND RETENTION TEMPLATE

trialinnovationnetwork.org/recruitment-retention-toolkit/

NIH UNITE

- **Resource portal** in development to advance health equity in research
- Best practices & tools for conducting health disparities and minority health research

https://www.nih.gov/ending-structural-racism/unite

Resources

Jake-Schoffman DE, Brown SD…Kiernan M. **Methods-Motivational Interviewing approach for enhanced retention and attendance**. *Am J Prev Med*. 2021;61(4):606-617.

Kusnoor…Wilkins. **Design and implementation of a massive open online course on enhancing the recruitment of minorities in clinical trials - Faster Together**. *BMC Med Res Methodol*. 2021 Mar 5;21(1):44.

Kiernan M, Oppezzo MA, Resnicow K, Alexander GL. **Effects of a methodological infographic on research participants' knowledge, transparency, and trust**. *Health Psychol*. 2018;37(8):782-786.

Kost et al. Impact of survey length and compensation on **validity, reliability, and sample characteristics for Ultrashort-, Short-, and Long-Research Participant Perception Surveys**. J Clin Transl Sci. 2018 Feb;2(1):31-37. doi: 10.1017/cts.2018.18.

Nicholson, Schwirian, Groner. **Recruitment and retention strategies in clinical studies with low-income and minority populations: Progress from 2004-2014**. *Contemp Clin Trials*. 2015; Nov;45(A):34-40.

Brueton, Tierney, Stenning, Meredith, Harding, Nazareth, Rait. **Strategies to improve retention in randomised trials: a Cochrane systematic review and meta-analysis**. *BMJ Open*. 2014 Feb 4;4(2):e003821.

Brown SD, Lee K, Schoffman DE…Kiernan M. **Minority recruitment into clinical trials: experimental findings and practical recommendations**. *Contemp Clin Trials*. 2012;33(4):620-3.

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Thank you

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