

Methods

Study design and participants

We did this three parallel group, randomised controlled trial in Auckland, New Zealand. First randomisation was on Sept 6, 2011, and last follow-up was on July 5, 2013. The published protocol describes procedures in detail.¹³ In brief, people were eligible if they were aged 18 years or older, had smoked ten or more cigarettes per day for the past year, wanted to stop smoking, and could provide consent. We recruited via community newspapers, inviting people to call the study centre for eligibility prescreening, done by research assistants, who also completed follow-up assessments. We excluded pregnant and breastfeeding women; people using cessation drugs or in an existing cessation programme; those reporting heart attack, stroke, or severe angina in the previous

2 weeks; and those with poorly controlled medical disorders, allergies, or other chemical dependence. Participants were mailed study information, and consent forms to sign and return. The Northern X Regional Ethics Committee approved the study (Number NTX/10/11/111); the Standing Committee on Therapeutic Trials approved the use of nicotine e-cigarettes because they were not permitted for sale in New Zealand, but could be imported for personal use or research.

Randomisation and masking

Callers who met the inclusion criteria and gave demographic details and information about nicotine dependence (Fagerström test for nicotine dependence [FTND]¹⁴) were randomised by the study statistician (VP) in a 4:4:1 ratio to nicotine e-cigarettes, patches, or placebo

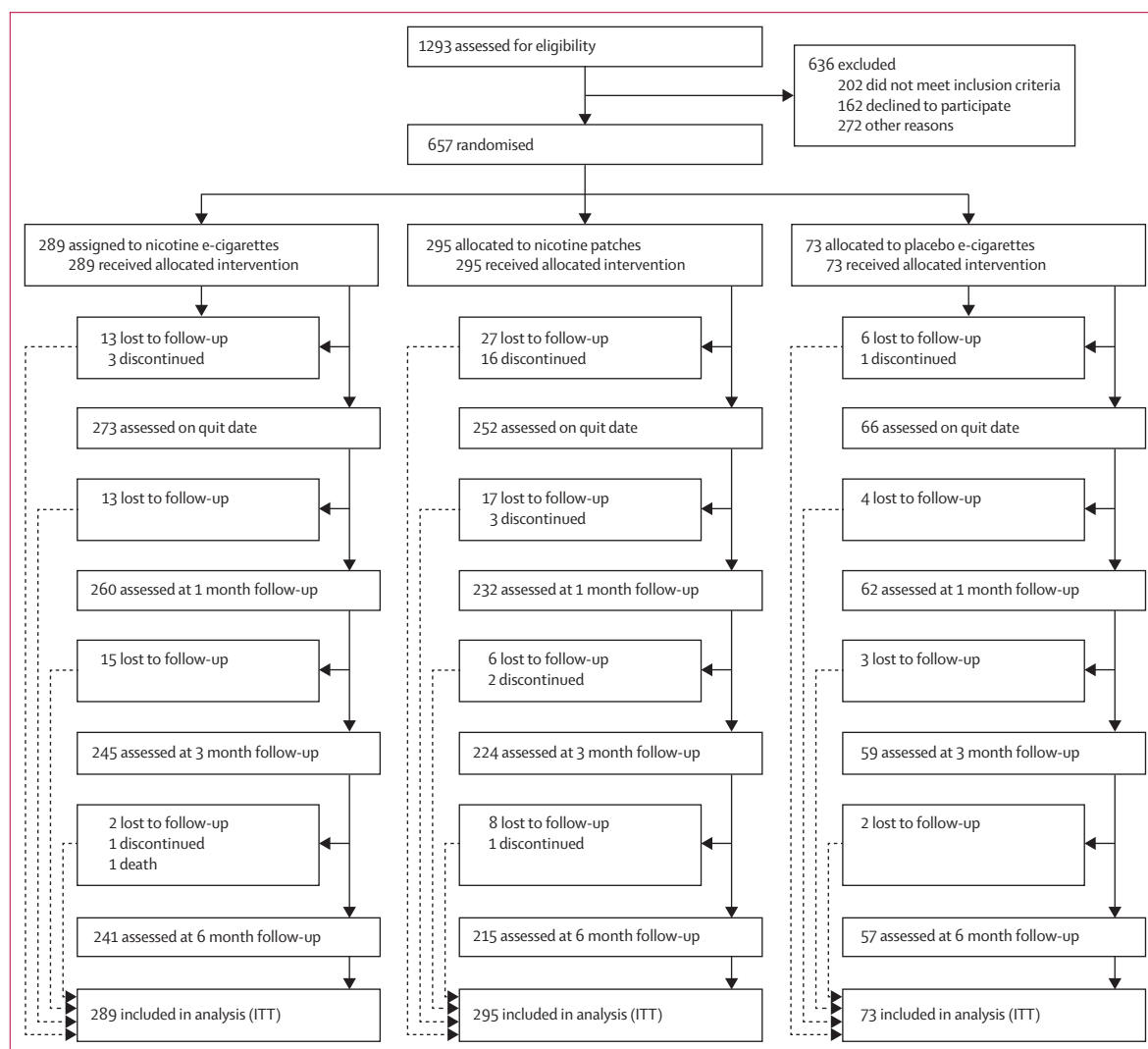


Figure 1: Trial profile

11 protocol violations occurred in the nicotine e-cigarettes group (three pregnancies, seven no biochemical validation, one undisclosed medication ineligibility). 11 protocol violations occurred in the patches group (four pregnancies, four no biochemical validation, three undisclosed medication ineligibility). Three protocol violations occurred in the placebo e-cigarettes group (one no biochemical validation, two undisclosed medication ineligibility). ITT=intention to treat.