Multimedia Psychoeducation for Cancer Patients Eligible for Clinical Trials: A Randomized Clinical Trial

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2018
28-30 JUNE
VIENNA, AUSTRIA

SUPPORTIVE CARE MAKES EXCELLENT CANCER CARE POSSIBLE

MASCC/ISOO
ANNUAL MEETING ON SUPPORTIVE CARE IN CANCER

MASCC Multinational Association of Supportive Care in Cancer
ISOO International Society of Oral Oncology

www.mascc.org/meeting

#MASCC18

Faculty Disclosure

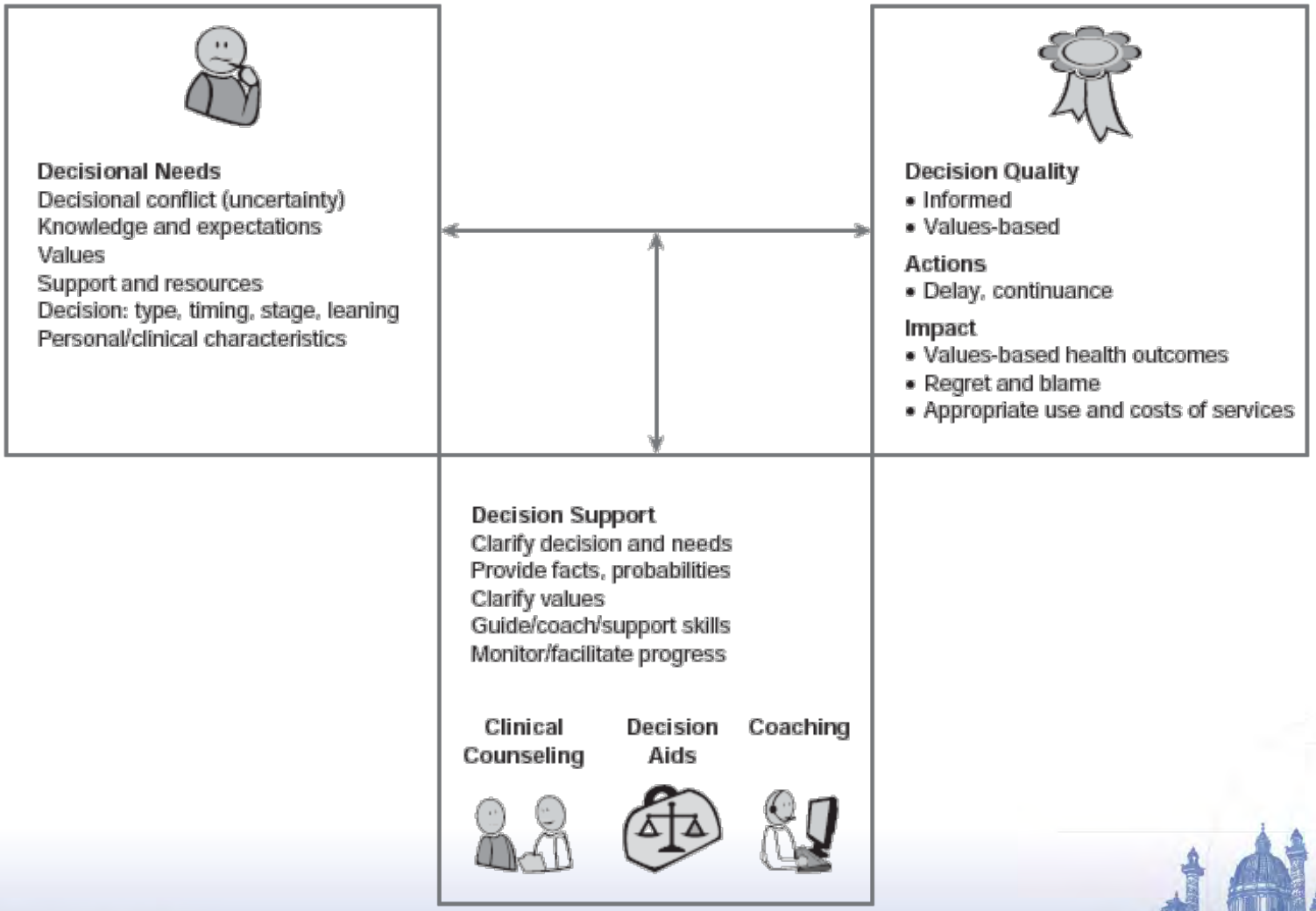
X	No, nothing to disclose
	Yes, please specify:

Significance

- 3% of cancer patients in the United States enroll in a clinical trial
- Low rates of participation cause up to 20% of registered trials to close prematurely
- Attitudinal barriers influence patients' willingness to participate in clinical trials
- Attitudes are modifiable, but require theory-based interventions

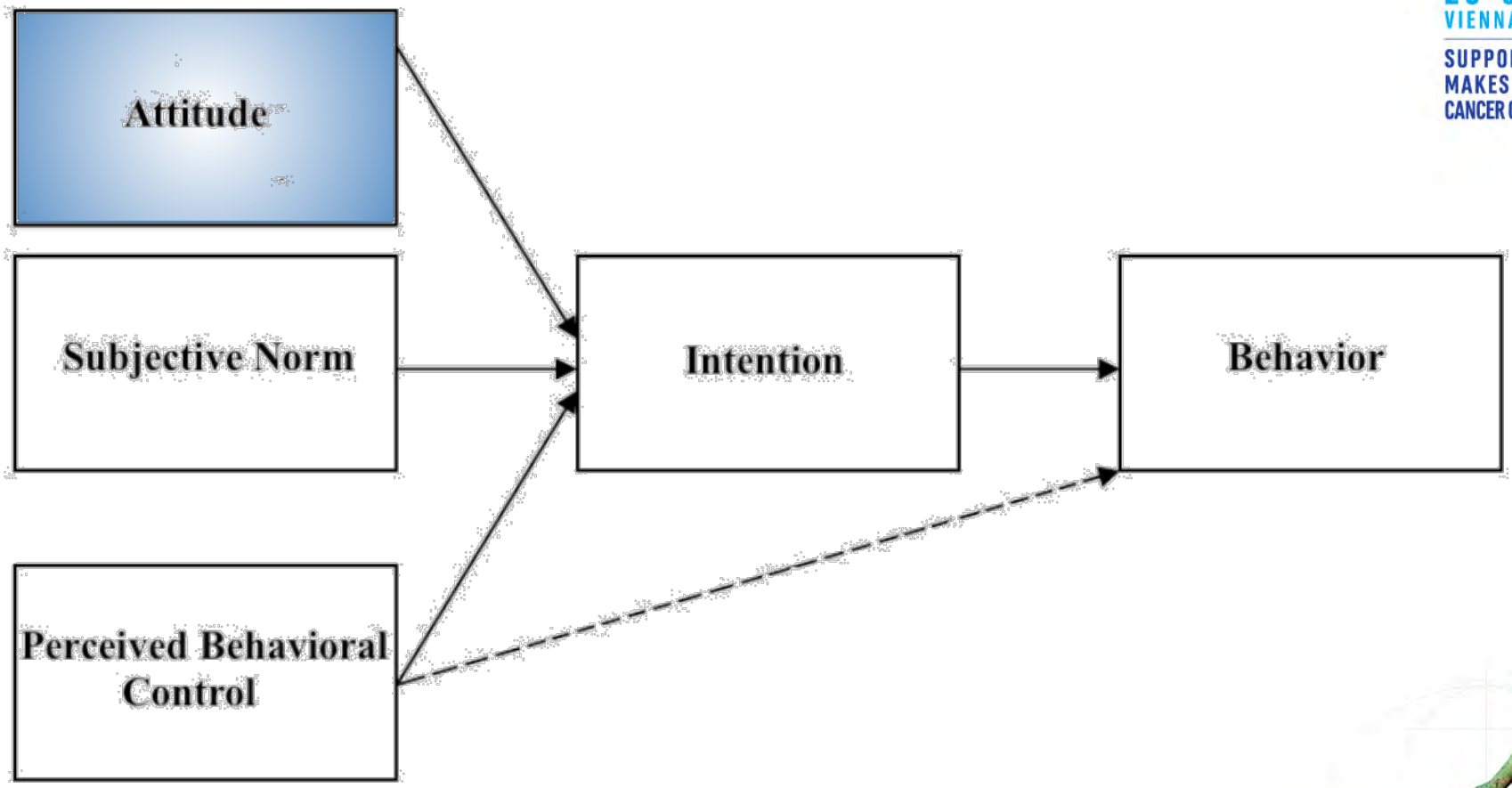
Schroen AT, Petroni GR, Wang H, et al. 2012.
Stensland KD, McBride RB, Latif A, et al. 2014.

Ottawa Decision Support Framework



O'Connor AM, Tugwell P, Wells GA, et al. 1998

Theory of Planned Behavior



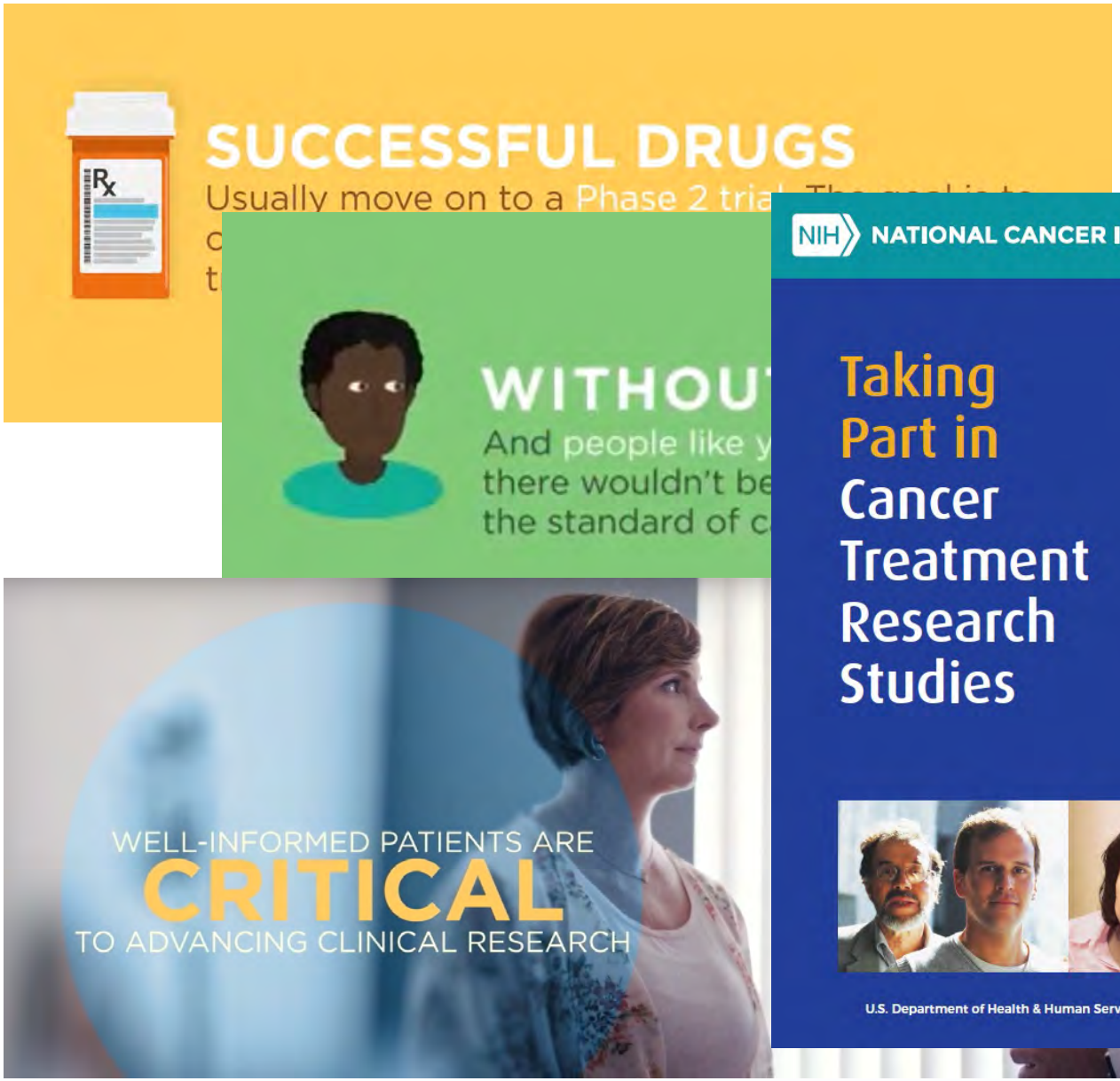
Ajzen I. 1991

Aims

- To test whether a theory-based, multimedia education program could improve decision support and attitudes
- To describe the impact of education on rates of clinical trial enrollment
- To examine the mediating relationship of attitudes on trial enrollment

Interventions

- Multimedia psychoeducation (MP)
  - DVD and booklet, *Clinical Trials: Are They Right for You?*
- Print education (PE)
  - NCI booklet, *Taking Part in Cancer Treatment Studies*
- Both arms
  - Research study coordinator, orientation to materials, question and answer



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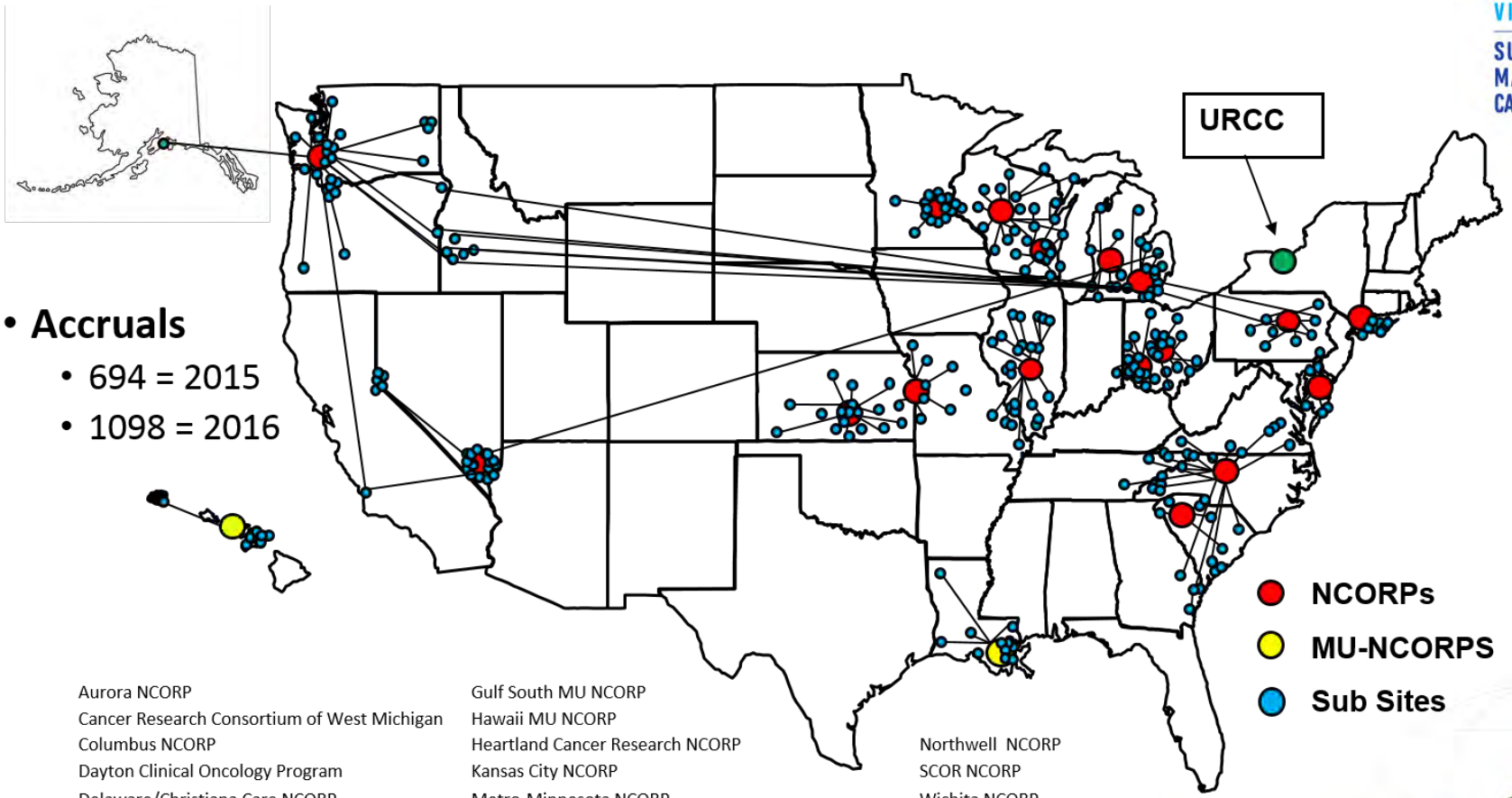
NCI Community Oncology Research Program (NCORP) Trial Network



- **Accruals**
  - 694 = 2015
  - 1098 = 2016

Aurora NCORP
Cancer Research Consortium of West Michigan
Columbus NCORP
Dayton Clinical Oncology Program
Delaware/Christiana Care NCORP
Geisinger Cancer Institute NCORP
Greenville NCORP of the Carolinas
Gulf South MU NCORP
Hawaii MU NCORP
Heartland Cancer Research NCORP
Kansas City NCORP
Metro-Minnesota NCORP
Michigan Cancer Research Consortium
Nevada Cancer Research Foundation NCORP
Northwell NCORP
SCOR NCORP
Wichita NCORP
Wisconsin NCORP
Pacific Cancer Research Consortium

Eligibility

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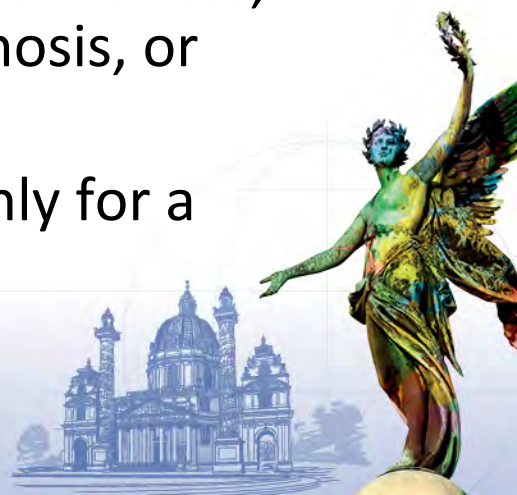
Inclusion:

- diagnosed with cancer
- eligible for a specific phase II or III therapeutic clinical trial
- informed of eligibility for a therapeutic clinical trial
- ≥ 18 years of age
- able to speak and read English
- capable of providing written informed consent

Exclusion:

- been asked previously to participate in a trial
- already made a decision to participate in a trial
- had visual, auditory, psychiatric/neurological disorders (e.g., blindness, deafness, psychosis, or dementia)
- been eligible only for a phase I trial



Measures

- Demographics
- Preparation for Decision Making Scale
- Clinical Trials Attitudes Scale
- Self-reported trial participation:
  - Had the patient been provided a written informed consent form?
  - Did the patient sign the consent form?
- Chart review to confirm participation

Bennett C, Graham ID, Kristjansson E, Kearing SA, Clay KF, O'Connor AM. 2010

Statistical Analyses

- MP = better decision support, attitudes
  - Linear mixed models
  - Intervention arm (PE vs. MP)
  - Demographic and clinical covariates at $p<0.15$
- Intervention effect on participation
  - 2 (arm: MP or PE) × 2 (clinical trial participation: Yes or No/Still Deciding) contingency tables using chi-square tests
- Trial participation mediated by attitudes
  - path coefficients, bootstrap confidence intervals

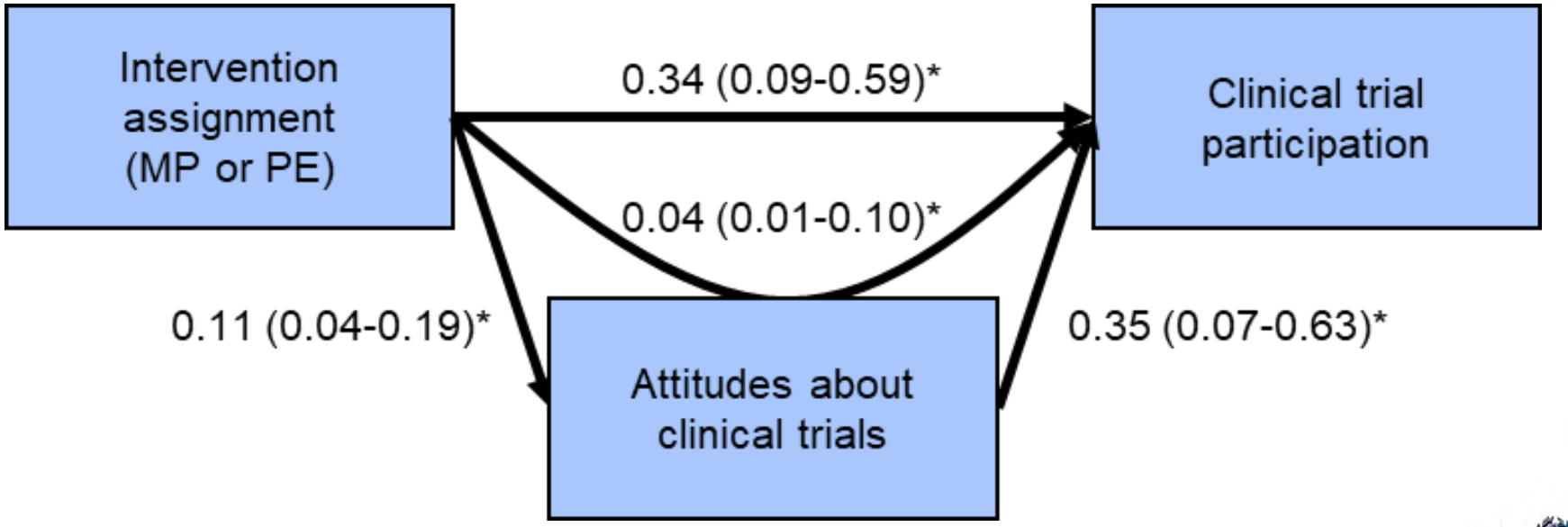
Patient Demographics

	Total N=418	MP n=199	PE n=219	Significance
Age in years*	61.5 (11.9)	61.5 (12.6)	61.6 (11.2)	p=0.97[1]
Marital status, n (%)				p=0.26[2]
Never Married	39 (9.4)	20 (10.0)	19 (8.8)	
Currently Married	246 (59.1)	113 (56.8)	133 (61.3)	
Separated/Divorced	85 (20.4)	38 (19.1)	47 (21.6)	
Widowed	46 (11.1)	28 (14.1)	18 (8.3)	
Female, n (%)	255 (61.0)	121 (60.8)	134 (61.2)	p=0.94[2]
Race, n (%)				p=0.66[3]
White	372 (89.0)	177 (88.9)	195 (89.0)	
Black	37 (8.9)	19 (9.6)	18 (8.2)	
Asian/Pacific Islander	5 (1.2)	1 (0.5)	4 (1.9)	
Ethnicity, n (%)				p=0.27[3]
Hispanic/Latino	8 (1.9)	5 (2.5)	3 (1.4)	
Not Hispanic	406 (97.1)	192 (96.5)	214 (97.7)	
Education, n (%)				p=0.07[2]
High School or Less	151 (36.2)	67 (33.6)	84 (38.8)	
Partial College	136 (32.7)	76 (38.2)	60 (27.6)	
College or More	129 (31.1)	56 (28.2)	73 (33.7)	
Yearly household income, n (%)				p=0.52[2]
< $20,000	61 (14.8)	23 (11.7)	38 (17.7)	
$20,000 - $39,999	64 (15.6)	32 (16.3)	32 (14.9)	
$40,000 - $59,999	62 (15.1)	29 (14.8)	33 (15.3)	
$60,000 - $100,000	81 (19.7)	37 (18.9)	44 (20.5)	
> $100,000	44 (10.7)	22 (11.2)	22 (10.2)	
Cancer type (top 4), n (%)				p=0.20[2]
Breast	122 (29.9)	69 (34.7)	53 (24.2)	
Lung	53 (12.7)	26 (13.1)	27 (12.3)	
Colon	33 (7.9)	16 (8.0)	17 (7.8)	
Prostate	31 (7.4)	11 (5.5)	20 (9.1)	
Months since diagnosis*	10.6 (28.5)	7.3 (17.5)	13.6 (35.4)	p=0.02[1]

Outcomes by Intervention Arm

	MP n=199 (47.6%)	PE n=219 (52.4%)	Significance
Preparedness for Decision Making			
Post-intervention (3-7 days)	71.16 (21.49)	71.26 (19.53)	p=0.96[1]
Decisional Conflict			
Follow-up (49-56 days)	17.94 (14.03)	17.99 (12.79)	p=0.97[1]
Decision Regret			
Follow-up (49-56 days)	18.26 (15.10)	18.07 (14.91)	p=0.91[1]
Attitudes about Clinical Trials			
Baseline	3.63 (0.50)	3.66 (0.44)	
Post-intervention (3-7 days)	3.80 (0.46)	3.71 (0.46)	p=0.004[3]
Clinical Trial Participation			
Follow-up (49-56 days)			p=0.01[2]
No	42 (24.7)	69 (36.0)	
Yes	117 (68.8)	119 (62.0)	
Undecided	11 (6.5)	4 (2.0)	

Mediation by Attitudes



Limitations

- Small sample size for racial and ethnic minorities.
- Participants who consented to this study may have been more likely by default to participate in a clinical trial.

Conclusions

- The MP intervention was able to improve patient attitudes toward clinical trials when compared with PE.
- This improvement led to increased rates of participation in trials.
- The MP intervention is easy to deliver and disseminate.

Thank you!

Patients

NCORP Staff

Paul Jacobsen, PhD

The study team

URCC NCORP Research Base members

Any questions?