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Short report

# Smoking cessation in severe mental illness: combined long-term quit rates from the UK SCIMITAR trials programme

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**Summary**

Smoking contributes to health inequalities for people with severe mental illness (SMI). Although smoking cessation interventions are effective in the short term, there are few long-term trial-based estimates of abstinence. The SCIMITAR trials programme includes the largest trial to date of a smoking cessation intervention for people with SMI, but this was underpowered to detect anticipated long-term quit rates. By pooling pilot and full-trial data we found that quit rates were maintained at 12 months (OR = 1.67, 95% CI 1.02–2.73, $P = 0.04$). Policymakers can now be confident that bespoke smoking cessation interventions produce successful short- and long-term quitting.

**Declaration of interest**

None.

**Keywords**

Psychotic disorders; statistical methodology; pharmaceutical drug trial; mortality; anthropology.



Life expectancy among people with severe mental illnesses (SMIs) such as schizophrenia and bipolar disorder is reduced by around 20 years.[1] Smoking contributes to this profound health inequality and remains one of the most important modifiable risk factors for early death and poor physical health.[2] Although the rates of smoking are falling for most sections of the population, the prevalence of smoking remains at around 50% for people with severe mental ill health.[3] Recent policy initiatives (including the 2019 NHS Long Term Plan: https://www.longtermplan.nhs.uk/) identify smoking cessation for people with SMI as a priority, but there remains uncertainty about how mental health services should deliver smoking cessation interventions.

The UK Smoking Cessation Trials for Severe Mental Ill Health programme was commissioned sequentially in 2009 and 2013 by the UK National Institute for Health Research (NIHR). The trials programme followed the Medical Research Council's complex interventions framework,[4] by first designing a combined behavioural and pharmacological intervention specifically for people with SMI – the Smoking Cessation Intervention for People with Severe Mental Ill Health (SCIMITAR) – and then undertaking a pilot trial (SCIMITAR),[5] before embarking on a full-scale randomised controlled trial (RCT) (SCIMITAR+) to determine clinical and cost-effectiveness.[6]

Policymakers find precise longer-term estimates of quitting to be helpful, but the research literature is dominated by small sample sizes and short-term follow-up.[7] The SCIMITAR+ trial is the largest trial of smoking cessation in SMI to date, and has demonstrated the success of smoking cessation programmes in the short term (6 months).[6] However, the SCIMITAR+ trial still lacked sufficient power to detect the expected differences in the prespecified primary outcome and might have failed to detect anticipated differences in long-term outcomes (making a type 2 error). In this short report we combine pilot and full-trial data to maximise the power and precision of long-term estimates of smoking cessation.

* Members of the SCIMITAR+ collaborative are listed in the Acknowledgements.

## Method

The design, methods and analysis of the SCIMITAR pilot and SCIMITAR+ trials were registered in the public domain (ISRCTN79497236 and ISRCTN72955454) and have been published elsewhere.[5,6] Briefly, the pragmatic SCIMITAR trials tested the effectiveness of a manualised combined behavioural and pharmacological intervention for people with SMI who smoked, compared with usual care. Participants received face-to-face behavioural support delivered by a mental health professional and were prescribed quit-smoking medication according to patient choice from a range of medications recommended by the National Centre for Smoking Cessation Training (NCSCT).[8] Participants mostly chose nicotine replacement as their pharmacological support.

The prespecified primary outcome for both trials was biologically verified 7-day point prevalence abstinence at 12 months post-randomisation (defined as self-reported no smoking in the previous 7 days and an expired carbon monoxide (CO) level of <10 ppm). The SCIMITAR pilot study included 97 participants and the full trial included 526. The SCIMITAR+ full RCT was powered at 80% to detect a relative increase in quitting of 1.7 (an effect size derived from the pilot trial and from our systematic reviews in this area[9]), assuming a control quit rate of 20%, equal randomisation and a two-sided alpha of 0.05. Allowing for 20% loss to follow-up at 12 months required a total of 393 participants to be recruited and randomised. In the final trial, this sample size was exceeded but the control event rate (10%) was lower than anticipated, meaning that statistical power was substantially reduced (*post hoc* power estimated at 35%).

In view of the mirror design (including primary end-point) we maximised precision and power to estimate the 12-month outcome by utilising a *post hoc* meta-analysis to combine the randomised data from both trials in RevMan 5 for Windows. We pooled the primary end-point of both trials using a fixed effects model of dichotomous outcomes (7 day quitting versus smoking). We calculated the pooled estimates of unadjusted quit rates using Mantel–Haenszel odds ratios (ORs) and 95% confidence intervals (CIs), and also pooled estimates of risk difference. We made the most conservative estimate by assuming that all participants

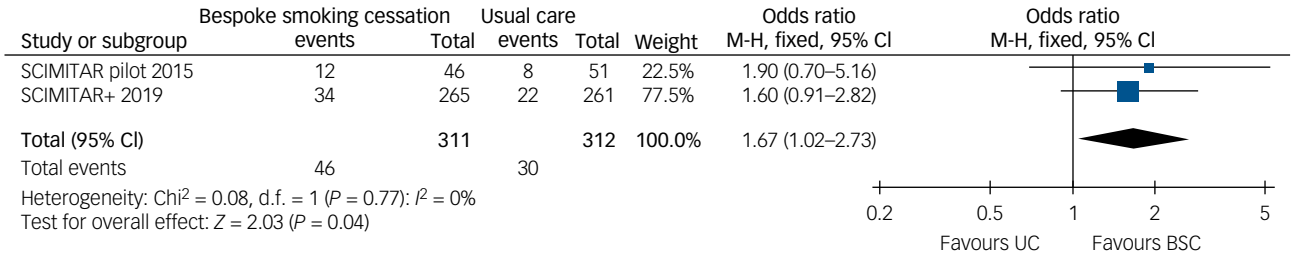


**Fig. 1** Combined 12-month abstinence, from SCIMITAR pilot and full-trial data.

M-H, Mantel–Haenszel; UC, usual care; BSC, bespoke smoking cessation.

without a 12-month CO measurement were still smokers. In each trial an odds ratio that adjusted for baseline differences in smoking severity had also been reported as the primary outcome, in line with a prespecified data analysis plan. We therefore conducted a sensitivity analysis by meta-analysing adjusted estimates using the inverse variance method.

## Results

The combined sample size of the pilot and full SCIMITAR trials was 623, comprising participants with schizophrenia or bipolar disorder. The combined odds ratio of successful quitting was in line with our prespecified estimate and favoured the bespoke SMI smoking cessation intervention (OR = 1.67, 95% CI 1.02–2.73, $P = 0.04$) with no between-study heterogeneity ($I^2 = 0$). Fig. 1 shows a forest plot of 12-month outcomes. The pooled absolute reduction in smoking rate at 12 months was 5.0% (95% CI 0.0–10.0%). A sensitivity analysis utilising adjusted estimates produced a largely consistent pooled odds ratio (OR = 1.76, 95% CI 1.05–2.96, $P = 0.03$).

## Discussion

The SCIMITAR trials programme measured long-term quit rates at 12 months using a biologically verified measure of abstinence, but was still underpowered to detect our prespecified estimate despite having planned the sample size in a pilot trial using conventional parameter estimates (80% power, $P < 0.05$, two-sided test). By using the opportunity to pool RCT data drawn from both pilot and trial data, the power and precision of estimates has been maximised. Our main finding is that bespoke smoking cessation resulted in a demonstrable effect at 12 months that we were not able to detect in analysis of single trials. The results of this pooled analysis present convincing evidence drawn from pragmatic trials of the impact of a bespoke intervention designed for people with SMI, and this can be used to formulate policy in this area.

Pilot trials are often used to derive estimates of recruitment and retention in evaluating novel interventions, but also in planning sample size calculations for fully powered trials.[10] The pilot trial of the bespoke smoking cessation intervention[6] did not correctly predict the baseline event rate and as a result the SCIMITAR+ trial was underpowered to detect our prespecified estimate of successful quitting. The present analysis utilises all trial-based data and represents an additional use of internal pilot-trial data. On the basis of these pooled data, the combined pharmacological and behavioural approach in SCIMITAR forms a candidate intervention to reduce historically elevated smoking rates among people with SMI.[11] The challenge is the implementation of research evidence in mental health services to ensure that effective treatments are offered as a matter of routine.

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