Supplementary File 2 – Coding Manual

Title/Abstract Screening

Does this study meet the title and abstract inclusion criteria for <u>Cohort-based</u> <u>Randomized Controlled Trials (RCTs)?</u>

No: not an RCT using a cohort. If it is clear from the title and abstract that the publication does not describe (1) issues related to methods or reporting of cohort-based RCTs, (2) a cohort intended to be used to conduct RCTs, or (3) a protocol or results from a RCT that will select or selected individuals from a cohort, it is excluded. For the purpose of this review, a cohort is defined as a group of individuals who are gathered for the purpose of conducting research and for whom there are multiple assessments over time. If it is clear from the title and abstract that the publication describes a study that enrolls patients only in a cohort or only in an RCT (e.g., comparative cohort trials, parallel cohorts) – but not both, it is excluded. If (observational) analyses are done on all participants or a subgroup of participants who were enrolled in an RCT, even if described by the authors as a 'cohort', it would be excluded. If the RCT involves non-human subjects, it is excluded.

No: the cohort is only used for identifying eligible participants. If it is clear from the title and abstract that the publication describes a trial in which a cohort was solely used to identify eligible trial participants, but for no other purposes related to the trial, it is excluded.

No: the cohort is only used for collecting trial outcomes. If it is clear from the title and abstract that the publication describes a trial that only links to a cohort to ascertain health outcomes as trial endpoints, but does not otherwise use the cohort in the trial, it is excluded.

Does this study meet the title and abstract inclusion criteria for <u>Registry-based</u> Randomized Controlled Trials (RCTs)

No: not an RCT using a registry. If it is clear from the title and abstract that the publication does not describe (1) issues related to methods or reporting of registry-based RCTs, (2) a registry used to conduct RCTs, or (3) a protocol or results from a RCT conducted using a registry, it is excluded. A registry has been defined by the European Medicines Agency as "an organized system that uses observational methods to collect uniform data on specified outcomes in a population defined by a particular disease, condition, or exposure, and that is followed over time." Entry in a registry is generally defined either by diagnosis of a disease (disease registry) or prescription of a drug, device, or other treatment (exposure registry). If the RCT involves non-human subjects, it is excluded.

No: the registry is only used for identifying eligible participants. If it is clear from the title and abstract that the publication describes a trial in which the registry was solely used to identify eligible trial participants, but for no other purposes related to the trial, it is excluded.

No: the registry is only used for collecting trial outcomes. If it is clear from the title and abstract that the publication describes a trial that only links to a registry to ascertain health outcomes as trial endpoints, but does not otherwise use the registry in the trial, it is excluded.

Does this study meet the title and abstract inclusion criteria for <u>Administrative</u> <u>Database-based Randomized Controlled Trials (RCTs)</u>

No: not an RCT using administrative data. If it is clear from the title and abstract that the publication does not describe (1) issues related to methods or reporting of administrative database-based RCTs, (2) an administrative dataset used to conduct RCTs, or (3) a protocol or results from a RCT conducted using an administrative database, it is excluded. Administrative data refers to information collected primarily for administrative purposes (e.g., all users of healthcare in a province, all persons enrolled in a health insurance plan). If the RCT involves non-human subjects, it is excluded.

No: the administrative database is only used for identifying eligible participants. If it is clear from the title and abstract that the publication describes a trial in which the administrative database was solely used to identify eligible trial participants, but for no other purposes related to the trial, it is excluded.

No: the administrative database is only used for collecting trial outcomes. If it is clear from the title and abstract that the publication describes a trial that only links to an administrative database to ascertain health outcomes, as trial endpoints, but does not otherwise use the administrative database in the trial, it is excluded.

Does this study meet the title and abstract inclusion criteria for <u>Electronic Health</u> Record (EHR)-based Randomized Controlled Trials (RCTs)

No: not an RCT using EHRs. If it is clear from the title and abstract that the publication does not describe (1) issues related to methods or reporting of electronic health records (EHR)-based RCTs, (2) EHRs that will be used to conduct RCTs, or (3) a protocol or results from a RCT conducted using EHRs, it is excluded. EHRs are electronic versions of a patient's medical history, and can include information that includes diagnoses, medications, and treatment plans, for instance. If the RCT involves non-human subjects, it is excluded.

No: the EHR is only used for identifying eligible participants. If it is clear from the title and abstract that the publication describes a trial in which the EHR was solely used to identify eligible trial participants, but for no other purposes related to the trial, it is excluded.

No: the EHRs is only used to ascertain health outcomes. If it is clear from the title and abstract that the publication describes a trial that only links to EHRs to ascertain health outcomes, as trial endpoints, but does not otherwise use EHRs in the trial, it will be excluded.

Full-text review

Does this study meet the inclusion criteria for <u>Cohort-based Randomized Controlled Trials (RCTs)?</u>

No: not an RCT using a cohort. If the publication does not describe (1) issues related to methods or reporting of cohort-based RCTs, (2) a cohort intended to be used to conduct RCTs, or (3) a protocol or results from a RCT that will select or selected individuals from a cohort, it is excluded. For the purpose of this review, a cohort is defined as a group of individuals who are gathered for the purpose of conducting research and for whom there are multiple assessments over time. If it is clear from the title and abstract that the publication describes a study that enrolls patients only in a cohort or only in an RCT (e.g., comparative cohort trials, parallel cohorts) – but not both, it is excluded. If (observational) analyses are done on all participants or a subgroup of participants who were enrolled in an RCT, even if described by the authors as a 'cohort', it would be excluded. If the RCT involves non-human subjects, it is excluded.

No: the cohort is only used for identifying eligible participants. If the publication describes a trial in which a cohort was solely used to identify eligible trial participants, but for no other purposes related to the trial, it is excluded.

No: the cohort is only used for collecting trial outcomes. If the publication describes a trial that only links to a cohort to ascertain health outcomes as trial endpoints, but does not otherwise use the cohort in the trial, it is excluded.

Does this study meet the inclusion criteria for <u>Registry-based Randomized</u> <u>Controlled Trials (RCTs)</u>

No: not an RCT using a registry. If the publication does not describe (1) issues related to methods or reporting of registry-based RCTs, (2) a registry used to conduct RCTs, or (3) a protocol or results from a RCT conducted using a registry, it is excluded. A registry has been defined by the European Medicines Agency as "an organized system that uses observational methods to collect uniform data on specified outcomes in a population defined by a particular disease, condition, or exposure, and that is followed over time." Entry in a registry is generally defined either by diagnosis of a disease (disease registry) or prescription of a drug, device, or other treatment (exposure registry). If the RCT involves non-human subjects, it is excluded.

No: the registry is only used for identifying eligible participants. If the publication describes a trial in which the registry was solely used to identify eligible trial participants, but for no other purposes related to the trial, it is excluded.

No: the registry is only used for collecting trial outcomes. If the publication describes a trial that only links to a registry to ascertain health outcomes as trial endpoints, but does not otherwise use the registry in the trial, it is excluded.

Does this study meet the inclusion criteria for <u>Administrative Database-based</u> Randomized Controlled Trials (RCTs)

No: not an RCT using administrative data. If it the publication does not describe (1) issues related to methods or reporting of administrative database-based RCTs, (2) an administrative dataset used to conduct RCTs, or (3) a protocol or results from a RCT conducted using an administrative database, it is excluded. Administrative data refers to information collected primarily for administrative purposes (e.g., all users of healthcare in a province, all persons enrolled in a health insurance plan). If the RCT involves non-human subjects, it is excluded.

No: the administrative database is only used for identifying eligible participants. If the publication describes a trial in which the administrative database was solely used to identify eligible trial participants, but for no other purposes related to the trial, it is excluded.

No: the administrative database is only used for collecting trial outcomes. If the publication describes a trial that only links to an administrative database to ascertain health outcomes, as trial endpoints, but does not otherwise use the administrative database in the trial, it is excluded.

Does this study meet the inclusion criteria for <u>Electronic Health Record (EHR)</u>-based Randomized Controlled Trials (RCTs)

No: not an RCT using EHRs. If the publication does not describe (1) issues related to methods or reporting of electronic health records (EHR)-based RCTs, (2) EHRs that will be used to conduct RCTs, or (3) a protocol or results from a RCT conducted using EHRs, it is excluded. EHRs are electronic versions of a patient's medical history, and can include information that includes diagnoses, medications, and treatment plans, for instance. If the RCT involves non-human subjects, it is excluded.

No: the EHR is only used for identifying eligible participants. If the publication describes a trial in which the EHR was solely used to identify eligible trial participants, but for no other purposes related to the trial, it is excluded.

No: the EHRs is only used to ascertain health outcomes. If the publication describes a trial that only links to EHRs to ascertain health outcomes, as trial endpoints, but does not otherwise use EHRs in the trial, it will be excluded.