Evaluating the process and ethics of randomizing African American and Latino adults with diabetes to a community health worker intervention

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Presenter Disclosures

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(1) The following personal financial relationships with commercial interests relevant to this presentation existed during the past 12 months:

No relationships to disclose

Healthy People 2010

- Eliminating disparities requires enhanced efforts at: (1) preventing disease, (2) promoting health, (3) delivering appropriate care, and (4) developing new knowledge about the determinants of disease, causes of disparities, and effective interventions for prevention and treatment.

RCT as the gold standard

- Randomized controlled trials (RCT) are the current "gold standard" through which interventions are evaluated for their effectiveness.
- Use experimental designs for clinical and health related outcomes.
- Considered highly reliable form of scientific evidence because it accounts for spurious causality.
- Treatments are allocated to participants at random; different treatment groups are statistically equivalent

Experimental Designs

Experimental design

Txt O---------X---------O----------O

Control O----------O----------O

Delayed control

Txt O---------X----------O----------O

Control O----------O--------X--------O----------O

Enhanced usual care design

Txt O--------X----------O----------O

EUC O----------O----------O

Challenges to RCT in disparities research

- Core challenge: (1) issues of mistrust from communities of color for medical research and (2) concerns over withholding treatment from individuals who are in need of services.
- Tuskegee Study of Untreated Syphilis in the Negro Male (TSUS; 1932-1972)
- By facilitating collaborative partnerships, community-based, participatory research (CBPR) methods can help to overcome these challenges.
  - Incorporates active involvement of community members, organizational representatives, and researchers in all aspects of the research process
  - promotes a co-learning and empowering processes
  - assists in building community trust and ownership in the research

Case example: REACH Detroit

- Multi-level, CBPR intervention aimed at eliminating disparities among African Americans and Latinos with diabetes in Detroit.
- Family-level: Community Health Worker intervention
- Health system: CMEs, residents program, workshops
- Community-level: Access to physical activity and healthy foods, support groups

REACH Detroit Partnership

- Community based organizations
  Alkebu-lan Village , Community Health & Social Services (CHASS) Center, Inc., Delray United Action Council, Friends of Parkside, Southwest Solutions-Community Partnership of Southwest Detroit
- **Local and state health departments**
  Detroit Department of Health and Wellness Promotion, Michigan Department of Community Health
- **Major health system**
  Henry Ford System

- **Research centers**
  Southeast Michigan Diabetes Outreach Network (SEMDOM) and the University of Michigan Schools of Social Work and Public Health

Family Health Advocates: Promoters of Healthy Lifestyles

- **Members of REACH target communities**
- **Share cultural beliefs and values**
- **Share social and ethnic characteristics**
- **Eliminate communication barriers**
- **Act as role models for change**
- **Disseminate information and educate families**

Family Health Advocates

- Baseline to six months
  - Home visits (2 per month)
  - Clinic visit (at least once)
  - Other contact (2 per month)
  - Journey to Health classes
  - Invitations to Community-level intervention activities
- Six months to nine months
  - One home visit and one other contact per month
  - Invitations to Community-level intervention activities
- Nine to 12 months
  - Maintenance phase
  - One contact per month

Staff Training

- FHA staff and data collection coordinators provided with training on RCT designs:
  - What is random assignment--"chance"
  - Why it is important to randomize
  - How we would be implementing the RCT
  - Reviewed orientation script and consent forms (6th grade reading level)

Delayed intervention procedure

- Participants recruited from health systems and invited to orientation
- Participants informed of random assignment to treatment and delayed group and asked to sign consent form
  - Both script and consent form read aloud
- Home visit scheduled by Data Collection Coordinator
- Participant is given a sealed letter with group assignment
- Group assignment is explained and baseline data collected

Consent in RCT

- "Consent or refusal to participate in an RCT is adequately informed only if participants comprehend "that participants will be randomly allocated to treatment arms, and that at the start of the trial there are no convincing grounds for supposing that any patient would be advantaged or disadvantaged if allocated into one treatment arm rather than the other" (Robinson, Kerr, Stevens, et al., 2004)
  - Must probe for a working or explicit understanding
  - Can do so by giving verbal feedback or definitions
  - Identify examples of random assignment

Delayed Intervention procedures

- Delayed group is called by phone once per month to update contact information
- Six months selected due to our ability to detect change at this time point in previous work.
- Delayed group over-sampled by 10% to account for attrition.
- Individuals in need of immediate medical attention were provided services and removed from the study (n=3)
- No adverse effects were reported

Recruitment and Retention

- 164 participants, n=77 in immediate group and n=87 in delayed group
- Non-significant differences in gender and education
- Six month retention 71%
- Drop out rates similar for both groups
- No significant difference in number of baseline interviews completed
- Women in the delayed group dropped out at a higher rate than men
- More Latinos in delayed group dropped out; more African Americans in the immediate group dropped out.

Personal Interviews

- 15 participants, 4 FHAs, and 2 DCCs were interviewed to assess acceptability and appropriateness of RCT
- Six Latino and nine African Americans participants, two Latino and two African American FHAs and DCC were interviewed
- Eight in delayed (four withdrawn), Seven in immediate (three withdrawn)
- Face-to-face interviews with trained research assistant

RESULTS—Participants

- Delayed group expressed disappointment
  - Viewed immediate group as "winning," Group A
  - Prefer to be in immediate group
- Several in immediate group would have preferred to be in the delayed group
  - See what intervention is like and decide to participate later
- Lack of trust and clarity of RCT process for both groups
  - Questioned whether process was truly random
  - Questioned fairness of process (not first come first served)
  - Those who withdrew did not do so because of the process, but rather due to work schedules and other commitments

Lack of understanding and clarity of RCT

"I was disappointed, because I was hoping to get into the (immediate) group… I feel that because I wasn't on insulin, I was on pills, that's the reason why I probably wasn't picked for the group, I don't know."

"I understood the whole process. But like I said, I think being on insulin probably made a difference. Like I said, me not being on insulin was a factor. Might have been some sort of point-scoring, depending on insulin. That's what I feel I don't know" [delayed withdrawn group]

Lack of understanding and clarity of RCT

"It seems like it [group selection] was like pulling a rabbit out of a hat…. And I remember thinking 'Oh my gosh'…" [Intervention group]

"Well, I think they already had their plans… they already knew what they were doing…. They looked at people and knew what group they were going to assign them to because I mean, to do it by chance – this is not a betting game." [Intervention group]

Fairness

"I explained to them that I would need to be in the first group because of my work schedule… and then I ended up in the second group… I had told two co-workers about it [REACH], and they had ended up joining the first group, and that was really a slap in the face. --They were losing weight and enjoying themselves, but I wasn't able to participate like I wanted to." [delayed withdrawn group]

"I would like everyone to be together in the same group so all of us can have the same amount of time dedicated to us" [intervention group]

"I got in…and the second class they had to wait six months to get in. The class really wasn't that big, why couldn't we all be in the same class?" [intervention group]

RESULTS—Staff

- For the most part, Staff did not like the RCT
  - Felt that randomization should not be done
  - Dissatisfaction with inability to provide help and services

"If you know they need help, you can begin not liking the process of the randomization when you know a client needs help."

"Regarding randomization, the immediate group should be the people who need it"

RESULTS--Staff

- Providing "special" or "secret" services for delayed group
  - Two staff said yes
  - *"they might've needed some extra information or something and I provided it"*
- FHAs wanted to conduct interviews (they had done so in the first cohort)
  - Felt like we were restricting their job and imposing on their autonomy
  - *"I'd like to be free to do things with my clients…"*

Lessons learned

- Successful collaboration to achieve RCT
- RCT successful from research perspective
  - Able to randomize and execute intervention
  - Able to detect differences
- Even with detailed training and procedures, maintaining integrity of RCT is a challenge
  - Community mistrust difficult to overcome
  - Retention of understanding is a major issue

Lessons learned

- When participants bring little or no prior understanding about research methods and design, they may be overwhelmed or confused when explained the process of randomization (Kerr, Robinson, Stevens, et al., 2004)
  - Providing examples not enough, e.g., flipping a coin versus pulling rabbit from a hat
  - Many trials have found participants do not believe assignments are by chance
  - Staff must be brought on board at the very beginning, little chance for success otherwise.

Enhanced Usual Care Control Group Design

- Not all participants receive the full intervention.
- Only treatment group receives the FHA services (home and clinic visits).
- All participants invited to community-level intervention.
  - Activities and events readily available to the general public and free of charge
  - Usual care typically included regular medical services
  - Isolates the unique services of the FHA

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Or visit our website:

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