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DOI:

[10.1186/s12875-023-01981-2](https://doi.org/10.1186/s12875-023-01981-2)

[Link to publication record in King's Research Portal](#)

Citation for published version (APA):

Tildy, B., McNeill, A., Perman-Howe, P., & Brose, L. (2023). Implementation strategies to increase smoking cessation treatment provision in primary care: a systematic review of observational studies. *BMC Primary Care*, 24(1), Article 32. <https://doi.org/10.1186/s12875-023-01981-2>

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Appendix 3: Risk of bias assessment

As outlined in the introduction, the ROBINS-I (Risk Of Bias in Non-randomized Studies of Interventions) tool was used to evaluate the risk of bias in non-randomized observational studies (23–25). If performed the risk of bias assessments. After the first five studies were assessed, it was assumed there, and if not, the assessment stage. The risk of bias assessment stage and justifications are included below.

The tool assesses risk of bias in seven domains (23):
 1) Who intervened (2) bias due to confounding (2) bias in selection of participants (2) bias in measurement of outcome (2) bias in selection of the reported result.
 2) Who intervened (2) bias due to confounding (2) bias in selection of participants (2) bias in measurement of outcome (2) bias in selection of the reported result.
 3) Who intervened (2) bias due to confounding (2) bias in selection of participants (2) bias in measurement of outcome (2) bias in selection of the reported result.

From an overall risk of bias rating, a description of each study (23):
 Low risk of bias. The study is considered to be a well-performed observational trial.
 Moderate risk of bias. The study provides moderate evidence for a non-randomized study but cannot be considered comparable to a well-performed randomized trial.
 Serious risk of bias. The study has some important problems.
 Critical risk of bias. The study has problems to provide any credible evidence about its effects and should not be included in any synthesis.
 No information. No information on which to base a judgment about risk of bias.

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 25. Harman MA, Berlin JA, Moher D, Altman D, Egger M, Pocock SJ, et al. Assessing risk of bias in non-randomized studies: to begin, to begin, to begin. *CMAJ*. 2014;186(18):1211-1214.
 26. Harman MA, Berlin JA, Moher D, Altman D, Egger M, Pocock SJ, et al. Assessing risk of bias in non-randomized studies: to begin, to begin, to begin. *CMAJ*. 2014;186(18):1211-1214.

First author, year	Bias due to confounding	Support for judgement	Bias in selection into the study	Support for judgement	Bias in classification of interventions	Support for judgement	Bias due to deviations from intended intervention	Support for judgement	Bias due to missing data	Support for judgement	Bias in measurement of outcome	Support for judgement	Bias in selection of the reported result	Support for judgement	Overall risk of bias	Grade		
Sutcliffe, 2016	Moderate	Flexible other events could have affected outcomes but there was no discussion of this in the paper, but authors do use ARIMA (autoregressive integrated moving average) modelling which is an account for underlying trends and seasonal trends. Sufficient pre- and post- intervention points included in the analysis. Several relevant confounding factors adjusted for.	Low	Electronic health records of 12 million patients aged >16 years from GGP GP clinics in the UK, broadly representative of the UK population in terms of the age and sex distribution.	Low	Population and intervention clearly outlined.	Low	Characteristics of GP clinics may have influenced, but there were measures in place to ensure any differences were accounted for in the analysis and the intervention.	Moderate	No mention of missing or excluded data but assumed that the proportion of participants and reasons for missing data are similar pre- and post- intervention.	Low	Outcome measure was the same pre- and post- the intervention. Electronic record of record of advice to quit, record of referral to the NHS Stop Smoking Service, and prescriptions for a smoking cessation medication. On other data electronic records, record of advice to quit could be subjective.	Moderate	Two analyses reported (pre period: Apr 2010 to Mar 2012, post: Apr 2012 to Apr 2013, and pre period: Apr 2012 to Mar 2012, post: Apr 2012 to Apr 2013). Reporting was transparent, but there were no pre-specified analysis plans.	Moderate	LB		
Sutcliffe, 2016	Moderate	Primary Care Trust Patient Survey data was standardized by age, sex and Strengths and Weaknesses Authority (SWA) for comparison with electronic health records, but no other confounders were mentioned or adjusted for.	Serious	Response rates for the PC Patient Survey was "47.4%, 45.4% and 38.2%" for the 3 years assessed - this could/should have been reported.	Low	Population and intervention clearly outlined.	Low	This is not expected in observational studies of individuals in routine care.	Moderate	No mention of missing or excluded data but assumed that the proportion of participants and reasons for missing data are similar pre- and post- intervention.	Low	The different types of the outcome measure are compared (self report by patients or self report by the GP).	Moderate	Only one effect estimate is reported (for the whole population). No pre-specified analysis plan.	Serious	LB		
Sutcliffe, 2010	Serious	This is a descriptive, repeated cross-sectional study, not controlling for confounders or secular trend. Causality cannot be inferred.	Low	Electronic health records from GGP GP clinics in the UK were used, broadly representative of the UK population in terms of the age and sex distribution. This was relatively representative in the post-trend.	Low	Population and intervention clearly outlined.	Low	This is not expected in observational studies of individuals in routine care.	Moderate	No mention of missing or excluded data but assumed that the proportion of participants and reasons for missing data are similar pre- and post- intervention.	Low	Outcome measure was the same pre- and post- the intervention. Electronic records of smoking status and smoking cessation advice. GP self-report data into electronic records, record of cessation advice could be subjective.	Moderate	Smoking status recording procedure for whole population pre- and post- intervention. Adjusted analyses were performed but not reported and adjusted results. No pre-specified analysis plan.	Serious	LB		
Tager, 2012	Serious	This is a descriptive, repeated cross-sectional study. There is some control for confounders but for the reasons stated or otherwise stated. Sufficient pre- and post- intervention points included in the analysis. Several relevant confounding factors adjusted for.	Low	Electronic health records from GGP GP clinics in the UK were used, broadly representative of the UK population in terms of the age and sex distribution. This was relatively representative in the post-trend.	Low	Population and intervention clearly outlined.	Low	This is not expected in observational studies of individuals in routine care.	Moderate	No mention of missing or excluded data apart from 'Treatment category: proportion of patients missing Treatment category is similar in 2002, 2004 and 2006.	Low	Outcome measure was the same pre- and post- the intervention. Electronic record of smoking status and smoking cessation advice. GP self-report data into electronic records, record of cessation advice could be subjective.	Moderate	Several adjusted analyses were performed but not reported and adjusted results. No pre-specified analysis plan.	Serious	LB		
Alghadi, 2019	Low	Used interrupted time series design, with matched controls, and adjusted for confounding factors.	Low	Patients who increased the health checks were identified from electronic health records - study authors had no input into the selection of the patients.	Low	Population and intervention clearly outlined.	Low	This is not expected in observational studies of individuals in routine care.	Low	High level of missing data, but attempted address using last observation carried forward (LOCF) method. Sensitivity analyses reported.	Low	Outcome measure was the same pre- and post- the intervention.	Low	Study protocol included and sensitivity analyses reported.	Low	LB		
Coleman, 2007	Serious	This is a descriptive, repeated cross-sectional study, not controlling for confounders or secular trend. Causality cannot be inferred.	Low	Electronic health records from GP clinics in the UK were used, broadly representative of the UK population. Note: the study period is from 1996. It is assumed that this was relatively representative in the post-trend.	Low	Population and intervention clearly outlined.	Low	This is not expected in observational studies of individuals in routine care.	Moderate	No mention of missing or excluded data but assumed that the proportion of participants and reasons for missing data are similar pre- and post- intervention.	Low	Outcome measure was the same pre- and post- the intervention. Electronic records of smoking status and smoking cessation advice. GP self-report data into electronic records, record of cessation advice could be subjective.	Moderate	Results reported against their relevant target group of interest. No pre-specified analysis plan.	Serious	LB		
Sutcliffe, 2011	Moderate	Flexible other events could have affected outcomes but there was no discussion of this in the paper, but authors do use ARIMA (autoregressive integrated moving average) modelling which is an account for underlying trends and seasonal trends. Sufficient pre- and post- intervention points included in the analysis. Several relevant confounding factors adjusted for.	Low	Electronic health records GP clinics in the UK, broadly representative of the UK population in terms of the age and sex distribution. Note: the study period is from 2000. It is assumed that this was relatively representative in the post-trend.	Low	Population and intervention clearly outlined.	Low	Likely that the policy was implemented differently nationally.	Moderate	No mention of missing or excluded data but assumed that the proportion of participants and reasons for missing data are similar pre- and post- intervention.	Low	Outcome measure was the same pre- and post- the intervention. Electronic records of prescriptions issued to a robust, objective outcome measure.	Moderate	The paper reports a relevant range of analyses of different age groups and sex effect of the policy. No pre-specified analysis plan.	Moderate	LB		
Langley, 2011	Moderate	Flexible other events could have affected outcomes. But authors did use segmented regression analysis with generalized additive mixed models (GAMM) to account for the secular trend.	Low	Electronic health records GP clinics in the UK, broadly representative of the UK population in terms of the age and sex distribution. Note: the study period is from 2002. It is assumed that this was relatively representative in the post-trend.	Low	Population and intervention clearly outlined.	Low	This is not expected in observational studies of individuals in routine care.	Moderate	No mention of missing or excluded data but assumed that the proportion of participants and reasons for missing data are similar pre- and post- intervention.	Low	Outcome measure was the same pre- and post- the intervention. Electronic records of NRT prescriptions issued in a robust, objective outcome measure.	Moderate	Results reported against their relevant target group of interest. No pre-specified analysis plan.	Moderate	LB		
Langley, 2012	Moderate	Flexible other events could have affected outcomes. But authors did use segmented regression analysis with generalized additive mixed models (GAMM) to account for the secular trend.	Low	Electronic health records GP clinics in the UK, broadly representative of the UK population in terms of the age and sex distribution. Note: the study period is from 2002. It is assumed that this was relatively representative in the post-trend.	Low	Population and intervention clearly outlined.	Low	This is not expected in observational studies of individuals in routine care.	Moderate	No mention of missing or excluded data but assumed that the proportion of participants and reasons for missing data are similar pre- and post- intervention.	Low	Outcome measure was the same pre- and post- the intervention. Electronic records of prescriptions issued to a robust, objective outcome measure.	Moderate	Results reported against their relevant target group of interest. No pre-specified analysis plan.	Moderate	LB		
Bakoy, 2012	Moderate	Relevant confounders identified and adjusted for. "All births were adjusted for known variables associated with smoking (sex, residence, race/ethnicity, gender, age category, household percentage of head of prime aged (16 to over 65)), measure rates at the region of which (county, urban/rural, number of visits in the measurement year, and comorbid diseases (hypertension, type 2 diabetes, asthma/chronic obstructive pulmonary disease, cancer, depression, diabetes, psychiatric diagnosis, and substance abuse diagnosis, including tobacco use disorders). Services area of the patient's primary care was included as a fixed effect to adjust for unexplained differences between health centres. The authors did not adjust for urban versus rural health centre as over 90% had a ZIP code in an urban setting across years, as identified using each county's commuting zone codes."	Low	Electronic health records of the same clinics, pre- and post- intervention.	Low	Population and intervention clearly outlined.	Low	This is not expected in observational studies of individuals in routine care.	Moderate	No mention of missing or excluded data apart from 'Household income: The proportion of patients missing this variable is similar across the study period.'	Low	Outcome measure was the same pre- and post- the intervention. GP self-report data into electronic records, smoking cessation advice could be subjective.	Moderate	Unadjusted and adjusted odds ratios are reported transparently. No pre-specified analysis plan.	Moderate	LB		
Sutcliffe, 2011	Moderate	Flexible other events could have affected outcomes. But authors did use segmented regression and tested for autocorrelation to account for the secular trend. Did not control for other confounders.	Low	Electronic health records GP clinics in the UK, representative of the UK population.	Serious	Intervention is not well defined. The "Transfer of public health budgets from the local to local authorities since 2007" is not well defined and it is unclear if the intervention was the "same" for all local authorities nationally.	Moderate	Due to the lack of clarity around the classification of the intervention, the time the policy was implemented may have differed between local authorities nationally.	Moderate	No mention of missing or excluded data but assumed that the proportion of participants and reasons for missing data are similar pre- and post- intervention.	Low	Outcome measure was the same pre- and post- the intervention. Electronic records of NRT prescriptions issued in a robust, objective outcome measure.	Moderate	Only one effect estimate is reported (change in prescription rate per whole population over time), but no subgrouped analyses or age group analyses were included or reported. Reporting was transparent, but no pre-specified analysis plan.	Serious	LB		
Langley, 2011	Moderate	Flexible other events could have affected outcomes. No mention of legislation in 2002 but authors included this in their model. Authors used ARIMA (autoregressive integrated moving average) modelling which is an account for underlying trends and seasonal trends. Sufficient pre- and post- intervention points included in the analysis. Several relevant confounding factors adjusted for.	Low	Electronic health records GP clinics in the UK, representative of the UK population.	Low	Population and intervention clearly outlined.	Low	This is not expected in observational studies of individuals in routine care.	Moderate	No mention of missing or excluded data but assumed that the proportion of participants and reasons for missing data are similar pre- and post- intervention.	Low	Outcome measure was the same pre- and post- the intervention. Electronic records of NRT prescriptions issued in a robust, objective outcome measure.	Moderate	Only one effect estimate is reported (change in prescription rate per whole population over time), but no subgrouped analyses or age group analyses were included or reported. Reporting was transparent, but no pre-specified analysis plan.	Moderate	LB		
Chikani, 2013	Serious	Examined several confounding factors: age, socioeconomic status, BMI, within, hypertension, diabetes, mental illness. But did not account for other plausible other events which could have affected outcomes, or the underlying secular trend.	Low	Electronic health records GP clinics in the UK, representative of the UK population.	Low	Population and intervention clearly outlined.	Low	This is not expected in observational studies of individuals in routine care.	Moderate	Missing data outlined. Data were reasonably complete. Although it was not stated whether missing data was missing in random, "missing data for Townsend grade and BMI were excluded to separate categories in the analysis."	Low	Outcome measure was the same pre- and post- the intervention. Electronic records of smoking status in a robust outcome measure.	Moderate	Methods was transparent regarding which confounding characteristics were included in the regression model, but there is no report of pre- and post- odds ratio reported. Only one intervention odds ratio reported for the relevant characteristics, but both adjusted and unadjusted odds ratios are reported. No pre-specified analysis plan.	Serious	LB		
Hendy, 2014	Serious	Examined several confounding factors: age, socioeconomic status, BMI, within, hypertension, diabetes, mental illness. But did not account for other plausible other events which could have affected outcomes, or the underlying secular trend.	Low	Electronic health records GP clinics in the UK, representative of the UK population.	Low	Population and intervention clearly outlined.	Low	This is not expected in observational studies of individuals in routine care.	Moderate	Missing data outlined. Data were reasonably complete. Although it was not stated whether missing data was missing in random, "missing data for Townsend grade and BMI were excluded to separate categories in the analysis."	Low	Outcome measure was the same pre- and post- the intervention. Electronic records of smoking status in a robust outcome measure.	Moderate	Methods was transparent regarding which confounding characteristics were included in the regression model, but there is no report of pre- and post- odds ratio reported. Only one intervention odds ratio reported for the relevant characteristics, but both adjusted and unadjusted odds ratios are reported. No pre-specified analysis plan.	Serious	LB		
Fahy, 2017	Low	Examined several confounding factors and used a control group. Causation cannot be inferred but the study is comparable to a well-performed randomized trial with regard to the domain.	Low	Electronic health records GP clinics in the UK, representative of the UK population.	Low	Population and intervention clearly outlined.	Low	This is not expected in observational studies of individuals in routine care.	Low	No direct mention of missing data but authors are transparent about the completeness of smoking status recording and the methods to do this across the cohort.	Low	Outcome measure was the same pre- and post- the intervention. Electronic records of smoking cessation advice. GP self-report data into electronic records, record of cessation advice could be subjective.	Low	Appropriate outcome measures reported, study protocol included.	Low	LB		
Chikani, 2014	Serious	Examined several confounding factors. But did not account for other plausible other events which could have affected outcomes, or the underlying secular trend.	Low	Electronic health records GP clinics in the UK, representative of the UK population.	Low	Population and intervention clearly outlined.	Low	This is not expected in observational studies of individuals in routine care.	Moderate	Data were reasonably complete. Although it was not stated whether missing data was missing in random, "missing data for Townsend grade and BMI were excluded to separate categories in the analysis."	Moderate	Outcome measure was the same pre- and post- the intervention. Electronic records of NRT prescriptions issued in a robust, objective outcome measure.	Moderate	The overall population effect "prevalence of progression" is reported but no pre-specified analysis plan.	Serious	LB		
Fahay, 2017	Serious	Flexible other events could have affected outcomes but there was no adjustment for these in analysis. Did not control for confounders. "Through the clinical quality data system that stores real and reported health data, this could be used to track healthcare utilization measures from the QDS, such as hospital inpatient procedures, other than the intervention provided by the practice, and control targets." Confounding factors in patient characteristics were not reported but the pre- post- design of the study potentially minimizes their effect.	Low	GP data used to control for selection bias. "To remove a potential source of bias and to be able to compare the GP data with the national datasets used, the proportion of patients achieving each quality indicator is each practice out of the total number of practices in the dataset is reported in practice rather than the absolute number provided by the practice, and calculated. These denominators provided by practice table take account expansion reporting and as a result, any possible bias of expansion reporting from the study data has been removed."	Moderate	Population and intervention clearly outlined. Time period of implementation of the intervention is 100% clear. Note: "The intervention (advice on smoking cessation) was implemented from 18th October 2008 instead of 8th 2008 - this is not transparently discussed."	Low	This is not expected in observational studies of individuals in routine care.	Moderate	No mention of missing or excluded data but assumed that the proportion of participants and reasons for missing data are similar pre- and post- intervention.	Low	Outcome measure was the same pre- and post- the intervention. Electronic records of NRT prescriptions issued in a robust, objective outcome measure.	Moderate	Only one effect estimate is reported (for the patient population). No pre-specified analysis plan.	Serious	LB		
Mullin, 2019	Serious	Flexible other events could have affected outcomes but there was no discussion of this in the paper (not clear for gender or race, which is a confounding factor) or smoking cessation provision. These populations were seen during different periods of time. Therefore, it is possible that other relevant confounding factors between the groups (such as TV consumption, or more physical health publicity)."	Serious	Electronic health records of the same clinic, pre- and post- intervention. Roughly equal number about outcomes. "Patients without a recorded smoking history were included. "Patients were defined as smokers if during their time their status was "smoker" or "former". If it is unclear whether a patient's status was "smoker" or "former", the "smoking" intervention data is usually "being the intervention".	Moderate	Population and intervention clearly outlined. Time period of implementation of the intervention is 100% clear. Note: "The intervention (advice on smoking cessation) was implemented from 18th October 2008 instead of 8th 2008 - this is not transparently discussed."	Low	This is not expected in observational studies of individuals in routine care.	Low	No mention of missing or excluded data.	Low	Outcome measure was the same pre- and post- the intervention. Electronic records of smoking status, tobacco cessation counselling. GP self-report data into electronic records, record of cessation advice could be subjective.	Moderate	Only one effect estimate is reported (for the whole patient population). No pre-specified analysis plan.	Serious	LB		
Thon, 2008	Serious	This is a descriptive, repeated cross-sectional study, not controlling for confounders or secular trend. Causality cannot be inferred.	Low	General Medical Services Payments Board prescription database (for patients eligible for free medication) was used pre- and post- intervention.	Low	Population and intervention clearly outlined.	Low	This is not expected in observational studies of individuals in routine care.	Moderate	No mention of missing or excluded data but assumed that the proportion of participants and reasons for missing data are similar pre- and post- intervention.	Low	Outcome measure was the same pre- and post- the intervention. Electronic records of NRT prescriptions dispensed in a robust, objective outcome measure.	Moderate	Only one effect estimate is reported (for the eligible patient population nationally). No pre-specified analysis plan.	Serious	LB		
Almeida, 2017	Moderate	2 different GP services used in 1980-1989 (differential response) compared to 1990-1999 (control) and 2000-2009 (intervention) and although there is response bias, the characteristics of the 1980 and 2002 samples is similar.	Serious	2 different GP services used in 1980-1989 (differential response) compared to 1990-1999 (control) and 2000-2009 (intervention) and although there is response bias, the characteristics of the 1980 and 2002 samples is similar.	Moderate	Intervention is not well defined. It is unclear if the intervention was the same for all local authorities nationally. The "Transfer of public health budgets from the local to local authorities since 2007" is not well defined and it is unclear if the intervention was the "same" for all local authorities nationally.	Moderate	The time the policy was implemented may have differed between local authorities nationally.	Moderate	No mention of missing or excluded data but assumed that the proportion of survey participants and reasons for missing data (non-respondents) are similar pre- and post- intervention.	Moderate	Outcome measure was the same pre- and post- the intervention. GP self-report data into electronic records, smoking cessation advice could be subjective.	Moderate	The question in the 1980 survey of GP service profiles was answered in 2012 with the purpose of comparing general practice between the last two periods. In the question and the responses of 2012, the data were used in 1980 were used after the study of only revised slightly without changing the meaning in 2012. The data is returned to the researchers. However, the outcome measure that is only directly self-reported responses of primary care doctors who are usually or otherwise always involved in patient preventive care service recording (counselling during separate clinic?).	Moderate	Only one effect estimate is reported (for the whole patient population). No pre-specified analysis plan. This reports outcomes from survey questions related to smoking cessation from survey questions.	Serious	LB

