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Improving Participation Among Older African Americans in Clinical Research:

Interim Results from a Randomized Controlled Faith-Based Intervention

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Study Overview

- RCT of intervention to increase clinical trial participation among older African Americans
  - Address problem of underenrollment of this aging population in clinical trials
  - Improve generalizability of results
- Faith-based intervention
  - Previous intervention tested similar outcomes
  - Matched pairs of churches
  - Community-level RCT

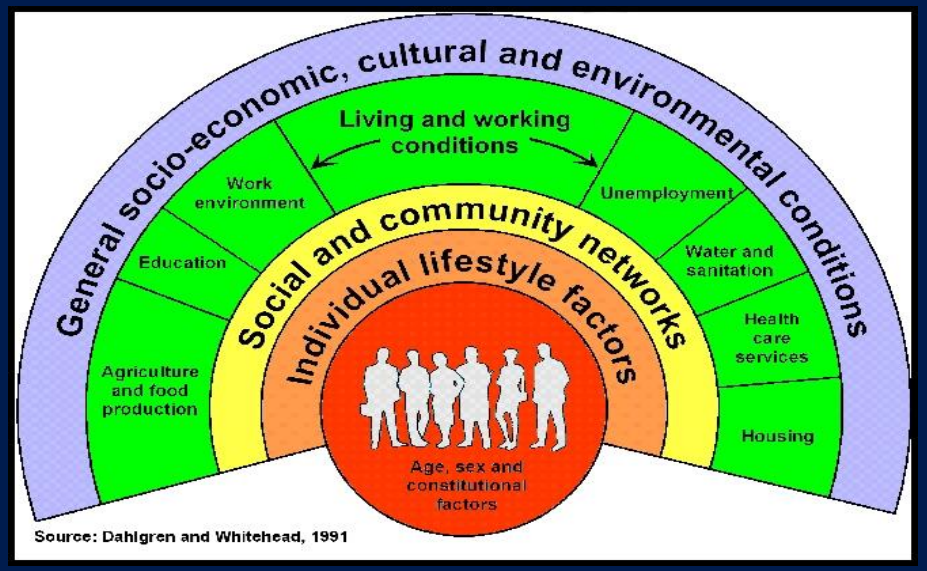
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Theoretical Orientation

- Prevention & Health Care/ACA Policies
- Neighborhoods & Community Structure
- Community & Personal Violence
- Partner Communication
- Income Inequality
- Transportation
- Employment
- Social Support
- Housing and Food Insecurity
- Community Myths & Misperceptions

- Personal Behaviors & Attitudes
- Structural Determinants of Health (access to food, insurance, education, transportation, healthcare providers)



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Study Design

- Longitudinal, community-randomized design
  - Church clustering effect
  - Rate of change in intentions and enrollment
  - Other changes observed at multiple timepoints
- Unit of analyses -> individuals
- Multilevel analyses
  - Multivariate
  - Ability to evaluate neighborhood-level effects (GIS)

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Trial Groups

- **Both Intervention and Control Group**
  - Regular parishioners
  - Received newsletter, emails, and phone calls about available clinical trials
- **Intervention Group**
  - One half-day session
  - Two follow-up sessions (1.5-2 hours each)
  - Surveys collected at initial session & 2 follow-up sessions
- **Control Group**
  - Recruited from standing events (e.g. bible study)
  - Initial survey
  - 2 follow-up surveys at 3 and 6 months

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Church Selection

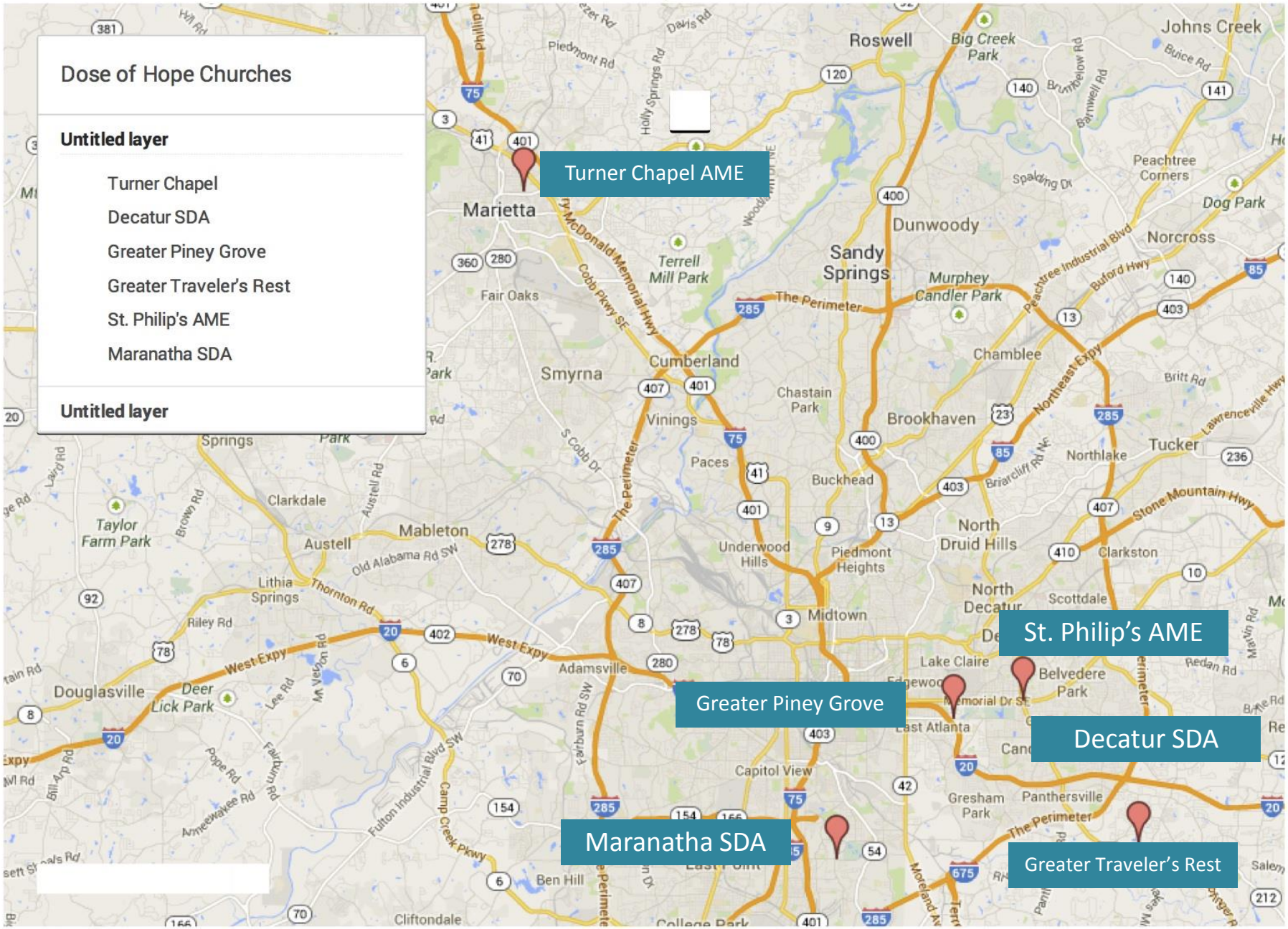
- Experience with academic-community partnership
- Denomination
- Size of congregation
- Willingness to participate irrespective of arm assignment
- Venue availability for all sessions

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Participant Eligibility

- Aged 50 – 89 years
- Live in metro Atlanta area
- Had not previously participated in faith intervention
- No plans to move for 12 months
- Not previous clinical trial volunteer
- Regular attendees or church members


Dose of Hope Churches
Untitled layer
Turner Chapel
Decatur SDA
Greater Piney Grove
Greater Traveler's Rest
St. Philip's AME
Maranatha SDA
Untitled layer
Turner Chapel AME
St. Philip's AME
Greater Piney Grove
Decatur SDA
Maranatha SDA
Greater Traveler's Rest
Roswell
Johns Creek
Marietta
Dunwoody
Sandy Springs
Norcross
Smyrna
Cumberland
Vinings
Chamblee
Brookhaven
Tucker
Northlake
Clarkdale
Austell
Mableton
Taylor Farm Park
Lithia Springs
Douglasville
Deer Lick Park
Underwood Hills
Piedmont Heights
North Druid Hills
Clarkston
Midtown
North Decatur
Scottdale
Lake Claire
Belvedere Park
East Atlanta
Capitol View
Gresham Park
Panthersville
Adamsville
Ben Hill
Cliftondale
College Park
Fair Oaks
Terrell Mill Park
Murphey Candler Park
Chastain Park
Paces
Buckhead
Peachtree Corners
Dog Park
Big Creek Park
Taylor Farm Park
Lithia Springs
Deer Lick Park
Terrell Mill Park
Murphey Candler Park
Chastain Park
Big Creek Park
Dog Park
Peachtree Corners
The Perimeter
West Expy
Thornton Rd
Old Alabama Rd SW
Cobb Pkwy SE
Peachtree Industrial Blvd
Buford Hwy
Northeast Expy
Stone Mountain Hwy
Lawrenceville Hwy
Fulton Industrial Blvd SW
Camp Creek Pkwy
Fairburn Rd SW
Moreland Ave
Spalding Dr
Britt Rd
Briarcliff Rd NE
Redan Rd
Memorial Dr SE
Piedmont Rd
Holly Springs Rd
Davis Rd
Buice Rd
Barnwell Rd
Brushbelow Rd
Woodstock Rd
Austell Rd
Brown Rd
Riley Rd
Lee Rd
Mt Vernon Rd
Pope Rd
Fairburn Rd
Nmeewakee Rd
Bill Arp Rd
Marvin Rd
Byrne Rd

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Participant Characteristics

Characteristic	n	%
Total	221	100
Gender		
Male	47	21.3
Female	174	78.7
Age (Mean=64, Median=64, Std. Dev.= 7.7)		
50-59	62	28.4
60-69	108	49.5
70-79	41	18.8
80-89	5	2.3
90-99	2	0.9
Education		
Grade K-8	3	1.4
Grade 9-11	10	4.5
High School/GED	66	29.9
Technical/Vocations/Associates	66	29.9
Bachelor's Degree	37	16.7
Master's Degree	33	14.9
Doctorate	6	2.7
Income		
<$20,000	61	27.6
$20,001-$40,000	49	22.2
$40,0001-$60,000	36	16.3
$60,001-$80,000	20	9.0
$80,001-$100,000	19	8.6
>$100,000	13	5.9
Missing	23	10.4
Relationship Status		
Single/Never Married	24	10.9
Married/Domestic Partner	102	46.2
Divorced/Separated	59	26.7
Widowed	35	15.8
Other	1	0.5
Treatment Group		
Treatment	112	50.7
Control	109	49.3

- Enrolled 221 participants
- 78.7% Female
- 49.5% aged 60-69
- 29.9% had a high school education/GED and 29.9% had a technical / vocational / associates degree
- 27.6% had an income of <$20,000
- 46.2% were married

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Baseline Themes

Attitude toward Clinical Trials:

- *"Um, there was a time when Black community didn't trust clinical research because we were forced upon to be used as research guinea pigs. And uh, for now during this time has past and now community is uh backing the community research because we find that it will help the community out"*

Trust of Clinical Research:

- *"When I say gaining trust it's by giving people the true message about what research is all about… if you give them the truth then everything will be all right."*

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Baseline Themes

Education:

- *"Knowledge is very important. To know what's going on with your body. That's one of the main things that you all [education intervention speakers] brought out to us is things that we probably don't even think about or realize. Is just doing these studies, what things can be brought out for our understanding. For us to realize it's very important to take care of your body. So ya'll brought out some things that we need. By doing certain things you can prevent other things, so that's one of the main things that y'all brought out to us and even that we need to do some of these studies."*

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Participant Retention

- After enrolling 221 persons at 6 churches, the overall retention rate was 97% at 3 months
- Evaluated 6 month retention following final sessions (95%)

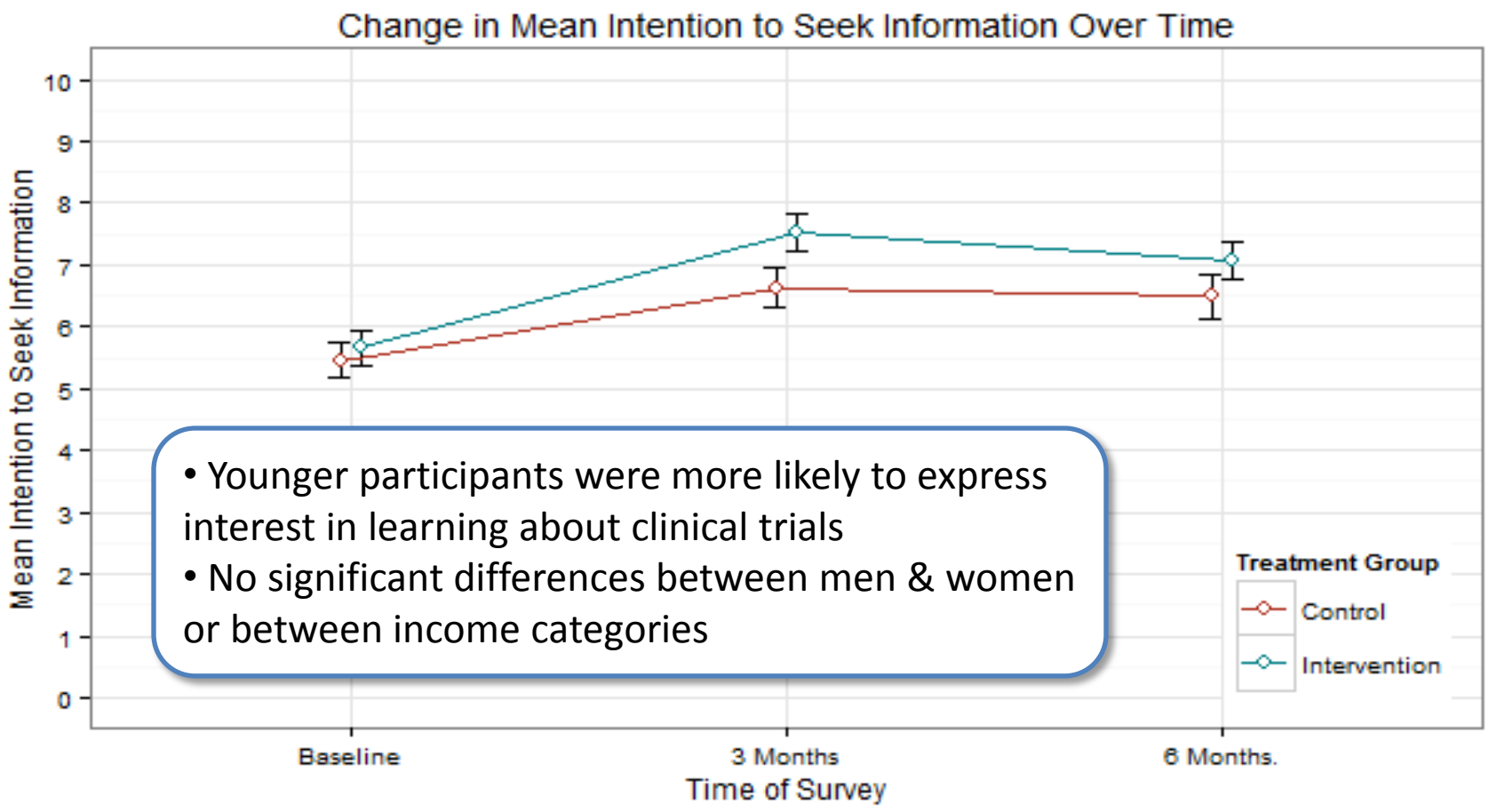




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Results



- Younger participants were more likely to express interest in learning about clinical trials
- No significant differences between men & women or between income categories

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Follow-Up Themes

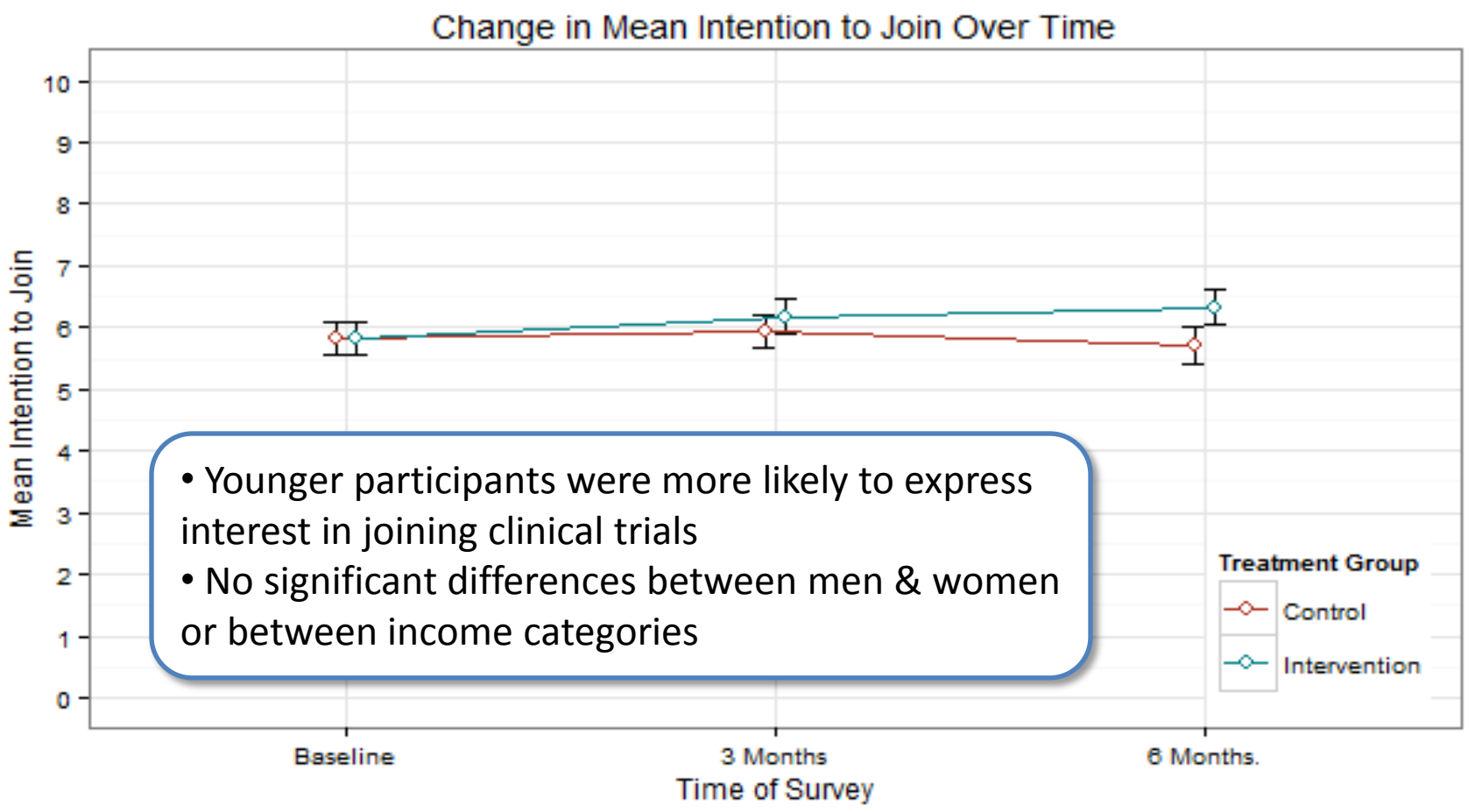
Lack of Awareness/Need for Knowledge:

- *"I haven't ever been places where things like [clinical trials] are really talked about. So I can't give you a reasonable answer. I guess if I knew exactly what was going on, I would want to be a part of it. But I can't tell you because I don't really know."*
- *"It's just for me, a good idea to have some knowledge of what's going on and what better knowledge than to know what's going on with you personally."*

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Results



- Younger participants were more likely to express interest in joining clinical trials
- No significant differences between men & women or between income categories

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Follow-Up Themes

Motivation to Participate in Clinical Trials:

- Trust: Peer and Medical Center Influences
  - *"Well, I have to admit, I have a little bit more [trust] in people that I already know or that I'm associated with, or have built up a quote track record with. With others I'm probably a little less sure…"*
- Relevant Health Topics
  - *"My health is would be more what I would be interested in. I don't know, that's about it. I guess I have, well I do have, high blood pressure, and I take cholesterol medicine. So anything in my area, I would be interested in."*

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Follow-Up Themes

Psychosocial Barriers:

- Knowledge of Historical Abuses
  - *"If you know about the past clinical trials African American's were taken advantage of, and then that makes them non trusting clinical trials, and even to go get healthcare."*

Logistical Challenges:

- Transportation Challenges and Study Procedures
  - *"I don't want to drive for so far, and then they were drawing blood like three times, and I have sunken veins…I told her I would be interested in something else…"*

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Programmatic Direction

- Church-Research Partnership
  - *"I thought it was a great because if it hadn't of come to my church I probably wouldn't have done it."*
- Trustworthy source of information
  - *"Everyone was so honest and open and they even from their own personal experience would tell you how it was and so, the info, the literature they gave was very revealing of everything that would be involved in a study."*
- Supportive environment
  - *"[The speakers] knew their topic, they were friendly, they made people feel at ease, and that helped…I think the atmosphere, having it at the church made it more relaxed…It kind of met people where they were, so I felt that was good."*

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Implications and Future Directions

- **Trend towards increased intentions to seek information and join clinical trials**
  - Within the intervention group, intention to seek information increased on average from baseline
- Education interventions may be successful for increasing knowledge and awareness of clinical trials if based on relevant, targeted information
- Tailored interventions based on psychosocial characteristics and informational needs

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