

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

Peter Hajek,¹ Anna Phillips-Waller,^{1*} Dunja Przulj,¹ Francesca Pesola,² Katie Myers Smith,¹ Natalie Bisal,¹ Jinshuo Li,³ Steve Parrott,³ Peter Sasieni,² Lynne Dawkins,⁴ Louise Ross,⁵ Maciej Goniewicz,⁶ Qi Wu³ and Hayden J McRobbie¹

¹Health and Lifestyle Research Unit, Wolfson Institute of Preventive Medicine, Queen Mary University of London, London, UK

²King's Clinical Trials Unit, Institute of Psychiatry, King's College London, London, UK

³Department of Health Sciences, University of York, York, UK

⁴Centre for Addictive Behaviours Research, School of Applied Sciences, London South Bank University, London, UK

⁵Leicester City Council, Leicester, UK

⁶Department of Health Behavior, Division of Cancer Prevention and Population Sciences, Roswell Park Comprehensive Cancer Center, Buffalo, NY, USA

*Corresponding author a.phillips-waller@qmul.ac.uk

Declared competing interests of authors: Peter Hajek received research funding from, and provided consultancy to, manufacturers of stop smoking medications (Pfizer Inc., New York City, NY, USA). Hayden J McRobbie received a grant from the National Institute for Health Research Health Technology Assessment programme; he also received honoraria for speaking at smoking cessation meetings and attended advisory board meetings organised by Pfizer Inc. and Johnson & Johnson (New Brunswick, NJ, USA). Dunja Przulj received a research grant from Pfizer Inc. Maciej Goniewicz provided consultancy to Johnson & Johnson. Lynne Dawkins reports personal fees from attorneys at law outside the submitted work. Jinshuo Li reports grants from the National Coordinating Centre for Health Technology Assessment (NCCHTA) during the conduct of the study.

Published August 2019

DOI: 10.3310/hta23430

Scientific summary

The TEC RCT

Health Technology Assessment 2019; Vol. 23: No. 43

DOI: 10.3310/hta23430

NIHR Journals Library www.journalslibrary.nihr.ac.uk

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 $\geq 50\%$, 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.

Funding

Funding for this study was provided by the Health Technology Assessment programme of the National Institute for Health Research. The trial was supported by the Cancer Research UK Prevention Trials Unit (grant A16893).

ISSN 1366-5278 (Print)

ISSN 2046-4924 (Online)

Impact factor: 3.819

Health Technology Assessment is indexed in MEDLINE, CINAHL, EMBASE, The Cochrane Library and the Clarivate Analytics Science Citation Index.

This journal is a member of and subscribes to the principles of the Committee on Publication Ethics (COPE) (www.publicationethics.org/).

Editorial contact: journals.library@nhr.ac.uk

The full HTA archive is freely available to view online at www.journalslibrary.nhr.ac.uk/hta. Print-on-demand copies can be purchased from the report pages of the NIHR Journals Library website: www.journalslibrary.nhr.ac.uk

Criteria for inclusion in the *Health Technology Assessment* journal

Reports are published in *Health Technology Assessment* (HTA) if (1) they have resulted from work for the HTA programme, and (2) they are of a sufficiently high scientific quality as assessed by the reviewers and editors.

Reviews in *Health Technology Assessment* are termed 'systematic' when the account of the search appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

HTA programme

The HTA programme, part of the National Institute for Health Research (NIHR), was set up in 1993. It produces high-quality research information on the effectiveness, costs and broader impact of health technologies for those who use, manage and provide care in the NHS. 'Health technologies' are broadly defined as all interventions used to promote health, prevent and treat disease, and improve rehabilitation and long-term care.

The journal is indexed in NHS Evidence via its abstracts included in MEDLINE and its Technology Assessment Reports inform National Institute for Health and Care Excellence (NICE) guidance. HTA research is also an important source of evidence for National Screening Committee (NSC) policy decisions.

For more information about the HTA programme please visit the website: <http://www.nets.nhr.ac.uk/programmes/hta>

This report

The research reported in this issue of the journal was funded by the HTA programme as project number 12/167/135. The contractual start date was in October 2014. The draft report began editorial review in April 2018 and was accepted for publication in September 2018. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the reviewers for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

This report presents independent research funded by the National Institute for Health Research (NIHR). The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, NETSCC, the HTA programme or the Department of Health and Social Care. If there are verbatim quotations included in this publication the views and opinions expressed by the interviewees are those of the interviewees and do not necessarily reflect those of the authors, those of the NHS, the NIHR, NETSCC, the HTA programme or the Department of Health and Social Care.

© Queen's Printer and Controller of HMSO 2019. This work was produced by Hajek *et al.* under the terms of a commissioning contract issued by the Secretary of State for Health and Social Care. This issue may be freely reproduced for the purposes of private research and study and extracts (or indeed, the full report) may be included in professional journals provided that suitable acknowledgement is made and the reproduction is not associated with any form of advertising. Applications for commercial reproduction should be addressed to: NIHR Journals Library, National Institute for Health Research, Evaluation, Trials and Studies Coordinating Centre, Alpha House, University of Southampton Science Park, Southampton SO16 7NS, UK.

Published by the NIHR Journals Library (www.journalslibrary.nhr.ac.uk), produced by Prepress Projects Ltd, Perth, Scotland (www.prepress-projects.co.uk).

NIHR Journals Library Editor-in-Chief

Professor Ken Stein Professor of Public Health, University of Exeter Medical School, UK

NIHR Journals Library Editors

Professor John Powell Chair of HTA and EME Editorial Board and Editor-in-Chief of HTA and EME journals. Consultant Clinical Adviser, National Institute for Health and Care Excellence (NICE), UK, and Honorary Professor, University of Manchester, and Senior Clinical Researcher and Associate Professor, Nuffield Department of Primary Care Health Sciences, University of Oxford, UK

Professor Andrée Le May Chair of NIHR Journals Library Editorial Group (HS&DR, PGfAR, PHR journals) and Editor-in-Chief of HS&DR, PGfAR, PHR journals

Professor Matthias Beck Professor of Management, Cork University Business School, Department of Management and Marketing, University College Cork, Ireland

Dr Tessa Crilly Director, Crystal Blue Consulting Ltd, UK

Dr Eugenia Cronin Senior Scientific Advisor, Wessex Institute, UK

Dr Peter Davidson Consultant Advisor, Wessex Institute, University of Southampton, UK

Ms Tara Lamont Director, NIHR Dissemination Centre, UK

Dr Catriona McDaid Senior Research Fellow, York Trials Unit, Department of Health Sciences, University of York, UK

Professor William McGuire Professor of Child Health, Hull York Medical School, University of York, UK

Professor Geoffrey Meads Professor of Wellbeing Research, University of Winchester, UK

Professor John Norrie Chair in Medical Statistics, University of Edinburgh, UK

Professor James Raftery Professor of Health Technology Assessment, Wessex Institute, Faculty of Medicine, University of Southampton, UK

Dr Rob Riemsma Reviews Manager, Kleijnen Systematic Reviews Ltd, UK

Professor Helen Roberts Professor of Child Health Research, UCL Great Ormond Street Institute of Child Health, UK

Professor Jonathan Ross Professor of Sexual Health and HIV, University Hospital Birmingham, UK

Professor Helen Snooks Professor of Health Services Research, Institute of Life Science, College of Medicine, Swansea University, UK

Professor Ken Stein Professor of Public Health, University of Exeter Medical School, UK

Professor Jim Thornton Professor of Obstetrics and Gynaecology, Faculty of Medicine and Health Sciences, University of Nottingham, UK

Professor Martin Underwood Warwick Clinical Trials Unit, Warwick Medical School, University of Warwick, UK

Please visit the website for a list of editors: www.journalslibrary.nihr.ac.uk/about/editors

Editorial contact: journals.library@nihr.ac.uk