

Detailed guide to article extraction

This section shows the detailed guide to extraction that was used by readers.

Form 1: Basic	
Record Number	Number of assigned article
Journal	Enter the full name of the journal- do not use abbreviations
Journal Type	<u>General Medical</u> Journals aimed at advancement in the medical field, without a specific focus on a particular medical specialty Ex: <i>British Medical Journal, JAMA, Lancet, Journal of Advanced Nursing</i> <u>Specialty</u> Journals aimed at advancement in a particular field or topic of medicine Ex: <i>American Journal of Clinical Nutrition, Diabetes Care</i>
Publication Year	YYYY format
Publication Year Category	Select the category that encompasses the publication year 2000-2004 2005-2009 2010-2014
Funding Source	Select all that apply This can often be found at the end of the article in a section preceding references entitled "Funding" or "Acknowledgements" <u>Industry includes</u> For-profit company, donation of study product by a for-profit company which manufactured the study product Not – for profit company that promoted the intervention <u>Non-Industry includes</u> Government: National, regional (provincial, county) government body with NO industry association. Foundation / Philanthropies: examples include Rockefeller foundation, Bill and Melinda Gates foundation. Institution: University, Research centers, teaching and academic hospitals. Other non-industry source of funding. <u>Not Reported</u> No source of funding is disclosed in study report.
Country	Country of first author affiliation
Region	Select the geographic region of the country the article was published
Is this study reported to be a registered clinical trial?	Check all that apply No Yes- <i>clinicaltrials.gov</i> Yes- <i>other registry</i>
Do authors report where to access to the study protocol?	Yes if authors provide directions to accessing the study protocol

[Type here]

Form 2: Intervention Details

Is the trial selection targeting individuals with multiple chronic conditions?

No

Participants are selected based on their diagnosis of only one chronic condition

Ex: All individuals in the study sample must have diabetes

Yes, individuals with a specific set of chronic conditions

Participants are selected based on their diagnosis of a specified set of 2 or more chronic conditions

Ex: All individuals in the study sample must have diabetes and hypertension

Yes, individuals with multiple chronic conditions, regardless of conditions

Participants are selected based on their diagnosis of 2 or more chronic conditions, regardless of specific combination of conditions

Ex: All individuals in the study sample must have 2 chronic conditions

Yes, individuals with any combination of chronic conditions within a specific set of conditions

Participants are selected based on their diagnosis of 2 or more chronic conditions, within a specified set of chronic conditions. Multiple combinations are possible.

Ex: All individuals in the study sample must have 2 or more of the following chronic conditions: depression, hypertension, diabetes, arthritis, and chronic heart failure.

Is the trial selection targeting individuals with one condition from a specific set of chronic conditions?

Please note that these trials may include people with multiple chronic conditions, but do not require patients to have multiple chronic conditions.

No, all participants have the same chronic condition

Yes, participants must have at least one chronic condition from a specified set of chronic conditions.

Ex: Each participant must have one of the following conditions: diabetes, hypertension or depression.

The study sample consists of individuals with which chronic condition?

Check each of the chronic condition(s) used for selecting patients in the trial

Arthritis

Includes:

Ankylosing Spondylitis (AS)

Ehlers-Danlos Syndrome (EDS)

Gout

Osteoarthritis

Psoriatic Arthritis

Reactive Arthritis

Rheumatoid Arthritis

Sjögren's Syndrome

Asthma

Any condition referred to as asthma

Autism spectrum disorder

Includes:

Asperger's Syndrome

Autistic Disorder

Pervasive Developmental Disorder not otherwise specified (PDD-NOS)

Cancer

All cancers except nonmelanoma skin

Cardiac arrhythmias

Includes:

[Type here]

Bradyarrhythmias

Supraventricular arrhythmias

Ventricular arrhythmias

*rrhythmia

Chronic kidney disease (CKD)

Includes:

Chronic renal disease

End stage renal disease (ESRD)

End stage renal failure (ESRF)

End-stage kidney disease (ESKD)

Chronic kidney failure (CKF)

Chronic renal failure (CRF)

DIAGNOSTIC INFO:

Individuals with a **glomerular filtration rate (GFR)** <60 ml/min/1.73 m² for 3 months are classified as having chronic kidney disease

All individuals with **kidney damage** are classified as having chronic kidney disease

CKD stage	GFR level (mL/min/1.73 m ²)
Stage 1	≥90
Stage 2	60-89
Stage 3	30-59
Stage 4	15-29
Stage 5	<15

Chronic obstructive pulmonary disease (COPD)

Includes:

Emphysema

Chronic bronchitis

Chronic obstructive lung disease (COLD)

Chronic obstructive airway disease (COAD)

DIAGNOSTIC INFO:

May be confirmed with spirometry, which measures forced expiratory volume in 1 second (FEV₁), and forced vital capacity (FVC).

FEV₁/FVC ratio < 70% (or sometimes <80%)

Congestive heart failure (CHF)

Includes:

Left ventricular failure

Systolic (congestive) heart failure

Diastolic (congestive) heart failure

Combined systolic (congestive) and diastolic (congestive) heart failure

DIAGNOSTIC INFO:

May be based on blood test for elevated B-type natriuretic peptide (BNP)

BNP levels > 300 pg/mL indicate the presence of CHF

Coronary artery disease (CAD)

Includes:

Coronary arteriosclerosis

Coronary atherosclerosis

Ischemic heart disease

Coronary heart disease

Dementia

[Type here]

Includes:

Alzheimer's

Other senile dementias

Depression

Includes:

Any condition referred to as depression

Presence of depressive symptoms

Type II Diabetes

Does not include: Type I diabetes or Gestational diabetes

DIAGNOSTIC INFO:

Can be diagnosed with glucose test (fasting or 2 hour), or based on glycated hemoglobin (HbA1c) level

Condition	2 hour glucose	Fasting glucose	HbA _{1c}	
			mmol/mol	DCCT %
Unit	mmol/l(mg/dl)	mmol/l(mg/dl)		
Diabetes mellitus	≥11.1 (≥200)	≥7.0 (≥126)	≥48	≥6.5

Hepatitis

Any condition referred to as hepatitis

Human immunodeficiency virus (HIV)

Includes: AIDS

Hyperlipidemia

AKA: High blood cholesterol

Includes:

Dyslipidemia

Hypercholesterolemia

Hypertriglyceridemia

Hyperlipoproteinemia

Dyslipoproteinemias

Inferred when a patient is prescribed cholesterol-lowering medications (statins)

DIAGNOSTIC INFO:

Total cholesterol

Total cholesterol level greater than or equal to 240 mg/dL (6.21 mmol/L) is high.

Triglycerides

High - 200 to 499 mg/dL (2.25 to 5.63 mmol/L)

Very high - greater than 500 mg/dL (5.65 mmol/L)

Hypertension (HTN)

AKA: High blood pressure

Defined as when systolic pressure is consistently greater than 140 mm hg or when diastolic pressure is consistently 90 mm hg or more.

Inferred when a patient is prescribed anti-hypertensives, such as ACE Inhibitor (ACEI) or

Angiotensin II receptor blockers (ARB)

DIAGNOSTIC INFO:

Classification	Systolic pressure		Diastolic pressure	
	mmHg	kPa	mmHg	kPa
Stage 1 hypertension	140–159	18.7– 21.2	90–99	12.0– 13.2
Stage 2 hypertension	≥160	≥21.3	≥100	≥13.3

[Type here]

Isolated systolic hypertension	≥140	≥18.7	<90	<12.0
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Osteoporosis

Any condition referred to as osteoporosis

DIAGNOSTIC INFO:

May be diagnosed using dual-energy X-ray absorptiometry (DXA) to measure bone mineral density, which is measured as a T-score.

Category	T-score range
Osteoporosis	T-score ≤ -2.5
Severe osteoporosis	T-score ≤ -2.5 with fragility fracture

Schizophrenia

Any condition referred to as schizophrenia

Stroke

Includes:

Cerebrovascular disease

Transient ischemic attack

Substance abuse disorders

Includes:

Alcohol use disorders

Other substance use disorders

Does not include:

Substance use not defined as a disorder

Chronic Condition (General)

Select this option if the trial targets individuals with a chronic condition, regardless of condition.

Number of experimental study arms

Number of groups aside from the control group that receive the experimental intervention

Usually 1-2, but a maximum of 4 can be entered

Is the number of participants randomized to this group reported?

Yes, if authors report the number randomized

Sample Size

Number of participants randomized to this arm of the study

How is the sex of the participants in this sample reported?

Check all that apply

Number – number of participants randomized to this study arm

Percentage - percentage of participants (out of study total) that were randomized to this study arm

Not Reported - no number or percentage of participants were reported for this study arm

Could the number of male participants studywide be calculated?

Yes if the number of male participants studywide was not reported, but can be calculated from adding up the number of reported males in each study arm.

Number Male

Number of male participants in this study arm (reported or calculated).

Percentage Male

Percentage of male participants (out of study total) that were randomized to this study arm (reported or calculated). Number format from 0 to 100

Number Female

Number of female participants in this study arm (reported or calculated).

Percentage Female

Percentage of female participants (out of study total) that were randomized to this study arm (reported or calculated). Number format from 0 to 100

[Type here]

<p>Sample Age Measures Reported Select all that apply <i>Mean</i> <i>Range</i> <i>Standard Deviation</i> <i>Median</i> <i>Not reported</i></p>
<p>Could the mean age studywide be calculated? Yes if the mean age of participants in the study was not reported, but can be calculated from the reported means for each study arm.</p>
<p>Could the age range studywide be calculated? Yes if the age range of participants in the study was not reported, but can be determined from the reported age ranges for each study arm.</p>
<p>Mean Average age of study sample (reported or calculated). Often reported in Table 1 of Baseline Characteristics</p>
<p>Range_Lower The age of the youngest participant enrolled in this study sample (reported or calculated).</p>
<p>Range_Upper The age of the oldest participant enrolled in this study sample (reported or calculated).</p>
<p>Standard Deviation Abbreviated SD Often reported in Table 1 of Baseline Characteristics, along with the mean</p>
<p>Median Median age of study sample reported</p>
<p>Calculated Studywide Sample Size Field calculated automatically from the number of reported participants in each study arm.</p>
<p>Studywide Sample Size Number of participants randomized in the study (reported or calculated).</p>
<p>What is the behavioral component of the intervention? This describes the behavioral component utilized in the main intervention (and is not necessarily the same as the target outcome) <u>Weight management/diet/physical activity</u> Any intervention manipulating participants' behaviors related to weight control, diet, or physical activity <u>Tobacco habits</u> Any intervention manipulating participants' behaviors related to smoking or consuming tobacco <u>Adherence to disease management</u> Any intervention <i>directly</i> influencing the participant's disease management behavior (in terms of taking medications or monitoring clinical measures, such as glucose) consistent with medical or health advice. Do not include behaviors such as exercising that may improve disease outcomes, as they are not directly related to disease management. <u>Psychological well-being</u> Any intervention utilizing methods (such as relaxation techniques, stress management, pain management, etc) primarily targeting the participant's psychological well-being (stress, anxiety, depression, social support, pain/discomfort, etc) <u>Other</u> The intervention influenced/manipulated a behavior not covered in one of the categories above</p>

[Type here]

Eligibility
Is eligibility criteria reported? Yes if any exclusion or inclusion criteria for participant eligibility is reported
Were any behavioral factors/conditions are used as inclusion or exclusion criteria? Yes if any of the eligibility criteria is behaviorally based. This includes substance use (alcohol, smoking, or other), level of physical activity, diet or weight.
Which of the following behavioral factors/conditions were reported as eligibility criteria? Check all that apply <u>Alcohol use</u> Levels of alcohol consumption If alcohol abuse disorder is an eligibility criteria (all participants have the condition), do not select this option Ex: Participants must not drink more than 1 serving of alcohol per day <u>Smoking or tobacco use</u> Smoking status or use of tobacco products Ex: Participants must be non-smokers, participants must not have used tobacco products in the past 10 years <u>Other substance use</u> Use of other controlled substances besides alcohol and tobacco If substance abuse disorder is an inclusion criteria (all participants have the condition), do not select this option Ex: Participants must not have used cocaine in their lifetime <u>Physical activity</u> Levels of physical activity or sedentary behavior This does not include criteria based on an individual's ability to perform physical activity (such as "Must be able to walk without assistance") Ex: Participants must not currently exercise more than 1 time per week <u>Diet</u> Any criteria based on the content of the diet, frequency of meals or other eating behaviors Ex: Participants must currently eat 3 meals per day, participants must not have an eating disorder <u>Weight</u> BMI restrictions, weight or obesity status Ex: BMI must be below 30, participants must not be overweight, participants must be obese
Did trial explicitly exclude individuals with multiple chronic conditions, regardless of conditions? Yes if individuals with more than one chronic condition (regardless of condition) were excluded from the trial
Is the number of individuals excluded for having comorbid chronic conditions reported? Yes if the study reported the number of individuals excluded explicitly for having other chronic conditions. Do not list numbers reported for specific chronic conditions here. Ex: 5 patients were excluded for comorbid chronic conditions.
Is a justification for MCC exclusion provided? <u>No</u> - did not provide rationale for excluding individuals with MCC <u>Yes</u> - did provide rationale for excluding individuals with MCC
Is this justification based on ability to participate in the study? Yes if exclusion is based on the patient's physical or mental capacity to participate in the study Ex: Excludes any co-morbid condition that limits the patient's ability to partake in the intervention

[Type here]

<p>Was the Charlson comorbidity index used in eligibility criteria? Yes if the authors explicitly mention use of the Charlson comorbidity index in their exclusion/inclusion criteria Ex: Individuals with a Charlson comorbidity index of >10 were excluded from the study</p>
<p>Are there any vague exclusions for medical or psychological conditions (not reported above)? Yes if there is any vague mention of exclusions due to medical or mental illness that is not captured in the form above. These are broad exclusions not specific to chronic conditions that may have implications for excluding individuals with chronic conditions Examples: Excludes patients with any “co-occurring medical condition”, “serious medical conditions”, “psychological illness”, “mental disorder”, etc.</p>
<p>Is this exclusion based on ability to participate in the study? Yes if exclusion is based on the patient’s physical or mental capacity to participate in the study Ex: Excludes for any illness that limits the patient’s ability to partake in the intervention</p>
<p>Vague medical/psychological condition exclusions Copy and paste the vague medical/psychological condition exclusion from the article</p>
<p>Did trial exclude individuals with specific chronic conditions? This does not include the chronic condition(s) shared by all participants- do not use this question to describe limitations on inclusion of the targeted chronic condition(s) (which is reported in Intervention Details) <u>No</u> Did not report exclusion of individuals specifically based on any of the 20 chronic conditions, even if individuals were excluded on the basis of having more than one chronic condition, but no specific condition is named <u>Yes</u> Individuals were excluded from the trial on the basis of having one or more of the 20 chronic conditions, which is specifically named or determined by diagnostic criteria for the condition Ex: Individuals with depression were excluded from the trial or individuals with systolic blood pressure >140 were excluded from the trial</p>
<p>Is this exclusion based on ability to participate in the study? Yes if exclusion is based on the patient’s physical or mental capacity to participate in the study Ex: Excludes individuals with dementia due to inability to complete intervention components</p>
<p>Which chronic conditions were subject to exclusions? Select all conditions that limit an individual’s eligibility for the study, aside from the chronic condition(s) shared by all participants in the study</p>
<p>Is the number of individuals excluded for having [SELECTED CHRONIC CONDITION] reported? Yes if the number excluded for this specific conditions is reported</p>
<p>Is exclusion of individuals with [SELECTED CHRONIC CONDITION] narrowed? <u>No</u>- all individuals with this broadly defined chronic condition were excluded from the study <u>Yes</u>- only individuals with a specific type and/or severity of this chronic condition were excluded from the study</p>
<p>Were there any age restrictions for trial participants (aside from 18 years or older)? <u>No</u>- the only age restriction for the trial is that participants had to be at least 18 years old <u>Yes</u>- additional age restrictions were used, which further limited eligibility</p>
<p>What type of age exclusion? <u>Minimum Age</u> Adult participants had to be at least X years of age <u>Maximum age</u></p>

[Type here]

Adult participants could not be over X years of age
Excluded those above age: Upper age restriction
Form 3: Patient Selection
Is a participant flow diagram presented? Yes if the article includes a diagram that details the process of patient selection This usually includes the number of individuals screened, ineligible, enrolled, randomized and followed up
Are multiple chronic conditions included in the participant characteristics? This may be reported in the Subjects section or in Table 1 Yes if article reported one of the following: Number of study participants who also had another chronic condition not necessary for inclusion Mean number of chronic conditions per participant Charlson Comorbidity index mean and standard deviation Ex: In a trial where all patients have diabetes, Table 1 lists the percentage of patients with hypertension Ex: In a trial where all patients have diabetes and hypertension, Table 1 lists the number of patients with depression.
Can the inclusion of individuals with multiple chronic conditions be inferred? Yes if participant characteristics inferring the presence of multiple chronic conditions were reported Ex: A trial with cancer as a selection criterion lists the number of participants taking anti-hypertensives. It can be inferred that these individuals have multiple chronic conditions because they have both cancer and hypertension.
Is this description general or condition specific? Check all that apply <u>General</u> - study broadly described a group of participants with multiple chronic conditions (ex: # of participants with comorbid conditions) <u>Condition Specific</u> - study specifically described group(s) of participants with certain chronic condition(s) (ex: # of participants with hypertension)
Is the total number of participants with [SELECTED CHRONIC CONDITION] reported? Yes, if the article reports the number of individuals in the study with this comorbid condition, including those inferred to have this chronic condition Ex: 20 diabetic patients in this trial had comorbid hypertension or 20 diabetic patients in this trial took hypertensive medications
Which specific conditions were reported or inferred in the participant characteristics? Select all conditions that apply, other than the condition(s) necessary for inclusion in the study
How many additional specific chronic conditions were reported or inferred? Calculated field. The total number of specific chronic conditions, aside from the target chronic condition(s), that were included or inferred in the participant characteristics.
Are any of the following statistics regarding participants with MCC reported? Select all that apply <u>Number</u> – number of enrolled participants with one or more comorbid chronic conditions <u>Percentage</u> - percentage of enrolled participants (out of study total) with one or more comorbid chronic conditions <u>Mean</u> - the mean number of chronic conditions per participant <u>Charlson comorbidity index</u> - a specific index for comorbidities, would be reported as a mean and standard deviation in participant characteristics <u>Not Reported</u> - number or percentage of participants with one or more comorbid chronic conditions is not reported

[Type here]

Form 4: Quality Assessment

Random sequence generation (selection bias)

Describe the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups.

Low Risk criteria:

The investigators describe a random component in the sequence generation process such as:

- Referring to a random number table;
- Using a computer random number generator;
- Coin tossing;
- Shuffling cards or envelopes;
- Throwing dice;
- Drawing of lots;
- Minimization*

*Minimization may be implemented without a random element, and this is considered to be equivalent to being random.

High Risk criteria:

The investigators describe a non-random component in the sequence generation process. Usually, the description would involve some systematic, non-random approach, for example:

- Sequence generated by odd or even date of birth;
- Sequence generated by some rule based on date (or day) of admission;
- Sequence generated by some rule based on hospital or clinic record number.

Other non-random approaches happen much less frequently than the systematic approaches mentioned above and tend to be obvious. They usually involve judgement or some method of non-random categorization of participants, for example:

- Allocation by judgement of the clinician;
- Allocation by preference of the participant;
- Allocation based on the results of a laboratory test or a series of tests;
- Allocation by availability of the intervention.

Unclear Risk criteria:

Insufficient information about the sequence generation process to permit judgement of 'Low risk' or 'High risk'.

Allocation concealment (selection bias)

Describe the method used to conceal the allocation sequence in sufficient detail to determine whether intervention allocations could have been foreseen in advance of, or during, enrollment.

Low Risk criteria:

Participants and investigators enrolling participants could not foresee assignment because one of the following, or an equivalent method, was used to conceal allocation:

- Central allocation (including telephone, web-based and pharmacy-controlled randomization);
- Sequentially numbered drug containers of identical appearance;
- Sequentially numbered, opaque, sealed envelopes.

High Risk criteria:

Participants or investigators enrolling participants could possibly foresee assignments and thus introduce selection bias, such as allocation based on:

- Using an open random allocation schedule (e.g. a list of random numbers);
- Assignment envelopes were used without appropriate safeguards (e.g. if envelopes were unsealed or nonopaque or not sequentially numbered);
- Alternation or rotation;
- Date of birth;
- Case record number;
- Any other explicitly unconcealed procedure.

Unclear Risk criteria:

Insufficient information to permit judgement of 'Low risk' or 'High risk'. This is usually the case if the method of concealment is not described or not described in sufficient detail to allow a definite judgement – for example if the use of assignment envelopes is described, but it remains unclear whether envelopes were sequentially numbered, opaque and sealed.

Blinding of participants and personnel (performance bias)

Describe all measures used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective.

Low Risk criteria:

Any one of the following:

No blinding or incomplete blinding, but the reader judges that the outcome is not likely to be influenced by lack of blinding;

Blinding of participants and key study personnel ensured, and unlikely that the blinding could have been broken.

High Risk criteria:

Any one of the following:

No blinding or incomplete blinding, and the outcome is likely to be influenced by lack of blinding;

Blinding of key study participants and personnel attempted, but likely that the blinding could have been broken, and the outcome is likely to be influenced by lack of blinding.

Unclear Risk criteria:

Any one of the following:

Insufficient information to permit judgement of 'Low risk' or 'High risk';

The study did not address this outcome.

Blinding of outcome assessment (detection bias)

Describe all measures used, if any, to blind outcome assessors from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective.

Low Risk criteria:

Any one of the following:

No blinding of outcome assessment, but the reader judges that the outcome measurement is not likely to be influenced by lack of blinding;

Blinding of outcome assessment ensured, and unlikely that the blinding could have been broken.

High Risk criteria:

Any one of the following:

No blinding of outcome assessment, and the outcome measurement is likely to be influenced by lack of blinding;

Blinding of outcome assessment, but likely that the blinding could have been broken, and the outcome measurement is likely to be influenced by lack of blinding.

Unclear Risk criteria:

Any one of the following:

Insufficient information to permit judgement of 'Low risk' or 'High risk';

The study did not address this outcome.

Incomplete outcome data (attrition bias)

Describe the completeness of outcome data for each main outcome, including attrition and exclusions from the analysis. State whether attrition and exclusions were reported, the numbers in each intervention group (compared with total randomized participants), reasons for attrition/exclusions where reported, and any re-inclusions in analyses performed by the review authors.

Low Risk criteria:

[Type here]

Any one of the following:

No missing outcome data;

Missing outcome data is clearly explained

Reasons for missing outcome data unlikely to be related to true outcome (for survival data, censoring unlikely to be introducing bias);

Missing outcome data balanced in numbers across intervention groups, with similar reasons for missing data across groups;

For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk not enough to have a clinically relevant impact on the intervention effect estimate;

For continuous outcome data, plausible effect size (difference in means or standardized difference in means) among missing outcomes not enough to have a clinically relevant impact on observed effect size;

Missing data have been imputed using appropriate methods.

High Risk criteria:

Any one of the following:

Reason for missing outcome data likely to be related to true outcome, with either imbalance in numbers or reasons for missing data across intervention groups;

Clearly missing outcome data with no explanation provided

For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk enough to induce clinically relevant bias in intervention effect estimate;

For continuous outcome data, plausible effect size (difference in means or standardized difference in means) among missing outcomes enough to induce clinically relevant bias in observed effect size;

'As-treated' analysis done with substantial departure of the intervention received from that assigned at randomization;

Potentially inappropriate application of simple imputation.

Unclear Risk criteria:

Any one of the following:

Insufficient reporting of attrition/exclusions to permit judgement of 'Low risk' or 'High risk' (e.g. number randomized not stated, no reasons for missing data provided);

Can not determine whether data is missing

The study did not address this outcome.

Selective outcome reporting (reporting bias)

State how the possibility of selective outcome reporting was examined by the review authors, and what was found.

Low Risk criteria:

Any of the following:

The study protocol is available and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way;

The study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were pre-specified (convincing text of this nature may be uncommon).

High Risk criteria:

Any one of the following:

Not all of the study's pre-specified primary outcomes have been reported;

One or more primary outcomes is reported using measurements, analysis methods or subsets of the data (e.g. subscales) that were not pre-specified;

One or more reported primary outcomes were not pre-specified (unless clear justification for their reporting is provided, such as an unexpected adverse effect);

One or more outcomes of interest in the review are reported incompletely so that they cannot be entered in a meta-analysis;

[Type here]

The study report fails to include results for a key outcome that would be expected to have been reported for such a study.

Unclear Risk criteria:

Insufficient information to permit judgement of 'Low risk' or 'High risk'. It is likely that the majority of studies will fall into this category.

Quality Score

Calculated risk of bias score from the sum of scores for each the 6 domains of bias.

Low Risk = -1; High Risk = 1; Unclear Risk = 0

Lower values indicate a lower risk of bias, while higher values indicate a higher risk of bias.

Source for quality assessment variables (excluding quality score) : Cochrane Risk of Bias Tool, Higgins J. Green S. Cochrane handbook for systematic reviews of interventions version 5.1. 0. 2011.

Form 5: Outcomes

Is comorbidity information considered in analysis?

Primary outcomes were compared between individuals with and without comorbidities