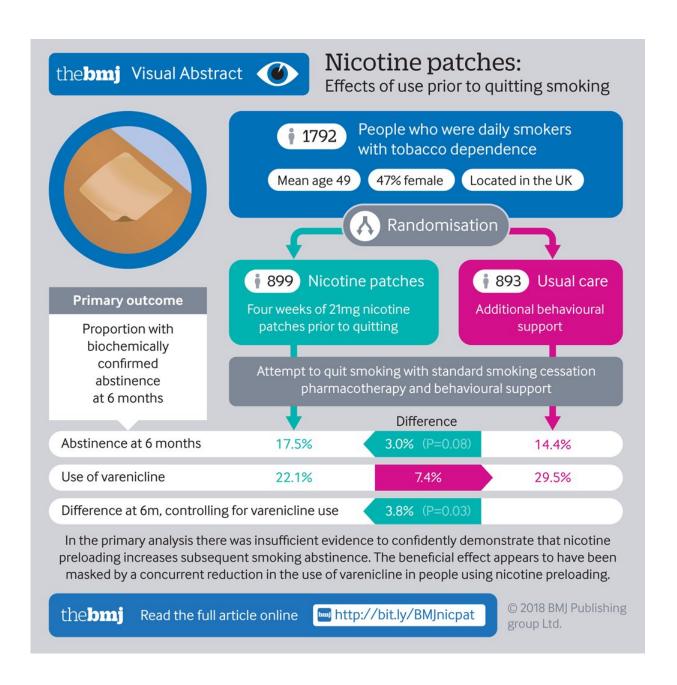


## No clear evidence that nicotine 'preloading' helps smokers to quit

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Credit: British Medical Journal

There is insufficient evidence to show that using nicotine patches for four weeks before a quit attempt (known as "preloading") improves long-term smoking abstinence, finds a trial published by *The BMJ* this week.

The researchers found that <u>nicotine</u> preloading reduces craving intensity and seems to make quitting easier, but that this beneficial effect may have been masked by a concurrent reduction in the use of varenicline in the period after quit day. As varenicline is the most effective <u>smoking</u> <u>cessation drug</u>, this may have undermined the benefit of preloading.

If it were possible to overcome this unintended consequence, nicotine preloading "could lead to a worthwhile increase in long term smoking abstinence," they say.

Although there have been several new drugs for tobacco cessation since the 1970s, treatment has remained largely the same, with behavioural support to motivate and strengthen a person's resolve to remain abstinent and drugs to reduce the strength of urges to smoke after quit day.

Some studies have suggested that using nicotine replacement therapy before a quit attempt is more effective than when used in the conventional way to support abstinence, while other studies suggest preloading has no effect.

A research team from the UK Centre for Tobacco and Alcohol Studies, led by Professor Paul Aveyard at the University of Oxford, set out to examine the effectiveness of a nicotine patch worn for four weeks before a quit attempt.



Their trial involved 1,792 nicotine dependent adults from four cities across England, who smoked an average of 19 cigarettes a day. Most were middle aged and had lower levels of education than the UK average, half were male and a quarter were from minority ethnic groups.

Smokers were randomly assigned to two groups—half received standard smoking cessation drug therapy and behavioural support, while the other half received the same treatment plus a daily <u>nicotine patch</u> to use for four weeks before quit day.

After nicotine preloading had ended, smokers could opt to continue to use either <u>nicotine replacement therapy</u> or non-nicotine drug therapy.

At six months, 18% of participants who used nicotine patches before their quit attempt had stopped smoking compared with 14% who received standard therapy.

At 12 months, the differences between the two groups were modest with 14% of participants achieving abstinence in the nicotine preloading group compared with 11% who had received standard therapy.

Prolonged abstinence from smoking was confirmed using a carbon monoxide breath test.

Use of varenicline after quit day differed between arms (22% in the preloading arm and 30% in the control arm). After statistically controlling for this, there was clearer evidence that preloading increased the likelihood of achieving abstinence (a 4% difference between arms).

While there was no excess of serious adverse events in the trial, around 1 in 20 people experienced minor adverse events caused by nicotine preloading, such as nausea and headaches.



This trial has both strengths and limitations, say the authors. For example, it was considerably larger than previous studies on this topic, thus achieving good precision, and the 'open-label' design makes the results easier to apply to clinical practice.

However, this design can be seen as a limitation because the participants know which treatment group they are in and this may have affected their expectations of success.

"Evidence was insufficient to confidently show that nicotine preloading increases subsequent <u>smoking abstinence</u>," they conclude. "The beneficial effect may have been masked by a concurrent reduction in the use of varenicline in people using nicotine preloading, and future studies should explore ways to mitigate this unintended effect."

**More information:** Effects on abstinence of nicotine patch treatment before quitting smoking: parallel, two arm, pragmatic randomised trial, *BMJ* (2018). <a href="www.bmj.com/content/361/bmj.k2164">www.bmj.com/content/361/bmj.k2164</a>

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