A Randomized Trial of Community Health Worker Support and Academic Detailing for Tobacco Cessation for Adults with Serious Mental Illness

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PCORI Large Pragmatic Trial

Disclosures

Trial Funding: PCORI Large Pragmatic Trial 1504-30472,
Integrated Smoking Cessation Treatment for Smokers with Serious Mental Illnesses, PI: AE Evins, co-PI: S Reyering

PCORI Qualitative Supplement: Identification of Barriers and Facilitators to Implementation of

Industry funding to investigators:
Dr. Evins has served as a consultant to Chair a Data Monitoring Board for Karuna Pharmaceuticals and is a founder of Highlight I, Inc.

Drs. Evins and Cather has served as consultants to Charles River Analytics for a NIDA SBIR grant

Other investigators report no potential conflicts.

Tobacco smoking remains highly prevalent in adults with serious mental illness

- Tobacco smoking single largest contributor to markedly elevated mortality in persons with SMI
- Most with SMI would like to quit smoking
- Combined pharmacotherapy and behavioral treatment improves smoking abstinence rates in persons with SMI
- Both smoking cessation treatment and smoking cessation are well tolerated in people with SMI
- However, evidence-based treatments are under-utilized in community settings
- We tested whether two interventions alone or combined improved use of first-line smoking cessation treatments for those with SMI in primary care

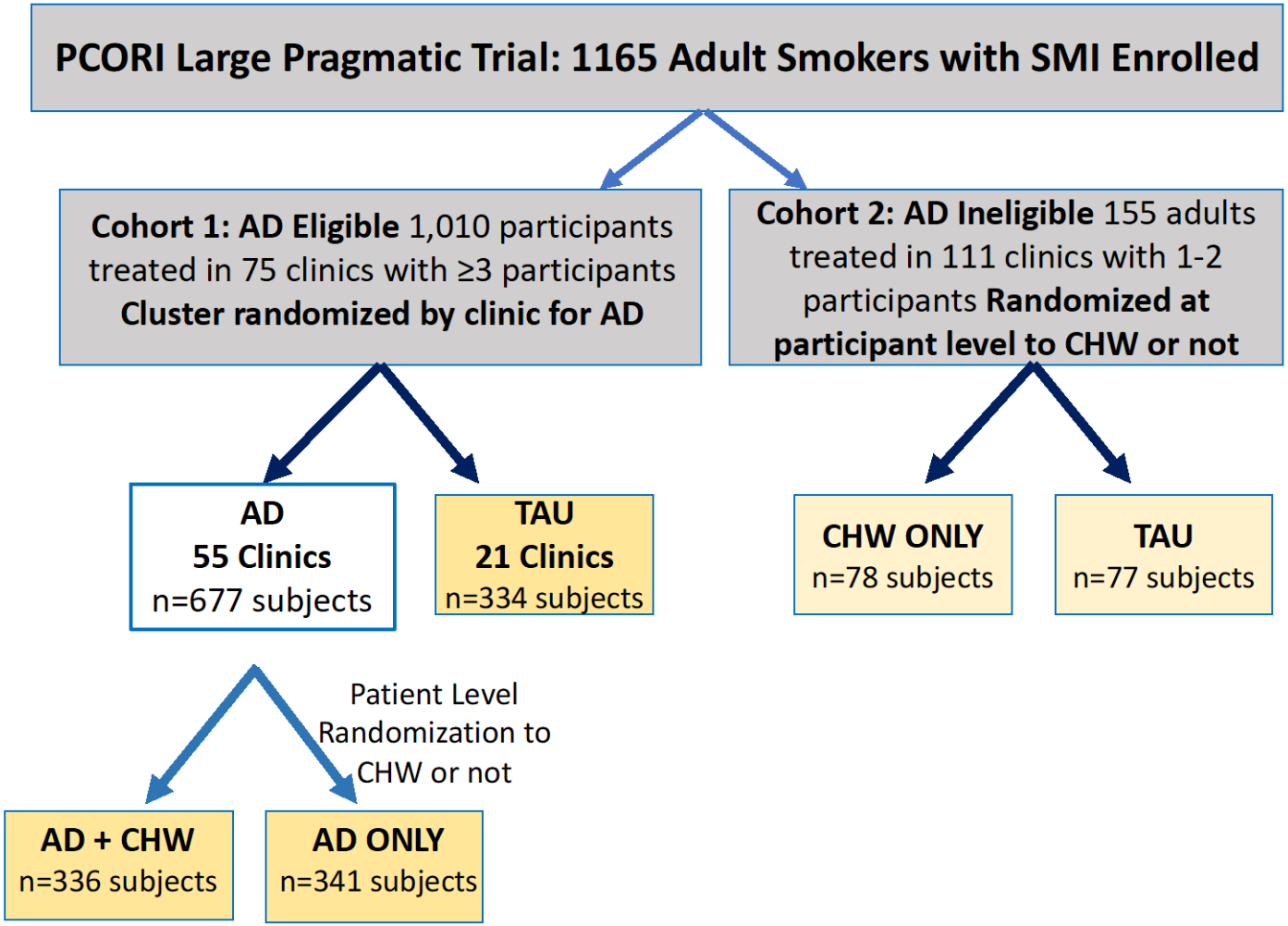
Trial Objective

- To test the effect of academic detailing (AD) to primary care physicians, community health worker (CHW) support to persons with SMI who smoked, or both, on provision of first-line smoking cessation treatment and tobacco abstinence rates in smokers with SMI eligible for CBFS services through Bay Cove Human Services or Vinfen.
- Primary outcome was biochemically-verified, 7-day point-prevalence tobacco abstinence at the end of the 2-year intervention.

Setting and Participants

- 1496 adults who received Department of Mental Health contracted psychiatric rehabilitation services and were current smokers were eligible; 1165 enrolled. Individuals did not need to express readiness or willingness to try to quit smoking to enroll.
- Academic Detailing was provided to primary care clinical teams and affiliated psychiatric treatment teams at their clinic sites, or by telephone.
- Community Health Worker support was provided in the community.

Study Design



Baseline Characteristics

Measure	
Sample size	1165
Age; M (SD)	47
Sex; % female (n)	31%
Race*	
% White	50%
% Black	35%
% Asian	4%
% other	4%
% multi-race	7%
Ethnicity; % Hispanic	17%
Group/shared living*; % yes	40%
SF-1; M	3.1

Baseline Characteristics

Measure	
Expired CO	23 ppm
HSI; M	2.8
Tobacco products per day; M	15.4
Cigarettes; %	83%
Mini-cigars; %	33%
Hand rolled cigarettes; %	7%
E-cigarettes; %	1%
Quit recommendation**; % yes	65%
Prescribed meds ; % yes	33%
Varenicline	6%
NRT (any form)	31%
Bupropion	1%

Intervention

- CHWs met regularly with participants who consented to this support with the goal of supporting smoking cessation treatment.
- Academic detailing focusing on the importance, safety and efficacy of offering first-line pharmacotherapeutic cessation aids to all smokers with SMI was offered to primary care physicians in group and individual formats.

Results

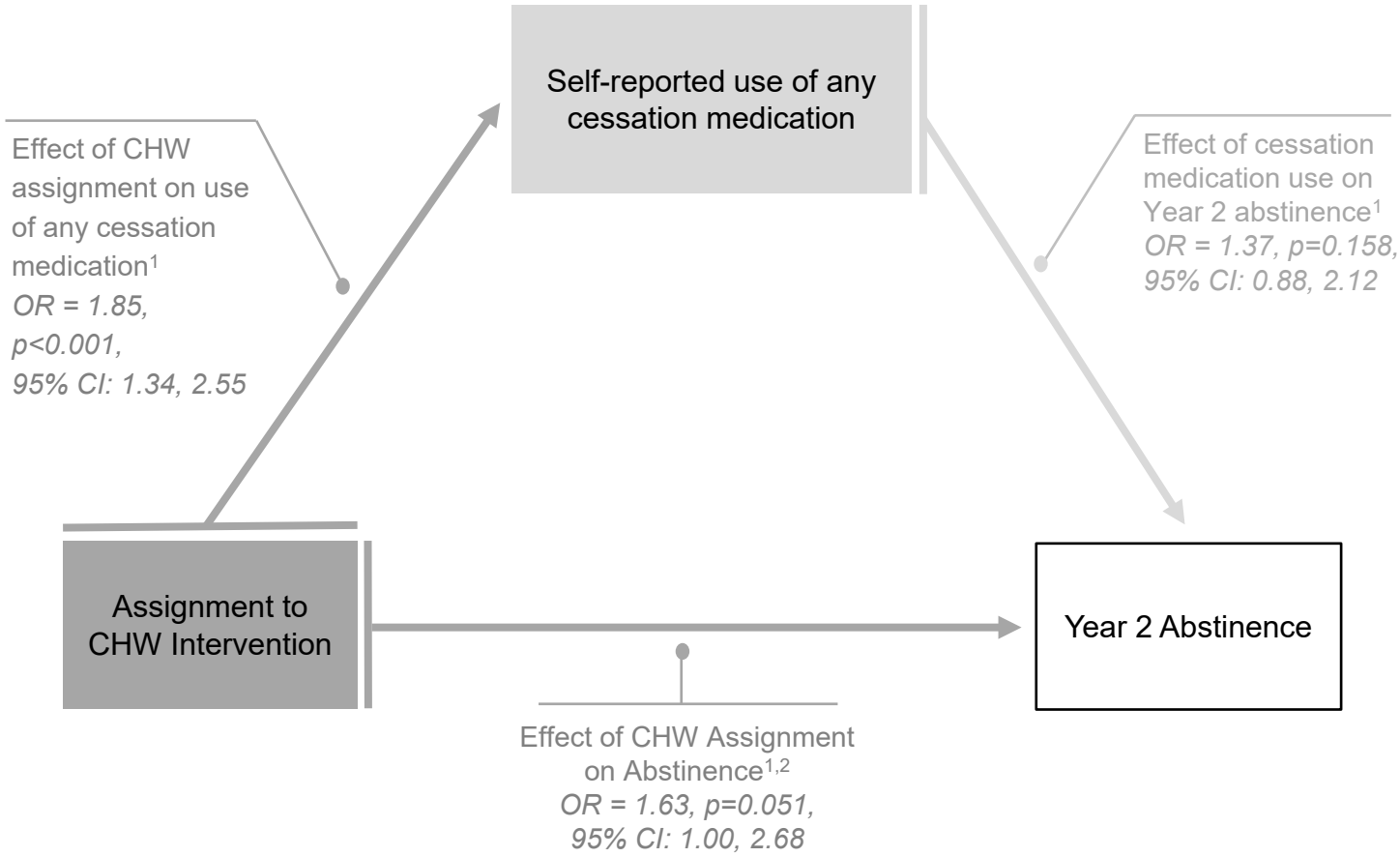
- CHW support improved odds of abstinence by 70% (OR=1.72, 95% CI, 1.05, 2.82).
- AD did not confer significantly increased odds of abstinence.
- No significant interaction effect of AD and CHW.
- A completer analysis yielded similar results.
- Those assigned to CHW were more likely to receive any cessation medication (OR=1.85, $p<0.001$), particularly varenicline (OR=3.10, $p<0.001$).
- Provision of any cessation medication (OR=1.64, $p=0.037$) and varenicline (OR=2.14, $p=0.004$) increased abstinence, while NRT or bupropion without varenicline did not.
- CHW intervention increased the effect of medication

7-day PPA rates by treatment arm and cohort

Cohort	Treatment arm	N	Imputed	7-day PPA rates
AD eligible	TAU	264	63	6.8%
	AD	264	60	8.3%
	AD + CHW	259	56	14.0%
AD ineligible	TAU	57	18	15.4%
	CHW	57	8	20.5%

Of 1165 enrolled; 872 provided smoking cessation data through year 1 of the intervention, and 667 participants provided smoking cessation data in year 2. Missing data for the 205 who had year 1 but not year 2 data were handled using multiple imputation.

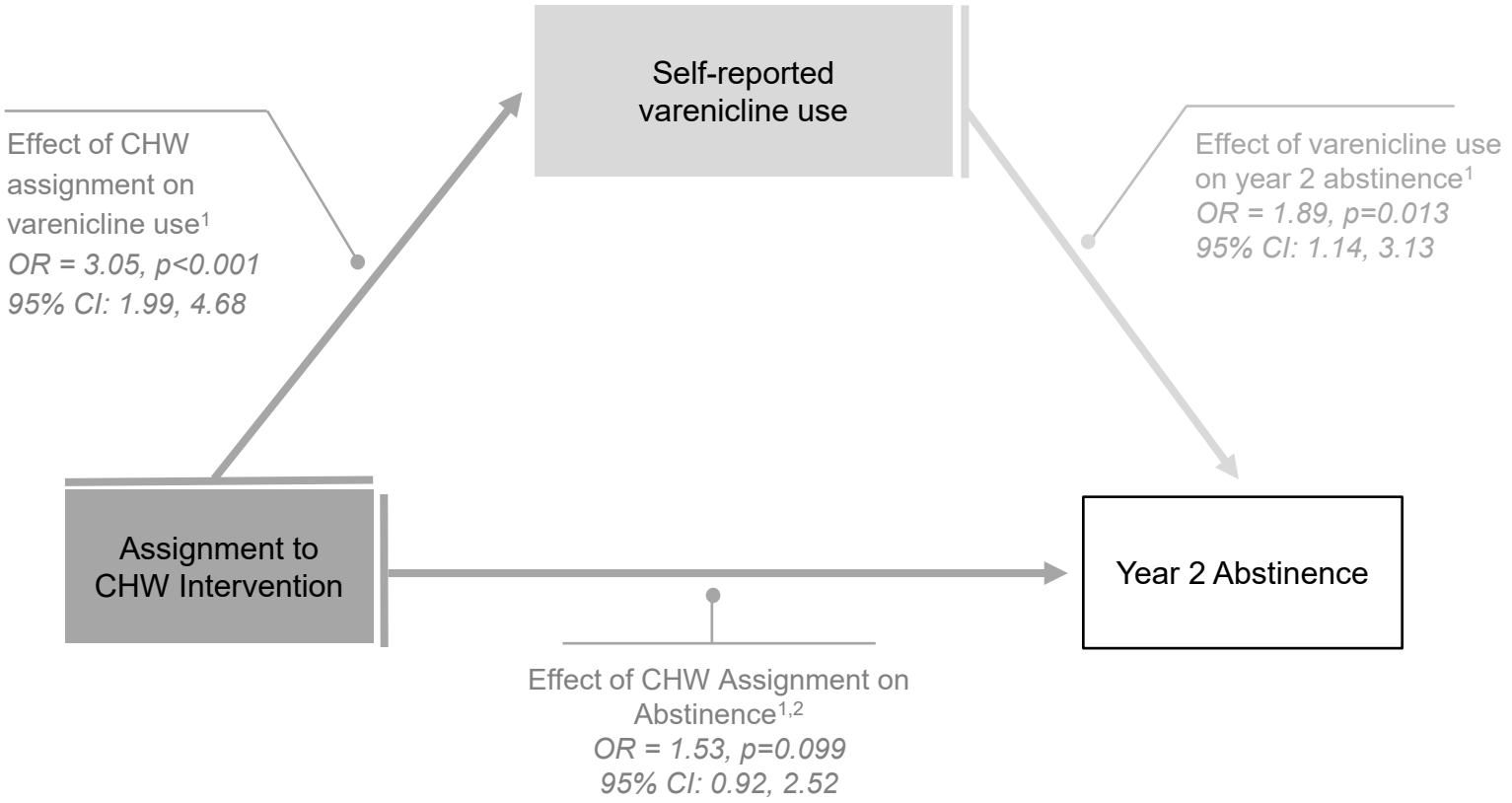
CHW Support Increased Use of Any TUD Medication But These Did not Significantly Increase Abstinence



Path analysis diagram showing how any cessation medication use (Panel A) and varenicline use (Panel B), both versus no medication use, mediate the association between CHW intervention and Year 2 abstinence status. Odds ratios and p-values are reported from the mediator (CHW on medication use) and full models (CHW and medication use on abstinence status), adjusting for cohort and AD intervention. Here medication use is defined as patient report of receipt of prescription for smoking cessation medication (including NRT), filling the prescription and taking at least one dose.

[1]Adjusting for cohort, AD, and clustering due to clinics; [2]Adjusting for cessation medication use

CHW Tripled Use of Varenicline Which Increased Abstinence by over 80%



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CHWs Increased Medication Use and Abstinence Rates with Effective Medication

CHW	Medication use	N (%)	Abstinence rate
No	None	363 (63.7%)	7.2% (26/363)
n=570	NRTs	141 (24.7%)	5.0% (7/141)
	Varenicline	31 (5.4%)	6.5% (2/31)
	Varenicline and NRTs	35 (6.1%)	5.7% (2/35)
Yes	None	162 (52.6%)	7.4% (12/162)
n=308	NRT/Bupropion	62 (20.1%)	14.5% (9/62)
	Varenicline	32 (10.4%)	28.1% (9/32)
	Varenicline and NRTs	52 (16.9%)	23.1% (12/52)

Conclusions and relevance

- CHW support increased tobacco abstinence in a large community cohort of adults with SMI who smoked, mediated by increased provision of smoking cessation medication, varenicline in particular.
- There was no evidence of an effect of AD.

Thank You to the Study Team!!


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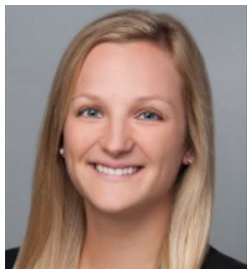
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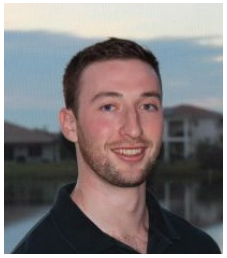
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Consort Diagram