

# Long-term varenicline treatment supports tobacco abstinence in people with mental illness

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Extended treatment with the smoking cessation drug varenicline (Chantix) significantly improved the ability of individuals with serious mental illness to maintain abstinence from tobacco after a standard 12-week course of treatment. In this Massachusetts General Hospital (MGH) study – the first randomized, controlled trial of maintenance pharmacotherapy for smoking cessation in such patients – participants who quit smoking and then received varenicline along with cognitive behavioral therapy for an additional 40 weeks were three times more successful in maintaining abstinence from smoking than those who received cognitive behavioral therapy and a placebo drug.

"We know that relapsing to smoking is a big problem for smokers without psychiatric illness, but relapsing after a course of smoking cessation medication appears to happen even more rapidly in those with schizophrenia and related disorders," says Eden Evins, MD, MPH, director of the MGH Center for Addiction Medicine and lead author of the report in the Jan. 8 *Journal of the American Medical Association*. "Maintenance therapy to help these patients sustain abstinence could reduce an important source of stigma, along with their heavy burden of smoking-related illness."

The authors note that, although the rate of smoking among U.S. adults has dropped more than 50 percent since the mid-1960s, the current prevalence of smoking among those with serious mental illness is even

higher than it was among the general population in 1965. Half of those who smoke and don't quit will die of a smoking-related illness. Although the majority of individuals with schizophrenia or bipolar disorder smoke tobacco, adults with serious mental illness are rarely offered even a 12-week course of smoking cessation medication. In fact, Evins notes, MassHealth – the Massachusetts Medicaid program – does not reimburse mental health care providers for behavioral smoking cessation treatment services.

One small, uncontrolled study conducted at MGH suggested that an additional 40 weeks of cessation medication treatment could significantly cut the relapse rate among those with serious mental illness. The current study was designed to carefully evaluate whether extended varenicline and cognitive behavioral therapy help maintain the success of patients who achieve abstinence after an initial 12-week cessation program. Participants currently being treated for schizophrenia, for a related condition called schizoaffective disorder, or bipolar disorder enrolled in the study at 10 mental health centers in six states.

After the initial 12-week cessation phase, during which all participants received daily doses of varenicline and weekly group cognitive behavioral therapy sessions, 87 of the original 203 participants (42 percent) were considered to be abstinent. Those individuals were randomized to either continued varenicline or a placebo during the 40-week relapse prevention phase. Both groups continued to receive cognitive behavioral therapy on a schedule of declining frequency during the prevention phase, at the end of which all smoking cessation therapies were discontinued.

At the end of the yearlong study period, 60 percent of participants who received varenicline during the relapse prevention phase were abstinent, based on both self-reporting and on measured levels of exhaled carbon monoxide. Only 19 percent of the placebo group were abstinent at this

point. While half of those in the placebo group had relapsed within 35 days of discontinuing varenicline, it took almost a year for half of those in the varenicline group to relapse. Although continued cognitive behavioral therapy was not enough to prevent relapse in the placebo group, the fact that those in the varenicline group who did relapse tended to do so after cognitive behavioral therapy was reduced to a monthly schedule suggests that it may have a role in supporting the benefits of drug therapy.

"Our study showed that cognitive behavioral therapy alone is not enough to help smokers with serious mental illness maintain the abstinence they achieved with a program combining both therapies," Evins explains. "Since we don't know yet how well varenicline would work without cognitive behavioral therapy, we would recommend that these patients be offered both therapies together to support smoking cessation and continued abstinence. Additional studies are needed to evaluate combinations of pharmacotherapy with less intensive behavioral support – like telephone quit lines – and to determine whether other smoking cessation drugs like bupropion would work as well for maintenance treatment."

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