



Smoking cessation treatment: A critical component of HIV/AIDS management

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THE UNIVERSITY OF TEXAS

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Overview

- 1. HIV/AIDS trends**
- 2. Cigarette smoking and HIV/AIDS**
(prevalence, correlates, and health outcomes)
- 3. Smoking cessation efforts**
- 4. Future directions**

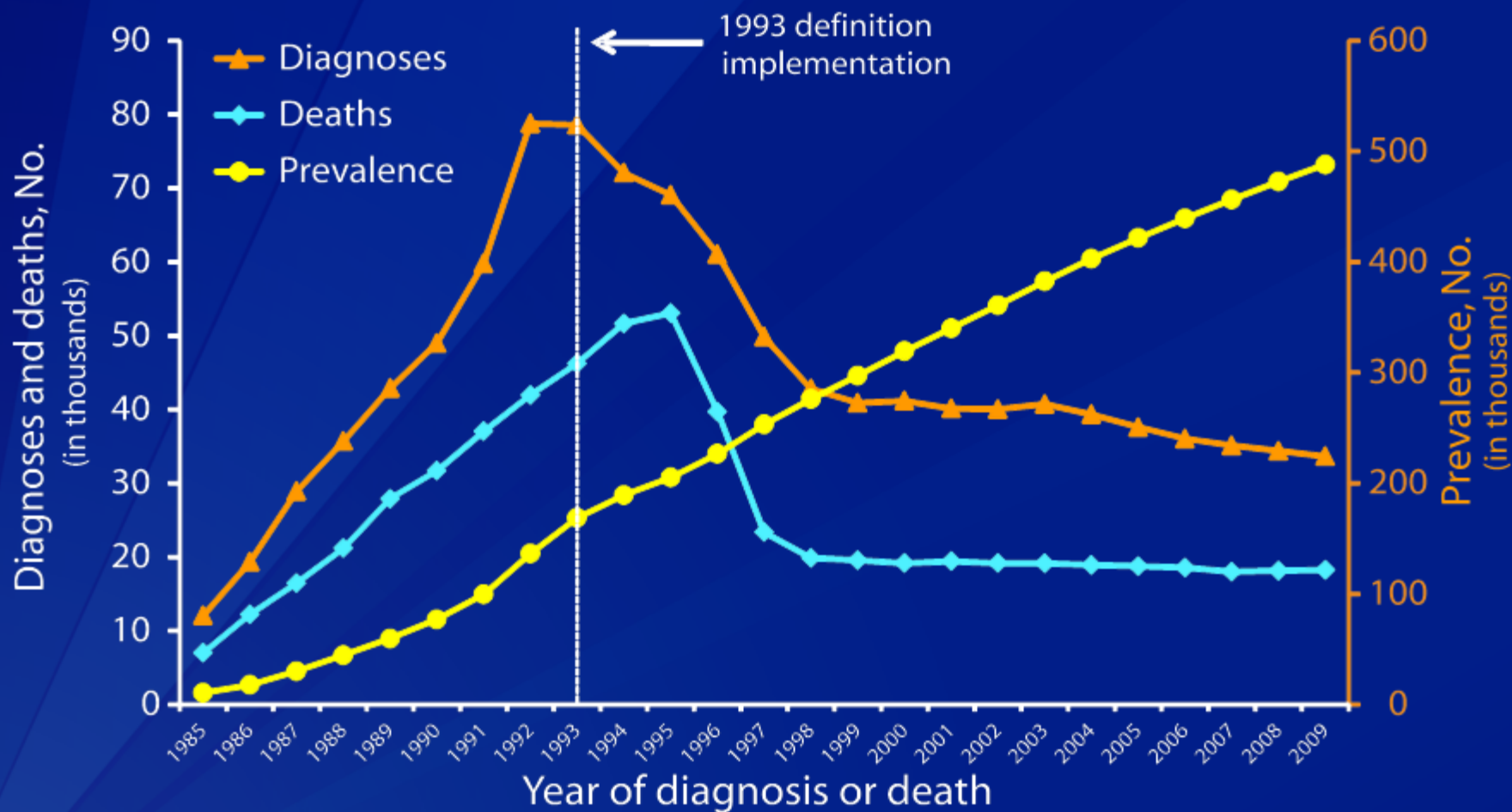
HIV/AIDS in the US

- Over 1.2 million people in the US are HIV positive
- 50,000 – 60,000 new cases each year
- Variables associated with HIV serostatus:
 - socioeconomic status
 - race/ethnicity
 - sexual orientation
 - depression
 - illicit drug use
 - heavy alcohol use
- **Combination ART**



Photo CDC, PHIL, 1989
CDC, 2012
Palella et al. *N Engl J Med* 1998
Walensky et al. *J Infect Dis* 2006
Lohse et al. *Ann Intern Med* 2007

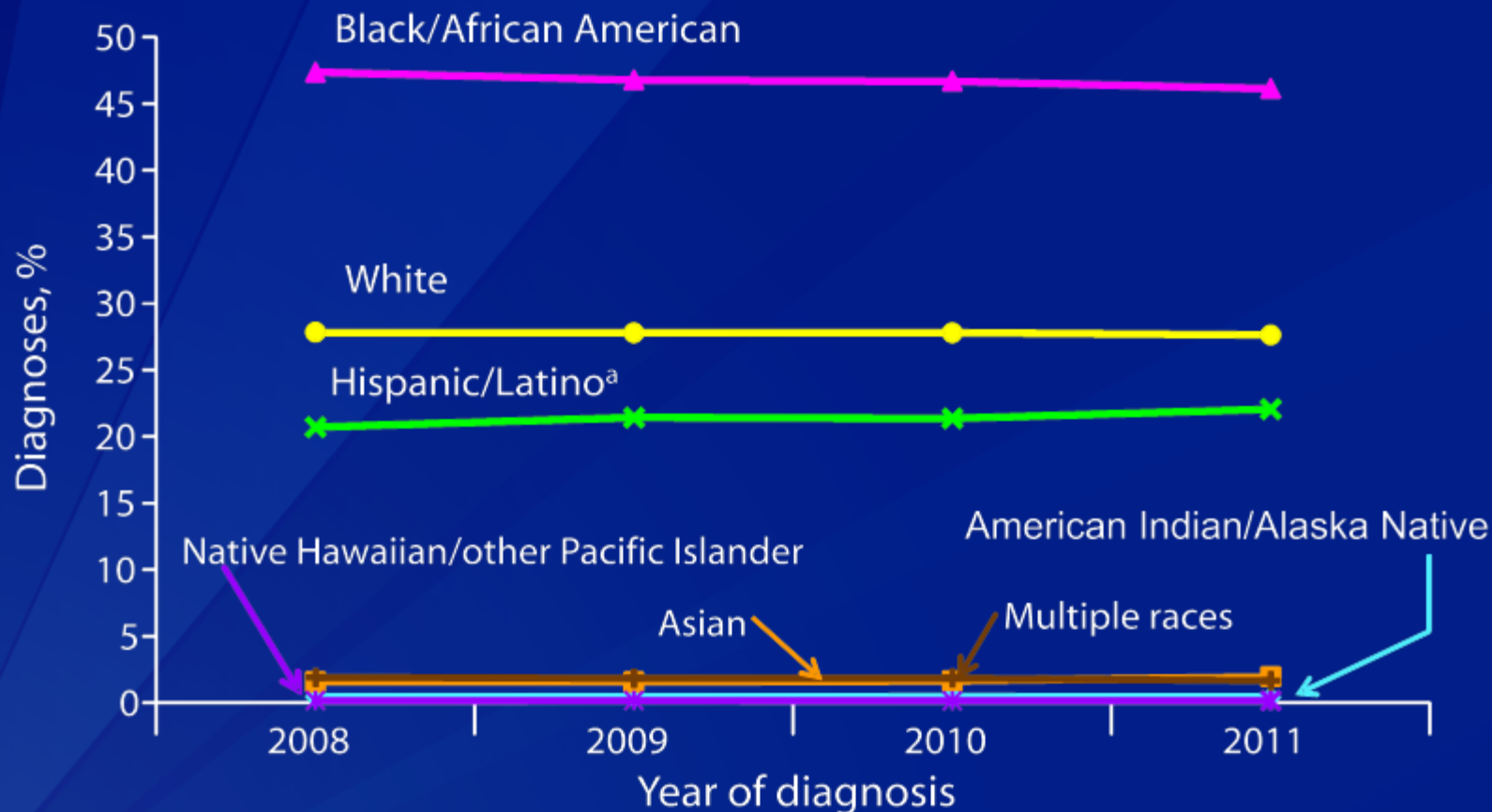
AIDS Diagnoses, Deaths, and Persons Living with AIDS, 1985–2009—United States and 6 U.S. Dependent Areas



Note. All displayed data have been statistically adjusted to account for reporting delays, but not for incomplete reporting. Death may be due to any cause.



Diagnoses of HIV Infection among Adults and Adolescents, by Race/Ethnicity, 2008–2011—United States and 6 Dependent Areas



Note. Data include persons with a diagnosis of HIV infection regardless of stage of disease at diagnosis. All displayed data have been statistically adjusted to account for reporting delays, but not for incomplete reporting.

^a Hispanics/Latinos can be of any race.



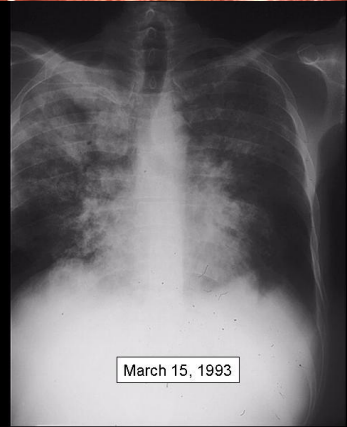
Tobacco use among PLWHA

- Prevalence of smoking:
 - General US population, 19.0%
 - **HIV-positive population, 45-65%**
 - Drug and alcohol use
 - Sexual orientation
 - Depressive symptoms
 - Low socioeconomic status
- Numerous health risks for HIV-positive smokers



Effects of smoking among PLWHA

- Health outcomes associated with smoking
 - Oral lesions
 - Pulmonary diseases
 - **Cardiovascular disease**
 - **Various malignancies** (e.g., anal, cervical, head and neck, lung)
- Antiretroviral treatment response
 - Virologic (higher viral load among smokers)
 - Immunologic (lower CD4 cell counts among smokers)
- Poorer functional status/health-related quality of life
- Increased risk of mortality

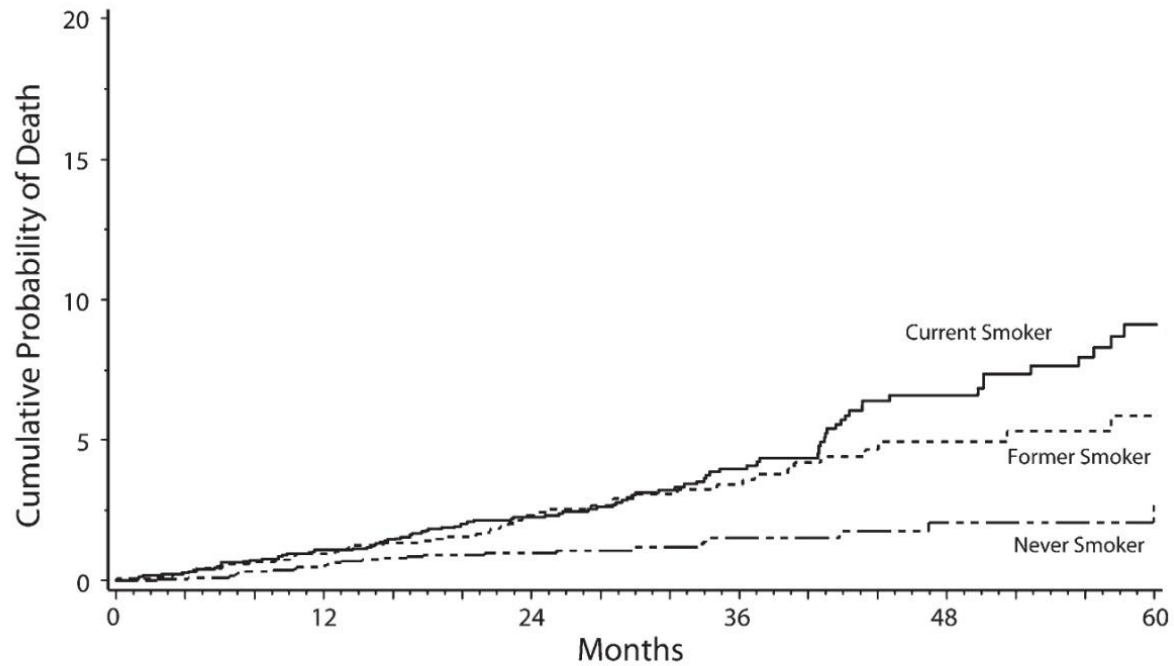


Vidrine *AIDS Educ Prev*, 2009

Oral photos, CDC PHIL, 1999, 1987

Bacterial pneumonia Images courtesy of: AIDS Images Library www.aidsimages.ch

HIV/AIDS, smoking and survival



	<u>No. at Risk</u>					
Current Smoker	2215	2159	1534	784	400	178
Former Smoker	1358	1330	957	529	277	134
Never Smoker	1899	1860	1197	575	293	135

FIGURE 1—Cumulative probability of death (all-cause mortality) by months of follow-up, among current, former, and never smokers: Strategies for Management of Antiretroviral Therapy clinical trial, 2002–2006.

HIV/AIDS, smoking and survival (cont.)

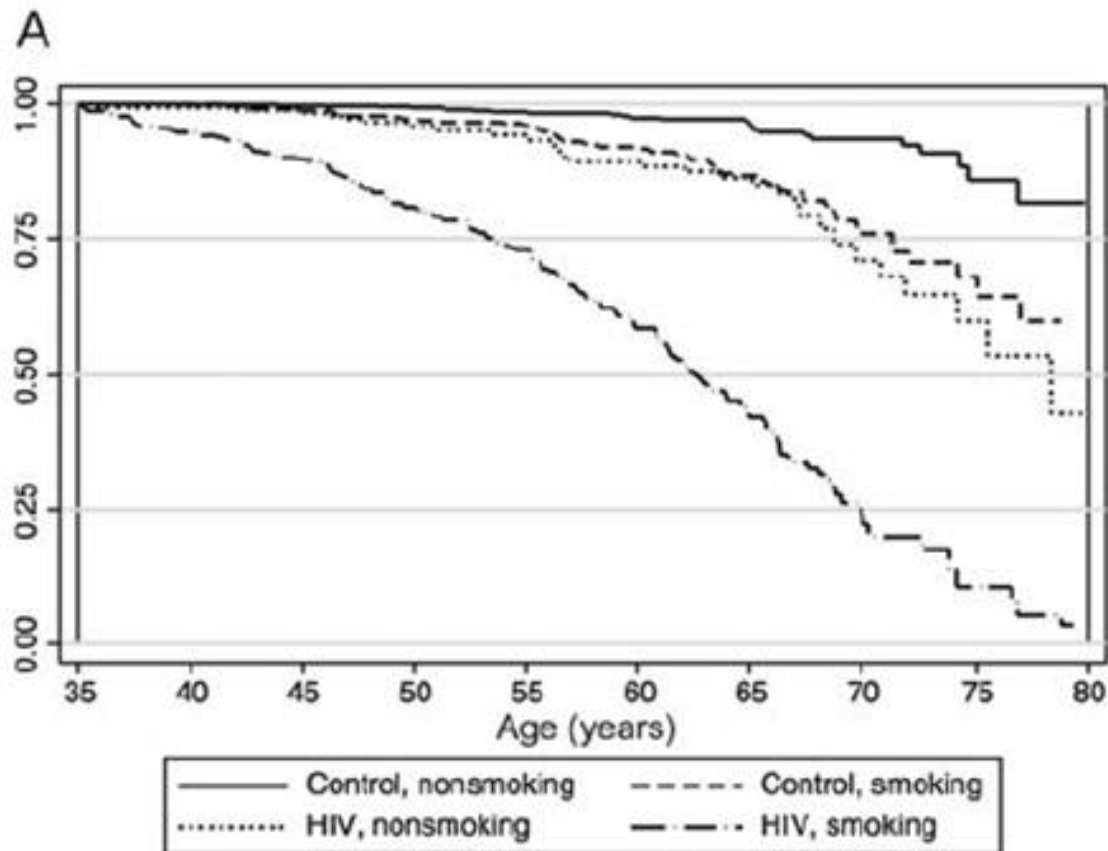


Figure 1. Kaplan-Meier curve showing survival by age, stratified by human immunodeficiency virus and smoking status for all study subjects (A), only males (B), only study subjects of Danish origin (C), and only study subjects from Copenhagen (D). Abbreviation: HIV, human immunodeficiency virus.

HIV/AIDS, smoking and survival (cont.)

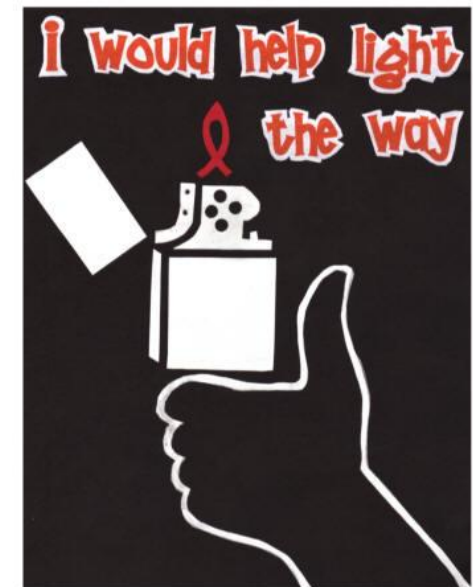
Table 3. Number of Life-Years Lost and Population-Attributable Risk of Death Associated With Smoking and With HIV Among Individuals in the Danish HIV Cohort and the Copenhagen General Population Study (Controls)

Factor	Lost Life-Years (Age 35–80 y) Years (95% CI)	PAR, %
HIV among never smokers		
(never smoking HIV patients vs never smoking controls)	5.1 (4.4–5.8)	0.3
Smoking among controls		
(smoking controls vs never smoking controls)	3.6 (3.1–4.0)	34.4
Smoking among HIV patients		
(smoking HIV patients vs never smoking HIV patients)	12.3 (11.5–13.0)	61.5

Abbreviations: CI, confidence interval; HIV, human immunodeficiency virus; PAR, population-attributable risk.

Hellenberg et al., Clinical Infectious Diseases, December 2012

"WHAT IF YOU WERE HIV POSITIVE?"



Poster by Barry Shepherd - Edgewood High School

WHAT IF IT WERE YOU?
"PROMOTING AWARENESS, COMPASSION, EDUCATION AND SUPPORT"

A project of HIVictorious, Inc.
HIVICTORIOUS.

www.whatifitwereyou.org - www.hivictorious.org

Summary of smoking cessation efforts with PLWHA

- PLWHA are receptive to smoking cessation treatment (Wewers et al. *J Nurse AIDS Care* 2000, Reynolds et al. *AIDS Educ Prev* 2009)
- Cessation programs can be successfully implemented in HIV clinic settings (e.g., Cummins et al. *Nurs Stand* 2005)
- Feasibility of using NRT + supportive counseling (Elzi et al., *Antivir Ther*, 2006)
- MI + NRT vs. self-help + NRT (Ingersoll et al. *AIDS Behav* 2009)
- Safety and tolerability of varenicline (Cui et al. *AIDS Patient Care STDS* 2012)
- Motivational enhancement + NRT vs. health education + NRT (Lloyd-Richardson et al. *Addiction* 2009)
- Intensive group therapy + NRT vs. standard care (Moadel et al. *JAIDS*, 2012)
- Individual counseling + NRT vs. computer-based treatment + NRT vs. self-help + NRT (Humfleet et al. *NTR*, 2013)

An innovative telephone intervention for HIV-positive smokers (R01CA97893)

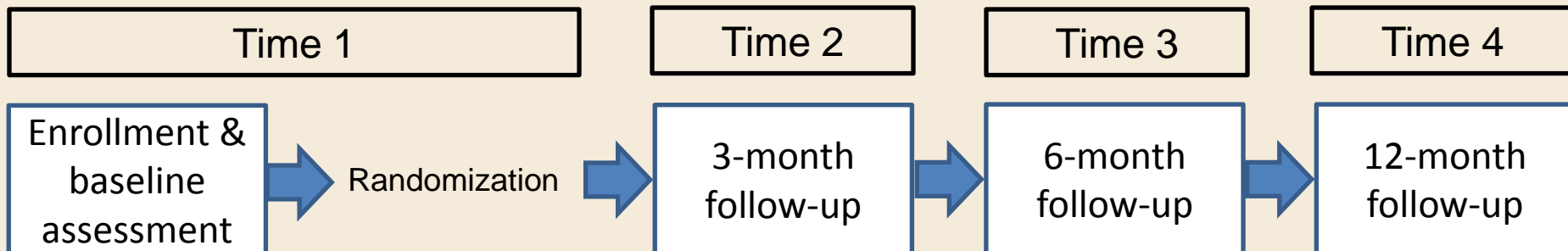
Project Reach Out



1. To develop an innovative smoking cessation intervention for individuals living with HIV/AIDS and compare it to standard cessation treatment in a randomized clinical trial
2. To evaluate the role of motivation, risk perception, self-efficacy, coping skills, social support, and negative affect as potential mediators of smoking abstinence

Study design

- **Two group, randomized controlled trial**
 - Cell phone intervention vs. Usual Care
- **Adaptive randomization**
 - Depression history
 - Nicotine dependence (FTND)



Study site and participants

- Thomas Street Health Center
- Serves predominantly low income, ethnically diverse HIV-positive patients in the greater Houston area
- Provides HIV/AIDS-related medical and psychological services to over 4,000 patients

Eligibility

- Inclusion criteria
 - HIV+
 - ≥ 18
 - Current smoker
 - English or Spanish speaking
 - Willing to set a quit day within 1 week
- Exclusion criteria
 - Physician deemed ineligible based on medical
 - Participation in another smoking cessation program

Intervention groups

Usual Care (UC)

- Brief provider advice to quit
- Written materials
- Instructions on how to receive NRT

Cell Phone Intervention

- All UC components
- Cell phone-delivered proactive counseling
 - 11 phone calls delivered over 3-months
 - Content based on CBT and MI
 - Prepaid cell phones given to participants

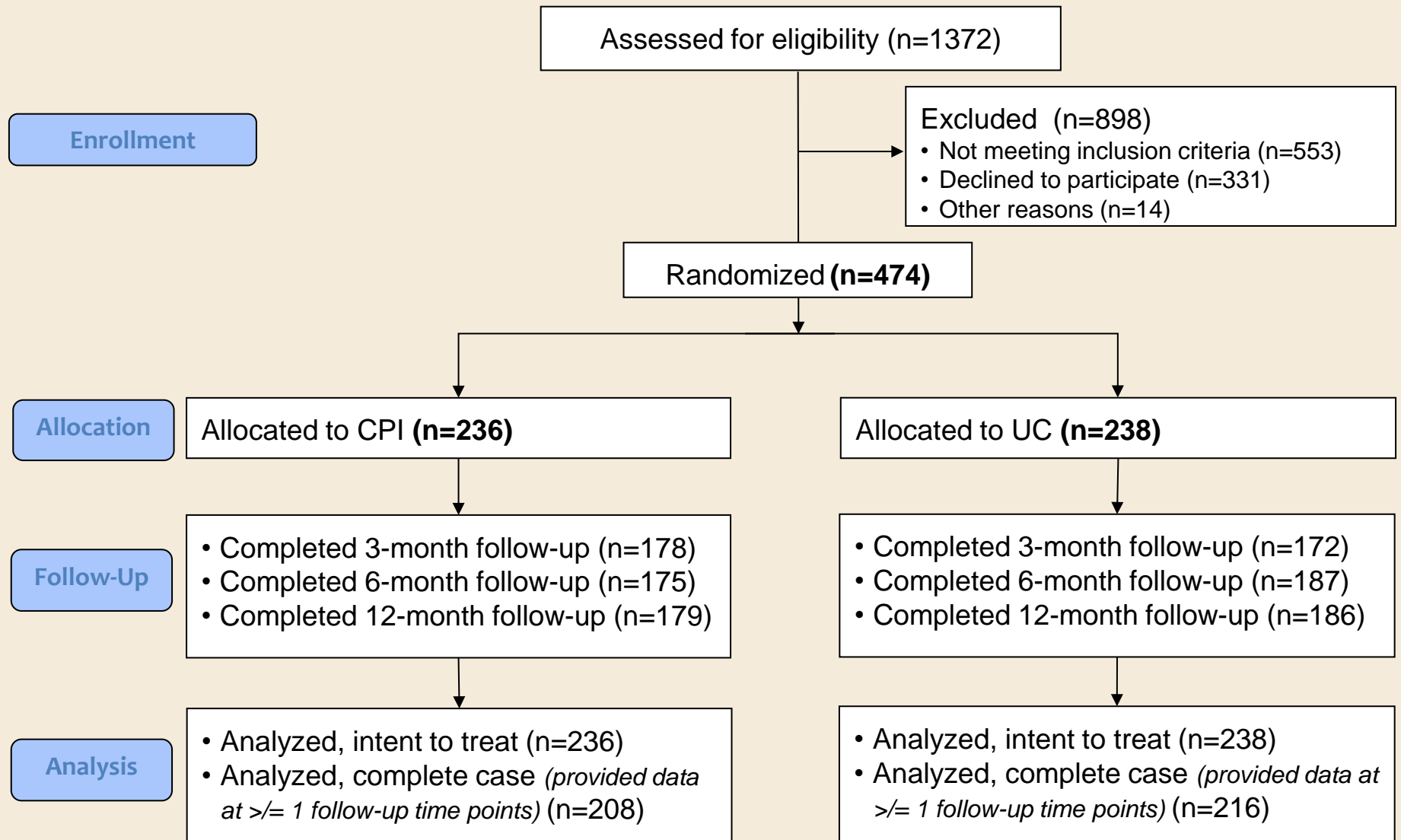


Cell phone intervention (CPI)

Session content and schedule

Call	Time of Call	Content of Call
1	1 day prior to quit date	Preparing to quit - why quit when you're HIV-positive? Making the commitment to quit
2	On Quit Date	Quitting smoking – getting through the first day
3	2 days post quit date	Surviving withdrawal - withdrawal facts and coping skills
4	4 days post quit date	Managing high risk situations
5	7 days post quit date	Stress, negative affect & smoking
6	10 days post quit date	Improving support and asserting yourself
7	2 weeks post quit date	Reviewing problem solving & dealing with lapses
8	4 weeks post quit date	Reinforcing benefits of being an HIV+ nonsmoker
9	6 weeks post quit date	Maintaining commitment – keeping motivated
10	9 weeks post quit date	Successes and challenges in smoking cessation
11	12 weeks post quit date	Long-term relapse prevention

CONSORT flow diagram



Project Reach Out: Socio-demographic characteristics

Baseline demographic characteristics, n=474

Characteristic	UC	CPI	Total
Mean age in years (SD)*	45.70 (7.79)	43.94 (8.26)	44.82 (8.07)
Sex %(n)			
Male	68.90 (164)	71.19 (168)	70.04 (332)
Female	31.09 (74)	28.81 (68)	29.96 (142)
Race/Ethnicity %(n)			
White	12.18 (29)	12.71 (30)	12.45 (59)
African American/Black	78.57 (187)	74.58 (176)	76.58 (363)
Hispanic/Latino	7.98 (19)	10.17 (24)	9.07 (43)
Other	1.26 (3)	2.54 (6)	1.90 (9)
Mean years of formal education (SD)	10.82 (2.53)	10.88 (2.68)	10.85 (2.60)
Education level %(n)			
Less than high school	36.97 (88)	39.83 (94)	38.40 (182)
High school or equivalent	38.14 (91)	37.71 (89)	37.97 (180)
More than high school	24.79 (89)	22.46 (53)	23.63 (112)

*p<0.05

Socio-demographic characteristics

Baseline demographic characteristics, n=474

Characteristic	UC	CPI	Total
Current work status %(n)			
Working full or part time	19.75 (47)	22.46 (53)	21.10 (100)
Not working due to health	65.97 (157)	60.59 (143)	63.29 (300)
Cannot find work	6.72 (16)	8.47 (20)	7.59 (36)
Not working for other reasons	7.56 (18)	8.47 (20)	8.02 (38)
HIV transmission %(n)			
MSM	24.05 (57)	26.38 (62)	25.21 (119)
Heterosexual	45.15 (107)	45.96 (108)	45.55 (215)
Injection drug use	19.83 (47)	14.47 (34)	17.16 (81)
Other	10.97 (26)	13.19 (31)	12.08 (57)
Married/ Living with significant other %(n)	18.91 (45)	16.53 (39)	17.72 (84)

Alcohol & Illicit Drug Use

Health risk behaviors at baseline assessment, n=474

Variable	UC	CPI	Total
Alcohol Use Hazardous/harmful drinking %(n) *AUDIT score of ≥ 8	32.77 (78)	28.81 (68)	30.80 (146)
Illicit drug use in the past month %(n)	38.24 (91)	41.95 (99)	40.08 (190)

Overall treatment effect

Results from generalized linear mixed model regression (GLMM)

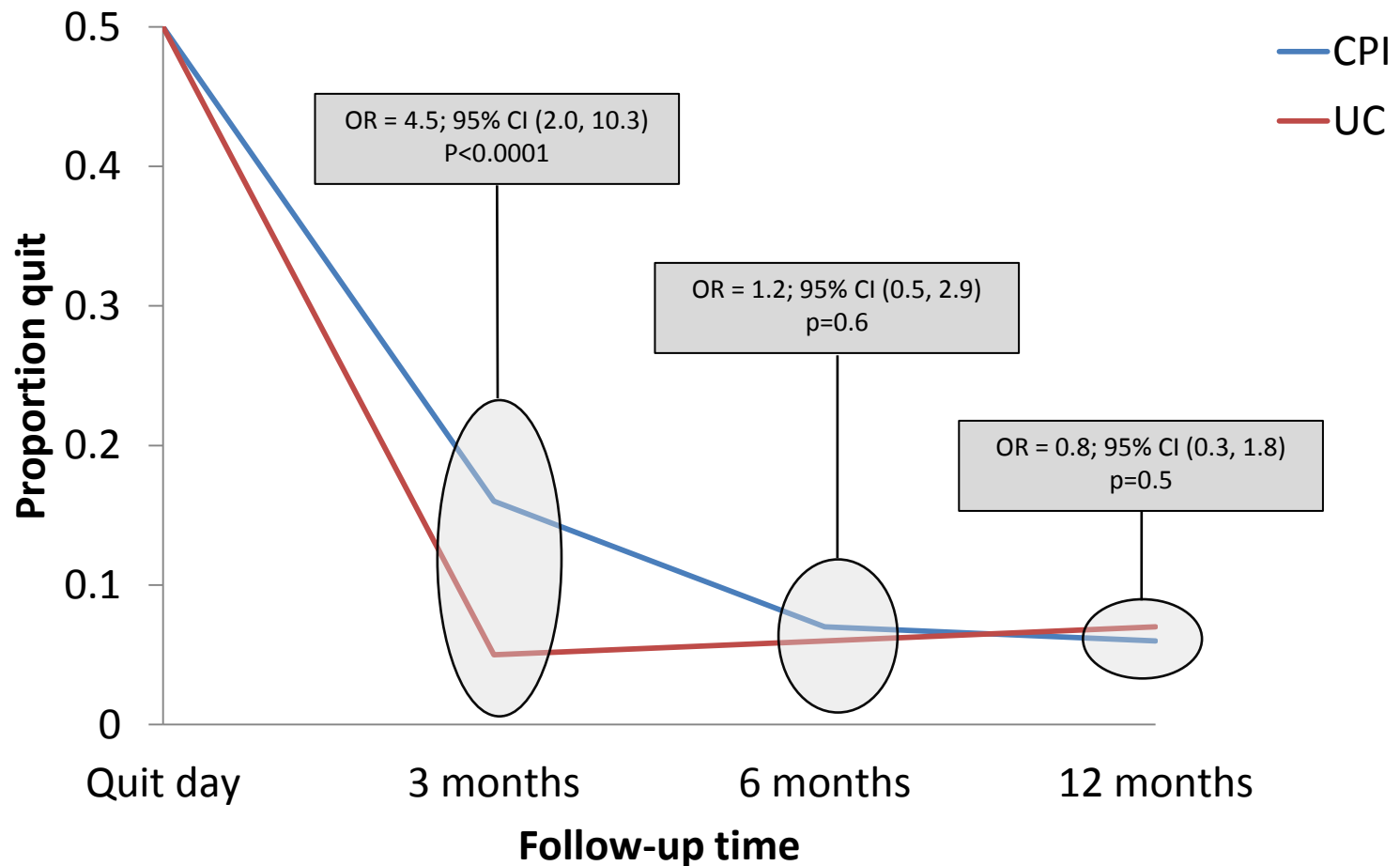
Smoking abstinence	Intention-to-treat		Complete case	
	OR (95% CI)	<i>p</i> value	OR (95% CI)	<i>P</i> value
Data through 12-month follow-up visit	(n=474)		(n=423)	
24 hr	2.36 (1.28, 4.38)	0.006	2.46 (1.31, 4.64)	0.005
7 day*	2.41 (1.01, 5.76)	0.049	2.47 (1.03, 5.94)	0.044
30 day	2.20 (0.83, 5.83)	0.114	2.29 (0.85, 6.15)	0.133

* *primary outcome*

All GLMM modeling adjusted for fixed effects of time and age and random effect of subject.

7-day abstinence by time point

Complete case analysis



Conclusions

Positive

- HIV+ population was receptive to smoking cessation treatment
- CPI (vs. UC) results in a significantly higher 7-day abstinence rate

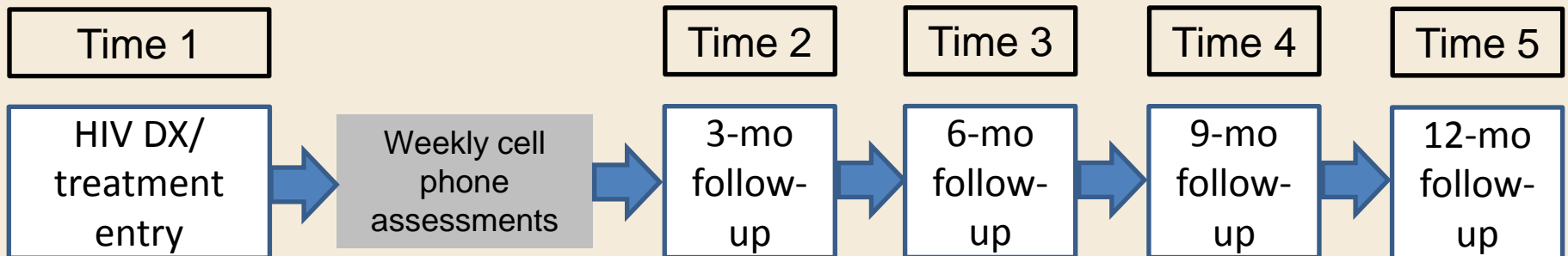
Negative

- Absolute quit rates were low
- Much of the CPI treatment effect was driven by the 3-month outcome (magnitude of effect at 6- and 12-months was smaller), rather than a sustained effect over time

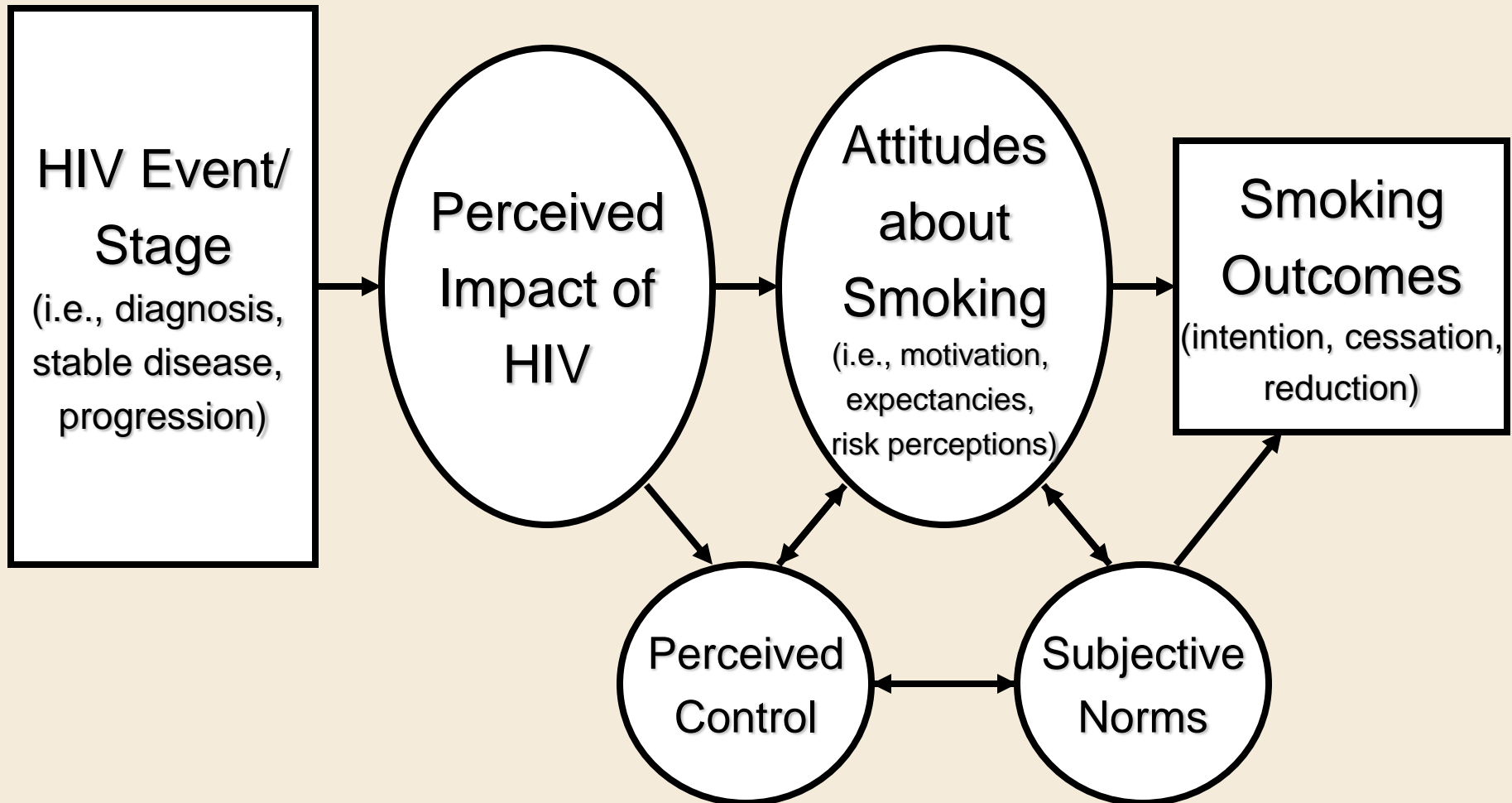
The influence of HIV disease events/stages on smoking attitudes and behaviors (R01CA132636)

Project STATE

1. Assess the relationship between HIV disease events/stages (i.e., HIV diagnosis, stable disease, and progressive disease) and smoking outcomes (i.e., intention to quit, number of quit attempts, and cessation outcomes).
2. Evaluate perceived impact of HIV as a potential mediator of the association between disease event/stage and smoking outcomes.



Conceptual framework Project STATE



Project STATE:

Socio-demographic characteristics

Baseline demographic characteristics, n=361 (English speaking)

Characteristic	Total
Mean age in years (SD)*	39.4 (11.9)
Sex %(n)	
Male	71.7 (259)
Female	28.3 (102)
Race/Ethnicity %(n)	
White	19.1 (69)
African American/Black	67.3 (243)
Hispanic/Latino	10.0 (36)
Other	2.7 (13)
Mean years of formal education (SD)	10.9 (2.7)
Education level %(n)	
Less than high school	35.5 (128)
High school or equivalent	40.2(145)
More than high school	24.3 (88)

Project STATE:

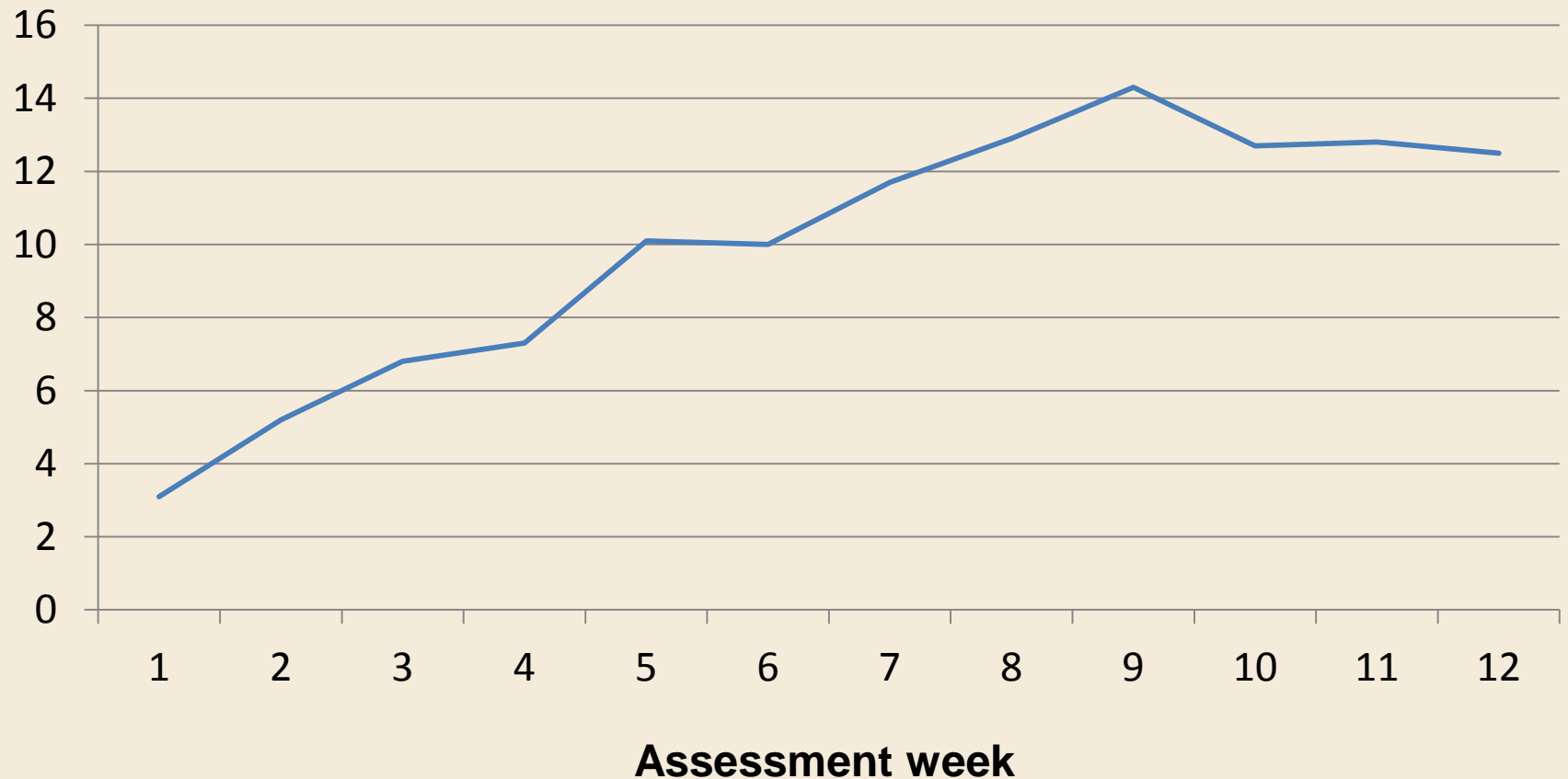
Socio-demographic characteristics

Baseline demographic characteristics, n=361 (English speaking)

Characteristic	Total
Married/ Living with significant other %(n)	17.5 (63)
Current work status %(n)	
Working full or part time	15.2 (55)
Not working due to health	49.6 (179)
Cannot find work	24.7 (89)
Not working for other reasons	10.5 (38)
HIV transmission %(n)	
MSM	36.3 (131)
Heterosexual	42.4 (153)
Injection drug use	9.7 (35)
Other	11.6 (42)
Depression (CES-D score ≥ 16), %(n)	67.9 (245)
Illicit drug use in past 30 days, % (n)	47.6 (172)
Harmful drinking (AUDIT score ≤ 8), % (n)	24.6 (89)

7-day smoking abstinence

Assessed weekly through month 12

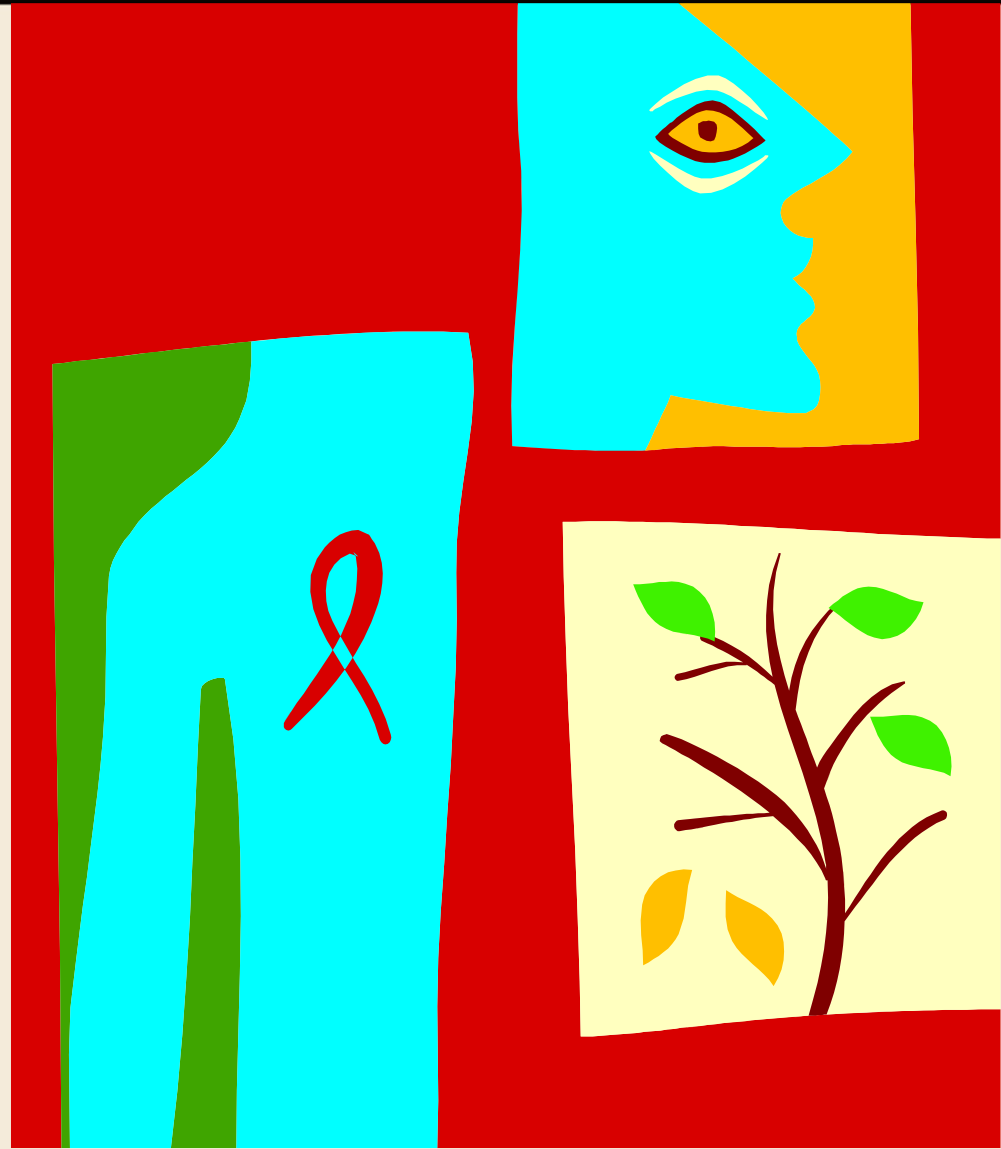


Soon to Start DSRIP

- **Legacy Community Health Services (a large Houston-based FQHC)**
- **N=1000**
- **2 group RCT (SMS/MMS vs. counseling)**
- **Major outcomes:**
 - quit attempts
 - abstinence at 6-months post enrollment

Future directions

- Exploration of potential mediators
- Addressing co-morbidities
- Involving other HIV-care providers
- More advanced mHealth approaches
 - Intervention delivery and assessment
- Reaching a larger population of PLWHA who smoke



Funding Sources

- R01CA097893, Project Reach Out (PI: E. Gritz)
 - R01CA132636, Project STATE (PI: D.Vidrine)
 - P30 CA016672 , Cancer Center Support Grant (PI: R. DePinho)
-
- No industry funding
 - No off-label medication uses



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