Smoking Cessation Intervention for severe Mental Ill Health Trial (SCIMITAR): a pilot randomised control trial of the clinical effectiveness and cost-effectiveness of a bespoke smoking cessation service

Emily Peckham,[1] Mei-See Man,[2] Natasha Mitchell,[1] Jinshuo Li,[1] Taeko Becque,[1] Sarah Knowles,[3] Tim Bradshaw,[4] Claire Planner,[3] Steve Parrott,[1] Susan Michie,[5] Charles Shepherd[6] and Simon Gilbody[1]*

[1]Department of Health Sciences, University of York, York, UK
[2]School of Social and Community Medicine, University of Bristol, Bristol, UK
[3]Centre for Primary Care, University of Manchester, Manchester, UK
[4]The School of Nursing, Midwifery and Social Work, University of Manchester, Manchester, UK
[5]Department of Clinical, Educational and Health Psychology, University College London, London, UK
[6]Faculty of Health and Social Care, University of Hull, Hull, UK

*Corresponding author

Declared competing interests of authors: none

Published March 2015
DOI: 10.3310/hta19250

Scientific summary

Smoking Cessation Intervention for severe Mental Ill Health Trial (SCIMITAR)
Health Technology Assessment 2015; Vol. 19: No. 25
DOI: 10.3310/hta19250

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

Scientific summary

Background

The prevalence of smoking among patients who have experienced severe mental ill health (SMI) is high, despite smoking being a known health hazard associated with numerous diseases such as cancer and heart disease. People with SMI such as bipolar disorder and schizophrenia smoke more heavily and are more likely than the general population to be nicotine dependent. Despite the culture of smoking in mental health services, around 50% of people with SMI express a desire to quit smoking. However, the services currently available to aid quitting may not be suitably responsive or clinically effective for patients with SMI. Therefore, the role of this study is to develop a bespoke smoking cessation (BSC) intervention specifically targeted at people with SMI with an emphasis on expert, individually tailored and enhanced support provided by a mental health professional trained in smoking cessation behavioural support [mental health smoking cessation practitioner (MHSCP)]. This initial pilot study will provide information on the introduction of the BSC intervention and give preliminary estimates of effect size, which can in the future form the basis of a definitive trial of clinical effectiveness and cost-effectiveness.

Objectives

The overarching objective is to eventually establish the clinical effectiveness and cost-effectiveness of a BSC intervention compared with usual general practitioner (GP) care for people with SMI. Prior to this, some preliminary development and research needs to be conducted, and our objective in this project was to deliver a pilot trial prior to conducting a definitive randomised controlled trial (RCT). The pilot trial will ultimately inform the design of a definitive trial.

The specific objectives of the Smoking Cessation Intervention for Serious Mental Ill Health Trial (SCMITAR) pilot trial were:

1. to develop a BSC service, based on evidence-supported treatments, for people with severe mental illness
2. to establish the acceptability and uptake of this BSC service by people with SMI in primary care and specialist mental health services
3. to test the feasibility of recruitment and follow-up in a pilot trial of a BSC service among patients with SMI
4. to obtain preliminary estimates of effect size in relation to smoking cessation at 12 months.

Design

A pragmatic, two-arm, parallel-group, pilot RCT.

Interventions

Participants were randomised to receive either a BSC service or usual care by their GP or mental health specialist. The BSC service was delivered by a mental health professional (MHSCP) trained to deliver smoking cessation behavioural support. The MHSCP provided an individually tailored smoking cessation service based on current guidelines for smoking cessation services but with enhanced levels of contact and

support. Participants randomised to usual GP care were advised to see their GP or to consult with usual NHS quit smoking services with no specific adaptation or enhancement in relation to SMI.

Participants

Potential participants were identified by (1) GP referral, (2) written approach by the GP after identification by GP database screening, (3) primary care referral after an annual health check, (4) referral from Care Programme Approach (CPA) co-ordinators and Community Mental Health Teams (CMHTs) or (5) self-referral by advertisements in outpatient departments, mental health clinics and day centres. To be eligible potential participants needed to be aged 18 years and over, have experienced severe mental illness such as bipolar disorder, schizophrenia or a related psychotic illness, smoke and have expressed a desire to either give up smoking or cut down to quit smoking.

Outcomes

The primary outcome was carbon monoxide (CO)-verified smoking cessation at 12 months. In the absence of a CO measurement, self-reported smoking cessation was used. Secondary smoking-related outcomes were reduction in number of cigarettes smoked, Fagerstrom Test for Nicotine Dependence (FTND) and motivation to quit (MTQ) questionnaire. Other secondary outcomes were a measure of mood [Patient Health Questionnaire-9 items (PHQ-9)], health status [Short Form Questionnaire-12 items (SF-12)], and a measure of health utility [European Quality of Life-5 Dimensions (EQ-5D)]. Secondary outcomes were each measured at 1, 6 and 12 months. Body mass index (BMI) was measured at the end of the trial (12 months) to explore whether or not smoking cessation was associated with weight gain. Aspects of health economics and service utilisation were collected by questionnaire in order to measure cost-effectiveness.

Results

Between May 2011 and May 2012, 97 participants were recruited into the SCIMITAR pilot study. The most common severe mental health problems were schizophrenia and other psychotic illness ($n = 57$; 59%), schizoaffective disorder ($n = 10$, 10%) and bipolar disorder ($n = 30$, 31%). Forty-six participants were randomised to a BSC service and 51 were randomised to usual GP care. Participants were aged between 19 years and 73 years and there were more male ($n = 58$) than female ($n = 39$) participants. At baseline, participants reported smoking between 5 and 60 cigarettes per day (mean 25 cigarettes) and had long smoking histories (mean 27 years).

Out of 46 participants in the intervention group, 41 attended at least one session. The number of sessions per participant ranged from 0 to 25. The average number of sessions per participant was 10. The mainstay of pharmacological treatment chosen by GPs and patients was nicotine replacement therapy. People in receipt of usual care rarely accessed any form of NHS smoking cessation treatment, but often purchased over-the-counter nicotine replacement products.

At 12 months, 36% of participants had stopped smoking in the BSC group, compared with 23% in the usual-care group. The adjusted odds ratio was 2.9 (95% confidence interval 0.8 to 10.5) indicating a greater likelihood of smoking cessation in the BSC group than the usual-care group, but this was not statistically significant.

In terms of secondary smoking-related outcomes at 12 months, the BSC group generally performed better than the usual-care group. At 12 months the MTQ score was higher, number of cigarettes smoked per day was lower, number of cessation attempts was higher and length of cessation was longer in the BSC group,

although these differences were not statistically significant. At 3 and 6 months, there were no differences in any of the smoking-related outcomes.

Mental well-being – as measured by the PHQ-9 and SF-12 – was not different between groups at 1 and 6 months. There was a non-significant difference at 12 months, with lower mood in the BSC group. In terms of physical health outcomes at 12 months, the BSC group fared better than the usual-care group overall, with slightly higher physical component scores and slightly lower BMI, although the differences were not statistically significant.

In the qualitative evaluation of the acceptability of BSC we identified four primary themes. Themes 1 and 2 reflected the lack of support for smoking cessation in current services and, consequently, the perceived benefits of the BSC intervention, which was more tailored to this population. Themes 3 and 4 reflect challenges and barriers reported by patients and professionals, including difficulties sustaining engagement and difficulties liaising with primary care.

The pilot economic analysis demonstrated that it was feasible to carry out a full economic analysis and highlighted ways in which questionnaires designed to capture information needed for the economic analysis could be improved.

Discussion

The main objectives of the pilot trial have been met. A BSC intervention designed for those with SMI has been developed to the point at which this can be delivered in a clinical trial. Sufficient people with SMI have been recruited to a trial and followed up to allow a biologically verified (Russell standard) outcome to be obtained at 12 months. Preliminary estimates of effect based on an underpowered pilot trial show a direction of effect across a range of outcomes that are in favour of a BSC intervention. There was some evidence of lowered mood in the BSC intervention and this issue needs to be explored further in a fully powered trial.

Conclusions

A definitive trial of clinical effectiveness and cost-effectiveness can now be conducted on the basis of the findings of the SCIMITAR pilot trial.

Implications for health care

Although it is important to ensure that there is equitable provision of smoking cessation services for all populations (including those with SMI), it would be premature to invest in BSC services without the results of a definitive clinical trial.

Recommendations for future research

A definitive trial is now needed to establish the clinical effectiveness and cost-effectiveness of BSC services for people with SMI.

Trial registration

This trial is registered as ISRCTN79497236.

Funding

This project was funded by the National Institute for Health Research Health Technology Assessment programme and will be published in full in *Health Technology Assessment*, Vol. 19, No. 25. See the NIHR Journals Library website for further project information.

Health Technology Assessment

HTA/HTA TAR

ISSN 1366-5278 (Print)

ISSN 2046-4924 (Online)

Impact factor: 5.116

Health Technology Assessment is indexed in MEDLINE, CINAHL, EMBASE, The Cochrane Library and the ISI Science Citation Index and is assessed for inclusion in the Database of Abstracts of Reviews of Effects.

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

Editorial contact: nihredit@southampton.ac.uk

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

This report

The research reported in this issue of the journal was funded by the HTA programme as project number 07/41/05. The contractual start date was in December 2010. The draft report began editorial review in December 2013 and was accepted for publication in April 2014. 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.

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