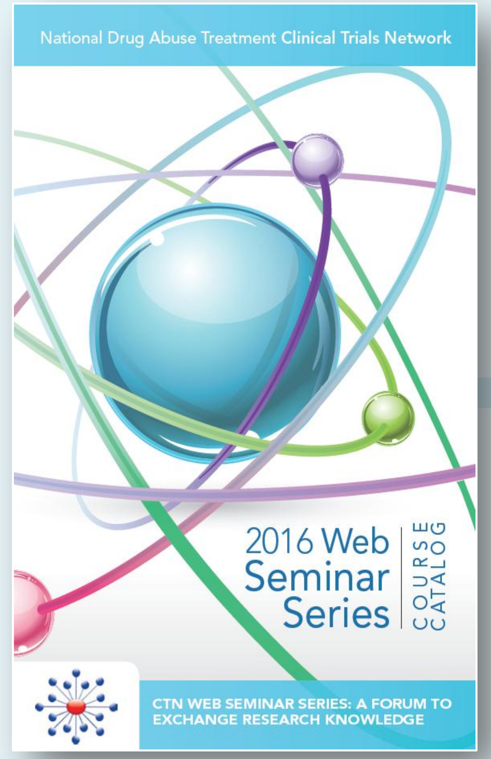

CTN-0044 WEB-TX: A REVIEW OF THE PRIMARY AND SECONDARY OUTCOMES

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CTN WEB SEMINAR SERIES:
A FORUM TO EXCHANGE RESEARCH KNOWLEDGE

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Learning Objectives

- Understand the design and methodological decisions critical to the implementation of an effectiveness trial of a technology-based intervention.
- Review the primary outcomes and key secondary outcomes of the WEB-TX study.
- Discuss new areas of research for technology-based interventions.

Promise of Technology for Behavioral Health

- Mental health and substance use issues are common
- Approximately 10% of those in need receive services
- Increase in service delivery demand
  - Mental Health Parity (2008)
  - Patient Protection and Affordable Care Act (2010)
- Technology as a critical component to promote access, cost efficiencies, and effectiveness of care

The "Smartphone-Dependent" Population: 7% of Americans Rely Heavily on a Smartphone for Online Access

% of U.S. adults who have a smartphone, but lack other broadband internet service at home, and/or have limited options for going online other than their cell phone

ALL ADULTS

64% own a smartphone

15% have limited options for online access other than cell phone

10% have no broadband service at home other than smartphone data plan

7% overlap have limited options for online access **and** no broadband service at home

Pew Research Center American Trends Panel survey, October 3-27 2014.

PEW RESEARCH CENTER

Addressing Traditional Barriers to Treatment

- Enables widespread reach of evidence-based practices
  - On demand access (e.g., geography, time, setting)
  - Extension of care/increase service capacity
- Improves standardization and quality
  - Consistent intervention delivery
  - Reduce cost, limits resource outlay
- Helps reduce stigma and barriers (disparities) in accessing recovery services
- Fosters engagement to enable individuals (and support networks) to lead in their own care management
- Enhances collaboration, communication, coordination, and continuity of care among providers

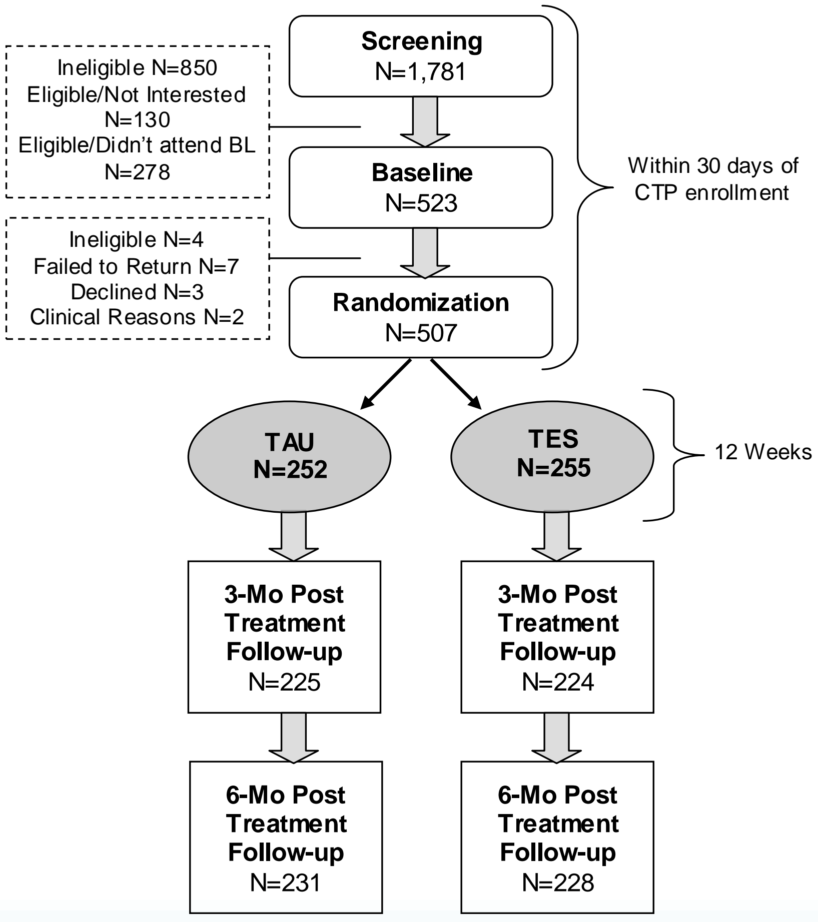
CTN0044 WEB-TX: Rationale

- To evaluate the effectiveness of Therapeutic Education System (TES), an internet-delivered intervention comprised of two science-based addiction treatments
  - Community Reinforcement Approach (Bickel et al., 1997; Higgens et al., 1993; Hunt & Azrin, 1973; Smith, Meyers, & Miller, 2001)
  - Contingency Management (Kellogg et al., 2005; Petry & Bohn, 2003; Stitzer et al., 2010)
- A prior TES study demonstrated comparable outcomes to CRA+CM delivered by therapists (Bickel et al., 2008)
- Studies running simultaneously to WEB-TX demonstrated:
  - Enhanced opioid abstinent rates over 12 months compared to TAU for patients on medication assisted treatment (Marsch et al., 2014)
  - TES benefits over and above CM alone (Christensen et al., 2014)

- We decided to study TES as a "clinician-extender"
  - TES when added to Treatment as Usual (TAU).
  - All patients received some level of face to face counseling with clinicians at the treatment programs
- We decided to study the TES package – CM + CRA
- We decided against a 3 arm design that would disentangle the CRA and CM components
  - [TES (CM + CRA) + TAU] vs. [CM + TAU] vs. TAU
  - Other studies had shown that both CM and CRA components of TES contribute to improved clinical outcome (Roozen et al., 2004; Higgins et al., 1994)

	TES	
CM	*No*	*Yes*
No	TAU	TES + TAU
Yes	CM + TAU	TES + CM + TAU

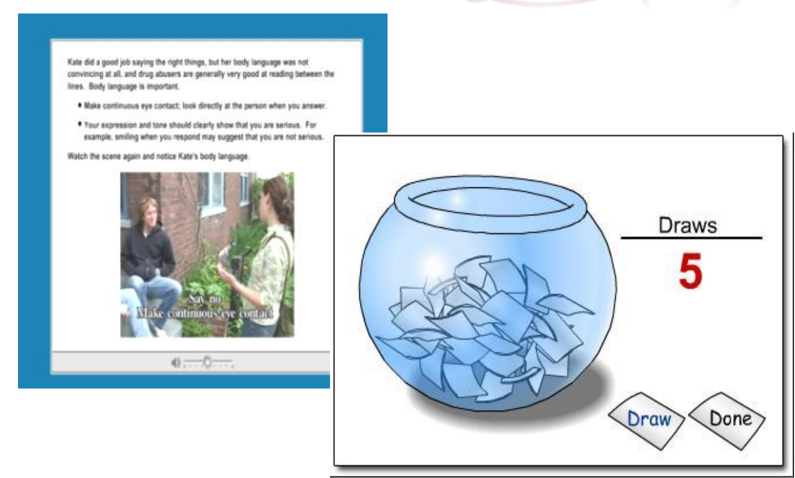
Study Design



- 10 intensive outpatient treatment programs
- TES substituted for about 2 hours/week of TAU
- Eligibility criteria kept broad
- Clinicians provided brief check-ins with TES clients
- TES completed on- or off-site

TES Details

- 32 core & 30 optional self-directed modules (topics) with accompanying audio
- Fluency-based instruction & experiential learning
- Prize-based motivational incentives
- Intermittent schedule of reinforcement: abstinence and module completion



TES Core Modules

- Training Module
- Conducting a Functional Analysis
- Introduction to Problem Solving
- Drug Refusal Skills Training
- Coping with Thoughts about Using
- Managing Negative Thinking
- Managing Negative Moods and Depression
- Increasing Self-Confidence in Decision-Making
- How to Express Oneself in an Assertive Manner
- Steps for Giving Constructive Criticism
- Giving and Receiving Compliments
- Nonverbal Communication
- Attentive Listening
- HIV and AIDS
- Sexual Transmission of HIV and STIs
- Identifying/Managing Triggers for Risky Sex
- What is Functional Analysis?
- Self-Management Planning
- Effective Problem Solving
- Seemingly Irrelevant Decisions
- Awareness of Negative Thinking
- Managing Thoughts about Using
- Decision-Making Skills
- Introduction to Assertiveness
- Introduction to Giving Criticism
- Receiving Criticism
- Communication Skills
- Social Recreational Counseling
- Sharing Feelings
- Sexually Transmitted Infections (STIs)
- Drug Use, HIV and Hepatitis
- Identifying/Managing Triggers for Risky Drug Use

Primary Outcomes

- Abstinence

Illicit drugs and alcohol use in the last 4 weeks of treatment assessed via urine drug screen and self report (TLFB)

- Retention

Time to drop out from TAU confirmed by treatment program records

Sample Characteristics

- Age
  - Mean=34.9 (SD=10.9)
  - Range=18-67
- Sex
  - 37.9% Female
  - 62.1% Male
- Race
  - 56.0% White
  - 22.9% Black/African American
  - 10.7% Multi-racial
  - 10.1% Other
- Ethnicity
  - 10.8% Hispanic/Latino
- Education
  - 23.3% < HS
  - 61.1% = HS
  - 15.6% > HS
- Primary Substance
  - 22.5% marijuana
  - 21.3% opioids
  - 20.5% alcohol
  - 20.1% cocaine
  - 13.6% stimulants
  - 2.0% other

PRIMARY OUTCOMES

Primary Abstinence Outcome: Proportion Abstinent by Abstinence at Study Entry and Treatment Arm

90
80
70
60
50
40
30
20
10
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 3 months 6 months
Half Week/Follow-Up Visit
OR=1.17; p=.489
OR=2.18; p=.003
Abstinent at baseline/study entry
Treatment as usual
Therapeutic Education System
Treatment as usual
Therapeutic Education System
Nonabstinent at baseline/study entry
Treatment as usual
Therapeutic Education System
Treatment as usual
Therapeutic Education System

Abstinent Study Entry 54.2%

Not Abstinent Study Entry 45.8%

Campbell ANC, Nunes EV, et al. (2014). *American Journal of Psychiatry*

Primary Retention Outcome: Kaplan Meier Plots by Treatment Arm

Survival Function

1.0
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0.0

0 1 2 3 4 5 6 7 8 9 10 11 12

Number of Weeks in Treatment

p=.017

Treatment as usual
Therapeutic Education System

Retained WK 12
TES = 47.8%
TAU = 39.7%

Campbell ANC, Nunes EV, et al. (2014). *American Journal of Psychiatry*

Summary of Primary Outcomes

- **Abstinence**
  - TES increased abstinence compared to TAU
  - This effect was mostly among patients still using substances at the time of randomization (urine positive at randomization), who had low abstinence overall, but greater abstinence if assigned to TES.
  - Patients already abstinent at randomization, continued to have high abstinence (~ 70%) during the trial, and TES made little difference in this group.

- **Retention in Treatment**
  - TES modestly improved retention compared to TAU

SECONDARY OUTCOMES

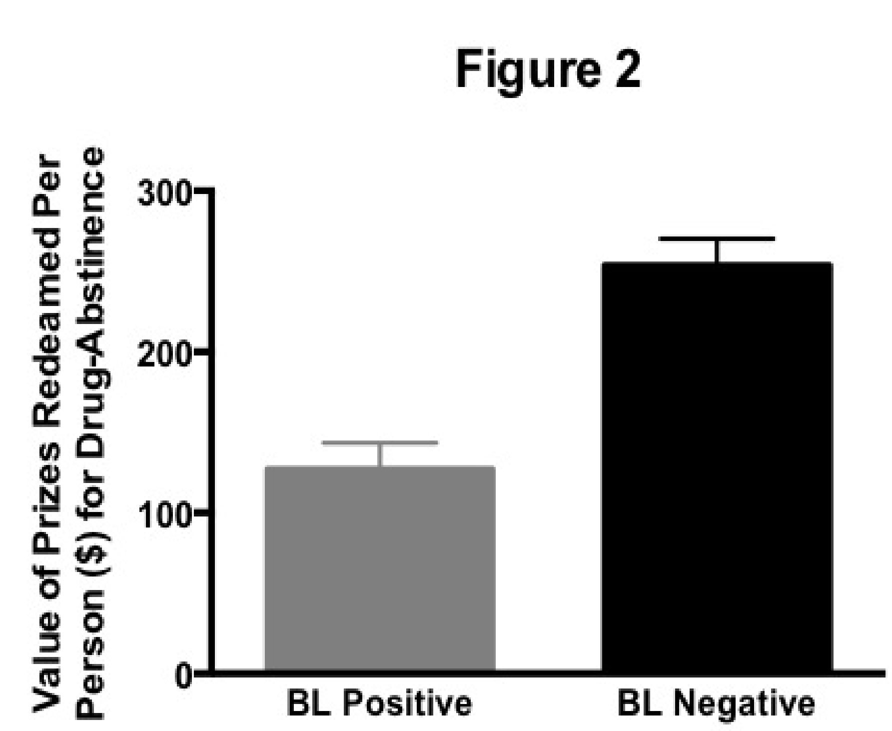
Smoking

- 77% of sample were smokers (n=391)
- Smokers were more likely to be:
  - Younger
  - Female
  - Less educated
  - Unemployed
- 16 smokers (4.1%) using smoking cessation meds at baseline; 12 (3.5%) using meds at week 12
- Overall, no reduction/quitting smoking over treatment phase
- Smoking was associated with poorer treatment outcomes
- Among a sub-set of participants there was a subtle difference favoring TAU (3-way interaction: treatment x baseline abstinence x baseline nicotine dependence)

McClure et al., (2015). *Journal of Substance Abuse Treatment*

Contingency Management Costs

- Distribution of draws earned (median=119 vs 17; $p<.0001$) and prizes redeemed (median=54 vs 9; $p<.001$) for abstinence differed by baseline abstinence status
- Baseline negatives (abstinent) earned on average twice as much in prizes as baseline positives ($245 vs $125)
- Median value of prizes earned: 5.4x greater for baseline negatives compared to baseline positives ($237 vs $44; $p<.001$).



Cunningham et al., (2015). *Journal of Substance Abuse Treatment*

MODERATOR ANALYSES

Primary Substance as a Moderator of Treatment

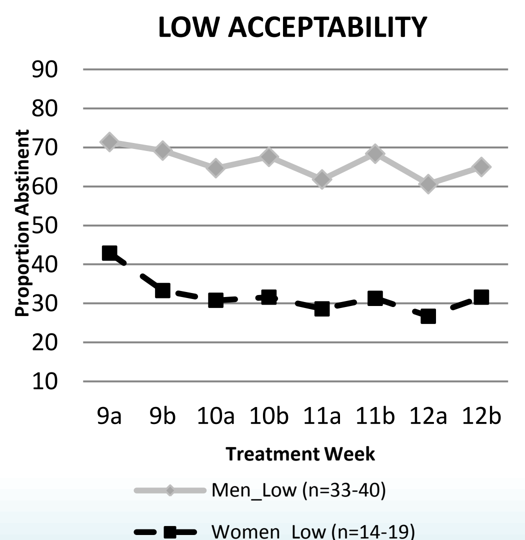
Primary Substance	Odds Ratio*	95% CI	p-value
Stimulants (n=171)	3.59	1.25, 10.27	.02
Alcohol (n=104)	3.15	0.85, 11.65	.09
Marijuana (n=114)	2.64	0.73, 9.52	.14
Opioids (n=108)	0.35	0.09, 1.47	.15

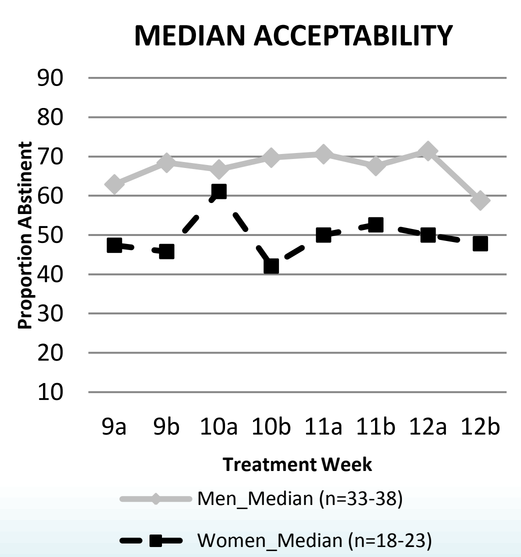
Final generalized linear model: treatment arm x primary drug group significant (p=.06)

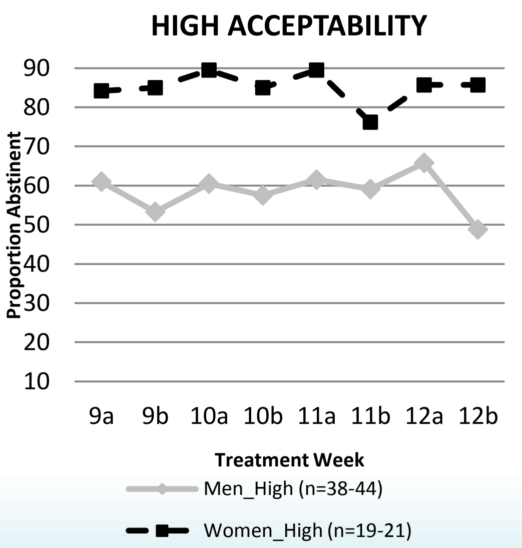
*Odds Ratio is for TES relative to TAU within each primary substance group.

Cochran et al., (2015). *Addictive Behaviors*

- Gender did not moderate treatment effect on abstinence, retention, social functioning or craving
- Women reported higher TES acceptability at week 4 (p=.02); no gender differences at weeks 8 or 12
- Acceptability positively associated with abstinence, but only among women; women with higher acceptability vs lower acceptability (AOR=2.08, 95% CI=1.20, 3.62, p=.01). This was not the case for men (p=.45).







Campbell et al., (2015). *Journal of Substance Abuse Treatment*

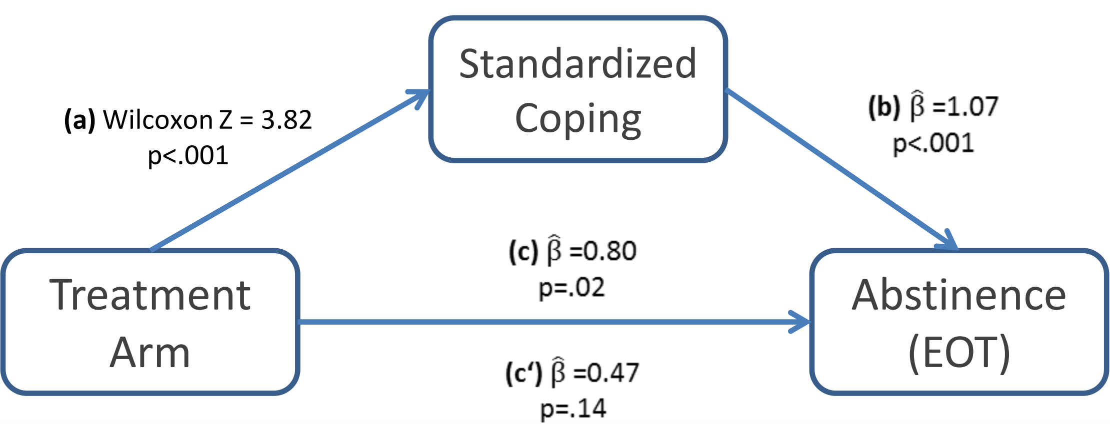
Other Moderator Analyses

- Age (Evans et al., under review)
  - 18-25 [n=118]; 26-44 [n=277]; 45-62 [n=112]
  - Age did not moderate treatment effect on abstinence or retention (wk 12)
  - Young adults dropped out of treatment earlier than oldest group ($p=.02$), irrespective of treatment arm
- Internet Access (Tofighi et al., under review)
  - Internet use was common (74%) and more likely among younger participants and those who completed high school ($p<.001$)
  - Significant interaction (treatment x internet access x baseline abstinence) on time to dropout ($p=.051$); non-abstinent TES participants with internet access had lower rates of attrition compared to TAU ($p=.008$)
- Criminal Justice (Lee et al., under review)
  - CJ status did not moderate the treatment effect on abstinence or retention

MEDIATION ANALYSES

Coping as a Mediator of Treatment

- TES associated with more coping strategies (M=19.3, SD = 4.3) compared to TAU (M=17.9, SD = 4.7) ($p=.001$) (path a)
- More coping strategies were associated with an increased likelihood of abstinence (path b)
- Effect of TES on abstinence (path c) was no longer significant after controlling for coping strategies (path c′), indicating at least partial mediation.



Levesque et al., (under review).

Summary and Implications

- TES is effective at improving treatment outcomes, abstinence and retention in a large, diverse sample
  - TES should be considered for implementation
  - Additional costs of TES and the vouchers was modest
  - Patients with opioid dependence did poorly, likely reflecting absence of medication assisted treatment
  - The study did not disentangle the effect of CM from the CRA component
    - But, coping skills mediated the effect of TES on abstinence outcome, suggesting that the coping skills taught by the CRA component made a difference

Summary and Implications

- Other NIDA supported computer-delivered interventions also promising (e.g., CBT4CBT; Carroll et al., 2008; 2009; 2014)
- Potential Barriers to Implementation
  - Funding and reimbursement under current service delivery models
  - Training clinicians on the opportunities of technology-based interventions; prescribing/integrating technologies into standard care

Future Directions

- Research outside specialty addiction services
- TES as an adjunct to medication-assisted treatment
- Mobile, hand-held devices that leverage benefits of technology-based applications
- Innovative research designs to keep pace with technological advancement
- Utilizing interdisciplinary teams to understand how technology is employed, adopted and sustained, including short- and long-term value added research

NIDA/SAMHSA Technology-based Interventions Blending Product [SUDTECH.org]

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Questions / Comments

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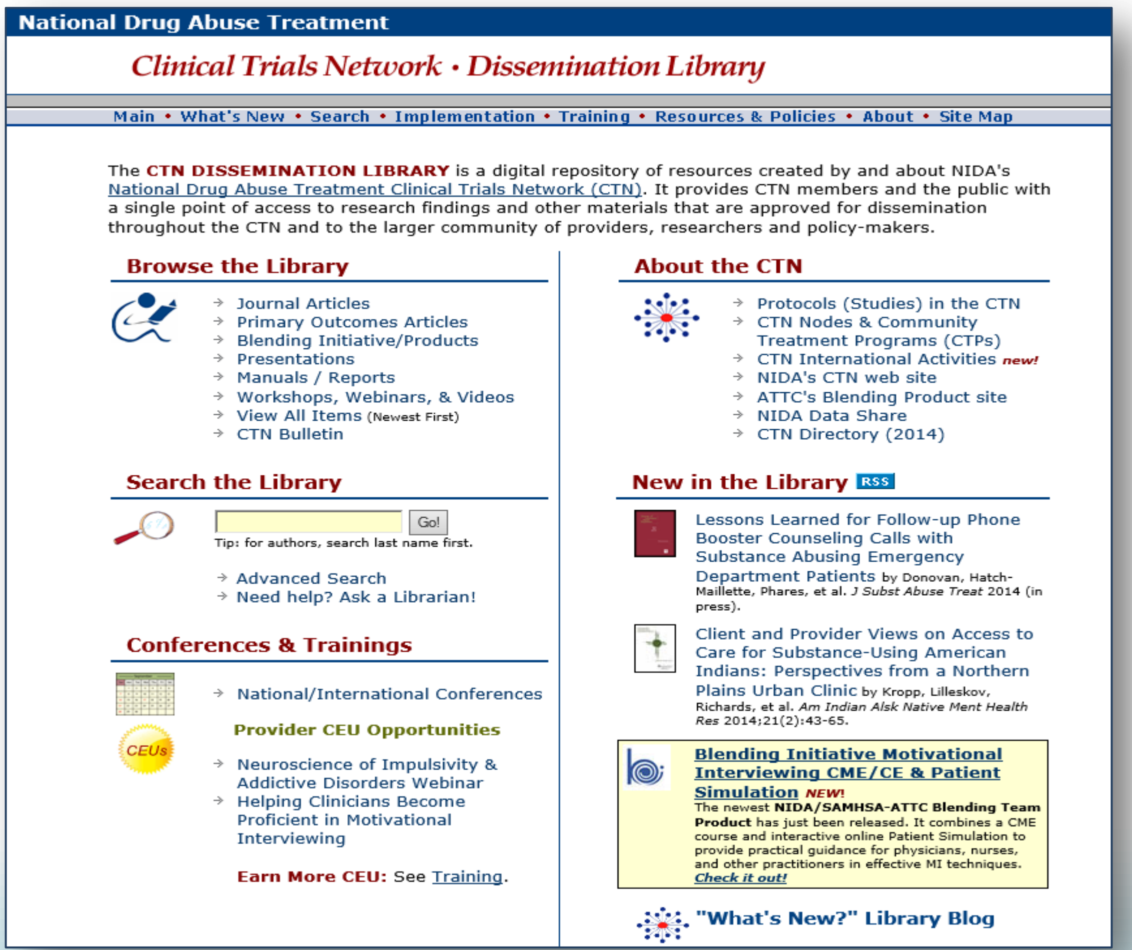

Next Topic…

In The Weeds: Assessing Neurocognitive Brain Imaging and Substance Abuse Measures in Emerging Adults

Wednesday, July 13, 2016
at 1:00 pm ET

THANK YOU FOR YOUR PARTICIPATION