Appendices

Appendix 1. Electronic search strategy

Adapted from published protocol (15). Searches were run in both MEDLINE and Cochrane Methodology Register simultaneously. As an example, in the registries search, lines 1-11 are the MEDLINE search and

lines 12-15 are tailored for the Cochrane Methodology Register. The final lines of each search isolate the records from each database, combine them so duplicate records can be removed, then isolate the remaining records so they can be downloaded and imported into Reference Manager using customized import filters.

Searching for RCTs conducted using Electronic Health Records

1. randomized controlled trial.pt.
2. controlled clinical trial.pt.
3. randomi?ed.ab.
4. placebo.ab.
5. randomly.ab.
6. clinical trials as topic.sh.
7. trial.ti.
8. or/1-7
9. exp animals/ not humans.sh.
10. 8 not 9
11. exp Electronic Health Records/
12. (EHR or electronic health record*).ab,kf,ti.
13. (EMR or electronic medical record*).ab,kf,ti.
14. (PHR or personal health record*).ab,kf,ti.
15. (EPR or electronic patient record*).ab,kf,ti.
16. exp Health Records, Personal/
17. or/11-16
18. 10 and 17
19. limit 18 to yr="2007 - 2018"
20. (Electronic health record or electronic health records or EHR).ti,ab,kw.
21. (Electronic medical record or electronic medical records or EMR).ti,ab,kw.
22. (Electronic patient record or electronic patient records or EPR).ti,ab,kw.
23. or/20-22
24. limit 23 to yr="2007 - 2018"
25. 19 use medall
26. 24 use clcmr
27. 25 or 26
28. remove duplicates from 27
29. 28 use medall
30. 28 use clcmr

Appendix 2. Inclusion criteria algorithm

Eligible RCTs have to use EHRs. Publications that report (1) issues related to methods or reporting of EHR-based RCTs, or (2) a protocol from an RCT conducted using EHRs are excluded. If the RCT involved non-human subjects, it is excluded. Only RCTs that use EHRs as a source of data for conducting the trial, including activities such as identifying eligible participants for the trial or as an intervention or collecting trial outcomes, are eligible. To be included in the review, a publication had to meet one of the following criteria:

1. The EHR is used for identifying eligible participants. If the publication describes a trial in which the EHR was used to identify eligible trial participants, it will be included.

2. The EHR can be used as an intervention or component of an intervention, such as alerting physicians to deliver a screening procedure for some patients, and different trial arms may involve different access to EHR functions. If the publication describes an RCT that used the EHR as part of the intervention, it will be included.

3. The EHR is used to ascertain health outcomes. If the publication describes a trial that links to an EHR to ascertain health outcomes, as trial endpoints, it will be included.

Appendix 3. Coding manual for the completeness and transparency of reporting

Section/Topic	Item No.	CONSORT 2010 Item	CONSORT-ROUTINE	Adequately reported	Partially reported	Inadequately or not reported	Not applicable
Title and abstract							
		Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)		Did the authors clearly describe a (1) structured summary of (2) trial design, (3) methods, (4) results, and (5) conclusions	Did the authors only report one, two, three or four element(s) of this item and not all five elements of the item?	Did the authors not describe a structured summary of trial design, methods, results and conclusions?	
	1b		Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts). Specify that a cohort or routinely collected data were used to conduct the trial and, if applicable, provide the name of the cohort or routinely collected database(s) (Modified)	Did the authors specify that a cohort or routinely collected data were used to conduct the trial?	Did the authors describe methods that would typically require routinely collected data for components of the trials but not specify they used routinely collected data?	Did the authors not specify that routinely collected data were used to conduct the trial?	
Introduction							
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio		Did the authors clearly describe the trial design including allocation ratio?	All other cases, where applicable.	Did the authors not describe the trial design including allocation ratio?	
			Description of trial design (such as parallel, factorial) including allocation ratio, that a cohort or routinely collected database(s) was used to conduct the trial (such as electronic health record, registry) and how the data were used within the trial (such as identification of eligible trial participants, trial outcomes) (Modified)	Did the authors clearly mention the (1) routinely collected database(s) that were used within the trial and (2) how the data were used within the trial (i.e. identification of participants, outcome measurement, other)?	Did the authors only report one element of this item and not both elements of the item?	Did the authors not describe the routinely collected database(s) that were used within the trial and not describe how the data were used within the trial (i.e. identification of participants, outcome measurement, other)?	
Cohort or routinely collected data							
	ROUTINE-		Name, if applicable, and description of	Did the authors clearly (1)	Did the authors only	Did the authors not name	

	1		the cohort or routinely collected database(s) used to conduct the trial, including information on the setting (such as primary care), locations, and dates, (such as periods of recruitment, follow-up, and data collection) (New)	name and (2) describe the routinely collected database(s) and (3) provide information on the setting, locations, and relevant dates (e.g. periods of recruitment, follow-up, and data collection)?	report one or two element(s) of this item and not all three elements of the item?	and describe the routinely collected database(s) and not provide information on the setting, locations, and relevant dates (e.g. periods of recruitment, follow-up, and data collection)?	
	ROUTINE-2		Eligibility criteria for participants in the cohort or routinely collected database(s) (New)	Did the authors clearly describe the eligibility criteria for the routinely collected database(s)?	All other cases, where applicable.	Did the authors not describe all eligibility criteria for the routinely collected database(s)?	
	ROUTINE-3		State whether the study included person-level, institutional-level, or other data linkage across two or more databases and, if so, linkage techniques and methods used to evaluate completeness and accuracy of linkage (New)	Did the authors clearly state whether the study included (1) person-level, institutional-level, or other data linkage across two or more databases and (2) the methods of linkage and (3) methods used to evaluate completeness and accuracy of linkage?	Did the authors only report one element of this item and not all three elements of the item?	Did the authors not state whether the study included person-level, institutional-level, or other data linkage across two or more databases and not state the methods of linkage and methods used to evaluate completeness and accuracy of linkage?	
Trial participants	4a	Eligibility criteria for participants		Did the authors clearly describe the eligibility for the trial participants?	All other cases, where applicable.	Did the authors not describe all eligibility criteria for the trial participants?	
			Eligibility criteria for trial participants, including information on how to access the list of codes and algorithms used to identify eligible participants, information on accuracy and completeness of data used to ascertain eligibility, and methods used to validate accuracy and completeness (e.g., monitoring, adjudication), if applicable (Modified)	Did the authors provide information on (1) how to access the lists of codes and algorithms used to identify participants, including (2) methods used to assess accuracy and completeness, if applicable?	Did the authors only report one element of this item and not both elements of the item?	Did the authors not provide information on how to access the lists of codes and algorithms used to identify participants, and not provide the methods used to assess accuracy and completeness?	The trial did not use routinely collected data to identify participants
	ROUTINE-4		Describe whether and how consent was obtained (New)	Did the authors describe clearly whether and how consent was obtained?	All other cases, where applicable.	Did the authors not describe whether and how consent was obtained?	
Outcomes	6a	Completely defined pre-specified primary and secondary outcome		Did the authors clearly define the pre-specified primary and secondary	Did the authors only define the pre-specified primary and	Did the authors not define the pre-specified primary and secondary outcome measures	

		measures, including how and when they were assessed		outcome measures, including how and when they were assessed?	secondary outcome measures but not how and when they were assessed, or did they describe how and when outcomes were assessed but not the measures?	and not define how and when they were assessed?	
			Completely defined pre-specified primary and secondary outcome measures, including how and when they were ascertained and the cohort or routinely collected database(s) used to ascertain each outcome (Modified)	Did the authors clearly describe the routinely collected database(s) used to ascertain each outcome?	All other cases, where applicable.	Did the authors not describe the routinely collected database(s) used to ascertain each outcome?	The trial did not use routinely collected data to ascertain the outcome
	ROUTINE-5		Information on how to access the list of codes and algorithms used to define or derive the outcomes from the cohort or routinely collected database(s) used to conduct the trial, information on accuracy and completeness of outcome variables, and methods used to validate accuracy and completeness (e.g., monitoring, adjudication), if applicable (New)	Did the authors clearly (1) describe information on how to access the list of codes and algorithms used to define or derive the outcomes from the routinely collected database(s), (2) including methods used to assess accuracy and completeness?	Did the authors only report one element of this item and not both elements of the item?	Did the authors not describe information on how to access the list of codes and algorithms used to define or derive the outcomes from the routinely collected database(s), and not describe the methods used to assess accuracy and completeness?	The trial did not use routinely collected data to ascertain the outcome
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Mechanism used to implement the random allocation sequence (such as embedding an automated randomiser within the cohort or routinely collected database(s)), describing any steps taken to conceal the sequence until interventions were assigned (Modified)	Did the authors clearly describe the mechanism used to implement the random allocation sequence (such as embedding an automated randomiser within the cohort or routinely collected database(s)), describing any steps taken to conceal the sequence until interventions were assigned?	All other cases, where applicable	Did the authors not describe the mechanism used to implement the random allocation sequence (such as embedding an automated randomiser within the cohort or routinely collected database(s)), describing any steps taken to conceal the sequence until interventions were assigned?	

Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome		Did the authors define clearly for each group, (1) the number of participants who were randomly assigned, (2) received intended treatment and (3) were analysed for the primary outcome?	Did the authors only report one or two elements of this item and not all three elements of the item or only presented this information for one group?	Did the authors not describe clearly for each group, the number of participants who were randomly assigned, and not received intended treatment and not were analysed for the primary outcome?	
			For each group, the number of participants in the cohort or routinely collected database(s) used to conduct the trial and the numbers screened for eligibility, randomly assigned, offered and accepted interventions (e.g., cohort multiple RCTs), received intended treatment, and analysed for the primary outcome (Modified)	Did the authors clearly define, for each group, the number of participants in the routinely collected database(s) used to conduct the trial and the numbers screened for eligibility, randomly assigned, received intended treatment, and analysed for the primary outcome?	Did the authors only report some, but not all, elements of this item?	Did the authors not define, for each group, the number of participants in the routinely collected database(s) used to conduct the trial and not define the numbers screened for eligibility, randomly assigned, received intended treatment, and analysed for the primary outcome	
Discussion							
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence		Did the authors clearly provide an interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence?	All other cases, where applicable	Did the authors not provide an interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence?	
			Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence, including the implications of using data that were not collected to answer the trial research questions (Modified)	Did the authors describe the implications of using data that were not collected to answer the trial research questions? Note: the authors have to report information about the issues of using routine data.	All other cases, where applicable	Did the authors not describe the implications of using data that were not collected to answer the trial research questions?	
Other information							
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders		Did the authors clearly describe the sources of funding and the role of funders?	All other cases, where applicable	Did the authors not describe the sources of funding and other support for the trial and the role of the funders?	

			Sources of funding and other support for both the trial and the cohort or routinely collected database(s), role of funders (Modified)	Did the authors clearly describe the sources of funding for the database(s) and trial and the role of the funder of the trial?	Did the authors only report some, but not all, elements of this item?	Did the authors not describe the sources of funding for routinely collected database(s) and trial and not describe the role of the funder of the trial?	

Appendix 4. References of the 60 RCT publications assessed for completeness and transparency of reporting

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