A bespoke smoking cessation service compared with treatment as usual for people with severe mental ill health: the SCIMITAR+ RCT

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Scientific summary

The SCIMITAR+ RCT

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Scientific summary

Background

Smoking is highly prevalent among patients who have experienced severe mental ill health (SMI). This is despite the fact that smoking is a known health hazard, a cause of cancer and associated with numerous diseases such as heart disease. People with SMIs such as bipolar disorder and schizophrenia smoke more heavily and are more likely to be nicotine dependent than the general population. Despite the 'culture' of smoking in mental health services, over half of people with SMI who are smokers express a desire to quit smoking. However, the services currently available to aid quitting may not be suitably responsive to or effective for patients with SMI. A bespoke smoking cessation (BSC) intervention tailored to the needs of people with SMI was developed and its acceptability to people with SMI was tested in a pilot randomised controlled trial (RCT) – the SCIMITAR (smoking cessation intervention for severe mental ill health) trial. The intervention was found to be acceptable to people with SMI and, therefore, the role of this study was to test the SCIMITAR intervention in a full-scale RCT.

Objectives

The specific objectives of the SCMITAR+ trial were to establish:

- the clinical effectiveness of a BSC intervention compared with usual care for people with SMI
- the cost-effectiveness of a BSC intervention for people with SMI.

Methods

Design

A pragmatic, two-arm, parallel-group, individually randomised controlled trial.

Interventions

Participants were randomised to receive either a BSC service or usual care. The BSC service was delivered by a mental health professional [mental health smoking cessation practitioner (MH-SCP)] trained to deliver smoking cessation interventions. The MH-SCP 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 care were advised to see their general practitioner (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 database screening, (2) direct GP referral or primary care referral following an annual health check, (3) direct referral via community mental health teams and psychiatrists, (4) recruitment from service user groups and (5) recruitment via an ongoing interventional cohort study [the Lifestyle Health and Wellbeing Cohort; see www.york.ac.uk/healthsciences/closing-the-gap/cohort/ (accessed 25 April 2019)].

To be eligible, potential participants needed to be aged ≥ 18 years, have experienced severe mental ill health (e.g. 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 exhaled CO-verified smoking cessation at 12 months. Secondary smoking-related outcomes were CO-verified smoking cessation at 6 months, reduction in the number of cigarettes smoked, the Fagerström Test for Nicotine Dependence and the Motivation to Quit questionnaire. Other secondary outcomes were measures of depression and anxiety (Patient Health Questionnaire-9 items and Generalised Anxiety Disorder Assessment-7 items) and health status (Short Form questionnaire-12 items) to measure general physical and mental health, and a measure of health utility (EuroQol-5 Dimensions, five-level version) and the Health Economics/Service Utilisation Questionnaire as measures of cost-effectiveness. Secondary outcomes were each measured at 6 and 12 months. Body mass index was measured at both follow-ups to explore whether or not smoking cessation was associated with weight gain.

Results

Between October 2015 and December 2016, 526 participants were recruited into the SCIMITAR+ RCT. The most common severe mental health problems were schizophrenia or other psychotic illness ($n = 342$, 65.0%), bipolar disorder ($n = 115$, 21.9%) and schizoaffective disorder ($n = 66$, 12.5%). Two hundred and sixty-five participants were randomised to a BSC service and 261 were randomised to usual care. Participants were aged between 19 and 72 years (mean 46 years), and there were more male ($n = 309$) participants than female ($n = 216$) participants, with one participant identifying as transgender. At baseline, participants reported smoking an average of 25 cigarettes per day and had long smoking histories (mean 30 years).

Out of 265 participants allocated to the BSC intervention, 232 (88%) attended at least one session (average number of sessions attended was 6.4, range 1–14). The intervention group had a higher rate of CO-verified smoking cessation at 6 and 12 months than the usual-care group [adjusted odds ratio (OR) 12 months: 1.6, 95% confidence interval (CI) 0.9 to 2.8; OR 6 months: 2.4, 95% CI 1.2 to 4.7]. This was not statistically significant at 12 months ($p = 0.12$) but was statistically significant at 6 months ($p = 0.01$). Participant follow-up exceeded 85% at 12 months. In total, 111 serious adverse events (SAEs) were reported (69 in the BSC group and 42 in usual care); the majority were unplanned hospitalisations due to unrelated deterioration in mental health condition ($n = 98$). The remaining SAEs were unplanned hospitalisations associated with pre-existing health problems ($n = 6$) or death ($n = 7$). One event was deemed to be possibly related to the trial procedures (inpatient hospitalisation due to infective chronic obstructive pulmonary disease).

The mainstay of pharmacological treatment was nicotine replacement therapy. People in receipt of usual care rarely accessed any form of smoking cessation treatment, but often purchased over-the-counter nicotine replacement products.

The BSC intervention for people with SMI is likely (57%) to be less costly but more effective than usual care, from a NHS and Personal Social Services perspective. Depending on the threshold considered, the probability of BSC being cost-effective could range from 62% at a willingness to pay threshold of £0 to nearly 90% at £100,000 per quality-adjusted life-year (QALY) gained. Although the difference in neither costs nor QALYs was statistically significant in itself, there was an indication that the intervention costs might be offset by the reduction in wider health-care services costs. However, this result was not necessarily associated with participants' smoking status.

Conclusions

In the SCIMITAR+ trial, we have shown that people with SMI are more ready to engage with a bespoke intervention that results in increased 6-month quit rates.

Implications for health care

Clinicians are sometimes reluctant to offer smoking cessation advice to patients under their care, and this is in part due to concerns that treatment is ineffective or that quitting might cause a deterioration in mental health. The results of the SCIMITAR+ trial will be helpful in informing clinical practice, as we have shown that quitting can be achieved for people who use mental health services just as much as it can be for all smokers. Clinicians should therefore ask all of their patients about their smoking status and offer referrals to effective smoking cessation services such as those described in the SCIMITAR+ trial. Clinicians can also be confident, on the basis of the results of this trial and systematic review evidence, that smoking cessation is likely to either be beneficial to mental health or not harm mental health.

The results of the SCIMITAR+ trial will be helpful for service commissioners who seek to implement guidance for smoking cessation among hard-to-reach groups, such as people with SMI.

Recommendations for future research

Research is needed to establish how quitting can be sustained among people with SMI who engage with an evidence-supported quit smoking intervention. The role of e-cigarettes in helping people with SMI to cut down on or quit smoking also needs to be explored.

In addition, research is needed to complement the findings of the SCIMITAR+ trial, to establish the clinical effectiveness and cost-effectiveness of very brief opportunistic interventions among people with SMI.

Trial registration

This trial is registered as ISRCTN72955454.

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This report

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