

News Release

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Researchers Identify Most Effective Current Treatments for Alcohol Dependence

Penn Participates in National Study of 1,383 Patients

(Philadelphia, PA) - According to a study that appears in the current issue of the *Journal of the American Medical Association*, researchers at the **University of Pennsylvania School of Medicine** and 10 other sites found that the medication naltrexone, when delivered with structured medical management, or specialized alcohol counseling by a behavioral specialist are equally effective treatments for alcohol dependence.

Results from the National Institutes of Health (NIH)-supported study - "Combining Medications and Behavioral Interventions for Alcoholism" (COMBINE) - show that patients who received naltrexone, specialized alcohol counseling, or both demonstrated the best drinking outcomes after 16 weeks of outpatient treatment. All patients also received Medical Management (MM), an intervention consisting of nine brief, structured outpatient sessions provided by a medical health care professional. Contrary to expectations, the researchers also found that the medication acamprosate had no effect on drinking and showed no benefit in combination with naltrexone.

"We are thrilled to have data from the largest government-sponsored pharmacotherapy study of alcohol dependence that has been done to-date that show how a medically-oriented treatment approach can be effective in treating alcohol disorders," said **Dr. Helen M. Pettinati**, Principal Investigator at Penn, and Professor and Division Director of Penn's Treatment Research Center (TRC).

Study Protocol

NIH's National Institute on Alcohol Abuse and Alcoholism (NIAAA) launched COMBINE in 2001 to identify the most effective current treatments and treatment combinations for alcohol dependence. The largest clinical trial ever conducted of pharmacologic and behavioral treatments for alcohol dependence, COMBINE was conducted at 11 academic sites that recruited and randomly assigned 1,383 recently-abstinent, alcohol-dependent patients to one of nine treatment groups. Eight treatment groups received MM plus medications or placebo: naltrexone (100 milligrams a day), acamprosate (3 grams a day), both naltrexone and acamprosate, or placebo pills. Four of the eight groups also received Combined Behavioral Intervention (CBI) - specialized alcohol counseling that integrated cognitive-behavioral therapy, motivational enhancement, and techniques to enhance mutual help group participation. Patients assigned to the specialized alcohol counseling could receive up to twenty 50-minute sessions in addition to medical management. To test for any effects of pill taking (placebo), the researchers assigned some patients to a ninth group that received specialized alcohol counseling, but no pills, and no more than four visits with a health professional for general medical advice.

Conclusions

During the 16 weeks of treatment and one year after the treatment, the researchers assessed the patients for the percentage of days abstinent from alcohol and time to the first heavy drinking day, defined as four or more drinks per day for women and five or more drinks per day for men. They also assessed the odds of good clinical outcome, defined as abstinence or moderate drinking without alcohol-related problems. As in other large clinical trials, the researchers found that most patients showed substantial improvement during treatment and that both the overall level of improvement and the differences among treatment groups diminished during the follow-up period. In the COMBINE study, however, naltrexone continued to show a small advantage for preventing relapse at one year after the end of active treatment.

"Alcoholism is a serious disease that destroys lives," says Pettinati. "These findings indicate that alcoholism can be treated in a medical setting, giving more people who struggle with an alcohol problem an alternative way to get treatment."

About the Treatment Research Center

The Treatment Research Center (TRC) at the University of Pennsylvania School of Medicine is an outpatient alcohol and drug treatment and research facility that is funded primarily by federal grants. The treatment provided at the TRC includes various types of counseling and the use of medications for detoxification, craving reduction and relapse prevention. Ongoing at the TRC are a number of treatment studies for alcohol, cocaine and nicotine dependence, including naltrexone, medication management, and Combined Behavioral Intervention (CBI). For more information or to schedule an appointment, call (215) 243-9959.

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Penn's School of Medicine is ranked #2 in the nation for receipt of NIH research funds; and ranked #3 in the nation in U.S. News & World Report's most recent ranking of top research-oriented medical schools. Supporting 1,400 fulltime faculty and 700 students, the School of Medicine is recognized worldwide for its superior education and training of the next generation of physician-scientists and leaders of academic medicine.

The University of Pennsylvania Health System includes three hospitals [Hospital of the University of Pennsylvania, which is consistently ranked one of the nation's few "Honor Roll" hospitals by U.S. News & World Report; Pennsylvania Hospital, the nation's first hospital; and Penn Presbyterian Medical Center]; a faculty practice plan; a primary-care provider network; two multispecialty satellite facilities; and home care and hospice.

This release is available online at http://www.uphs.upenn.edu/news/News_Releases/may06/COMBINE.htm