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## Smoking cessation in severe mental illness: what works?

Banham L, Gilbody S

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### CRD summary

The authors concluded treating tobacco dependence was effective in patients with severe mental illness. Treatments that worked in the general population worked for those with severe mental illness and appeared approximately equally effective. Treating tobacco dependence in patients with stable psychiatric conditions did not worsen mental state. The authors' conclusions reflect the evidence presented and are likely to be reliable.

### Authors' objectives

To evaluate the clinical and cost effectiveness of smoking cessation and reduction strategies for people with severe mental illness.

### Searching

MEDLINE, EMBASE, CINAHL, PsycINFO, HMIC, Cochrane Central Register of Controlled Trials (CENTRAL) and DARE were searched from inception to January 2008. Authors of retrieved studies were contacted to locate ongoing trials and unpublished results of completed trials.

### Study selection

Randomised controlled trials (RCTs) of behavioural or pharmacological interventions compared to placebo or usual care aimed at smoking cessation or reduction that were conducted in adult smokers with severe mental illness in either in-patient or outpatient settings were eligible for inclusion. The primary outcome was smoking status (confirmed using biochemical validation). Secondary outcomes of interest were smoking reduction, change in weight, change in psychiatric symptoms and adverse events. Included studies had to state evaluation of a priori outcomes of smoking abstinence or reduction. Severe mental illness was defined as any non-organic disorder with psychotic features that resulted in a substantial disability. Included participants could be adults with any form of severe and enduring mental ill health diagnosed using International Classification (ICD) of Disease or Diagnostic and Statistical Manual (DSM) criteria. Studies of participants with unipolar depression or with a primary diagnosis of alcohol or substance abuse were excluded.

Most of the studies used combined interventions including nicotine replacement therapy (NRT), bupropion and group or individual therapy. The two studies that reported setting stated the studies were conducted in a psychiatric day unit or community psychiatric clinic. Most studies were conducted in USA and the rest were in Australia. Most participants had schizophrenia or schizoaffective disorders; one study included participants with psychotic disorders. In most studies participants were reported to be symptomatically stable and/or on a stable dose of antipsychotic medication. Most studies reported that participants had to show a willingness to quit smoking.

The authors did not state how many reviewers selected studies for inclusion.

### Assessment of study quality

Validity was assessed using criteria devised by the Centre for Reviews and Dissemination and the Jadad Scale. Criteria included randomisation, concealment of allocation, double blinding and intention to treat (ITT) analyses.

One reviewer conducted the validity assessment, which was checked independently by a second reviewer. Differences were resolved with reference to a third party.

### Data extraction

Data were extracted for relevant outcomes and used to calculate risk ratios (RR) with corresponding 95% confidence intervals (CIs). For comparability all time-points for outcomes were converted to months post trial start date. Behavioural interventions were classified as group or individual therapy.

One reviewer extracted data, which were checked independently by a second reviewer. Differences were resolved with reference to a third party.

### Methods of synthesis

Summary risk ratios with 95% CIs for the primary outcome were estimated using a random-effects model. Heterogeneity was assessed using  $I^2$ . Subgroup analyses of interventions using bupropion were conducted. Data for other outcomes were combined in a narrative synthesis.

### Results of the review

Eight RCTs (n=565 participants) were included in the review. Sample size ranged from 10 to 298. One study reported methods of randomisation. Two RCTs described allocation concealment. Seven RCTs reported double-blinding but did not report methods. Seven RCTs reported use of ITT analyses.

**Smoking abstinence:** Greater abstinent rates were reported at trial end for: individual therapy together with NRT compared with usual care (RR 2.74, 95% CI 1.10 to 6.81; one RCT), bupropion together with group therapy compared with placebo with group therapy (RR 4.18, 95% CI 1.30 to 13.42; three RCTs), bupropion together with group therapy and NRT compared with placebo, group therapy and NRT (RR 2.34, 95% CI 1.12 to 4.91; two RCTs). None of these trials reported any significant differences between intervention and control groups at the end of follow-up. There were no significant differences between a specialised severe mental illness smoking programme with NRT compared with standard smoking cessation group therapy with NRT at either trial end or end of follow-up (one RCT).

Subgroup analyses reported that combined interventions that included bupropion significantly improved quit rates compared to placebo (RR 2.77, 95% CI 1.48 to 5.16; five RCTs).

There was no evidence of heterogeneity for these analyses ( $I^2=0\%$ ).

**Smoking Reduction:** A significant increase in the number of participants who met criteria for smoking reduction was reported for individual therapy plus NRT compared with usual care at 13 months (RR 1.75, 95% CI 1.15 to 2.66; one RCT). Overall there were no significant differences between treatments for all other comparisons.

**Adverse events:** Five RCTs reported adverse events. One RCT reported no adverse events. One RCT reported three adverse events that required trial withdrawal (study arm not clearly identified). One RCT reported four withdrawals due to medication side effects. One RCT assessed toxicity and found no evidence. One RCT reported three serious adverse events that study authors deemed not to be related to study medication.

### Authors' conclusions

Treating tobacco dependence was effective in patients with severe mental illness. Treatments that worked in the general population worked for those with severe mental illness and appeared approximately equally effective. Treating tobacco dependence in patients with stable psychiatric conditions did not worsen mental state.

### CRD commentary

The research question was clear with appropriately defined inclusion and exclusion criteria. Several relevant sources were searched. Efforts were made to locate unpublished studies. Validity was assessed using appropriate criteria and results were reported. Methods to reduce reviewer error and bias were used for validity assessment and data extraction; it was unclear whether similar methods were used to select studies. Data were appropriately combined in a meta-analysis. Statistical heterogeneity was assessed with appropriate methods.

The authors appropriately reported limitations of the included studies that included small sample sizes, no reporting of drop-outs and heterogeneous populations with severe mental illness (although most people included were judged to be symptomatically stable). The authors reported that a range of outcomes were used with a lack of standardisation to outcome and time-point selection.

The authors' conclusions reflect the evidence presented and are likely to be reliable.

### Implications of the review for practice and research

**Practice:** The authors stated that in the absence of protocols for smoking cessation in severe mental illness, measures that were effective for the general population should be employed.

**Research:** The authors stated that evaluating the effectiveness of smoke-free policies for in-patient psychiatric facilities was a research priority. Future large-scale trial-based evaluations of smoking cessation with pharmaceutical and behaviour interventions for populations with severe mental illness were required. Future trials should adopt the Russell Standard for outcome assessment of smoking reduction and include detailed reporting of content of behavioural interventions and of adverse events. Standardisation of psychiatric symptom reporting and inclusion of a scale such as the Beck Scale for Suicidal Ideation was needed. Future research should consider both cost and how new interventions fit into existing service structures.

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This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.