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RJ Reynolds has not published a negative randomised clinical trial of Camel Snus for smoking cessation

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In 2009, RJ Reynolds Tobacco (RJR) created ‘The Smoker Cessation/Migration Study’, a randomised control trial, to compare Camel Snus to Nicorette nicotine replacement therapy (NRT) for smoking cessation over 1 year. RJR also examined the effect of providing information on the health benefits of switching from cigarettes to smokeless tobacco (ST).¹²

RJR’s clinical studies division,³ together with legal, financial, marketing and innovation teams,⁴ created the earliest protocols.

The study had three arms, with 200 smokers in each: (1) Camel Snus with one-time relative risk ST information; (2) Camel Snus without ST information; and (3) Nicorette lozenges. All participants were given study products for 12 weeks to aid with smoking cessation.⁵ Biochemically-verified cigarette smoking status (exhaled carbon monoxide and cotinine) was recorded at baseline and at 3, 6 and 12 months, to determine the primary end points of point prevalence and continuous abstinence. The study was powered to detect an absolute ~10% difference in smoking cessation.²⁵

RJR considered comparing Camel Snus to quitting ‘cold turkey’, but opted not to, over concerns that the study would show that Camel Snus was not superior to ‘cold turkey’, and the large number of participants required to detect the unknown differences in smoking cessation rates between Camel Snus and placebo.¹

Recruitment occurred in 2011–2012,^{6–10} and data collection appears to have been completed in 2013.

Two abstracts on the study, which were presented at the October 2014 CORESTA Congress, an international tobacco industry trade association, were found in the Truth Tobacco Documents Library.⁵¹¹

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Contributors SAG developed the idea for the study. EEN collected the data and drafted the paper. Both authors revised the paper and approved it for submission.

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Smoking cessation rates were low, 1–5%, depending on the end point, and were statistically insignificant among the three arms. Participants who continued smoking and using study products reduced their cigarette consumption ($p < 0.05$), although the amount was not reported.¹¹

Before the study was designed, RJR was aware of a similar study planned by University of Minnesota professor, Dorothy Hatsukami, because Hatsukami had contacted RJR, in 2006, to purchase Camel Snus at wholesale rates, for a pilot study.^{12–15}

Subsequently, in 2010–2014, Hatsukami completed a full study that had 80% power to detect a 10% difference in smoking cessation—similar to the RJR study, where participants were randomised to either Camel Snus (Hatsukami did not obtain the product directly from RJR) or NRT for 12 weeks—and found no significant difference in continuous smoking cessation at 26 weeks between Camel Snus and nicotine gum (2.6% vs 5.1%, respectively).¹⁶

As of April 2016, we have found no evidence that RJR's study protocol was registered at ClinicalTrials.gov and no evidence that the full results were published in a peer-reviewed journal. The demonstration that Camel Snus with or without education on the lower risk of smokeless tobacco was no better than NRT at promoting smoking cessation is of concern because over-the-counter NRT is associated with significantly depressed smoking cessation.¹⁷

Regulatory agencies, including the US Food and Drug Administration, should require RJR to provide the full results of the trial and use that information, together with the published scientific literature, as part of assessing the accuracy of claims that snus is an effective smoking cessation aid.

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