

BMJ Open Adapted motivational interviewing for brief healthcare consultations: protocol for a systematic review and meta-analysis of treatment fidelity in real-world evaluations of behaviour change counselling

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ABSTRACT

Introduction Treatment fidelity is an important and often neglected component of complex behaviour change research. It is central to understanding treatment effects, especially for evaluations conducted outside of highly controlled research settings. Ensuring that promising interventions can be delivered adequately (ie, with fidelity) by real-world clinicians within real-world settings is an essential step in developing interventions that are both effective and 'implementable'. Whether this is the case for behaviour change counselling, a complex intervention developed specifically for maximising the effectiveness of real-world consultations about health behaviour change, remains unclear. To improve our understanding of treatment effects, best practice guidelines recommend the use of strategies to enhance, monitor and evaluate what clinicians deliver during patient consultations. There has yet to be a systematic evaluation of whether and how these recommendations have been employed within evaluations of behaviour change counselling, nor the impact on patient health behaviour and/or outcome. We seek to address this gap.

Methods and analysis Methods are informed by published guidelines. Ten electronic databases (Medline, PubMed, EMBASE, PsycINFO, CINAHL Complete, ScienceDirect, Taylor and Francis; Wiley, ProQuest and Open Grey) will be searched for published and unpublished articles that evaluate behaviour change counselling within real-world clinical settings (randomised and non-randomised). Eligible papers will be rated against the National Institute of Health fidelity framework. A synthesis, evaluation and critical overview of fidelity practices will be reported and linear regression used to explore change across time. Random-effect meta-regression is planned to explore whether fidelity (outcomes reported and methods used) is associated with the impact of behaviour change counselling. Standardised effect sizes will be calculated using Hedges' *g* (continuous outcomes) and ORs (binary/dichotomous outcomes).

Strengths and limitations of this study

- Protocol for the first systematic review of treatment fidelity in behaviour change counselling.
- Methodologically rigorous approach to identifying and evaluating published and unpublished literature for the fidelity methods used, overall quality and risk of bias.
- Pending an adequate number of articles, this will be the first systematic evaluation of the relationship between treatment fidelity (methods used and outcomes reported) and the impact of behaviour change counselling on health behaviour(s) and/or outcome(s).
- The definition of 'behaviour change counselling' is such that there is likely to be considerable heterogeneity in the included articles, potentially limiting the conclusions that can be drawn.
- Although language will not be set as an exclusion criteria during searches, only articles with a full-text English version will be included, potentially limiting the generalisability of the findings.

Ethics and dissemination No ethical issues are foreseen. Findings will be disseminated via journal publication and conference presentation(s).

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INTRODUCTION

Complex behaviour change interventions

Complex interventions are widely used by healthcare providers to affect change in patient behaviour.¹ This may take the form of working with patients to reduce behaviours that increase the risk of morbidity and premature mortality (eg, smoking); to increase behaviours that reduce such risk (eg, physical exercise) and/or increase behaviours that

decrease the impact of health conditions once present (eg, diet).² Such health behaviour change interventions can be considered ‘complex’ due to the multiple interacting components employed.³ Additional factors that contribute complexity to the design, evaluation and/or implementation of these interventions include (1) interacting components within experimental and control arms; (2) the number and difficulty of behaviours performed by interventionists and/or required of participants; (3) the number of intervention arms and/or organisational levels involved; (4) the number and variability of outcomes assessed and (5) the level of flexibility and/or tailoring of the intervention.³

Treatment fidelity: an important and largely neglected consideration

Several guidelines^{3 4} cite treatment fidelity as a key consideration when designing, evaluating and reporting complex interventions. Indeed, treatment fidelity is now specified as an item in the 2017 revision of the Consolidated Standards of Reporting Trials statement for randomised trials of non-pharmacological treatments.⁵ Broadly, treatment fidelity refers to whether an intervention was delivered as intended (integrity) and the degree to which it is distinguishable from comparison conditions (differentiation).⁶ Key components of intervention integrity include adherence (the degree to which intervention delivery is informed by essential content, strategies and/or theory and avoids proscribed behaviour) and competence (the skill with which the intervention was delivered).⁷ Treatment fidelity is central to interpreting the outcome of intervention evaluations, since the presence or absence of treatment effects can be more confidently attributed to the intervention under investigation (ie, relative to non-adherence and/or other factors unrelated to the intervention).⁸

The National Institutes of Health (NIH) Behaviour Change Consortium provides a framework for enhancing⁸ and evaluating^{6 9} treatment fidelity in health behaviour research. This framework offers best practice recommendations across five domains (study design, provider training, treatment delivery, treatment receipt and treatment enactment^{8 9}). When this framework has been used to systematically evaluate fidelity methods within evaluations of health behaviour change interventions, the results are concerning. In a 2005 review of over 300 health behaviour change interventions conducted between 1990 and 2000, more than half of the studies neglected to report on treatment fidelity.⁶ Over a decade later, there remains considerable room for improvement in the reporting of treatment fidelity. In a recent review of fidelity methods pertaining to treatment delivery, receipt and enactment, fewer than half of the included face-to-face health behaviour change interventions addressed these components of treatment fidelity.¹⁰ Similarly, in another recent systematic review of health intervention research, treatment receipt was reported in less than 20% of the studies reviewed.¹¹ Accordingly, despite the

importance of treatment fidelity to evaluations of complex behaviour change interventions, inadequate consideration and/or reporting remains commonplace. This has profound implications for interpretation of treatment effects, and the ultimate dissemination and implementation of interventions.⁹

Translational research

Demonstrating that promising interventions can be delivered adequately (ie, with fidelity) by real-world clinicians within real-world settings¹² is a key task of stage III research, as defined by the National Institute of Health Stage Model for Behavioral Intervention Development.¹² Treatment fidelity is, therefore, a particularly important consideration for translational research.¹³ That is, when clinicians receive training in an intervention, which is then delivered and evaluated within the context of every day service provision (ie, often without the same control and resources afforded research settings¹³), without the assessment, monitoring and evaluation of treatment fidelity, there is no way of knowing what is actually being delivered and the (in)consistency with the intervention under investigation. Simply put, ‘people cannot benefit from a treatment to which they have not been exposed’.¹³ To the best of our knowledge, an in-depth evaluation of treatment fidelity within evaluations of complex behaviour change interventions delivered by real-world clinicians in real-world healthcare settings has yet to be undertaken. Improved understanding of whether complex interventions can be effectively delivered by real-world clinicians within real-world healthcare settings represents an important step in bridging the widely acknowledged ‘science-to-service’ gap.¹²

Conversations about change

The way in which a clinician approaches the topic of health behaviour change during a consultation can profoundly impact the likelihood of change.¹⁴ Motivational interviewing is a ‘directive, client-centred counselling style for eliciting behaviour change by helping clients to explore and resolve ambivalence’.¹⁵ According to this approach, elements of the therapeutic encounter (including empathy, collaboration, exploring ambivalence and eliciting reasons for change) are critical for strengthening commitment, thereby promoting momentum towards behaviour change and/or maintenance.¹⁶ Although originally employed within drug and alcohol treatment settings, the applicability of this approach to conversations about health behaviour change more broadly led to a range of adaptations.¹⁴

Behaviour change counselling

In its broadest sense, ‘behaviour change counselling’ has been used to refer to counselling efforts focused on promoting health behaviours and/or changing unhealthy behaviours.¹⁷ Within the motivational interviewing literature, behaviour change counselling refers to a time-limited adaptation of Motivational Interviewing that extends

beyond brief advice.¹⁸ Within this context (and the focus of the current review), behaviour change counselling is informed by key principles, skills and strategies from both motivational interviewing and person-centred therapies¹⁹ and is designed to maximise the effectiveness of conversations about health behaviour change.¹⁸ Although there is considerable overlap between motivational interviewing and behaviour change counselling, according to the seminal definition of this approach, a defining feature of behaviour change counselling is delivery within time-limited consultations (ie, 5–30 min vs 30–60 min for motivational interviewing¹⁸). As per Medical Research Council guidelines, behaviour change counselling can be considered a complex intervention due to the multiple components, flexibility and integration into routine consultations.³

The efficacy of behaviour change counselling has yet to be explored within a systematic review and/or meta-analysis. However, findings from related (and possibly overlapping) ‘adaptation of motivational interviewing’²⁰ as well as motivational interviewing more broadly are generally positive—for promoting change in both health outcome(s)²¹ and/or health behaviour(s).²² However, variable effect sizes and inconsistency in the direction of treatment effects have also been noted.^{13 23} Central to this variability is inadequate consideration of treatment fidelity.^{13 24} Clarifying the conditions under which motivational interviewing is more or less effective has been identified as an important research priority.¹³ One key question that has yet to be addressed is whether the benefits of motivational interviewing are evident when evaluations move beyond controlled research settings to ordinary treatment delivery, using everyday clinicians trained to deliver the intervention.

Why it is important to do this review

Treatment fidelity is central to the conduct and evaluation of complex behaviour change interventions.^{3 4} To improve our understanding of treatment effects, best practice guidelines recommend the use of strategies to enhance, monitor and evaluate what clinicians are actually delivering during patient consultations.^{8 9} However, there has yet to be a systematic evaluation of whether and how these recommendations have been employed within evaluations of behaviour change counselling, an important and widely used therapeutic approach for facilitating health behaviour change. We seek to address this gap by systematically evaluating the fidelity methods used in real-world evaluations of behaviour change counselling interventions and exploring the relationship between treatment fidelity and treatment outcome. By systematically identifying and appraising real-world evaluations of behaviour change counselling, this review represents an important step towards improving the implementation, evaluation and dissemination of this important complex behaviour change intervention. It will also serve as a useful resource for guiding future real-world evaluations

of behaviour change counselling, and complex interventions more broadly.

Objectives

Guided by the review questions listed below, we aim to provide a comprehensive overview of treatment fidelity within real-world evaluations of behaviour change counselling for adult health behaviour(s) and/or outcome(s), including:

1. A synthesis, evaluation and critical overview of the practices used to assess, monitor and/or enhance treatment fidelity per NIH recommendations.
2. An examination of the relationship between treatment fidelity (both the outcomes reported and NIH methods used) and the impact of behaviour change counselling on patient behaviour and/or health outcome(s).

Review question

For real-world evaluations of behaviour change counselling for adult health behaviour(s) and/or outcome(s)

1. What is the level of adherence to the NIH framework for assessing, monitoring and enhancing treatment fidelity and has it improved (changed) over time?
2. What is the pooled estimate for reported fidelity (adherence) in intervention studies?
3. What is the relationship between treatment fidelity (ie, level of adherence and/or competence achieved) and the impact of behaviour change counselling on the primary health behaviour and/or health outcomes reported within the literature?
4. What is the relationship between the methods reported to enhance, monitor and assess fidelity (ie, NIH Fidelity checklist score) and the impact of behaviour change counselling on the primary health behaviour and/or health outcomes reported within the literature?

METHODS AND ANALYSIS

The methods outlined below are informed by published guidelines for conducting systematic reviews.^{25 26} They are reported here according to the preferred reporting items for systematic review and meta-analysis protocols.²⁷

Eligibility criteria

Articles will be deemed eligible for the proposed systematic review via inclusion and exclusion criteria applied to the following domains (described in turn below): types of studies, types of participants, types of interventions and comparison conditions and the outcome measures assessed.

Types of studies

To ensure that we identify all studies that evaluate a behaviour change counselling intervention delivered by health workers within real-world healthcare settings/services, we will adopt liberal inclusion criteria. Studies may be randomised, non-randomised or observational. No limits will be set on follow-up duration. To be eligible, a full-text English version of the article must be available. To be classified as an ‘evaluation’ of behaviour change counselling, the

article must assess the impact of behaviour change counselling on one or more health behaviours and/or outcomes (defined below).

In the absence of an accompanying evaluation of patient outcomes, papers that report exclusively on training health workers in behaviour change counselling will be excluded. For clarity, we will restrict the focus of our review to interventions delivered to adults (defined as 18+). Parent and/or family focused studies will be excluded unless an adult health behaviour and/or outcome is specified as the primary focus of the intervention. Studies that include both adults and those younger than 18 will only be included if outcome data is presented separately for the adult participants. Qualitative only studies will be excluded.

Types of participants

A health worker must deliver the behaviour change counselling intervention to adults in a real-world healthcare setting or service. 'Health worker' will be defined according to WHO definition of 'people engaged in actions whose primary intent is to enhance health'.²⁸ That is, any person who's primary function relates to 'delivering preventive, promotive or curative health services'²⁹ and/or whose occupation is listed in the following domains of the standard occupational classification system, specifically psychologists (19–3030); counsellors, social workers and other community and social service specialists (21–1000); healthcare practitioners and technical occupations (29–1000; excluding veterinarians and paediatricians)—and healthcare support occupations (31–0000; excluding veterinary assistants and laboratory animal caretakers).

Health workers may be paid or unpaid. They must be involved in delivering treatment and/or support services within any real-world healthcare setting (community, hospital, rehabilitation, residential, etc) and/or service (eg, information and support lines, employee assistance programmes, etc) on an ongoing basis. As the health worker must be responsible for delivering the majority of the intervention, should a study employ technology-based delivery of the behaviour change counselling intervention (eg, automated text message; on-line modules, etc) it will only be included if >80% of intervention occasions are delivered by the health worker. Studies that use a research assistant and/or study investigator to deliver the behaviour change counselling Intervention will be excluded unless that person is already embedded within the real-world setting/service (ie, is involved in ongoing service delivery that extends beyond the duration of the research evaluation).

Types of interventions

The intervention of interest is 'behaviour change counselling', a time-limited adaptation of motivational interviewing.^{18 19} The behaviour change counselling must be delivered by a healthcare worker within a real-world healthcare setting/service, but can be of any intensity, session number and delivery mode (eg, face to face, telephone, Skype, etc). As we are interested in the use of behaviour change counselling with adult populations, the focus of the

intervention must be on the health behaviour(s) of patients aged 18 years or older.

Papers will be included if they define the intervention being evaluated wholly or in part as 'behaviour change counselling', per the seminal definition offered by Rollnick.¹⁸ That is, for the purposes of this review the intervention must meet the following four criteria:

1. Use motivational interviewing skills, principles and/or strategies.
2. Consist of more than 'brief advice'.
3. Be time limited (designed for consultations lasting 5–30 min).
4. Focus on helping participants to change a health behaviour.

To help inform research and clinical practice, we will maintain a record of how 'behaviour change counselling' is defined across papers (including underlying theory, intervention components, intensity, duration and delivery mode).

Types of comparison conditions

The 'behaviour change counselling' may be compared with active (eg, psychological intervention and/or pharmacotherapy) and/or inactive (eg, no treatment, wait-list control, standard care, placebo) condition(s). Studies with no comparison conditions will also be eligible.

Types of outcome measures

Studies must evaluate the impact of 'behaviour change counselling' on patient health behaviour(s) and/or outcome(s) (including those related to physical health, mental health and/or addiction). Papers that only report on practice-level outcomes (implementation/dissemination papers) will be excluded. Since we are interested in assessing whether and how fidelity is assessed and/or reported within evaluations of behaviour change counselling, articles that meet the above eligibility criteria will be eligible for inclusion irrespective of whether they use and/or report methods to evaluate fidelity of behaviour change counselling delivery (and/or other domains of fidelity).

As it is commonplace to report fidelity assessment and/or outcomes separate to the primary evaluation, in accordance with published methodology for systematically evaluating treatment fidelity,⁶ papers that are cited for further information regarding fidelity methods employed in the evaluation (eg, training methods, intervention details) will also be eligible. Cited references will be sourced, data extracted and then combined with the data from the parent article. Data extraction sheets will be developed such that the coder can indicate whether the data was obtained from the originally retrieved ('primary') or subsequently sourced ('sourced') article. Linking ID's (eg, 1.1, 1.2, etc) will be assigned to reports of the same study/sample.

Information sources

Search strategy

Searches will be conducted in eight electronic databases (Medline, PubMed, EMBASE, PsycINFO, CINAHL

Complete, Science Direct, Taylor and Francis; and Wiley Online Library). Additionally, unpublished dissertations will be sourced via Open Grey and ProQuest. To identify real-world evaluations of behaviour change counselling delivered by health workers, search terms that describe the intervention of interest (ie, behaviour change counselling) will be combined with those that describe the target population (ie, health workers) and setting (ie, real-world settings/services) (see online supplementary file 1 for the full MEDLINE search strategy).

Abstract, title, keywords and/or subject headings specific to each of the identified databases will be searched. Searches will be run from the inception of each database until present. Although only full-text articles available in English will be included in the review, to ensure we adequately capture all relevant literature a language restriction will not be included in the search strategy. Reference lists of eligible papers will be hand searched and potentially relevant articles sourced, including any citations to previously published fidelity methods and/or outcomes. All publications will be organised in Endnote and the systematic review management software Covidence (<https://www.covidence.org/home>). All searches will be performed by AKB. Searches were initiated in November 2018, and completed in December 2018.

Study records

Selection process

AKB will review the titles and/or abstracts from the initial searches and exclude articles if they clearly meet any of the exclusion criteria outlined in [box 1](#).

Abstracts from conference proceedings will be excluded due to the limited information available for assessing eligibility, extracting data and evaluating quality/risk of bias. However, searches will be performed and/or authors contacted to retrieve any full text versions of the identified abstracts so that they can be screened for eligibility. Duplicates will be excluded.

If eligibility is unclear from the title and/or abstract, the full text will be accessed. Eligibility of the retrieved full-text articles will be independently assessed against the inclusion and exclusion criteria by two review authors (AKB and EF). Discrepancies will be resolved via discussion until a consensus is reached and/or with input from a third reviewer (ALB, BB and/or GC) as needed. If insufficient

information is reported to determine whether inclusion criteria are met (eg, intervention duration, components, setting and/or delivery method) we will contact the authors of that study on no more than three occasions to obtain further information. In the absence of sufficient information to determine eligibility, articles will not be retained for data extraction.

Data collection process

Data extraction will be performed by AKB and checked by EF. Extraction forms will be piloted on several papers and modified as needed before use. When multiple reports of the same study are identified (eg, pilot, definitive and process evaluations), data from each report will be extracted separately and then combined across multiple data collection forms. As per Cochrane guidelines,²⁵ assessment of fidelity methods, quality and risk of bias (described below) will be performed independently by two raters (AKB and EF). In the event of disagreement, final ratings will be made via consensus with a third, independent rater (ALB, BB and/or GC). As per previously published methods used by the team³⁰ we will ensure that any disagreements and their resolution are carefully recorded (ie, via original and consensus ratings) to allow for assessment of the reliability of coding.

Data items

Extraction forms will be developed by the team and will be informed by published guidelines²⁵ and the latest iteration of the NIH Behaviour Change Consortium treatment fidelity checklist⁹ and will include information about

1. The article (eg, citation, author contact details, country, study objectives, design, study duration).
2. Risk of bias (eg, sequence generation, allocation sequence concealment, blinding, any other concerns about bias).
3. Setting (eg, health worker characteristics, delivery setting, participant characteristics).
4. Intervention methods (eg, definition of behaviour change counselling, intervention components, health behaviour(s)/outcome(s) targeted, duration and delivery method(s)).
5. Fidelity methods (eg, across design, training, delivery, receipt and enactment) as described in the NIH checklist.⁶
6. Fidelity outcomes reported (eg, adherence and/or competence of intervention delivery).
7. Primary outcome (as specified by the authors of the included papers). In the event that a primary outcome is not specified or when multiple primary outcomes are specified, extraction of the primary outcome will be guided by the Cochrane Community's published definition (ie, the outcome of greatest importance³¹). The outcome of greatest importance will be identified by considering a) the variable of interest cited in the study aims/hypotheses and b) which outcome was reported first in the results section. AKB and EF will independently determine which variable to extract

Box 1 Key exclusion criteria for title/abstract screening

Exclusion criteria

1. Not an evaluation article (ie, review, commentary, discussion papers, etc).
2. Clearly employs qualitative only methodology.
3. Is clearly focused on the health behaviour and/or outcomes of participants <18 years of age.
4. The intervention under evaluation is clearly
 - a. Not behaviour change counselling and/or.
 - b. Not delivered by health workers within a real-world setting.

Table 1 Overview of NIH Fidelity Domains

Domain	Overview	Example item
Study design	Factors that are intended to ensure adequate hypothesis testing relative to underlying theory and proposed mechanism(s) of action.	'Theoretical model on which the intervention is based is clearly articulated'.
Training providers	Practices to ensure that providers are capable of delivering the intervention as intended.	'Description of how providers will be trained (eg, manual of training procedures)'.
Delivery of treatment	Assessment and monitoring of what providers actually deliver and strategies to maximise that the intervention is delivered as intended.	'Method to ensure that the content of the intervention is delivered as specified'.
Receipt of treatment	Strategies to ensure that patients understand and perform intervention related behaviours.	'There is an assessment of the degree to which participants understood the intervention'.
Enactment of treatment skills	Processes to maximise the likelihood that patients will perform treatment related behaviours within real-life settings.	'Participant performance of the intervention skills will be assessed in settings in which the intervention might be applied'.

outcome data for, and in case of disagreement, consensus will be reached via discussion with ALB, BB and/or GC. All decisions will be clearly documented. Where multiple methods have been used to assess the primary outcome (eg, both clinician and self-report measures), we intend to extract all data pertaining to that outcome. For primary outcomes with multiple follow-up time points, data will be extracted separately for each follow-up occasion.

8. Treatment Effects—impact of behaviour change counselling on primary outcome (ie, positive vs negative vs null effect and accompanying statistics) within and/or between groups effects versus the control arm (where applicable).

NIH treatment fidelity checklist

The fidelity practices of included articles will be assessed using the NIH Behaviour Change Consortium treatment fidelity checklist.⁹ This 40-item checklist assesses the presence/absence of fidelity practices across five domains (study design, provider training, treatment delivery, treatment receipt, treatment enactment). A brief description and an example item from each domain is outlined in table 1 (see^{6,9} for further information).

We will follow scoring guidelines,⁹ and each checklist item will be assessed on a three point scale of 'present' ('1'), 'absent but should be present' ('0') and 'not applicable' (99).

Study quality assessment

The methodological quality of included studies will be assessed using the Effective Public Health Practice Project qualitative assessment tool for quantitative studies.³² This quality appraisal tool is suitable for randomised and non-randomised studies and is composed of eight sections (selection bias, study design, confounders, blinding, data collection methods, withdrawals and drop-outs, intervention integrity and analysis) and the tool is used to generate

an overall methodological rating (strong vs moderate vs weak) within each domain.

If appropriate, we intend to use the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach to assess the overall quality of evidence for each fidelity outcome reported (eg, adherence, competence), including any predictive relationships identified between intervention fidelity and patient outcome(s).³³ Quality of evidence for each outcome will be presented according to the following categories: 'high', 'moderate', 'low', 'very low', in line with published definitions.³³

Risk of bias

Risk of bias (within and across studies) will be assessed using the appropriate Cochrane Collaboration risk of bias tool for randomised (eg, RoB 2.0) or non-randomised (eg, Risk of Bias in Non-randomised Studies (ROBINS-I)) studies as described in the Cochrane Handbook for Systematic Review of Interventions.²⁵ We will judge each item as being high, low or unclear risk, in line with published guidance.²⁵ All eligible studies will be included irrespective of risk of bias assessment.

Synthesis

The tentative analysis plan is detailed below. All analyses will be conducted using Stata V.14 (StataCorp).

Review question 1. What is the level of adherence to the NIH fidelity framework for assessing, monitoring and enhancing treatment fidelity and has it improved (changed) over time?

Scores from the fidelity checklist⁹ will be synthesised following the methods originally published by Borrelli *et al*⁶ and adopted by subsequent systematic reviews of treatment fidelity in health behaviour change research (eg, Toomey *et al*³⁴) and psychosocial interventions more broadly (eg, Toomey *et al* and McArthur *et al*^{34,35}). First, adherence of each article to the NIH fidelity recommendations (overall, and within each of the five fidelity domains:

treatment design; training providers; treatment delivery; treatment receipt; treatment enactment) will be indexed by dividing the number of strategies deemed appropriate for that study design by the number of strategies coded as 'present'. These scores will then be used to calculate the mean proportion of adherence to fidelity recommendations (overall, and within each of the five fidelity domains) across all included studies. Second, to determine the use of individual fidelity processes across studies, the number of studies using each strategy will be calculated as a percentage of the total number of articles for which that strategy was deemed applicable. High fidelity will be defined as >80% of the total number of applicable checklist items coded as 'present'.⁹

To determine whether the reporting of fidelity methods has improved over time, linear regression is planned to explore the relationship between year of publication (calendar year) and the mean proportion of adherence to fidelity recommendations (overall, and for each of the five fidelity domains). This analysis will be supplemented by descriptive statistics and a narrative synthesis and critical commentary of whether and how the included articles have used strategies to assess, enhance and monitor treatment fidelity (structured around healthcare setting/service provider; intervention characteristics; primary outcome and the impact of the behaviour change counselling).

Review question 2. What is the pooled estimate for reported fidelity (adherence and/or competence) in intervention studies?

We intend to adopt the following methods to generate the pooled estimate of reported fidelity to behaviour change counselling. To minimise error and increase our confidence in the pooled estimate,²⁵ the following will only be conducted if a minimum of 10 studies is available. First, if not reported by the primary study, the available data (eg, mean, SD, percentage, frequency, etc) will be used to create standardised estimates that will be pooled (prevalences will be pooled for dichotomous measures). Random-effects models will then be used to calculate the weighted mean and variance (95% CI) separately for continuous and binary/dichotomous fidelity outcomes. When a study reports multiple fidelity outcomes, outcomes will be classified (eg, intervention adherence, intervention competence, change relative to routine care) and separate analyses performed.

Review question 3.

A. What is the relationship between treatment fidelity (ie, level of adherence and/or competence achieved) and the impact of behaviour change counselling on the primary health behaviour and/or health outcomes reported within the literature?

Where study numbers are large enough (≥ 10 ,²⁵) random-effect meta-regression is then planned to explore whether fidelity to behaviour change counselling is associated with the impact of the intervention on primary outcome. If the effect size for the impact of the intervention on the primary patient outcome and CI is not reported, these will be calculated using the data that is available (eg,

mean, SD, percentage, frequency, t-test, F-t, etc) using published conversion formulas.³⁶ Standardised effect sizes will then be calculated using Hedges' g for continuous fidelity outcomes and ORs for binary/dichotomous outcomes. As we expect that most primary health behaviour and/or health outcomes will be reported on a continuous scale, we intend to convert ORs into standardised mean difference effect sizes.

When a study reports multiple indices of the primary outcome (eg, clinician and self-report assessment), outcome data will be classified (eg, observer vs self-report) and separate analyses performed. As per the Cochrane Convention for classifying follow-up interval,²⁵ separate analyses will be performed for short (<6 months) and long (≥ 6 months) term primary outcome data. Where possible, primary outcomes will be grouped and separate analyses will be conducted for each type of primary outcome identified.

B. What is the relationship between the methods reported to enhance, monitor and assess fidelity (ie, NIH Fidelity checklist score) and the impact of behaviour change counselling on the primary health behaviour and/or health outcomes reported within the literature?

Following the same methods outlined above, random-effect meta-regression will be used to analyse the relationship between the overall mean proportion of adherence to fidelity recommendations (calculated following the methods described under review question one) and the impact of behaviour change counselling on patient health behaviour/outcome (using the pooled estimate described under review question two).

Assessment of study heterogeneity

We intend to assess heterogeneity via visual inspection of forest plots and I^2 . When 'considerable heterogeneity' is found (75%–100%²⁵), moderator analyses may be used to explore the patient, treatment and/or study characteristics that influence the relationship between treatment fidelity to affect the outcome of behaviour change counselling.

Patient and public involvement

The focus of this review is on the delivery and efficacy of behaviour change counselling within the context of real-world consultations. As behaviour change counselling is a common method employed by healthcare professionals when working with patients to modify health behaviours,² the review is of direct relevance to both healthcare professionals and patients. Although no direct consultation with patients and/or public was undertaken to inform the conduct of this review, efforts to improve the quality of communication between healthcare professionals and their patients represent an important research priority for people living with chronic conditions.³⁷

DISSEMINATION

We plan to present the findings of the proposed systematic review for peer review in an appropriate journal. We also

intend to disseminate findings to clinicians, researchers and consumers at appropriate conferences.

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Contributors AKB is guarantor of the review. This work has been conducted in partial fulfilment of the requirements of the degree of PhD (Psychiatry). AKB led the development of the protocol and manuscript preparation in collaboration with supervisors ALB, BB, GC and corater EF. CO advised on statistical methods. All authors contributed to the conception and design of the systematic review and offered critical revisions to the manuscript. All authors have approved the final version of the manuscript. No patients and/ or public were directly consulted regarding the design and conduct of this review.

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Competing interests None declared.

Patient consent for publication Not required.

Ethics approval As no primary data collection will be undertaken, no formal ethical assessment is required.

Provenance and peer review Not commissioned; externally peer reviewed.

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REFERENCES

1. Michie S, Abraham C. Interventions to change health behaviours: evidence-based or evidence-inspired? *Psychol Health* 2004;19:29–49.
2. Swann C, Carmona C, Ryan M, et al. *Health systems and health-related behaviour change: a review of primary and secondary evidence*. Copenhagen: National Institute for Clinical Excellence, 2010.
3. Craig P, Dieppe P, Macintyre S, et al. Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ* 2008;337:a1655.
4. Michie S, Fixsen D, Grimshaw JM, et al. Specifying and reporting complex behaviour change interventions: the need for a scientific method. *Implement Sci* 2009;4:40.
5. Boutron I, Altman DG, Moher D, et al. CONSORT Statement for Randomized Trials of Nonpharmacologic Treatments: A 2017 Update and a CONSORT Extension for Nonpharmacologic Trial Abstracts. *Ann Intern Med* 2017;167:40–7.
6. Borrelli B, Sepinwall D, Ernst D, et al. A new tool to assess treatment fidelity and evaluation of treatment fidelity across 10 years of health behavior research. *J Consult Clin Psychol* 2005;73:852–60.
7. Mars T, Ellard D, Carnes D, et al. Fidelity in complex behaviour change interventions: a standardised approach to evaluate intervention integrity. *BMJ Open* 2013;3:e003555.
8. Bellg AJ, Borrelli B, Resnick B, et al. Enhancing treatment fidelity in health behavior change studies: best practices and recommendations from the NIH Behavior Change Consortium. *Health Psychol* 2004;23:443–51.
9. Borrelli B. The Assessment, Monitoring, and Enhancement of Treatment Fidelity In Public Health Clinical Trials. *J Public Health Dent* 2011;71(s1):S52–63.
10. Walton H, Spector A, Tombor I, et al. Measures of fidelity of delivery of, and engagement with, complex, face-to-face health behaviour change interventions: A systematic review of measure quality. *Br J Health Psychol* 2017;22:872–903.
11. Rixon L, Baron J, McGale N, et al. Methods used to address fidelity of receipt in health intervention research: a citation analysis and systematic review. *BMC Health Serv Res* 2016;16:663.
12. Onken LS, Carroll KM, Shoham V, et al. Reenvisioning Clinical Science: Unifying the Discipline to Improve the Public Health. *Clin Psychol Sci* 2014;2:22–34.
13. Miller WR, Rollnick S. The effectiveness and ineffectiveness of complex behavioral interventions: impact of treatment fidelity. *Contemp Clin Trials* 2014;37:234–41.
14. Rollnick S, Butler CC, McCambridge J, et al. Consultations about changing behaviour. *BMJ* 2005;331:961–3.
15. Rollnick S, Miller WR. What is Motivational Interviewing? *Behav Cogn Psychother* 1995;23:325–34.
16. Miller WR, Rollnick S. *Motivational interviewing: Helping people change*. 3rd edn. New York: Guilford Press, 2013.
17. Ramseier CA, Suvan JE. Behaviour change counselling for tobacco use cessation and promotion of healthy lifestyles: a systematic review. *J Clin Periodontol* 2015;42(Suppl 16):S47–58.
18. Rollnick S, Allison J, Ballasiotes S, et al. Variations on a Theme: Motivational Interviewing and Its Adaptations. In: Miller WR, Rollnick S, eds. *Motivational Interviewing: Preparing People for Change*. 2nd edn. New York: The Guilford Press, 2002.
19. Rollnick S, Mason P, Butler C. *Health Behaviour Change: A guide for practitioners*. 2nd edn. London: Churchill Livingstone, 2010.
20. Burke B, W L, Dunn C, Atkins D, et al. The Emerging Evidence Base for Motivational Interviewing: A Meta-Analytic and Qualitative Inquiry. 2004.
21. Lundahl B, Moleni T, Burke BL, et al. Motivational interviewing in medical care settings: a systematic review and meta-analysis of randomized controlled trials. *Patient Educ Couns* 2013;93:157–68.
22. Morton K, Beauchamp M, Prothero A, et al. The effectiveness of motivational interviewing for health behaviour change in primary care settings: a systematic review. *Health Psychol Rev* 2015;9:205–23.
23. Miller WR, Rollnick S. Meeting in the middle: motivational interviewing and self-determination theory. *Int J Behav Nutr Phys Act* 2012;9:25.
24. Norris AR, Estes Miller J, Miller JE. Motivational interviewing or counseling, medical therapies or no intervention to improve tobacco cessation in adults and adolescents. *J Okla State Med Assoc* 2017;110:142–3.
25. Higgins JP, Green S. eds. *Cochrane Handbook for Systematic Reviews of Interventions: The Cochrane Collaboration*, 2011.
26. Moher D, Liberati A, Tetzlaff J, et al. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. *PLoS Med* 2009;6:e1000097.
27. Moher D, Shamseer L, Clarke M, et al. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. *Syst Rev* 2015;4:1.
28. World Health Organization. *Working together for health: The world health report Geneva*. Switzerland: WHO Press, 2006.
29. World Health Organization. In: Alliance GHW, ed. *Health Workforce 2030: A global strategy on human resources for health*. Geneva, Switzerland: WHO Press, 2014.
30. Beck AK, Baker A, Kelly PJ, et al. Protocol for a systematic review of evaluation research for adults who have participated in the 'SMART recovery' mutual support programme. *BMJ Open* 2016;6:e009934.
31. CochraneCommunity. *Glossary: Cochrane.Org*, 2018.
32. Effective Public Health Practice Project. Dictionary for the Effective Public Health Practice Project Quality Assessment Tool For Quantitative Studies. 1998.
33. Schünemann H, Brozek J, Guyatt G, et al. *GRADE handbook for grading quality of evidence and strength of recommendations. The GRADE Working Group, 2013: Cochrane*, 2013.
34. Toomey E, Currie-Murphy L, Matthews J, et al. Implementation fidelity of physiotherapist-delivered group education and exercise interventions to promote self-management in people with osteoarthritis and chronic low back pain: a rapid review part II. *Man Ther* 2015;20:287–94.
35. McArthur BA, Riosa PB, Preyde M. Treatment fidelity in psychosocial intervention for children and adolescents with comorbid problems. *Child Adolesc Ment Health* 2012;17:139–45.
36. Lipsey MW, Wilson DB. *Practical meta-analysis*. Thousand Oaks, CA, US: Sage Publications, Inc, 2001.
37. Tulskey JA, Beach MC, Butow PN, et al. A Research Agenda for Communication Between Health Care Professionals and Patients Living With Serious Illness. *JAMA Intern Med* 2017;177:1361–6.