Tailored strategies to address determinants of practice

Protocol for a Cochrane review update

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Differences between the 2015 review and this proposed update

Broadening the type of literature
We will search for grey literature for organisational reports by including two grey literature repositories in the sources to be search

Broadening the study designs
We will include all RCT designs, bar cross over RCTs given carry over effects. The previous review focused on cluster RCTs only.

New terminology

Other terms have begun over the last few years to be used to refer to tailoring (i.e., implementation mapping, intervention mapping) or may be considered alternate ways of referring to tailoring which is a collaborative process (i.e., co-design, co-production, co-creation). We have included these terms in the search.

Background

Description of the condition

There are often gaps between what is recommended in guidelines and what health professionals do and service users receive. There can be delays before evidence-based interventions (EBIs) (which range from programs, practices, principles, procedures, products, pills, and policies(1)) are widely adopted(2) with interventions This 'implementation gap' has become the focus of much research in recent years.(3,4) For example, there has been more interest in understanding the reasons for gaps in clinical practice, and the design and testing of implementation strategies(5) to enhance the adoption(6), implementation(7), and impact of EBIs.(8) Implementation strategies, as distinct from EBIs, are "methods or techniques used to enhance the adoption, implementation, and sustainment of a clinical program or practice".(9)

Growing interest in the factors which affect implementation, has been complemented by the development of implementation science frameworks to categorise and synthesise these factors (e.g., Consolidated Framework for Implementation Research(10)) across phase and setting (EPIS(11)) and guide the selection of implementation strategies.(12) Given the growing recognition of the wide range of factors which may contribute to the implementation gap, along with greater emphasis on rigorously assessing them, it would seem increasingly important to tailor strategies to address them.

Description of the intervention

Tailoring

This review updates a Cochrane review of the effects of tailored interventions(13) originally completed in 2005 and subsequently updated in 2010 and 2015.(13) The focus of the current review is tailored implementation *strategies* noting that an 'implementation strategy' can comprise multiple different *strategies,* some delivered by different actors (implementation facilitators or 'coaches' versus. clinical staff) or not focused on just one EBI but or supporting implementation of EBIs more broadly within a given context.(14) 'Implementation intervention' is sometimes used interchangeably with 'Implementation strategy' but to avoid confusion with EBIs we use the latter.(15)

Although descriptions and applications of tailoring vary, tailoring has generally been described as a prospective process for selecting and modifying strategies to address contextual determinants of implementation in an effort to increase implementation success.(16,17) In line with the definitions adopted for the previous version of this review, in this update we define tailored implementation strategies as planned strategies to improve professional practice specifically that take account of prospectively identified determinants of practice. It is important to acknowledge that while we adopt <u>one</u> particular definition of tailoring, tailoring is sometimes also considered to take place after deployment of the implementation strategy.(18) Furthermore, tailoring itself may be part of the implementation strategy.(19–23)For example, a strategy could involve facilitation (one type of strategy) to support or coach an organisation to tailor their own implementation strategies to site-specific needs. Also, the focus in this review update is on implementation of just one type of EBI, guideline-recommended care.

The argument for tailoring is that it takes a more systematic approach to developing strategies, which contrasts, for example, with applying a universal strategy based on assumptions about the primary barriers to implementation..(3) While efforts to support implementation may identify determinants, they may not necessarily select strategies suitable to address them. Research previously conducted as part of the Tailored Implementation in Chronic Diseases (TICD) study highlighted the mismatch between implementation determinants and the functions of the proposed solution, indicative of the problems associated with the lack of systematic and well-described tailoring methods.(24,25)There is an important distinction between the process (tailoring) and output (tailored strategy). The focus of the current review is the initial output (tailored intervention) and its application/evaluation. We are conducting a separate, complementary scoping review to characterise the tailoring process.(26)

Determinants of practice

Determinants of practice are factors that could influence implementation and the effectiveness of an EBI to improve care. Determinants have previously been referred to using alternative terms, including barriers, obstacles, enablers, and facilitators. They have been classified by the Cochrane Effective Practice and Organisation of Care (EPOC) Group into nine categories (information management, clinical uncertainty, sense of competence, perceptions of liability, patient expectations, standards of practice, financial disincentives, administrative constraints, and other).(27) This categorisation has not been used extensively and there are now several ways of categorising determinants including TCID checklist(28), the Consolidated Framework for Implementation Research (CFIR) and Exploration Preparation Implementation Sustainment (EPIS) framework representing determinants at different phases/levels of implementation.(11)

How the intervention might work

Determinants are factors which can influence the success of implementation strategies. If the determinants of practice are identified, and strategies are then selected and implemented to address the determinants, it would appear reasonable to expect performance to improve. Identifying and understanding determinants, and the selection of strategies to address them, is a critical part of processes to improve implementation. While there are assumptions about how tailoring is intended to work, there are challenges and unknowns with respect to tailoring. First, the relationships between determinants and the causal pathways by which implementation strategies address these determinants is not well understood. Work is underway to address these gaps.(29,30) A compilation of implementation strategies(31) and a tool to match candidate strategies to determinants (coded according to CFIR)(32) have been developed. Second, further exploration of the underpinning logic by which tailoring works is needed. This could develop our understanding of the circumstances in which tailoring methods would be most effective.(17) Third, there is growing recognition that barriers are dynamic(33) and so approaches to strategy development that execute strategies based on assessments at a single point in time may miss important determinants.

Why it is important to do this review

The effects of attempts to translate research evidence into practice and improve performance remain inconsistent.(3,34) Reviews in specific clinical fields,(35,36) have discussed the possibility that tailored strategies might be more effective than strategies selected without taking account of determinants. However, we have not identified any reviews evaluating the effects of tailored implementation strategies on professional performance other than the earlier versions of this review, which identified 32 studies and reported a small to moderate effect compared to no strategy or a non-tailored strategy.(13) Only the review by Baker *et al.* assessed effect or financial costs of tailored strategies specifically.

Bosch and colleagues undertook a qualitative analysis of 20 quality improvement studies reporting investigation of determinants.(24) Individual and group interviews of professionals were the most commonly used method of identifying determinants, but in many studies the reasons for believing a particular strategy would address a particular determinant were not explained. Again, the effectiveness of tailored strategies was not evaluated.

The previous review conducted by Baker *et al.* had limited evidence on the applicability of the method to low-income countries and with disadvantaged groups was also limited. Since the publication of the last revision of this review(13), several new studies of tailored strategies have been published.(18,37–39) in part owing to the legitimization of the field in 2006 with the flagship journal, Implementation Science, and establishment of subsequent, dedicated journals, including Implementation Science Communications (2020), Implementation Research and Practice (2020), and Global Implementation Research and Applications (2021). Consequently, there may be additional evidence on the effectiveness of tailoring or on how it can be undertaken most effectively. Baker *et al.* concluded that methods of tailoring are not yet well developed and are not described in detail in published studies. This may have changed since the last review over seven years ago. Since tailoring is advised as an approach for selecting and modifying strategies(18,29,40), we feel it important to undertake an update of this review.

Objectives

Primary objective

We will address the same two questions considered in the previous versions of the review:

1. are tailored strategies effective in improving professional practice?
2. are tailored strategies effective in improving healthcare outcomes?

To answer these questions, we will compare:

- implementation strategies tailored to address identified determinants of practice compared to no strategy;
- implementation strategies tailored to address identified determinants of practice compared to non-tailored strategies

We anticipate that sufficient numbers of studies will have been published to allow these separate comparisons.

Secondary objectives

We will address two secondary objectives as part of this review update:

1. To assess whether the effects of tailored strategies differ according to whether theory, evidence and stakeholders were involved in the tailoring process
2. To assess whether the effects of tailored strategies differ according to setting (high or low income)

Methods

Criteria for considering studies for this review

Types of studies
Randomised controlled trials, namely trials where the allocation to the intervention is stated as being randomised.

Types of participants
Individual health care professionals or health care teams that influence professional practice and the delivery of healthcare (as they could be targeted by an implementation strategy). Healthcare teams could include health professionals responsible for patient care, administrators, managers, and those responsible for financing or regulating health care. To be included the team must involve health care professionals. We will exclude studies that involve only students. We will include studies irrespective of publication status (i.e., studies awaiting peer review) and language.

Types of interventions
We define tailored strategies as "strategies to improve professional practice that are planned, taking account of prospectively identified determinants of practice". Drawing on the compilation developed by the Expert Recommendations on Implementing Change (ERIC)(31) types of strategies include, for example, clinician reminders, audit and feedback, and the use of advisory boards and champions. A strategy could comprise a single strategy or be multi-faceted comprised of combination of strategies targeted at individuals or health care teams that influence professional practice and the delivery of healthcare. For example, a multifaceted strategy could involve educational materials designed for professionals, revision of professional roles, along with an audit and feedback process to support change.

We will exclude studies that use gap analysis only (i.e., audits identifying a gap between actual and desired performance), and studies of educational interventions based on an identified lack of knowledge and designed to improve knowledge only. Determinants may be identified by various methods, including observation, brainstorming, focus group discussions, interviews, or surveys of the involved healthcare professionals, and/or through an analysis of the organisation or system in which care is provided.

The identification of determinants must have been undertaken before the design and delivery of the strategy. If the timing of the identification of determinants is unclear, we will contact the study authors for clarification.

Studies have to involve a comparison group that did not receive a tailored strategy, or a comparison between a strategy that aimed to address determinants, compared with a strategy not explicitly addressing identified determinants.

Types of outcome measures

Primary outcomes

<u>Measures of professional practice</u>

We will include studies if they assess:

Quality of care; objectively measured adherence of health professionals to recommended practice or guidelines, in a healthcare setting.

Professional practice may be measured by:

- Dichotomous process adherence outcomes: the percentage of patients receiving a target process of care (e.g., prescription of a specific medication, documentation of performance of a specific task, such as referral to a consultant) or whose care was in compliance with a guideline recommendation;
- Continuous process outcomes: any continuous measure of how providers delivered care (e.g., duration of antibiotic therapy, time to respond to a critical lab value).

Measures of patient healthcare outcomes

We will include studies if they assess:

Patient outcomes:

- Health status and wellbeing, including: Physical health and treatment outcomes: mortality, morbidity, surrogate physiological measures; Psychological health: psychological wellbeing, and; Psychosocial outcomes: quality of life, social activities
- Health behaviour, e.g., patient adherence to treatment or care plans, health care seeking behaviour

Patient outcomes may be measured by:

- Dichotomous clinical outcomes: patient-important endpoints (such as death or development of a pulmonary embolism), as well as surrogate or intermediate endpoints, such as achievement of a target blood pressure or serum cholesterol level;
- Continuous clinical outcomes: various markers of disease or health status (e.g. mean blood pressure or cholesterol level).

Measures of adverse effects

Adverse effects (unintended consequences on undesirable effects) will be included where these have been specified as an adverse effect in the reported manuscript. These may include:

- Health or health behaviours
- Utilisation, coverage, or access
- Quality of care
- Resource use
- Health care providers (e.g., increased attrition, increased workload)
- Social outcomes (i.e., poverty measures, employment, education)
- Equity (i.e., differential effects across advantaged and disadvantaged populations)
- Clinical adverse effects

We will not include measures of knowledge or performance in a test situation as an outcome measure and we will exclude studies that include only this outcome.

Patient healthcare outcomes, quality of care, and adverse effects, are as defined in the EPOC guidance on outcomes to be reported in EPOC reviews).(41)

Search methods for identification of studies

Electronic searches

We will search the following databases:

- The Cochrane Database of Systematic Reviews (CDSR) and Cochrane Central Register of Controlled Trials (CENTRAL) via The Cochrane Library (current issue);
- Medline (Ovid MEDLINE® Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE® Daily and Ovid MEDLINE®) via OvidSP, 1946 onwards;
- EMBASE via OvidSP, 1974 onwards;
- Cumulative Index to Nursing and Allied Health Literature (CINAHL) via EBSCOHost, 1982 onwards;
- British Nursing Index (BNI), ProQuest, 1994 onwards;

We will not apply language restrictions. We will use two methodological search filters to limit retrieval to appropriate study designs: the 'Cochrane Highly Sensitive Search Strategy to identify randomised trials in MEDLINE: sensitivity- and precision-maximising version to identify randomised trials and a partial EPOC methodological search filter).(42)

Search strategies will be comprised of keywords and controlled vocabulary terms. We will search all databases from the date of the last search in the previous version of the review.(16) We will revise search strategies from the original review to reflect our improved knowledge, following previous versions of this review, of terms used in the literature to describe tailored strategies (i.e., implementation mapping, intervention mapping, concept mapping, conjoint analysis, group model building, co-design, co-production, co-creation) (Appendix: Draft Medline search).

Searching other resources

We will search the following trial registers:

- International Clinical Trials Registry Platform (ICTRP), World Health Organization (WHO) https://www.who.int/clinical-trials-registry-platform/the-ictrp-search-portal which includes ISRCTN
- ClinicalTrials.gov, US National Institutes of Health (NIH) clinicaltrials.gov
- Trials Register of Promoting Health Interventions (TRoPHI) https://eppi.ioe.ac.uk/webdatabases4/Intro.aspx?ID=12

We will also:

- review reference lists of all included studies, relevant systematic reviews, and primary studies;
- perform a forward citation search on CitationChaser for papers citing the original review(16)
- contact authors of relevant studies or reviews to clarify information presented in published articles where necessary or to request further details and unpublished results or data;
- contact researchers with expertise relevant to the review topic.

Grey literature

Two grey literature sources will be searched for organisational reports:

- Grey Literature Report (New York Academy of Medicine; www.greylit.org
- Agency for Healthcare Research and Quality (AHRQ); www.ahrq.gov

Data collection and analysis

Selection of studies

We will download all titles and abstracts retrieved by electronic searching to Covidence and remove duplicates. At least two review authors will independently assess the potential relevance of all titles and abstracts identified from the electronic searches. We will retrieve full text copies of the articles identified as potentially relevant by either one or both review authors.

Two review authors will independently screen the full-text to identify studies for inclusion and identify and record reasons for exclusion of the ineligible studies. When review authors disagree, a discussion will be held to obtain consensus. If no agreement is reached, a third review author will be asked to make an independent assessment. Where appropriate, we will contact trial authors for further information and clarification.

We will list studies that initially appeared to meet the inclusion criteria but that we later exclude in the 'Characteristics of excluded studies' table. We will also provide any information we can obtain about ongoing studies (e.g., described in protocols). We will record the selection process in sufficient detail to complete a PRISMA flow diagram.(43)

Data extraction and management

We will extract data from included studies by using the EPOC standard data collection form and adapting it for study characteristics and outcome data.(44) The form will be piloted on at least two randomised trials and changes made if needed. Two review authors will independently extract data from the included studies and enter the data into Review Manager 5.(45) We will resolve disagreements by consensus or by involving a third review author.

Where contact information is available, we will make up to three attempts to contact primary trial authors to obtain any missing information.

We will extract the following data from all included studies:

- **Study characteristics**: first author, publication year, country
- **Methods:** study design, number of study centres and location, study setting, withdrawals, date of study, duration, follow-up.
- **Setting:** high-, middle- or low-income countries based on the World Bank Classification.(46)
- **Professional participants:** number, mean age, age range, gender, specialty, inclusion criteria, exclusion criteria, other relevant characteristics.
- **Service users:** number, mean age, age range, gender, severity of condition, diagnostic criteria, inclusion criteria, exclusion criteria, other relevant characteristics whether some or all were disadvantaged or low-income
- **Use of theory;** whether development of the tailored strategy and tailoring process was informed by theory, for example, the Theoretical Domains Framework(47), or Normalisation Process Theory.(48)
- **Use of evidence;** whether evidence of the effectiveness of strategies was drawn on during the tailoring process
- **Involvement of stakeholders;** whether the target group were involved in the tailoring process

- **Strategy and comparator characteristics:** components and mode of delivery, comparison, fidelity assessment; where possible, strategies will be classified based on ERIC
- **EBI components**
- **Outcomes:** main and other outcomes specified and collected, time points reported.

To summarise the tailoring *process,* we will summarise the determinants of practice identified and if the included papers provide sufficient information, we will classify determinants into the seven domains of the Tailored Implementation in Chronic Disease (TICD) checklist: guideline factors, individual health professional factors, patient factors, professional interactions, incentives and resources, capacity for organisational change, and social, political, and legal factors.(28)

To summarise the tailored *strategy*, we will record the timings of strategy whether at the start of the programme and whether delivered once or repeated at intervals). We will classify strategies according to reporting recommendations for implementation strategies.(9) and clearly outline how strategies are operationalized (e.g., actor, action targets, intended implementation outcomes).(14)

Assessment of risk of bias in included studies

At least two review authors will independently assess risk of bias for each study using the Risk of Bias (ROB) Version 2 criteria outlined in the Cochrane Handbook *for Systematic Reviews of Interventions.*(49) We are interested in quantifying the effect of *assignment* to the tailored strategies at baseline, regardless of whether the strategies are received as intended (the 'intention-to-treat effect'). We will resolve any disagreements by discussion or by involving a third review author. We will assess the risk of bias according to the following domains:

1. Bias arising from the randomization process;
2. Bias due to deviations from intended interventions;
3. Bias due to missing outcome data;
4. Bias in measurement of the outcome
5. Bias in selection of the reported result.

Appropriate ROB assessment tools will be used for cluster-randomised trials.(49)

We will judge each potential source of bias as high, low, or some concerns and provide a quote from the study report together with a justification for our judgement in the 'Risk of bias' table. We will summarise the 'Risk of bias' judgements across different studies for each of the domains listed. We will assign an overall 'Risk of bias' assessment to each of the included studies using the approach suggested in Chapter 8 of the *Cochrane Handbook for Systematic Reviews of Interventions*.(49) We will consider studies with low risk of bias if more than 50% of the domains are low risk. We will consider studies where risk of bias in at least one domain was unclear or judged to have some bias that could plausibly raise doubts about the conclusions, to have a low risk of bias if the majority of domains are low, high if the majority of domains are high, and in other circumstances, consider it to have an unclear risk of bias. We will consider studies with a high risk of bias in at least one domain or judged to have serious bias that decreases the certainty of the conclusions, to have a high risk of bias.

We will consider blinding separately for different key outcomes where necessary (e.g. for unblinded outcome assessment, risk of bias for all-cause mortality may be very different than for a patient reported pain scale). Where information on risk of bias relates to unpublished data or correspondence with a

trialist, we will note this in the 'Risk of bias' table. We will not exclude studies on the grounds of their risk of bias but will clearly report the risk of bias when presenting the results of the studies.

When considering treatment effects, we will take into account the risk of bias for the studies that contribute to that outcome.

We will conduct the review according to this published protocol and report any deviations form it in the 'Differences between protocol and review' section of the systematic review.

Measures of treatment effect

The outcome measures will either be dichotomous extracted as number of events (for example number of patients receiving recommended care) out of the total eligible (N), or as continuous extracted as the observed mean (or median) and standard deviation (or estimated from any reported dispersion measure).

We will estimate the effect of the intervention using [risk ratio/risk difference for dichotomous data, together with the appropriate associated 95% confidence interval] and mean difference or standardised mean difference for continuous data, together with the 95% appropriate associated confidence interval.(50) We will ensure that a change in scores for continuous outcomes can be interpreted in the same way for each outcome, explain the direction to the reader, and report where the directions were reversed, if this was necessary.

Where possible, we will include extracted results in a random-effects meta-analysis, with the aim of providing an overall assessment of the effectiveness of tailored interventions in comparison to either no intervention or non-tailored interventions. If the majority of outcomes are reported as continuous measures then we will standardise the effects (conversion of dichotomous outcomes to continuous) to enable pooling as a standardised mean difference (SMD).

Unit of analysis errors

For clustered designs (such as cluster randomised trials) the reported results in included studies will often be on another level than the level of allocation. If this is the case, we will perform an analysis adjusting for clustering in order to avoid unit-of-analyses errors. As all the trials will be cluster-randomised, studies will need to report results for each cluster or, failing that, provide an estimate of the intra-class correlation coefficient (ICC) to enable the clustering effect to be accounted for in the overall effect size estimate from each study.(51) Where no ICC can be derived from the study, we will utilise published ICCs for the relevant setting. We will then use the design effect to adjust the estimated effect sizes for clustering, whereby the variances of the odds ratios will be increased by multiplying them by the design effect.(52) We will examine studies for unit of analysis errors and note any in the characteristics of included studies table.

Dealing with missing data

We will contact investigators in order to verify key study characteristics and obtain missing outcome data where possible. We will try to compute missing summary data from other reported statistics. Whenever it is not possible to obtain data, we will report the level of missingness and consider how that might impact the certainty of the evidence.

Assessment of heterogeneity

If we find a sufficient number of studies, where we judge participants, interventions, comparisons and outcomes to be sufficiently similar, we will conduct a meta-analysis.(53) We will use the I^2 statistic to

measure heterogeneity among the trials in each analysis.(54) If we identify substantial heterogeneity we will explore it by prespecified subgroup analysis. We will investigate heterogeneity within the effectiveness of tailored strategies to identify factors that need consideration when designing and implementing a tailored strategy. We will conduct pre-specified subgroup analyses (**see 'Subgroup analyses'**) to see if the heterogeneity may be explained by these factors.

Assessment of reporting biases

We will minimise reporting bias by attempting to contact study authors, asking them to provide missing outcome data. Where this is not possible, and the missing data are thought to introduce serious bias, we will explore the impact of including such studies in the overall assessment of results**.** If we are able to pool more than 10 trials, we will create and examine a funnel plot to explore possible publication biases, interpreting the results with caution.(55)

We will apply no language restrictions in the searches or inclusion of studies. We will conduct a sensitive search of major biomedical databases and trial registries (see Search methods for identification of studies).

Data synthesis

We will undertake meta-analyses only where this is meaningful i.e. if the strategies, participants, and the underlying clinical question are similar enough for pooling to make sense.(53) A common way that trialists indicate when they have skewed data is by reporting medians and interquartile ranges. When we encounter this, we will note that the data are skewed and consider the implication of this. Where multiple trial arms are reported in a single trial, we will include only the relevant arms. If two comparisons (e.g., strategy A versus usual care and strategy B versus usual care) must be entered into the same meta-analysis, we will halve the control group to avoid double-counting. We will have two possible comparisons: tailored strategy vs. no strategy and tailored strategy vs. non-tailored strategy.

For each comparison for each outcome, we will first seek to conduct a pooled quantitative synthesis (e.g., random effects meta-analysis), and where meta-analysis is not possible, we will use a narrative synthesis approach as informed by Cochrane Consumers and Communication Review Group guidance.(56) Specifically, we will group the data based on the comparison (tailored strategy vs non-tailored strategy, tailored strategy vs no strategy). Within each category, we will present the data in tabular format, and narratively describe the results, as grouped by outcome. The narrative synthesis approach used will be reported according to the Synthesis Without Meta-analysis (SWiM) guidance.(57)

We will consider whether there is any additional outcome information that was not able to be incorporated into meta-analyses and note this in the comments and state if it supports or contradicts the information from the meta-analyses. If it is not possible to meta-analyse the data we will summarise the results in the text.

'Summary of findings' and assessment of certainty of evidence

We will summarise the findings in a 'Summary of findings' table(s) for the main intervention comparison(s) and include the primary outcomes in order to draw conclusions about the certainty of the evidence within the text of the review. Two review authors will independently assess the certainty of the evidence for the primary outcomes (high, moderate, low, and very low) using the five GRADE considerations (risk of bias, consistency of effect, imprecision, indirectness, and publication bias).(58) We will use methods and recommendations described in Section 8.5 and Chapter 12 of the *Cochrane Handbook for Systematic Reviews of interventions*(50), and the EPOC worksheets(59), and we will use GRADEpro software. We will resolve disagreements on certainty ratings by discussion and provide justification for decisions to down- or upgrade the ratings using footnotes in the table and make

comments to aid readers' understanding of the review where necessary. We will use plain language statements to report these findings in the review.(59)

If during the review process, we become aware of an important outcome that we failed to list in our planned 'Summary of findings' table(s), we will include the relevant outcome and explain the reasons for this is the section 'Differences between protocol and review'.

Subgroup analysis

Based on the findings of the preliminary searches conducted in preparation for a scoping review on processes and outcomes of tailoring(26) we will use the following characteristics of the tailoring process and characteristics of tailored strategies to perform a number of subgroup analyses, where feasible to assess the effect of the following study characteristics on the magnitude of the effect:

- Sample size: large versus small studies defined by the number of sites/HCPs delivering the intervention or the size of the population receiving the intervention (recipients).
- Study setting: high-, middle- or low-income countries based on the World Bank Classification.(46)
- Use of theory, evidence, and stakeholder in the tailoring process; studies involving each element only, two elements (theory + stakeholders, theory + evidence, or evidence + stakeholders) or all three elements will be compared to studies with none of the three elements. We will use these categories if there is sufficient number and diversity of studies, otherwise we will collapse them into more meaningful groupings.

Sensitivity analysis

We will perform sensitivity analyses defined a priori to assess the robustness of our conclusions and explore its impact on effect sizes. This will involve the following:

1. Restricting the analysis to published studies.
2. Restricting the analysis to studies with a low risk of bias, as specified above.

If applicable, we will carry out sensitivity analyses assuming a larger clustering effect than had been accounted for in the standard analyses, by using higher ICC estimates (i.e., the reported upper quartile range values) than those published for the relevant setting.

We will conduct the review according to this published protocol and report any deviations form it in the 'Differences between protocol and review' section of the systematic review

Stakeholder consultation and involvement

When writing the findings and preparing the lay summary we will involve members of a Patient and Public Involvement (PPI) panel already formed to advise on work within our research group. This panel currently comprises five people with diabetes. We will also form a panel of health care professionals to advise on the key messages from the review. This panel will be established in the latter stages of the review and, as with the PPI panel, will have a once-off involvement in the review. Input will be sought separately from the PPI and professional panels during consultation meetings.

Contributions of authors

Conceiving the protocol: SMH

Designing the protocol: SMH, FR, CK, EM, EOR, CCL, RM, BJP, LW

Co-ordinating the protocol: SMH, FR

Designing search strategies: NR

Writing the protocol: SMH, FR, CK, EM, EOR, CCL, RM, BJP, LW

Providing general advice on the protocol: Sasha Sheppard (EPOC Co-coordinating Editor)

Securing funding for the protocol: SMH

Performing previous work that was the foundation of the current study: Baker R, Camosso-Stefinovic J, Gillies C, Shaw EJ, Cheater F, Flottorp S, Robertson N, Wensing M, Fiander M, Eccles MP, Godycki-Cwirko M, van Lieshout J, Jäger C are authors of the original review. Janette Camosso-Stefinovic and Michelle Fiander were responsible for developing, editing, and running search strategies for the original version of the review.

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Declarations of interest

None known.

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Appendix:
Medline search

Medline (Ovid MEDLINE® Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE® Daily and Ovid MEDLINE®) 1946 to present

No.	Search terms	Results
1	Implementation Science/	1150
2	tailor$.ti.	13229
3	(tailor$ adj5 (intervention? or strategy or strategies or program$ or model$ or implement$)).ab,kf.	25008
4	(tailor$ adj5 (educat* or training or feedback or guidance or guideline$)).ab,kf.	5444
5	((multifacet$ or multi-facet$ or multicomponent$ or multi-component$) and (intervention$ or strategy or strategies or program$)).ti. and (implement$ or adopt$ or uptake).ti,ab,kf.	664
6	(((multifacet$ or multi-facet$ or multicomponent$ or multi-component$) adj3 (intervention$ or strategy or strategies or program$)) and (implement$ or adopt$ or uptake)).ti,ab,kf.	3219
7	1 or 2 or 3 or 4 or 5 or 6	43902
8	(target* adj3 (intervention? or strategy or strategies or program$)).ti,ab,kf.	106681
9	(target* adj3 (educat* or training or feedback or guidance or guideline$)).ti,ab,kf.	12250
10	(target* adj3 (barrier? or obstacle? or challenge? or facilitator? or enabler?)).ti,ab,kf.	4142
11	((co-design* or co-produc* or co-creat*) adj3 (intervention? or strategy or strategies or program$ or implement$)).ab,kf.	605
12	((implementation or intervention) adj (mapping or framework)).ti,ab,kf.	1217
13	exp education, continuing/ or exp inservice training/ or mentoring/ or Feedback, Psychological/ or Formative Feedback/	94875

14	(education* adj3 (intervention? or strategy or strategies or program$)).ti,ab,kf.	87915
15	(dissemination adj3 (intervention? or strategy or strategies or program$ or model$)).ti,ab,kf.	2649
16	((education* or academic*) adj2 (outreach or detailing)).ti,ab,kf.	2415
17	((audit or performance) adj2 feedback).ti,ab,kf.	4120
18	((opinion or local or practice or physician? or nurse?) adj2 (influencer? or leader? or champion? or expert?)).ti,ab,kf.	38712
19	8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18	336470
20	Practice Guidelines as Topic/ or Practice Guideline/ or Critical Pathways/	163304
21	practice patterns, nurses'/ or practice patterns, physicians'/ or practice patterns, pharmacists'/	68984
22	Inappropriate prescribing/ or Deprescriptions/	5116
23	Overdiagnosis/	107
24	(guideline? adj3 (treatment or therap* or diagnos* or prescri*)).ti,ab,kf.	48392
25	((appropriate* or inappropriate*) adj3 (treatment or therap* or diagnos* or prescri*)).ti,ab,kf.	91534
26	(overtreat* or overdiagnos* or overprescri* or deprescri* or represcri*).ti,ab,kf.	12793
27	(((appropriate* or inappropriate*) adj3 "use") or nonuse or "non-use" or utili?ation or utili?ed).ti,ab,kf.	540700
28	((improve* or increas*) adj3 "use").ti,ab,kf.	93656
29	20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28	958488
30	guideline adherence/	34823
31	(adheren* or nonadhere* or complian* or noncomplian* or concord*).ti,ab,kf.	414599
32	(change? or changing or unchange? or unchanging or modif* or context* or integrat*).ti,ab,kf.	5610885
33	(implement$ or adopt$ or uptake).ti,ab,kf.	1308139
34	30 or 31 or 32 or 33	6823302
35	19 and 29 and 34	15873
36	7 or 35	59033
37	exp Health Personnel/ or exp Nursing/ or exp medicine/ or general practice/ or family practice/ or (doctor? or physician? or medic? or clinician? or practitioner? or nurse? or therapist? or physiotherapist? or dieti?ian? or nutritionist? or pharmacist? or prescriber? or dentist? or counsel?or? or assistant? or aide? or auxiliar* or technician? or professional? or staff* or personnel or worker? or team? or provider? or manager? or administrator? or executive? or leader? or expert?).ti,ab,kf.	3719263
38	36 and 37	28134
39	randomized controlled trial.pt.	577088
40	controlled clinical trial.pt.	95028
41	multicenter study.pt.	325584
42	pragmatic clinical trial.pt.	2140
43	(randomis* or randomiz* or randomly).ti,ab.	1064192
44	(trial or multicenter or multi center or multicentre or multi centre).ti.	325522
45	or/39-44	1578130
46	38 and 45	5652
47	(review or systematic review or meta analysis or news or comment or editorial).pt. or "cochrane database of systematic reviews".jn. or comment on.cm. or (systematic review or literature review).ti.	4802065
48	46 not 47	4866
49	exp Animals/ not Humans/	5046262
50	48 not 49	4865
51	limit 50 to yr="2014 -Current"	2982