

A systematic review of behavioural smoking cessation interventions for people with severe mental ill health—what works?

Panagiotis Spanakis¹  | Emily Peckham¹  | Ben Young²  | Paul Heron¹  | Della Bailey¹  | Simon Gilbody^{1,3} 

¹Department of Health Sciences and Closing the Gap Network, University of York, York, UK

²Institute of Health and Wellbeing, University of Glasgow, Glasgow, UK

³York Hull Medical School, University of York, Heslington, York, UK

Correspondence

Panagiotis Spanakis, Department of Health Sciences and Closing the Gap Network, University of York, Heslington, York YO10 5DD, UK.

Email: panagiotis.spanakis@york.ac.uk

Funding information

Department of Health; National Institute for Health Research

Abstract

Background and Aims: People with severe mental ill health smoke more and suffer greater smoking-related morbidity and mortality. Little is known about the effectiveness of behavioural interventions for smoking cessation in this group. This review evaluated randomized controlled trial evidence to measure the effectiveness of behavioural smoking cessation interventions (both digital and non-digital) in people with severe mental ill health.

Design: Systematic review and random-effects meta-analysis. We searched between inception and January 2020 in Medline, EMBASE, PsycINFO, CINAHL, Health Management Information Consortium and CENTRAL databases.

Setting and participants: Randomized controlled trials (RCTs) assessing the effects of behavioural smoking cessation and reduction interventions in adults with severe mental ill health, conducted in any country, in either in-patient or community settings and published in English.

Measurements: The primary outcome was biochemically verified smoking cessation. Smoking reduction and changes in mental health symptoms and body mass index (BMI) were included as secondary outcomes. Narrative data synthesis and meta-analysis were conducted and the quality of included studies was appraised using the risk of bias 2 (RoB2) tool.

Findings: We included 12 individual studies (16 articles) involving 1861 participants. The first meta-analysis (three studies, 921 participants) demonstrated effectiveness of bespoke face-to-face interventions compared with usual care across all time-points [medium-term: relative risk (RR) = 2.29, 95% confidence interval (CI) = 1.38–3.81; long-term: RR = 1.58, 95% CI = 1.09–2.30]. The second (three studies, 275 participants) did not demonstrate any difference in effectiveness of bespoke digital on-line interventions compared with standard digital on-line interventions (medium-term: RR = 0.87, 95% CI = 0.17–4.46). A narrative overview revealed mixed results when comparing bespoke face-to-face interventions with other active interventions. The methodological quality of studies was mixed, with the majority having some concerns mainly around risk of selective reporting.

Panagiotis Spanakis and Emily Peckham joint first authors.

This is an open access article under the terms of the Creative Commons Attribution-NonCommercial-NoDerivs License, which permits use and distribution in any medium, provided the original work is properly cited, the use is non-commercial and no modifications or adaptations are made.

© 2021 The Authors. *Addiction* published by John Wiley & Sons Ltd on behalf of Society for the Study of Addiction.

Conclusions: Face-to-face bespoke smoking cessation interventions for adults with severe mental ill health appear to be effective when compared with treatment as usual, but evidence is equivocal when compared with other active interventions. There is limited evidence comparing bespoke digital interventions with generic interventions, and we found no studies comparing them with usual treatment.

KEYWORDS

Bipolar disorder, psychosis, quit smoking, schizophrenia, severe mental illness, smoking cessation

INTRODUCTION

People with severe mental ill health (SMI), such as schizophrenia or bipolar disorder, experience a mortality gap of 15–20 years compared to those without this diagnosis [1], primarily due to greater prevalence of preventable conditions such as respiratory disease, hypertension, cardiovascular disease and diabetes [2, 3]. Smoking is one of the main causes of these physical health conditions [4], and while smoking prevalence has continually declined in most sectors of the general population, this has not happened among people with SMI [5], suggesting an unmet need for smoking cessation interventions in this population.

However, people with SMI might need different smoking cessation support compared to the general population. They are likely to smoke more heavily with higher levels of nicotine addiction [6], although they are as likely to want to cut down or quit [7]. SMI symptoms and side effects of anti-psychotic medication can be further barriers to smoking abstinence, and there can be the belief among both smokers with SMI and clinicians that smoking helps to manage these symptoms (e.g. improving cognitive dysfunction) and side effects [8].

Previous reviews [9, 10], including our own [11], have concluded that pharmacotherapy (varenicline or bupropion) for smoking cessation in people with SMI is effective and tolerable. Our previous findings suggested that bupropion was effective in the medium (≤ 6 months) and long term (> 6 months), while varenicline was effective in the medium term. Behavioural randomized control trials (RCT) differ from pharmacological trials in that they examine the effectiveness of a psychological intervention [e.g. cognitive-behavioural therapy (CBT) or motivational enhancement therapy] over no or alternative psychological intervention, regardless of any pharmacotherapy. Evidence-synthesis results regarding the effectiveness of behavioural smoking interventions for people with SMI are currently unclear. Consequently, it is difficult to recommend whether interventions targeting smoking among people with SMI should include a behavioural component alongside pharmacotherapy.

In our previous meta-analysis four studies of behavioural programmes were pooled, but were insufficiently powered to detect any effects in the medium or long term. In a subsequent meta-analysis in SMI [12], results supported the effectiveness of varenicline at 3 and 6 months and bupropion at 3 months, but data from behavioural programmes were not pooled and were narratively reported to show little effect. A systematic review in adults with mental health problems (but not exclusively SMI) supported the effectiveness of CBT,

motivational interviewing and behavioural or supportive counselling, in combination with NRT or pharmacotherapy [13]. However, it is unclear whether the findings are applicable to adults with SMI, who may require more intensive and tailored support, due to the reasons discussed earlier.

New large-scale pragmatic trials of combined behavioural and pharmacological approaches demonstrated increased rates of cessation in people with SMI at 6 months compared to usual care [14]. This has not been included in recent reviews (e.g. [13]) so these new findings, together with other recent studies, should be incorporated to update the review-level evidence on this topic.

While our review protocol was conceived before the COVID-19 pandemic, during the COVID-19 pandemic many smoking cessation services transitioned to remote delivery and the UK National Centre for Smoking Cessation and Training strongly recommended that all smoking cessation interventions be delivered remotely (https://www.ncsct.co.uk/publication_COVID-19_18.11.20.php). However, we do not know how this could impact upon smokers with SMI who might not engage with digital technologies [15]. The effectiveness of this form of delivery should be assessed to inform the development of an evidence-based digital intervention for people with SMI.

In this review we aim to update the review-based evidence for the effectiveness and cost-effectiveness of behavioural smoking cessation interventions in people with SMI. Due to the shift from traditional face-to-face delivery during the COVID-19 pandemic, this review also explores the effectiveness of digital and non-digital interventions separately where possible.

METHODS

A protocol has been registered on the PROSPERO register of systematic reviews (PROSPERO 2020 CRD42020166607 https://www.crd.york.ac.uk/prospERO/display_record.php?ID=CRD42020166607).

Search strategy

We used an electronic search strategy based on our previous reviews [11, 16] which combined search terms for SMI, smoking cessation and randomized controlled trials, adapted from terms developed by the Cochrane Groups for schizophrenia and tobacco addiction (see example in Supporting information, Figure S1). MEDLINE (PubMed),

EMBASE, PsycINFO, CINAHL, Health Management Information Consortium (HMIC) and CENTRAL databases were searched for eligible studies from inception year of each database until 23 January 2020. Reference lists of all eligible studies, existing reviews and trial registries were checked for potentially relevant studies. For trial registries and conference abstracts, we searched whether or not a paper had been published.

Study types

We included randomized controlled trials (RCTs), including cluster-randomized controlled trials, which assessed the effects of behavioural smoking cessation and reduction interventions in people with SMI, conducted in any country, in either in-patient or community settings and published in English. Due to financial and practical constraints it was not possible to use translation services for non-English studies.

Participant types

Eligible studies included adults (aged ≥ 18 years) with a diagnosis of SMI and no substance abuse problems (other than nicotine addiction) or learning disability, dementia, other neurocognitive disorders or terminal illness. Studies should report that diagnosis was based on the International Classification of Disease (ICD) or Diagnostic and Statistical Manual (DSM). As no standard definition of SMI has been agreed, we adopted a pragmatic definition based on those diagnoses that would be included in the UK primary care SMI register (schizophrenia or other psychotic disorders, bipolar disorder or depression with psychotic features) [17]. Studies including SMI and other diagnoses were included if they reported stratified results per patient population or if they provided descriptive statistics demonstrating that more than 70% of participants had SMI.

Intervention types

We included trials that compared any type of behavioural smoking cessation and reduction strategies to each other, usual care or no intervention. Trials that used electronic cigarettes or adjunctive pharmacotherapy alongside a behavioural programme were also eligible for inclusion. Solely pharmacotherapeutic trials were excluded.

Behavioural interventions were classed as group or individual therapy, person-based (intervention provided by a person) or machine-based [intervention delivered over a digital platform, such as website or smartphone application (app.), without involvement of a person], and bespoke (specifically designed or adapted to meet the needs of people with SMI as, for example, considering the purpose of smoking in the context of the person's illness and smoking cessation effects in metabolism and anti-psychotic medication dosage) or generic (designed for smokers drawn from any section of the

population). Person-based interventions could have been delivered face-to-face or via the telephone.

Outcomes

Based on expert consensus [18], biochemically verified 7-day point prevalence abstinence is an important outcome in smoking cessation trials which is commonly reported in studies (e.g. [11, 19, 20]). Therefore, it was selected as the primary outcome. To be included, eligible studies should report on this, even if not their primary outcome. Accepted methods of biochemical verification were expired carbon monoxide, salivary cotinine, urinary cotinine or serum cotinine. To be consistent with our previous reviews [11, 16] and according to our protocol, follow-up time-points were categorized as short- (≤ 4 weeks), mid- (up to 6 months) and long-term quit (> 6 months).

The secondary outcomes were smoking reduction, change in psychiatric symptoms (any validated symptom scale) and cost-effectiveness [treatment cost and quality-adjusted life years (QALYs)]. Change in body mass index (BMI) was also included, as people with SMI have higher rates of obesity compared to people without SMI [21], and therefore an increase in BMI after smoking cessation can be a concern among patients and clinicians.

Study selection

Titles and abstracts found through the search were screened for eligibility. As per common practice (see, for example [11, 22]), a subset of records was screened by two authors to ensure consistency in decision-making; although the desired inter-rated agreement was not achieved ($k > 0.80$), this process was terminated after 60% of the records had been screened due to constraints of time and resources. The remaining records were screened by a single author. Any redundant records (e.g. duplicates) were removed.

Two authors independently screened the full texts and extracted data from all eligible studies. Data were extracted on the study design, population, the intervention and its components, smoking cessation outcomes and time-points and secondary outcomes. In cases of missing data or reporting ambiguities for the primary outcome, authors were contacted for clarification. At all screening stages, any disagreements were resolved by discussion with a third author.

Risk of bias

Studies were assessed independently by two reviewers with the Cochrane risk of bias 2 (RoB2) tool, following the effect of assignment to intervention and based on our primary outcome. Each of the tool domains was assessed as 'high', 'low' or 'some concerns', aided by signalling questions. These contributed to an overall rating for each study following criteria outlined in Chapter 8 of the *Cochrane Handbook for Systematic Reviews of Interventions* [23]. Any disagreements

were resolved by discussion with a third author. No reviewers assessed any studies they had previously co-authored.

To address and minimize publication bias we inspected trial registries and inquired area experts to identify any completed but unpublished eligible trials.

Analysis

For the primary outcome, studies were pooled and meta-analysed together if they were similar in terms of type of intervention (bespoke or generic), modality (person- or machine-based) and comparison group (no treatment, usual treatment or other active intervention). This led to two groups of studies: (a) bespoke person-based compared to treatment as usual and (b) bespoke machine-based compared to generic machine-based.

Analysis included random-effects standard pairwise meta-analyses (RevMan version 5.3: Review Manager computer program, version 5.3; Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2014) presenting risk ratios (RRs) with 95% confidence intervals (CIs). The unit of analysis was the individual, and participants

with missing data were treated as still smoking [24]. Pooled effectiveness was estimated by time-frame (short-, medium- or long-term). We took the most distal time-point measured within each time-frame, apart from the long-term time-frame which was capped at 1 year. For example, for the medium-term time-point, if a study reported abstinence at 16 and 26 weeks, we took the 26-week abstinence rate.

For the secondary outcomes, as well as primary outcome data that were not included in the meta-analyses, a narrative overview of findings is provided.

RESULTS

The search identified 1125 unique records, of which 69 full texts were screened for eligibility and 16 (based on 12 studies with 1861 participants) met the inclusion criteria (Figure 1). A total of 696 abstracts were screened independently by two authors (inter-rater agreement k from 0.39 to 0.64) and the rest were screened by a single author. Forty disagreements at the abstract-screening phase and one during data-extraction were resolved by discussing with a third rater. There were no disagreements at the full-text screening stage.

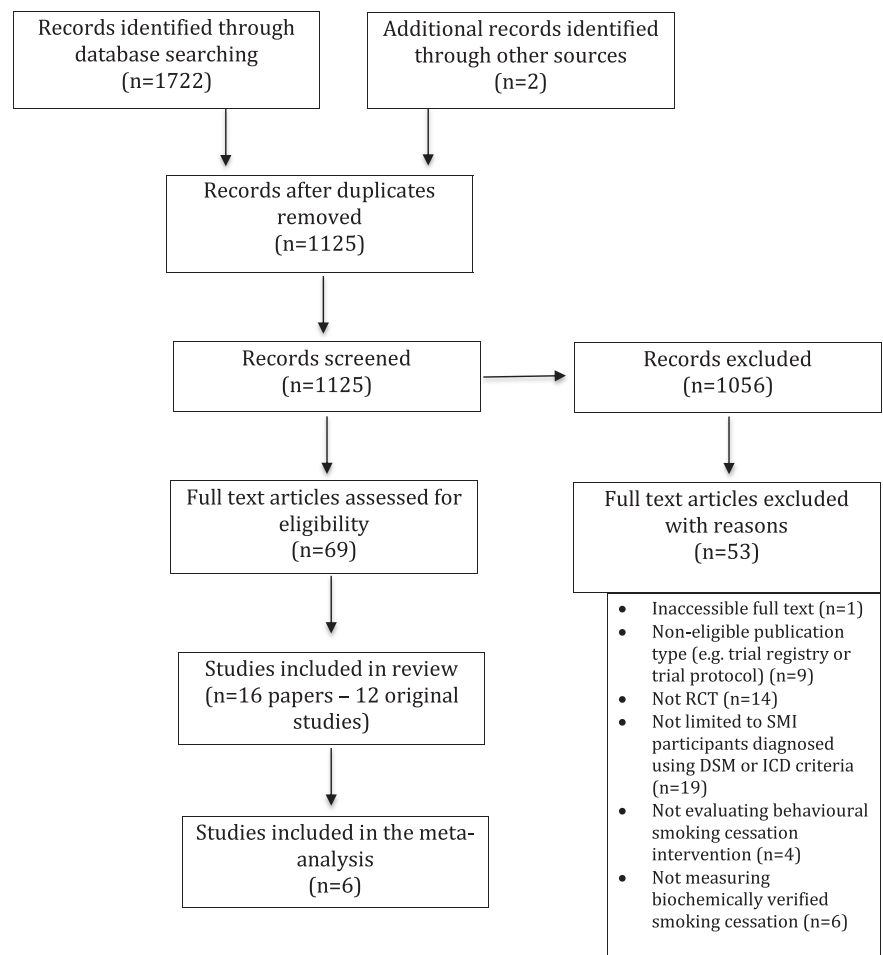


FIGURE 1 Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) diagram

Study characteristics (Table 1)

All studies were individually randomized (but not cluster-randomized) controlled trials, conducted within a single country, in an outpatient or community setting. Seven studies were conducted in the United States [25–31], two in the United Kingdom [14, 32] and two in Australia [33, 34]. One study did not clearly state the country [35].

Six of the studies recruited participants with schizophrenia or schizoaffective disorder [25, 27–29, 33, 36], five included participants with schizophrenia, schizoaffective disorder or bipolar disorder [14, 31, 32, 34, 35] and one recruited participants with bipolar disorder only [30]. Seven studies had a requirement that participants had stable symptoms and/or dose of medication [28–31, 33–35] and five studies did not state whether participants had stable symptoms and/or medication [14, 25, 27, 32, 36].

In seven studies participants had expressed a willingness to quit smoking at the point of trial entry [14, 28, 30–33, 36], in one study participants were excluded if planning on quitting in the next 30 days [35], in one study intention to quit was not required [29] and in three studies participants' intentions were not stated [25, 27, 34].

All studies included a bespoke smoking cessation intervention designed or adapted for people with SMI, apart from two [28, 35] (Table 2). Three studies involved a person-based intervention compared to usual care [14, 32, 33] and six studies involved a person-based intervention compared to another active intervention [25, 27, 28, 34–36]. In Brody *et al.* [28] the usual care arm involved an active intervention of weekly CBT and medication management; hence, for the purpose of this review, we have included it in the intervention versus other active group. Three studies compared a bespoke machine-based intervention to a generic one [29–31]. All person-based interventions were face to face, apart from one study which also included a telephone delivery [34], while all machine-based were via the internet.

Seven studies included NRT, one of which included NRT plus bupropion. Two studies supported participants to receive NRT from their GP but did not provide the NRT [14, 32] and one encouraged participants to use NRT [27]. Two studies made no mention of smoking cessation medication [29, 35].

Two studies involved a group intervention [25, 27], six involved an individualized intervention [14, 32–36] and one involved both [28].

Primary outcome

Biochemically verified 7-day point prevalence of abstinence is given for each time-point in Table 3. Six studies were included in the meta-analyses and the other six in the narrative description of findings.

Three trials ($n = 921$) compared a person-based bespoke behavioural intervention to usual care. Pooling data showed that the intervention improved quit rates significantly in the medium and long term (medium term: $RR = 2.29$ (95% $CI = 1.38$ – 3.81), long term: $RR = 1.58$

(95% $CI = 1.09$ – 2.30) (Figure 2). None of the studies reported on short-term effects.

Three trials ($n = 275$) compared a bespoke machine-based intervention to a generic machine-based intervention, but provided data only for medium-term quit. Pooling these data failed to demonstrate any difference between interventions in the medium term, with wide CI s ($RR = 0.87$, 95% $CI = 0.17$ – 4.46) (Figure 3). None of the studies reported on short- or long-term effects.

Six studies were not pooled due to heterogeneity of interventions and comparator groups, which precluded meta-analytical pooling in line with our pre-specified protocol. All included person-based interventions. Three studies compared between two bespoke interventions and had no control or usual care arm, two of which provided NRT to all groups [34, 36] while one did not [27]. One study compared between two generic interventions, and had no control or usual care arm [35]. These studies did not find evidence for a significant between-group difference in rates of abstinence at any time-point, but also had limited statistical power and wide CI s.

One study [25] compared a bespoke intervention to a generic one for two mid-term time-points (12 weeks and 6 months). They found higher rates of abstinence in the bespoke intervention at 6 months but not at 12 weeks. The last study [28] compared across three generic interventions of increased complexity and all groups were provided with NRT and pharmacotherapy. They found higher rates of abstinence in the mid-term in the most complex intervention compared to the least complex, but were not sufficiently powered to detect any differences between any of the other groups.

Methodological quality and bias in the included studies (Figure 4)

The majority of studies were assessed as 'some concerns' [26, 27, 29, 30, 32, 33, 35], with only two studies being at low risk of bias [14, 34] and three studies at high risk [25, 28, 31]. The main source of concern was potential bias due to the selection of the reported result. Three studies were at high risk of bias due to the randomization process [25, 28, 31]. These issues may be due, in part, to lack of clarity in reporting rather than study conduct, as many studies did not publish a protocol or analysis plan or there was a lack of clarity in reporting method of randomization. Other sources of concern were potential deviations from the stated interventions [25, 28, 35] and there were some concerns over missing outcome data for only one of the included studies [36]. There were no concerns over measurement of the outcome for any of the included studies.

Our inspection of trial registries and inquiries with area experts did not identify any unpublished completed trials. We did not use funnel plots to assess for publication bias due to the low number of studies ($n = 3$) in each meta-analysis. Funnel plots are simple scatterplots of effect size against sample size and bias is inferred by lack of symmetry [37]. Such lack of symmetry would be impossible to detect with only three studies, making the funnel plot uninterpretable.

TABLE 1 Study characteristics

Study/design	Population	Intervention and delivery	Smoking abstinence outcomes	Secondary outcomes
Baker 2006 (including data from Baker 2010 [41]) RCT	n = 298; psychotic disorder (ICD-10); interest in quitting smoking; CPD \geq 15 Australia 52% male, mean age 37.2 years, ethnicity not stated	1. Individual motivational interviewing + CBT + NRT + self-help booklets 2. Usual care + NRT + self-help booklets	For 1: 8 \times 1 h manualized sessions over 10 weeks Self-reported, 7-day point prevalence abstinence at 3, 6 and 12 months and 4 years	Smoking reduction (\geq 50% reduction in CPD) Change in psychiatric symptoms (BDI-II, BPRS, SF-12, STAI)
Baker, 2015 RCT (including data from Baker, 2018 [42]) RCT	n = 235; schizophrenia spectrum or bipolar disorder (MINI), CPD \geq 15; any stage of motivation to change Australia 59% male, mean age 41 years, 84% Australian-born	1. Intensive healthy life-style intervention + NRT 2. Telephone healthy life-style intervention + NRT	For 1: 1 \times 90 m + 7 \times 60 m + 3 \times 60 m + 6 \times 60 m manualized face-to-face sessions For 2: 16 \times 10 m telephone calls + 2 \times 90 m face-to-face manualized sessions	Smoking reduction (\geq 50% reduction in CPD) Change in psychiatric symptoms (BPRS-24, BDI-II, SF-12, GAF) BMI (in Baker 2015 but not 2018)
Bennett, 2015 RCT	n = 178; schizophrenia spectrum, affective psychosis, other psychotic disorder, major depression with psychotic features or post-traumatic stress disorder (DSM-IV); no current alcohol or drug use problems; CPD \geq 10 or FTND \geq 5 United States 89.3% male, mean age 54.8 years, 70.8% black	1. Behavioural treatment of smoking cessation in serious mental illness 2. Supportive smoking cessation programme	For 1: 24 twice-weekly group meetings, reminder calls + assistance with transportation For 2: as 1	Smoking reduction (number of CPD)
Brody, 2017 RCT	n = 42; schizophrenia (DSM-IV); no substance use problems or other current psychiatric illness; CPD = 10-40; desire to quit. United States 100% male, mean age 56.7 years, 53% black	1. CBT + medication management home visits + 3 forms of medication (NRT patch + lozenge + bupropion) + SHS exposure assessment home visits 2. CBT + medication management home visits + 3 forms of medication (NRT patch + lozenge + bupropion)	For 1: manualized group CBT via 1 h weekly sessions for 6 months; weekly medication management meeting at home with medication initiated at first visit, NRT initiated at week 2; biweekly 20-30 m SHS assessments at home For 2: as 1.	Reduction in smoking (number of CPD) Change in psychiatric symptoms (AIMS, BPRS, SANS, CGI, BDI-II, C-SSRS).

(Continues)

TABLE 1 (Continued)

Study/design	Population	Intervention and delivery	Smoking abstinence outcomes	Secondary outcomes
Brunette, 2020 RCT	n = 162; schizophrenia spectrum (DSM-IV); no alcohol or drug dependence; not used smoking cessation treatment; daily smokers. United States 66.7% males, average age 46 years, 53.1% black	3. CBT + medication management home visits + 1 form of medication (NRT patch or bupropion or varenicline) 1. Web-based interactive intervention tailored for SMI 2. Computerized version of National Cancer Institute patient education handout (static)	For 3: delivered as 1 except medication initiated at the first or second visit For 1: Computer-based delivery in 1 × 30–90 m session. Linear modules guided by virtual peer host For 2: computer-based delivery in 1 × 30–90 m session	Self-reported 7-day point prevalence abstinence at 6 months Current abstinence verified by expired CO < 9 p.p.m. at 6 months None
George 2000 RCT	n = 45; schizophrenia or schizoaffective disorder (DSM-IV); FTND ≥ 5 United States 66.7% male, mean age 41.6 (specialized group) and 36.6 (ALA groups) years, 62.2% Caucasian	1. Specialized group therapy programme + NRT patches 2. American Lung Association group therapy programme + NRT patches	For 1: 3 × weekly 60 m manualized motivational enhancement therapy, then 7 × weekly 60 m manualized psychoeducation For 2: 7 × weekly 60 m manualized behavioural group counselling sessions, then 3 × weekly 60 m supportive group counselling	Change in psychiatric symptoms (AIMS, BDI, PANSS, WEPS and SJNWS). Self-reported point prevalence abstinence at 12 weeks and 6 months Self-reported 4 weeks continued abstinence at 12 weeks Current abstinence verified by expired CO < 10 p.p.m. at 12 weeks and 6 months
Gilbody 2019 RCT (including data from Peckham, 2019 [43])	n = 526; schizophrenia, psychotic/delusional illness or bipolar disorder (DMS-5 or ICD-10); no drug or alcohol problem; CPD ≥ 5, interest in cutting down; not receiving advice from smoking adviser England 59% male, mean age 46 years, 89.7% white	1. Bespoke programme adapted for SMI patients + GP-prescribed pharmacotherapies + regular follow-up by mental health practitioner 2. Usual care: access to a smoking cessation counsellor and evidence-supported treatments (behavioural + pharmacotherapy)	For 1: up to 12 × 30 m face-to-face meetings at home or NHS premises	Number of CPD Change in psychiatric symptoms: (PHQ-9, GAD-7 and SF-12), BMI
Gilbody 2015 RCT (including data from Peckham, 2015 [43])	n = 97; schizophrenia, schizoaffective disorder or bipolar disorder (ICD-10 or DSM); smokers; desire to cut down or quit; no alcohol or drug problems.	1. Bespoke programme adapted for SMI patients + GP-prescribed pharmacotherapies + regular follow-up by mental health	For 1: 8–10 × 30 m manualized sessions	Number of CPD Change in psychiatric symptoms (SF-12, PHQ-9) BMI

(Continues)

TABLE 1 (Continued)

Study/design	Population	Intervention and delivery	Smoking abstinence outcomes	Secondary outcomes
Heffner 2019 RCT	England 58% male, average age 46.8 years, 86.5% white British	smoking cessation practitioner 2. Usual care: access to a smoking cessation counsellor and evidence-supported treatments (behavioural + pharmacotherapy)	reporting smoking cessation was used	
	n = 51; bipolar disorder and no mania, severe major depression or psychotic symptoms (DSM-5); no substance use disorder; psychiatric hospitalization, CPD \geq 5; desire to quit; not receiving cessation intervention United States 55% male, mean age 47.4 years, 24% identified as racial or ethnic minority	1. WebQuit Plus + NRT patches 2. Smokefree.gov + NRT patches	Self-reported 7-day point prevalence abstinence at end of treatment and 1 month post-treatment Current abstinence verified by expired CO \leq 4 p.p.m.	Smoking reduction (50% reduction in CO levels) Change in psychiatric symptoms (Altman self-rating mania scale, PHQ-9)
Steinberg 2016 RCT	n = 100; schizophrenia, schizoaffective disorder, or bipolar disorder (DSM-IV); CPD \geq 10; not planning to quit. 59.2% male, mean age 41.3 years, 59.18% (motivational interviewing arm) and 63.27% (interactive education arm) Caucasians	1. Motivational interviewing with personalized feedback + referral to tobacco dependence treatment clinic 2. Interactive education + referral to tobacco dependence treatment clinic	Self-reported 7-day point prevalence abstinence at 1 month Current abstinence verified by expired CO < 10 p.p.m. at 1 month	None
Vilardaga, 2020 RCT	n = 62; schizophrenia, schizoaffective, bipolar, or major depressive disorder (ICD-10); no acute psychotic; no alcohol or illicit drug use problems, CPD \geq 5; desire to quit; not receiving cessation treatment. United States	1. Learn to Quit digital app + smartphone device + NRT 2. NCI QuitGuide digital app + smartphone device + NRT	Self-reported 7-day point prevalence abstinence at weeks 4, 8, 12 and 16 Self-reported 30-day point prevalence abstinence at week 16 Current abstinence verified by expired CO < 5 p.p.m. at weeks 4, 8, 12 and 16	Smoking reduction (number of CPD) Change in psychiatric symptoms (BSI, PANSS, AIS)

(Continues)

TABLE 1 (Continued)

Study/design	Population	Intervention and delivery	Smoking abstinence outcomes	Secondary outcomes
Williams 2010 RCT	64% (Learn to Quit) and 55% (QuitGuide) female, mean age of 46.1 (Learn to Quit) and 45.6 (QuitGuide) years, 49% (Learn to Quit) and 55% (QuitGuide) white	1. High-intensity motivational interviewing + nicotine patch 2. Moderate intensity treatment + nicotine patch	For 1: 24 × 45 m manualized sessions delivered over 26 weeks in mental health settings For 2: 9 × 20 m manualized sessions delivered over 26 weeks in mental health settings	Smoking reduction (number of CPD and reduction in CO levels) Change in psychiatric symptoms (BDI, PANSS)
	n = 100; schizophrenia or schizoaffective disorder (DSM-IV); CPD ≥ 10, desire to quit United States 64% male, mean age 43.5 (high-intensity motivational interviewing) and 47.1 (moderate intensity treatment) years, 66% white		Self-reported continues abstinence at 12 weeks, 26 weeks and 1 year Self-reported 7-day point prevalence abstinence at 12 weeks Current abstinence verified by expired CO < 10 p.p.m.	

AIMS = abnormal involuntary movement scale; AIS = avoidance and inflexibility scale; ALA = American Lung Association; BDI = Beck Depression Index; BMI = body mass index; BPRS = Brief Psychiatric Rating scale; BSI = brief symptom inventory; CBT = cognitive-behavioural therapy; CGI = clinical global impression; CO = carbon monoxide; CPD = cigarettes per day; C-SSRS = Columbia suicide severity of illness scale; DSM = Diagnostic and Statistical Manual; FTND = Fagerstrom Test for Nicotine Dependence; GAD = generalized anxiety disorder; GAF = global assessment of functioning; GP = general practitioner; h = hours; ICD = International Classification of Disease; m = min; MINI = Mini International Neuropsychiatric Interview; NCI = National Cancer Institute; NHS = National Health Service; NRT = nicotine replacement therapy; PANSS = positive and negative syndrome scale; PHQ = patient health questionnaire; p.p.m = parts per million; RCT = randomized controlled trial; SANS = scale for assessment of negative symptoms; SF = short form survey on general functioning; SHS = second-hand smoking; SJNWS = Shiffman-Jarvik nicotine withdrawal scale; SMI = severe mental illness; STAI = state-trait anxiety inventory; WEPS = Webster extrapyramidal movement scale.

TABLE 2 Interventions' behavioural content

Study	Description of intervention and comparison group
Baker 2006 (including data from Baker 2010 [41])	<ol style="list-style-type: none"> Motivational interviewing + CBT; feedback on behaviour, pros and cons of smoking, goal-setting, action planning (treatment plan, quitting plan, setting a quit date, craving plan); problem-solving; coping planning (assessment of personal triggers); information about withdrawal symptoms; managing withdrawal and cognitive restructuring, review of withdrawal symptoms, information about NRT, engaging a support person (if requested), discussing the abstinence/rule violation effect, identifying and challenging negative thoughts; cigarette refusal skills; assertiveness and communication skills; stress management Usual care + NRT + self-help booklets
Baker, 2015 (including data from Baker, 2018 [42])	<ol style="list-style-type: none"> Motivational interviewing + CBT; feedback on behaviour (e.g. level of dependence) and CVD risk factors; case formulation about CVD status and unhealthy behaviours; education about health consequences and NRT; examining beliefs about relationship between smoking and symptoms; monitoring of nicotine withdrawal, cravings and adverse medication side effects; rewards (certificates and financial) for meeting reduction or abstinence goals; physical activity and healthy eating promotion Motivational interviewing; feedback on smoking (e.g. level of dependence) and other CVD risk factors; case formulation about CVD status and unhealthy behaviours, monitoring of smoking, NRT use, side effects from medication, nicotine withdrawal; and symptoms of psychosis and mood. Similar content as 1 but less intensive and without CBT or rewards
Bennett, 2015	<ol style="list-style-type: none"> Review personal negative consequences of smoking and identify reasons for change; feedback on CO monitoring, social and financial reward for CO < 10 p.p.m.; health consequences of smoking/quitting; encouragement to set a quit date; goal-setting, skills training; coping planning; basic education on medication options; extended support with use of bupropion or NRT if desired Topic-based meetings (e.g. support for quitting; harm from smoking; smoking as a habit; barriers and confidence) addressed via discussion, education and assistance with planning to quit; health consequences of smoking/quitting; encouragement to set a quit date; CO monitoring without feedback or rewards; basic education on medication options
Brody, 2017	<ol style="list-style-type: none"> CBT: education about smoking addiction, withdrawal and relapse prevention; recognizing relapse triggers; developing coping skills, such as avoiding triggers, coping with negative affective states, reducing overall stress and distracting attention from smoking using thought-stopping techniques; developing life-style changes and social support; encouragement to taper off cigarettes; CO monitoring. Medication management home visits: assessment of medication adherence, monitoring of smoking and side effects. SHS home visits: to assess and reduce SHS exposure in the home environment; walk-through of the home to complete an observation form about visible signs of smoking; information about SHS exposure; brief behavioural counselling to encourage minimization of SHS exposure and promote abstinence, such as suggesting behavioural strategies for avoiding SHS and other smoking triggers As 1 but no SHS home visits As 2
Brunette, 2020	<ol style="list-style-type: none"> Motivational interviewing and decision aid exercises designed to increase motivation to quit: personalized feedback about personal, financial and health consequences of smoking; information about cessation treatment; personalized pros and cons list; education about cessation treatments and referral via quit story videos, text and video information, including benefits of combined behavioural counselling with pharmacotherapy; personalized report highlighting desire to quit, treatment choices and referral information Information about risk factors and protective factors for smoking-related disease, quitting as a prevention factor, and cessation treatments including counselling and pharmacotherapy
George 2000	<ol style="list-style-type: none"> Motivational enhancement therapy (eliciting self-motivational statements, affirming that change is difficult, and considering pros and cons of smoking versus quitting), psychoeducation, social skills training, relapse prevention strategies including identifying personal triggers and developing coping strategies and quit date Not reported
Gilbody 2019 (including data from Peckham, 2019 [43])	<ol style="list-style-type: none"> Delivered according to the Manual of Smoking Cessation by the National Centre for Smoking Cessation Training, UK. Identify reasons for wanting and not wanting to stop smoking; CO monitoring; barrier identification and problem-solving; relapse prevention and coping; action planning/know how to help identify relapse triggers; goal setting; advice on conserving mental resources; advice on stop-smoking medication; options for additional and later support; assess current and past smoking behaviour; assess current readiness and ability to quit; assess nicotine dependence; assess physiological and mental functioning; elicit client views; monitor psychiatric medication levels and side effects throughout the quit attempt. Adaptations for SMI included making several assessments before setting

(Continues)

TABLE 2 (Continued)

Study	Description of intervention and comparison group
Gilbody 2015 (including data from Peckham, 2015 [43])	<p>a quit date, offering nicotine replacement before setting a quit date (cut down to quit), recognizing the purpose of smoking in the context of mental illness (e.g. smoking to relieve side effects from anti-psychotic medication), home visits, additional face-to-face support after unsuccessful quit attempt or relapse and informing primary care physician and psychiatrist of successful quit attempt to review anti-psychotic medication doses if metabolism changed. Encouragement to reduce smoking to quit, set own quit date and make several quit attempts if initial attempt failed</p> <p>2. Advice on how to access full range of smoking cessation services offered by local services and family doctors and information about a free telephone helpline. Encouragement to reduce smoking to quit and set own quit date</p>
Heffner 2019	<p>1. As Gilbody 2019</p> <p>2. As Gilbody 2019</p> <p>1. Aims to make a quit plan, develop awareness of smoking triggers, develop acceptance-based coping skills to handle triggers, and identify and engage personal values and self-compassion to support long-term abstinence: ACT exercises and education to address challenges to cessation for smokers with bipolar disorder; 'inspiring stories' describing how a person with bipolar disorder used programme skills to overcome challenges; text messages to promote NRT adherence; two-way keyword messaging to request assistance with mood-specific triggers and challenges; self-monitoring of behaviour (smoking, use of cessation medications, values-guided activities and practice of ACT skills) with feedback and earned 'badges'; feedback on money and minutes of life saved by reducing or quitting smoking; forum to post questions and view responses</p> <p>2. Guidance on setting a quit date, preparing to quit, identifying and coping with triggers, and staying motivated; interactive content including screening questionnaires for depression and nicotine dependence; information about health consequences of smoking in text and graphic form</p>
Steinberg 2016	<p>1. Feedback about CO reading, and information about medical conditions endorsed as being personally relevant using an 'elicit-provide-elicit' strategy; feedback about financial expenditure on cigarettes designed to highlight discrepancy between current behaviour and goal; modified importance-confidence-readiness ruler exercise focusing on self-reported importance for quitting and self-reported confidence in ability to quit; advice to quit</p> <p>2. Non-personalized education about the effects of smoking; advice to quit</p>
Vilardaga, 2020	<p>1. ACT-based education and skills modules; elements of US clinical practice guidelines, e.g. setting a quit date; education and tips on adhering to NRT; daily prompt to self-monitor mood, smoking urges, and cigarettes smoked</p> <p>2. Delivery of US clinical practice guidelines for smoking cessation: information about health consequences of smoking; self-monitoring of smoking habits, mood and cravings; tips for quitting</p>
Williams 2010	<p>1. Organized into three stages of treatment: engagement, achieving abstinence and relapse prevention. Review of mental status and general medication compliance, with a focus on the clinical issue of tobacco dependence. Emphasis on relapse prevention, development of coping strategies to prevent relapse and social skills training. Use of role-plays to help identify and cope with situations and moods that might precipitate relapse</p> <p>2. Organized into stages as 1. Review of mental status and general medication compliance, with a focus on the clinical issue of tobacco dependence. Emphasis on medication compliance and education about NRT. Monitoring psychiatric symptoms; understanding medication interactions with tobacco</p>

ACT = acceptance and commitment therapy; CBT = cognitive-behavioural therapy; CO = carbon monoxide; CVD = cardiovascular disease; NRT = nicotine replacement therapy; p.p.m = parts per million; SHS = second-hand smoking.

Secondary outcomes

Smoking reduction

Nine studies reported outcomes related to reduction in smoking (Table 3). However, the outcomes, time-points and information reported were heterogeneous, precluding meta-analysis. Two studies reported a group effect, with participants in the intervention group smoking fewer cigarettes per day (CPD) [28] or demonstrating greater reduction in CPD [31] compared to the comparison group. One study found an effect of time on reduction but no group effect [26]. The

other six studies narratively reported a reduction in the number of cigarettes smoked in all arms of the trial, with no reported significant differences between arms.

Change in psychiatric symptoms

Of the included studies, nine used one or more validated symptom scales to ascertain whether psychiatric symptoms had altered during the course of the trial (Table 3). Eight found no significant worsening of symptoms in terms of measures of SMI or mood and only one

TABLE 3 Study outcomes

	Change in BMI	Change in psychiatric symptoms	7-day point prevalence of quit rate (%) in main intervention (I) and comparison (C)	Smoking reduction main intervention (I) and comparison (C)
Baker 2006 (including data from Baker 2010 [41])	Not reported	(Time effects) BDI: significantly lower at all time points versus baseline BPRS: not significant SFmental: significantly higher at all time-points versus baseline STAI: significantly reduced in 3 m and 4 years versus baseline	3 m: I: 22/147 (15.0) C: 9/151 (6.0) 6 m: I: 14/147 (9.5) C: 6/151 (4.0) 12 m: I: 16/147 (10.9) C: 10/151 (6.6) Y: I: 13/147 (8.8) C: 17/151 (11.3)	CPD reduction ≥ 50% 3 m: I: 43.5% C: 16.6% 6 m: I: 29.9% C: 18.5% 12 m: I: 31.3% C: 17.9% 4 y: I: 33.7% C: 35.8%
Baker 2015 (including data from Baker 2018 [42])	Non-significant effect of group on BMI change at all time-points	BPRS, BDI: improvement from baseline to 36 m was significantly greater in C GAF, SF-12: non-significant effect of group on symptoms Change at all time-points	15 weeks: I: 13/122(10.7) C: 13/113 (11.5) 12 m: I: 8/122 (6.6) C: 7/113 (6.2) 18 m: I: 11/122 (9.0) C: 9/113 (8.0) 2 y: I: 11/112 (9.0) C: 9/113 (8.0) 30 m: I: 13/122 (10.7) C: 9/113 (8.0) 3 y: I: 13/122 (10.7) C: 9/113 (8.0)	CPD reduction ≥ 50% 15 w: I: 31% C: 42% 12 m: I: 16% C: 19% 18 m: I: 16% C: 19% 2 y: I: 16% C: 16% 30 m: I: 20% C: 24% 3 y: I: 22% C: 23%
Bennett 2015	Not reported	Not reported	3 m: I:10/91 (11.0) C: 6/87 (6.9)	CPD: mean (SD) Baseline: I: 15.6 (9.7) C: 14.9 (10.0) 3 m: I: 7.6 (8.6) C: 7.5 (6.7)
Brody 2017	Not reported	AIMS, BPRS, SANS, CGI, BDI-II, C-SSR: non-significant effect of time at all time-points	6 m: I: 5/11 (45.5) C: 8/11 (72.7)	CPD: mean (SD) Baseline: I: 18.6 (9.2) C: 19.6 (8.5) 6 m: I: 2.5 (3.6) C: 12.2 (12.1)
Brunette 2020	Not reported	Not reported	6 m: I: 1/78 (1.2) C: 6/84 (7.1)	Not reported
George 2000	Not reported	BDI, PANSS: non-significant effect of group on symptoms AIMS, WEPS: non-significant effect of smoking status on symptoms SJNWS: non-significant smoking status × time interaction	3 m: I: 10/28 (35.7) C: 6/17 (35.3) 8.5 m: I: 3/28 (10.7) C: 3/17 (17.6)	Not reported
Gilbody 2015 (including data from Peckham 2015 [43])	No changes in BMI from baseline to 12 m in either group (no significance test reported)	PHQ-9, SF-12: changes in scores reported for all time points but with no significance test	12 m: I: 12/46 (26.1) C: 8/51 (15.7)	CPD: mean (SD) Baseline: I: 26.5 (12.0) C: 23.3 (12.3) 1 m: I: 18.4 (9.6) C: 19.4 (12.3) 6 m: I: 16.8 (9.6) C: 17.1 (11.6) 12 m: I: 20.1 (10.6) C: 18.4 (11.6)
Gilbody 2019 (including data from Peckham, 2019 [43])	Non-significant effect of group on BMI at all time-points Significantly higher BMI for quitters at 6 m	GAD-7, PHQ-9 SF-12 mental: non-significant effect of group on symptoms at all time-points	6 m: I: 32/265 (12.1) C: 14/261 (5.4) 12 m: I: 34/265 (12.8) C: 22/261 (8.4)	CPD mean (SD) Baseline: I: 24.7 (13.5) C: 23.2 (12.8) 6 m: I: 17.8 (12.7) C: 18.3 (10.0) 12 m: I: 20.2 (12.3) C: 18.7 (12.1)

(Continues)

TABLE 3 (Continued)

	Change in BMI	Change in psychiatric symptoms	7-day point prevalence of quit rate (%) in main intervention (I) and comparison (C)	Smoking reduction main intervention (I) and comparison (C)
Heffner 2019	Not reported	Altman mania scale, PHQ-9: non-significant effect of group on symptoms Change from baseline to 1 m	10 w: I: 3/25 (12.0) C: 2/26 (7.7) 14 w: I: 2/25 (8.0) C: 2/26 (7.7)	Expired CO reduction \geq 50% EOT: I: 24% C: 15% 1 m: I: 28% C: 27%
Steinberg 2016	Not reported	Not reported	1 m I: 8/49 (16.3) C: 5/49 (10.2)	Not reported
Villardaga 2020	Not reported	Effect of group on symptom change from baseline to 4 m: non-significant for BSI, PANSS and AIS Effect of time on symptom scores from baseline 4 m (regardless of group): non-significant for BSI and PANSS positive. Significant increase in PANSS negative and decrease in AIS	2 m: I: 6/33 (18.1) C: 0/29 (0) 3 m: I: 3/33 (9.1) C: 2/29 (6.9) 4 m: I: 4/33 (12.1) C: 1/29 (3.4)	Reduction in CPD from baseline to 4 m (mean, SD) I: 12.3 (11.5) C: 5.9 (5.9)
Williams 2010	Not reported	BDI and PANSS: non-significant effect of group or smoking status on symptom change from baseline to 17 w	3 m: I: 7/45 (15.6) C: 11/42 (26.2) 6 m: I: 7/45 (15.6) C: 8/42 (19.0) 12 m: I: 6/45 (13.3) C: 6/42 (14.3)	Reduction in CPD and CO from baseline to 17 w Did not report mean (SD) within each group

AIMS = abnormal involuntary movement scale; AIS = avoidance and inflexibility scale; BDI = Beck Depression Inventory; BMI = body mass index; BPRS = brief psychiatric rating scale; BSI = brief symptom inventory; CGI = clinical global impression; CO = carbon monoxide; CPD = cigarettes per day; C-SSRS = Columbia suicide severity of illness scale; EOT = end of treatment; GAD = generalized anxiety disorder; GAF = global assessment of functioning; m = months; PANSS = positive and negative syndrome scale; PHQ = patient health questionnaire; SANS = scale for assessment of negative symptoms; SD = standard deviation; SF = short form survey on general functioning; SJNWS = Shiffman-Jarvik nicotine withdrawal scale; STAI = state-trait anxiety inventory; w = weeks; WEPS = Webster extrapyramidal movement scale; y = years.

FIGURE 2 Meta-analysis results for bespoke person based behavioural interventions compared to usual care

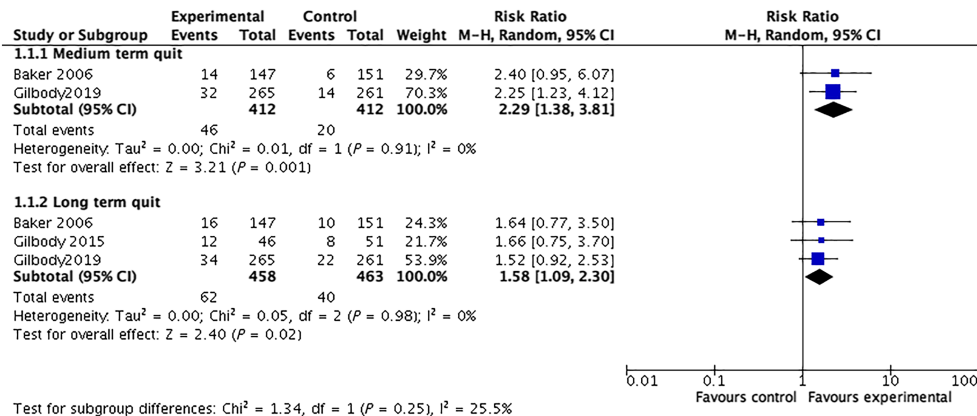


FIGURE 3 Meta-analysis results for bespoke machine-based smoking cessation intervention compared to standard machine-based interventions

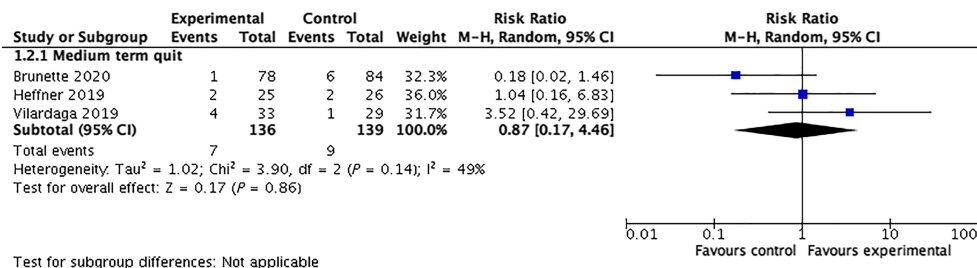
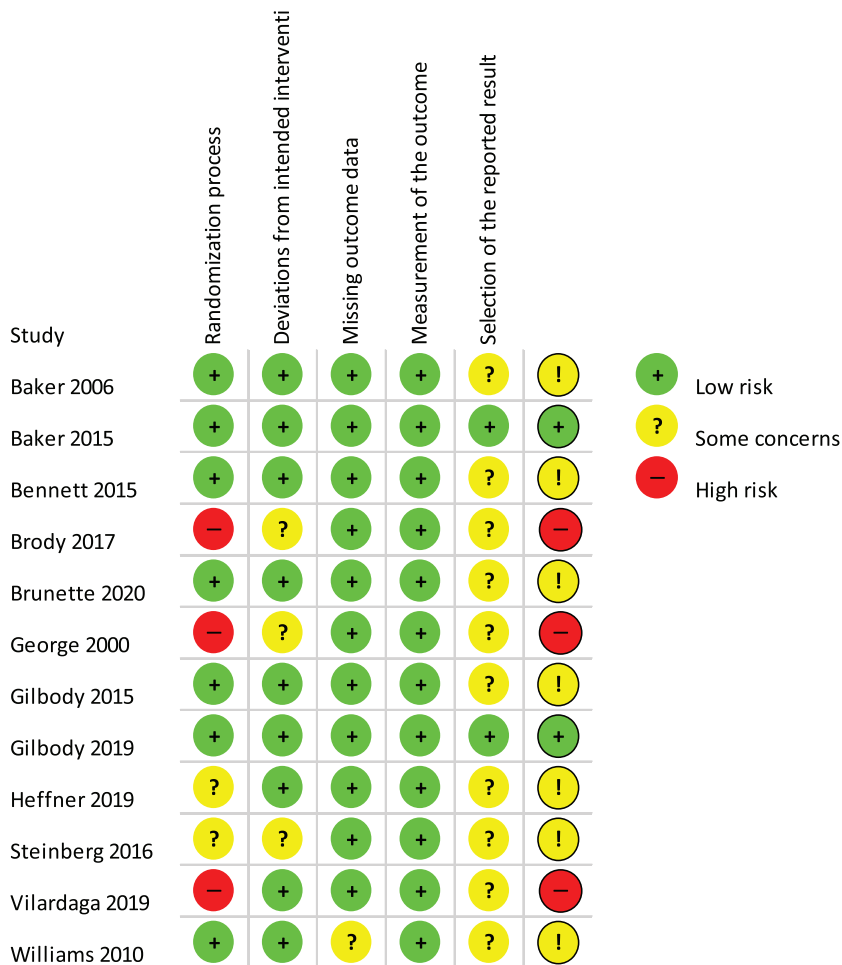


FIGURE 4 Risk of bias critical appraisal



found a worsening of the positive and negative syndrome scale (PANSS) after smoking cessation. This suggests that smoking cessation interventions do not seem to lead to a worsening of psychiatric symptoms; however, due to heterogeneity between the symptom scales and time-points, used no meta-analysis was conducted.

Change in body mass

Only three studies [14, 32, 34] reported results regarding changes in weight (as measured by BMI) and none found an effect of smoking cessation on BMI. However, the Smoking Cessation Intervention for Severe Mental Ill Health (SCIMITAR) studies of 2015 and 2019 [14, 32] reported only narrative results with no statistical analysis.

Cost effectiveness

Only two studies set out to explore the cost-effectiveness of the intervention. The SCIMITAR study (2015) [32] was a pilot study that was not sufficiently powered for any firm conclusions to be drawn; however, in Peckham *et al.* (2019) [38] and Li (2020) [39] (who report the cost-effectiveness of the SCIMITAR intervention [14]) it was demonstrated that a smoking cessation intervention, tailored to the needs of people with SMI, was cost-effective over 12 months. The mean total cost in the intervention group was £270 (95% = -£1690 to 1424) lower than in the usual care group, while the mean QALYs were 0.013 (95% CI = -0.008 to 0.045) higher, leading to smoking cessation dominating usual care (76% probability of cost-effective at £20 000/QALYs).

DISCUSSION

Our previous reviews [11, 16] have focused upon all types of smoking cessation interventions for people with SMI, including pharmacotherapy. In this updated review we focus upon behavioural interventions to understand whether behavioural support should form part of an effective intervention to support quitting in this group with some of the highest rates of smoking. We identified 12 studies that met the inclusion criteria, examining both bespoke and non-bespoke interventions, with or without adjunctive pharmacotherapy. Compared to our previous review, the number of larger-scale trials has increased (four new studies, each of 100+ participants included in this review), bringing greater statistical power and precision to our evidence synthesis.

When we undertook a meta-analysis, we found that bespoke person-based smoking cessation interventions for people with SMI were more effective than usual care across all time-points. This is in line with previous reviews suggesting that smoking cessation interventions are effective in people with mental health problems (but not exclusively SMI) [13] and the general population [40]. The largest of the three trials ($n = 526$) in this meta-analysis was at low risk of bias (there were some concerns for the other two), meaning that we are

reasonably confident in our conclusion. Furthermore, the cost-effectiveness analysis of the SCIMITAR+ study [14] indicated that the bespoke smoking cessation intervention was more cost-effective and associated with improvements in quality of life compared to usual care.

Although our protocol precluded a meta-analysis for studies comparing bespoke person-based interventions with other active interventions, the narrative overview revealed equivocal findings with wide CIs and imprecise estimates of effect. The great variability in the content of intervention and control groups makes interpretation of these findings difficult.

The second meta-analysis was not sufficiently powered to detect a difference between bespoke machine-based and generic machine-based interventions due to small sample size. Two of the studies were also identified as having some concerns, and one was at high risk of bias. The potential sources of bias were the randomization process being inadequately described and selection of the reported result.

Due to the fact that many smoking cessation programmes switched to remote delivery during the COVID-19 pandemic, we wanted to examine how this change might affect the effectiveness of these interventions. However, there were no sufficient data to assess this. We only identified three studies where interventions were delivered via the internet (the machine-based interventions subgroup), for which the comparison group was another on-line active intervention, rather than treatment as usual or at least a face-to-face intervention.

Ten of the 12 studies in this review included a bespoke intervention, adapted to the specific needs of people with SMI. However, the nature of these adaptation was often unclear. Even in studies that provided enough information, there was great variability in the 'bespoke' content. Given the high prevalence of smoking in people with SMI, it is important that smoking cessation interventions are tailored to meet their needs, that the people delivering the intervention understand those needs and that a systematic way of tailoring is developed.

It is encouraging that, as per findings in our previous reviews, quitting smoking did not appear to worsen participants' mental state. However, it remains unclear whether this generalizes to remote delivery. Given the COVID-19 pandemic and the increasing remote delivery of services (many times via digital means) it is important to understand whether internet-based and other remote (e.g. via the telephone) smoking cessation programmes are effective and acceptable for people with SMI. We suggest that this is an important area for further research.

There are some limitations to this review. First, the review only contained English-language publications and grey literature was not searched, potentially excluding relevant studies in other languages or not published through traditional academic channels. Secondly, we were not able to determine the most effective intervention elements due to the great differences in intervention content throughout studies. The strengths of this review are that it followed a rigorous process with stringent inclusion criteria. The review followed a pre-specified protocol and studies were eligible for inclusion if they used a biochemically validated smoking cessation measure. We also took steps

to avoid reviewer bias. Members of the review team are co-authors of two of the included studies; inadvertent bias in the process was avoided, as they were not involved in the data extraction or risk of bias assessment for those studies.

In summary, trial-based evidence supports the effectiveness of bespoke person-based behavioural smoking cessation interventions in promoting smoking cessation in people with SMI compared to usual treatment. Effectiveness is enhanced by the inclusion of a behavioural element. There is now also evidence from trial-based economic evaluations that interventions are cost-effective. Findings are equivocal when comparing such interventions with other active interventions, precluding identification of the most effective intervention elements. As we did not identify any studies comparing digital intervention with no treatment or usual treatment, it is yet unclear whether they are effective at promoting smoking cessation. This is an important topic for further research, which has been accelerated by the drive to shift the provision of care to remote and digital delivery with the advent of COVID and system re-design.

DECLARATION OF INTERESTS

E.P. and S.G. worked on the SCIMITAR study and E.P., S.G., P.H. and D.B. all worked on the SCIMITAR+ study. For these studies the assessment of risk of bias and data extraction was performed by authors not involved in the studies. P.S. and B.Y. have no interests to declare.

ACKNOWLEDGEMENTS

This report is independent research supported by the National Institute for Health Research, Yorkshire and Humber Applied Research Collaborations. The views expressed in this publication are those of the author(s) and not necessarily of the NHS, the National Institute for Health Research or the Department of Health and Social Care.

AUTHOR CONTRIBUTIONS

Panagiotis Spanakis: Conceptualization; data curation; formal analysis; investigation; methodology; visualization. **Emily Peckham:** Conceptualization; data curation; formal analysis; investigation; methodology. **Ben Young:** Data curation; formal analysis; investigation; methodology; visualization. **Paul Heron:** Conceptualization; data curation; formal analysis; investigation; methodology. **Della Bailey:** Data curation; investigation; methodology. **Simon Gilbody:** Conceptualization.

ORCID

Panagiotis Spanakis  <https://orcid.org/0000-0002-2732-8300>

Emily Peckham  <https://orcid.org/0000-0002-9377-1968>

Ben Young  <https://orcid.org/0000-0001-6451-9360>

Paul Heron  <https://orcid.org/0000-0003-3529-5737>

Della Bailey  <https://orcid.org/0000-0002-6059-2111>

Simon Gilbody  <https://orcid.org/0000-0002-8236-6983>

REFERENCES

1. Brown S, Kim M, Mitchell C, Inskip H. Twenty-five year mortality of a community cohort with schizophrenia. *Br J Psychiatry*. 2010;196:116–21.
2. Correll CU, Solmi M, Veronese N, Bortolato B, Rosson S, Santonastaso P, et al. Prevalence, incidence and mortality from cardiovascular disease in patients with pooled and specific severe mental illness: a large-scale meta-analysis of 3,211,768 patients and 113,383,368 controls. *World Psychiatry*. 2017;16:163–80.
3. Osborn DPJ, Levy G, Nazareth I, Petersen I, Islam A, King MB. Relative risk of cardiovascular and cancer mortality in people with severe mental illness from the United Kingdom's general practice research database. *Arch Gen Psychiatry*. 2007;64:242–9.
4. Royal College of Psychiatrists (RCP). Smoking and Mental Health: A Joint Report by the Royal College of Physicians and the Royal College of Psychiatrists. London, UK: RCP; 2013.
5. Cook BL, Wayne GF, Kafali EN, Liu Z, Shu C, Flores M. Trends in smoking among adults with mental illness and association between mental health treatment and smoking cessation. *JAMA*. 2014;311:172–82.
6. de Leon J, Diaz FJ. A meta-analysis of worldwide studies demonstrates an association between schizophrenia and tobacco smoking behaviors. *Schizophr Res*. 2005;76:135–57.
7. Cheeseman H, Harker K. The Stolen Years. London, UK: Action on Smoking and Health; 2016.
8. Prochaska JJ. Smoking and mental illness—breaking the link. *N Engl J Med*. 2011;365:196–8.
9. Roberts E, Eden Evins A, McNeill A, Robson D. Efficacy and tolerability of pharmacotherapy for smoking cessation in adults with serious mental illness: a systematic review and network meta-analysis. *Addiction*. 2016;111:599–612.
10. Anthenelli RM, Benowitz NL, West R, St Aubin L, McRae T, Lawrence D, et al. Neuropsychiatric safety and efficacy of varenicline, bupropion, and nicotine patch in smokers with and without psychiatric disorders (EAGLES): a double-blind, randomised, placebo-controlled clinical trial. *Lancet*. 2016;387:2507–20.
11. Peckham E, Brabyn S, Cook L, Tew G, Gilbody S. Smoking cessation in severe mental ill health: what works? An updated systematic review and meta-analysis. *BMC Psychiatry*. 2017;17:252. <https://doi.org/10.1186/s12888-017-1419-7>
12. Pearsall R, Smith DJ, Geddes JR. Pharmacological and behavioural interventions to promote smoking cessation in adults with schizophrenia and bipolar disorders: a systematic review and meta-analysis of randomised trials. *BMJ Open*. 2019;9:e027389.
13. Lightfoot K, Panagiotaki G, Nobes G. Effectiveness of psychological interventions for smoking cessation in adults with mental health problems: a systematic review. *Br J Health Psychol*. 2020;25:615–38.
14. Gilbody S, Peckham E, Bailey D, Arundel C, Heron P, Crosland S, et al. Smoking cessation for people with severe mental illness (SCIMITAR+): a pragmatic randomised controlled trial. *Lancet Psychiatry*. 2019;6:379–90.
15. Robotham D, Satkunanathan S, Doughty L, Wykes T. Do we still have a digital divide in mental health? A five-year survey follow-up. *J Med Internet Res*. 2016;18:e309.
16. Banham L, Gilbody S. Smoking cessation in severe mental illness: what works? *Addiction*. 2010;105:1176–89.
17. British Medical Association (BMA) and National Health Service (NHS) Employers. Revisions to the GMS Contract, 2008/9. Delivering Investment in General Practice. London, UK: BMA; 2008.
18. Cheung KL, de Ruijter D, Hilgsmann M, Elfeddali I, Hoving C, Evers SMAA, et al. Exploring consensus on how to measure smoking cessation. A Delphi study. *BMC Public Health*. 2017;17:890. <https://doi.org/10.1186/s12889-017-4902-7>
19. Brunette MF, Ferron JC, Aschbrenner KA, Pratt SI, Geiger P, Kosydar S. Attitudes about smoking cessation treatment, intention to quit, and cessation treatment utilization among young adult smokers with severe mental illnesses. *Addict Behav*. 2019;89:248–55.

20. Shoemith E, Huddleston L, Lorencatto F, Shahab L, Gilbody S, Ratschen E. Supporting smoking cessation and preventing relapse following a stay in a smoke-free setting: a meta-analysis and investigation of effective behaviour change techniques. *Addiction* 2021; 116:2978–2994.
21. Bradshaw T, Mairs H. Obesity and serious mental ill health: a critical review of the literature. *Healthcare*. 2014;2:166–82.
22. Boulton E, Kneale D, Stansfield C, Heron P, Sutcliffe K, Hayanga B *et al*. Rapid systematic review of systematic reviews: what befriending, social support and low intensity psychosocial interventions, delivered remotely, may reduce social isolation and loneliness among older adults and how? [version 2; peer review: 2 approved with reservations]. *F1000Research*. 2021;9:1368.
23. Higgins JP, Savović J, Page MJ, Elbers RG, Sterne JA. Chapter 8: Assessing risk of bias in a randomized trial. In: Higgins JP, Thomas J, Chandler J., Cumpston M, Li T, Page MJ, *et al*. editors. *Cochrane Handbook for Systematic Reviews of Interventions*. 2nd ed. Chichester, UK: John Wiley & Sons; 2019. p. 205–28.
24. Lindson N, Klemperer E, Hong B, Ordóñez-Mena JM, Aveyard P. Smoking reduction interventions for smoking cessation. *Cochrane Database Syst Rev*. 2019;9:CD013183.
25. George TP, Ziedonis DM, Feingold A, Pepper WT, Satterburg CA, Winkel J, *et al*. Nicotine transdermal patch and atypical antipsychotic medications for smoking cessation in schizophrenia. *Am J Psychiatry*. 2000;157:1835–42.
26. Williams JM. Comparison of two intensities of tobacco dependence counseling in schizophrenia and schizoaffective disorder. *J Subst Abuse Treat*. 2010;38:384–93.
27. Bennett ME, Brown CH, Li L, Himelhoch S, Bellack A, Dixon L. Smoking cessation in individuals with serious mental illness: a randomized controlled trial of two psychosocial interventions. *J Dual Diagn*. 2015;11:161–73.
28. Brody AL, Zorick T, Hubert R, Hellemann GS, Balali S, Kawasaki SS, *et al*. Combination extended smoking cessation treatment plus home visits for smokers with schizophrenia: a randomized controlled trial. *Nicotine Tob Res*. 2017;19:68–76.
29. Brunette MF, Ferron JC, McGurk SR, Williams JM, Harrington A, Devitt T, *et al*. Brief, web-based interventions to motivate smokers with schizophrenia: randomized controlled trial. *J Med Internet Res Ment Health*. 2020;7:e16524.
30. Hefner JL, Kelly MM, Waxmonsky J, Mattocks K, Serfozo E, Bricker JB, *et al*. Pilot randomized controlled trial of web-delivered acceptance and commitment therapy versus Smokefree.gov for smokers with bipolar disorder. *Nicotine Tob Res*. 2019;22:1543–52.
31. Vilardaga R, Rizo J, Palenski PE, Mannelli P, Oliver JA, McClernon FJ. Pilot randomized controlled trial of a novel smoking cessation app designed for individuals with co-occurring tobacco use disorder and serious mental illness. *Nicotine Tob Res*. 2020;22:1533–42.
32. Gilbody S, Peckham E, Man MS, Mitchell N, Li J, Becque T, *et al*. Bespoke smoking cessation for people with severe mental ill health (SCIMITAR): a pilot randomised controlled trial. *Lancet Psychiatry*. 2015;2:395–402.
33. Baker A, Richmond R, Haile M, Lewin TJ, Carr VJ, Taylor RL, *et al*. A randomized controlled trial of a smoking cessation intervention among people with a psychotic disorder. *Am J Psychiatry* [internet]. 2006;163:1934–42. Available at: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/275/CN-00573275/frame.html>
34. Baker AL, Richmond R, Kay-Lambkin FJ, Folia SL, Castle D, Williams JM, *et al*. Randomized controlled trial of a healthy lifestyle intervention among smokers with psychotic disorders. *Nicotine Tob Res*. 2015;17:946–54.
35. Steinberg ML, Williams JM, Stahl NF, Budsock PD, Cooperman NA. An adaptation of motivational interviewing increases quit attempts in smokers with serious mental illness. *Nicotine Tob Res*. 2016;18: 243–50.
36. Williams JM, Steinberg ML, Zimmermann MH, Gandhi KK, Stipelman B, Budsock PD, *et al*. Comparison of two intensities of tobacco dependence counseling in schizophrenia and schizoaffective disorder. *J Subst Abuse Treat*. 2010;38:384–93.
37. Egger M, Smith GD. Meta-analysis bias in location and selection of studies. *BMJ*. 1998;316:61.
38. Peckham E, Arundel C, Bailey D, Crosland S, Fairhurst C, Heron P, *et al*. A bespoke smoking cessation service compared with treatment as usual for people with severe mental ill health: the SCIMITAR+ RCT. *Health Technol Assess*. 2019;23:50.
39. Li J, Fairhurst C, Peckham E, Bailey D, Arundel C, Hewitt C, *et al*. Cost-effectiveness of a specialist smoking cessation package compared with standard smoking cessation services for people with severe mental illness in England: a trial-based economic evaluation from the SCIMITAR+ study. *Addiction*. 2020;115:2113–22.
40. Hartmann-Boyce J, Livingstone-Banks J, Ordóñez-Mena JM, Fanshawe TR, Lindson N, Freeman SC, *et al*. Behavioural interventions for smoking cessation: an overview and network meta-analysis. *Cochrane Database Syst Rev*. 2021;1:CD013229.
41. Baker A, Richmond R, Lewin TJ, Kay-Lambkin F. Cigarette smoking and psychosis: Naturalistic follow up 4 years after an intervention trial. *Aust NZ J Psychiatry* [internet]. 2010;44:342–50. Available at: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/490/CN-00750490/frame.html>
42. Baker AL, Richmond R, Kay-Lambkin FJ, Folia SL, Castle D, Williams JM, *et al*. Randomised controlled trial of a healthy lifestyle intervention among smokers with psychotic disorders: outcomes to 36months. *Aust NZ J Psychiatry*. 2018;52:239–52. (accessed 04 May 2020).
43. Peckham E, Man MS, Mitchell N, Li J, Becque T, Knowles S. 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. *Health Technol Assess*. 2015;19:1–148.

SUPPORTING INFORMATION

Additional supporting information may be found in the online version of the article at the publisher's website.

How to cite this article: Spanakis P, Peckham E, Young B, Heron P, Bailey D, Gilbody S. A systematic review of behavioural smoking cessation interventions for people with severe mental ill health—what works? *Addiction*. 2022;117: 1526–42. <https://doi.org/10.1111/add.15724>