E-cigarettes compared with nicotine replacement therapy within the UK Stop Smoking Services: the TEC RCT

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Scientific summary

The TEC RCT

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Scientific summary

Background

UK Stop Smoking Services (SSSs) provide a combination of behavioural support and licensed stop smoking medications. Over the past few years, a large number of smokers in the UK have stopped smoking with the help of e-cigarettes. So far, SSSs have been reluctant to include e-cigarettes among their treatment options because data on their efficacy compared with licensed medications are lacking.

Design

This was a randomised controlled trial comparing e-cigarettes with nicotine replacement therapy (NRT).

Setting

The setting comprised three sites that provide local SSSs.

Participants

The participants were 886 smokers seeking help, who were aged ≥ 18 years, not pregnant or breastfeeding, had no strong preference to use or not to use NRT or e-cigarettes in their quit attempt and were currently not using NRT or e-cigarettes.

Interventions

The NRT arm received NRT of their choice (single or combination), provided for up to 12 weeks. The e-cigarette arm received an e-cigarette starter pack and were encouraged to buy additional e-liquids and e-cigarette products of their choice. Both arms received the same standard behavioural support. Participants attended weekly sessions at their SSS, as per standard practice, and provided outcome data at 4 weeks. They were then followed up by telephone at 6 and 12 months. Participants reporting abstinence or at least a 50% reduction in smoking at 12 months were invited to attend for carbon monoxide (CO) validation.

Main outcome measures

The primary outcome was CO-validated sustained abstinence rates at 52 weeks post target quit date. Several sensitivity analyses were also prespecified. Participants lost to follow-up or not providing biochemical validation were included as non-abstainers. Secondary outcomes included CO-validated sustained abstinence rates between 26 and 52 weeks, abstinence rates at previous time points [4 weeks (CO validated) and 26 weeks (self-report)], CO-validated reduction in smoking and smoke intake of ≥ 50%, and treatment adherence and ratings. A cost-efficacy analysis of the intervention was also conducted.

Results

Clear differences between the two trial arms emerged early on. Participants in the e-cigarette arm showed significantly better adherence and experienced fewer urges to smoke throughout the initial 4 weeks of their quit attempt than those in the NRT arm, and gave their allocated product more favourable ratings. The e-cigarette arm had significantly higher validated quit rates at all time points. Regarding the primary outcome, sustained biochemically validated 1-year quit rate with NRT was 10%, which corresponds with success rates reported previously for the UK SSSs. In the e-cigarette arm, the quit rate was 18% (risk ratio 1.83, 95% confidence interval 1.30 to 2.59; $p < 0.001$). Participants assigned to e-cigarettes reported significantly less coughing and phlegm at 1 year than those assigned to NRT. A detailed economic analysis confirmed that, because e-cigarettes incur lower NHS costs than NRT and generate a higher quit rate, e-cigarette use is more cost-effective.

Conclusions

Within the context of multisession treatment for smokers seeking help, e-cigarettes were significantly more effective than NRT. If SSSs provide e-cigarette starter packs, it will boost their success rates and improve the cost-efficacy and probably also the attractiveness of their service.

Limitations

E-cigarettes are popular and easily accessible. Participants in the NRT arm were more likely to switch to e-cigarettes than participants in the e-cigarette arm were to switch to NRT. However, this could be expected to bias the results towards the null hypothesis. The control intervention included NRT combinations and so it was not possible to compare e-cigarettes with a single NRT, but, as NRT combinations are more effective than a single NRT, this too makes the trial more conservative. The trial results apply to settings in which smokers can freely select the types of e-cigarettes and e-liquids that they like, namely real-life usage, but may not be generalisable to providing just a single e-cigarette product to all.

Trial registration

This trial is registered as ISRCTN60477608.

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