COMpAAAS Intervention

Integrated Stepped Care for Unhealthy Alcohol Use in HIV

October 13, 2011
Unhealthy Alcohol Use

- At risk drinking
  - Binge drinking
- Alcohol Abuse or Dependence
- Moderate Alcohol with Liver Disease
Treatments for Unhealthy Alcohol Use

• Brief interventions
  – At risk drinkers
  – Moderate Alcohol with Liver Disease

• Medications
  – Alcohol Abuse or Dependence
    • Oral naltrexone, injectable naltrexone, disulfiram, acamprosate

• Counseling
  – Alcohol Abuse or Dependence
    • Motivational enhancement therapy, cognitive behavioral therapy, twelve step facilitation

• Infrequently provided to HIV-infected patients
• Not effective for all patients
Rationale for stepped care trial

• Some patients do not benefit from our interventions
  – Patient features may lead to treatment failure
    • Motivation, psychiatric comorbidity
  – Intervention potency may lead to treatment failure
    • Brief interventions
    • Medications
    • Formal counseling

• Standard clinical trial research designs do not allow for assessment of serial interventions after treatment failure

• Efforts after failure are part of standard clinical practice
Stepped Care Evaluations

• Low level treatment is attempted first
  – If successful – continue treatment
  – If unsuccessful, increase treatment intensity

• Reserves more intensive therapies for those patients who need them
  – Efficient use of resources

• More closely mimics clinical care

• Models have been described in smoking, back pain, migraine, anxiety, depression, eating disorders, and opioid dependence
COMpAAAS Intervention

- Integrated Stepped Care for Unhealthy Alcohol Use in HIV
  - 4 sites (Atlanta, Houston, Manhattan, Washington, D.C.)
  - 642 subjects
  - Randomized clinical trial
COMpAAAS Intervention Staffing

- PI: David Fiellin, M.D.
- Co-Investigators:
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    - Kelly Haines
Aims

• In HIV-infected patients with unhealthy alcohol use, to examine the impact of integrated stepped care treatment on:
  – Alcohol consumption
  – VACS Index
Study Design

• 3 linked clinical trials
• 642 subjects
  – At-risk drinking
  – Alcohol Abuse or Dependence
  – Moderate Alcohol and Liver Disease
• Randomized, Integrated Stepped Care vs. Treatment as Usual
• 24 weeks of treatment with follow-up at 12 months
Integrated Stepped Care for Unhealthy Alcohol Use in HIV
Subjects

Inclusion criteria

- HIV-infected
- At-risk Drinking Study – NIAAA criteria
- Alcohol Abuse or Dependence Study – DSM criteria
- Moderate Alcohol and Liver Disease Study
  - No at-risk drinking, abuse or dependence, HCV+ (confirmed by viral load) or Fib-4 >1.45
- Able to understand English and provide informed consent

Exclusion criteria

- Psychotic or severely psychiatrically disabled
- Enrolled in formal alcohol treatment
- Medical conditions that would preclude completing or be of harm during the course of the study
- Pregnant, nursing or unable to use an effective method of birth control
Outcomes

• The primary outcome is alcohol consumption
  – At-risk drinking and Alcohol Abuse and dependence
    • Drinks per week over the last 28 days at 6 months
  – Moderate alcohol + Liver disease
    • Abstinence over the last 28 days at 6 months

  – Adequate power in all 3 groups to detect a clinically meaningful difference in the percent of subjects with no heavy drinking days (PSNHDD)

• Secondary study outcome:
  – 1) Change in VACS index
Progress and timeline

- Yale IRB and NIAAA COC approved
- Interventionist Training
- Trial DB
  - Completed by 1/12
- Research Coordinator training
  - Completed by 2/12
- Interventionist supervision and booster
  - Ongoing