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Methodology for task-shifting evidence-based psychological treatments to non-licensed/lay health workers: Protocol for a systematic review

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ABSTRACT

Introduction: "Task-shifting" or "task-sharing" is an effective strategy for delivering behavioral health care in lower-resource communities. However, little is known regarding the actual steps (methods) in carrying out a task-shifting project. This paper presents a protocol for a systematic review that will identify steps in adapting an evidence-based psychological treatment for delivery by lay/non-licensed personnel.

Methods and analysis: This protocol was developed following the 2015 guidelines of the Preferred Reporting Items for Systematic Review and Meta-analysis Protocols. We outline planned eligibility criteria, information sources, search strategy, study screening and selection, data extraction, risk of bias assessment, and data synthesis and analysis.

Ethics and dissemination: This review will analyze data from published studies only, thus it will not require Institutional Board Review. Findings will be presented at conferences and the final systematic review will be published in a peer-reviewed journal.

Key Words: Task-shifting; evidence-based psychological treatment; lay health worker; treatment delivery

Article Summary

Strengths & limitations:

- This protocol describes a planned systematic review to identify best-practices for task-shifting evidence-based psychological treatments to non-licensed/lay health workers
- We will use established operationalized terms to identify and describe implementation strategies
- Studies will be identified via a thorough search strategy using independent data extraction techniques, with risk of bias mitigation strategies
- This protocol adheres to the 17-item checklist, Preferred Reporting Items for Systematic review and Meta-analysis Protocols (PRISMA-P)
- The review will only include studies in English and focuses on non-licensed/lay health workers (e.g., not nurses or teachers), and identifies only studies examining delivery of psychological treatments (i.e., not education or other programming).

INTRODUCTION

Mental health disorders are common worldwide[1] and although there are evidence-based psychological treatments (EBPTs) that improve health outcomes, most of the people who need treatment do not receive it.[2] Mental health treatment is often provided by licensed mental health professionals in specialty settings[3]. These specialty providers may not be available due to workforce shortages, cost of care, and/or access difficulty, especially for lower-income and economically challenged populations[4], who disproportionately suffer from physical and mental health concerns[5 6].

Dissemination and implementation of EBPTs (e.g., cognitive behavioral therapy) to communities in need requires a multidimensional approach with innovative delivery methods.[7] "Task-shifting" or "task-sharing" is one notable strategy that has emerged over the past two decades, largely in low-and middle-income countries, as a method for delivering health care in lower-resource communities. As described by the World Health Organization, with task-shifting, "specific tasks are moved, where appropriate, from highly qualified health workers to health workers with shorter training and fewer qualifications in order to make more efficient use of the available human resources for health."[8]

Task-shifting has great promise in improving access to EBPTs. A recent review of 27 trials in low-and middle-income countries found that task-shifted EBPTs delivered by lay persons in primary care and community settings produced a pooled effect size of 0.49.[9] Findings from this review indicate that EBPTs can be task-shifted and maintain effectiveness, while delivered in nontraditional settings that improve scalability. Therefore, task-shifting EBPTs to lay personnel or paraprofessionals such as community health workers could help reduce disparities in access to evidence-based mental healthcare, thus improving health equity[8 10].

Task-shifted psychological treatments

Many different EBPTs have been effectively task-shifted with cultural and contextual adaptations. For example, Patel and colleagues[11] developed a task-shifted treatment program for moderately-severe to severe depression based on Behavioral Activation[12], an established EBPT. Their rigorous randomized controlled trial (RCT) in India showed that the Healthy Activity Program (HAP), delivered by non-specialist lay counselors in primary care, significantly improved patients' levels of depression (moderate effect size) and led to remission in almost two-thirds of patients treated.[11] Likewise, the "Friendship Bench" program by Chibanda and colleagues[13] was a task-shifting study conducted in Zimbabwe to address depression and common mental disorders. Their treatment program was based on Problem Solving Therapy[14], an established EBPT[15], and was delivered by lay health workers in a population with a high prevalence of people living with HIV. Results of their initial non-controlled clinical trial and a later RCT[16] showed that this approach was efficacious in reducing psychological morbidity; a large cluster RCT is now underway.[17] In both the HAP and the Friendship Bench studies, lay health workers were trained and supervised by licensed professional specialists (i.e., clinical psychologists and/or psychiatrists).

While task-shifting is a recognized method for disseminating EBPTs, the best-practice procedural steps for *how* to task-shift are unclear. A recognized problem in implementation research is that strategies are "often inconsistently labeled and poorly described … lack operational definitions … and are part of 'packaged' approaches whose specific elements are poorly understood" (p.254)[18]. It is critical to operationalize strategies used in task-shifting studies to better understand methods to (a) appropriately adapt the treatment for the new delivery context; (b) train lay personnel; (c) implement the new treatment protocol while maintaining

fidelity; and (d) sustain the task-shifted program. Efforts to scale up EBPTs are critical, yet there is no straightforward roadmap for how to implement task-shifting in new settings. This gap in the literature leaves interested stakeholders without clear guidance in deploying this promising dissemination strategy. Therefore, our research question is: *What are the steps in adapting an evidence-based psychological treatment for delivery by lay/non-licensed personnel?*

Objectives

This protocol outlines our specific methods and planned analyses for a systematic review. This paper adheres to the Preferred Reporting Items for Systematic review and Meta-analysis Protocols (PRISMA-P).[19] The systematic review seeks to identify specific task-shifting strategies using established definitions as described by Proctor and colleagues.[18 20] In Proctor's framework for operationalizing implementation strategies, there are 7 dimensions to consider: *The Actor, The Action, Action Target, Temporality, Dose, The Implementation Outcome Affected,* and *The Justification*. We expect that most studies meeting our inclusion criteria for review will have fairly uniform *justifications* and *action targets*; however, *implementation outcomes* are likely to be wide-ranging and beyond the scope of this paper. Therefore, we will focus on identifying the *actors, actions, temporality*, and *dose* employed in task-shifting studies (see Table 1). The most important outcome of this review is to identify best practices for conducting task-shifting implementation projects.

Dimension	***Operational definition for the planned review***
Actors	Those persons delivering the implementation strategy
Actions	The methodology used to (a) adapt the treatment for the new delivery context, (b) train the lay personnel to protocol adherence, (c) implement the new treatment protocol with fidelity, and (d) sustain the new program
Temporality	The order/sequence of the action strategies
Dose	The amount or intensity of the actions, and how much those doses differ from standard/non-shifted EBPTs

Table 1. Different dimensions of task-shifting strategies to be identified in the systematic review.

Methods and Analysis

Eligibility criteria

Types of studies

Study Inclusion Criteria: 1. Studies must involve a non-licensed, non-specialist (e.g., community health worker, promotor/a, peer, lay person) who is delivering the intervention; 2. Studies must address a "behavioral health" problem, broadly defined as any psychological/mental health issue (e.g., depression, eating disorders, parenting issues, substance use) and/or physical health concern (e.g., chronic disease management, health behavior change, lifestyle changes, adherence) using behavioral/psychological strategies. 3. The treatment components that have been shifted must be derived from an EBPT that has been found efficacious in at least 1 prior peer-reviewed RCT (e.g., cognitive behavioral therapy, motivational interviewing, behavioral activation, interpersonal psychotherapy). 4. The studies must include a statistical comparison of some kind. The comparator condition must be any of the following: baseline functioning of participants (as in pre-post design); or in an RCT, the control group must be attentional control, a waitlist control, a non-treated group, a treatment-as-usual group, a group receiving a different form of treatment, or a group receiving treatment delivered by an expert provider (e.g., licensed psychologist). Eligible study designs also include RCTs, quasi-experimental trials, pre-post designs, pragmatic trials (e.g., using stepped wedge or cluster RCT designs). 5. Eligible studies must report evidence of effectiveness of the task-shifting strategy by using a study design that statistically analyzes outcomes using a comparator/control.

Study Exclusion Criteria: 1. Studies that deliver care using a licensed or specialist/non-lay person (e.g., nurse, educator); 2. Studies focused solely on task-shifting a primarily medical task (e.g., HIV treatment, prenatal care); 3. Studies reporting psychological/behavioral

treatments that have not been previously proven effective as outlined above, or not involving treatment (e.g., screening only); 4. Patient education studies with no behavioral intervention (e.g., nutritional information only); 5. Studies not involving a comparison; 6. Descriptive studies, case reports, or exclusively qualitative studies; 7. Studies not published in a peer-reviewed journal (e.g., dissertations, poster or paper presentations, newsletter articles); 8. Books and book chapters; 9. Study protocol publications.

Types of participants

Participant Inclusion Criteria: 1. Study participants must have received a psychological/behavioral-based (i.e., non-pharmacological) intervention for a "behavioral health" problem, broadly defined as any psychological/mental health problem (e.g., depression, eating disorder, parent-child behavioral issues, substance use) and/or physical health concern (e.g., chronic disease management, lifestyle changes, adherence); 2. Study participants must have received interventions delivered by non-licensed, non-specialists.

Participant Exclusion Criteria: 1. Patients treated using pharmacological, surgical, or medical procedures as the primary intervention tested in the study; 2. Participants treated exclusively by licensed health professionals (e.g., physicians, nurses); 3. Students receiving interventions delivered by teachers in schools.

Setting and timeframe

Inclusion Criteria for Setting and Timeframe: 1. Task-shifting research studies conducted in high-, low- and middle-income countries. 2. Studies conducted in any setting (e.g., healthcare or community settings) or region (e.g., urban, rural).

Exclusion Criteria for Setting and Timeframe: Studies conducted prior to 2000 (i.e., the approximate time when task-shifting was first reported).

Report characteristics

Information sources

The search strategy will be adapted for each of the following sources/databases: PubMed, the Cochrane Library, Cochrane Central Register of Controlled Trials (CENTRAL), SCOPUS, Cumulative Index to Nursing and Allied Health Literature (CINAHL), APA PsycInfo, and Google Scholar. The search will cover the time frame from January 2000 to July 2020. Peer-reviewed published literature will be sought and posters, dissertations, presentations; descriptive or protocol articles; books and book chapters; studies not published in English will be excluded. Unpublished studies will not be sought. The search will be re-run prior to the final analysis and any further studies identified will be retrieved for inclusion.

Search strategy

The search strategy will be developed and overseen by a medical librarian in consultation with the primary researchers throughout the review. Medical Subject Headings and free-text terms relating to lay health workers and the implementation of task-shifting/sharing will be included (see Table 2).

Key Words	***Search Terms***
Task-Shifting	task-shifting; task-sharing; "care sharing"
Lay workers	Community health worker; church; community based facilitator; community based organization; health manpower; integrated care; lay counsellor; lay counselor; lay health worker; non-licensed; nonprofessional; non-specialist; nonspecialists; patient care teams; patient navigator; peer; peer-coach; peer-counsellor; peer-counselor; peer-facilitator; promotor; promotora; promotoras; promotores; self care; self management; shared care; staff development; telehealth; telemedicine; telepsychiatry; traditional healer; unlicensed
EBPTs	psychological; psychological treatment; psychological intervention; empirically-supported psychological treatment; evidence-based psychological treatment; evidence-based behavioral treatment; evidence-based behavioural treatment; mental health; cognitive behavioral therapy;

	cognitive behavioural therapy; behavioral therapy; behavioural therapy; interpersonal therapy; acceptance and commitment therapy; psychotherapy; motivational interviewing; interpersonal therapy

Table 2. Key word search terms.

Study screening and selection

Using a coding guide and form, two reviewers will independently search titles and abstracts to remove publications not meeting inclusion criteria. Full texts will be retrieved. Multiple reports of the same study will be linked together (collated) per Cochrane guidelines (see Handbook sec 4.6.2)[21] so that the unit of interest is each study, not each article. For example, if a single study was split into separate publications such as a protocol paper, report of the actual study, a qualitative analysis on acceptability, and a follow-up, it will be counted as one study, and each of these articles will be searched for relevant data. We will examine prior reviews on the same topic and employ hand-searching of the reference lists for articles identified in the inclusion stage. We will iteratively refine our search strategy to refine the coding guide and form. We will add indexing terms as needed during the preliminary development of the inclusion article guide.

Data extraction

A data extraction chart has been developed by the team to aid in extracting the specific task-shifting steps from the included articles (see Table 3 for example of primary extractions). Data extracted will follow established definitions as described by Proctor and colleagues.[18 20] Additional data we anticipate extracting include year of study publication; design; setting; participant demographics; geographic location of study; type of personnel delivering the intervention; demographics of personnel delivering intervention; and reported effect sizes.

Study	Actors	Actions				Temporality	Dose
		Adaptations	Training	Implementation steps	Sustainment		
A	Community health workers	Focus groups of CHWs and patients to help adapt standard CBT; modified language, developed weekly handouts, created CHW manual	2 half-day workshops delivered by licensed psychologist	Competency benchmarks were established; 20% of recordings listened to by licensed psychologist as fidelity checks	Weekly group supervision via phone with individual meetings as needed	1. Baseline evaluation of TAU program 2.Modifications to protocol based on focus groups 3. Training developed & delivered 4. Delivery of new program 5. Program evaluation	Modified protocol from 6-week hour-long CBT sessions in clinic to 6 modules of CBT basics delivered in homes
B	Peer facilitators	Needs assessments, focus groups with existing peer supporters; changed format from weekly individual visits to group-based meetings; developed workbook for use by peer supporters and patients	8-hour workshop delivered by licensed social worker	Observed by licensed social worker until competent in manualized	Weekly group case conferences with social worker over virtual platform	1.Modifications to existing EBPT protocol 2. Training 3. Observations till competence reached 4. Two groups of patients randomized to care 4. Case conferences throughout study	Modified a 12-week individual protocol based on MI to a 12-week group-based protocol

Table 3. Example extraction summary table.

Two co-authors will independently conduct data extraction and an additional author will review the data extracted for completion and accuracy. When necessary, consensus will be reached through discussions with an independent fourth author. Missing data will be sought out by contacting study investigators for unreported data and/or additional details. Data will be recorded in an Excel spreadsheet.

Assessing risk of bias

Reviewers will consider risk of bias by assessing scientific rigor used in the study design (e.g., methods of randomization; treatment allocation; control comparator). Two reviewers will independently rate risk of bias and when necessary, disagreements will be resolved by reaching consensus with a third reviewer. Risk of publication bias will be mitigated by searching as extensively as possible using diverse databases, reviewing reference lists and any related systematic reviews.

Data synthesis and analysis

Data synthesis will primarily involve descriptive statistics with tables and graphs to visually communicate findings. Descriptive statistics will be employed to categorize and tally the different types of methodologies used in task-shifting studies, based on standardized language for operationalizing implementation strategies[18], to include *actors, actions, temporality* and *dose*. Frequency counts and measures of central tendency will be included. We will report effect sizes for each study. Although we are not grading evidence (i.e., incorporating all GRADE criteria[22]), we have developed strict inclusion criteria for rigor and quality as outlined above.

We will consider different subgroups of studies in our review, such as design, population, personnel delivering intervention, location of studies, and setting. Although this review is descriptive (no inferential statistical analyses are planned), different tables for each subgroup will be developed. Various subgroups are important to consider separately because differences are anticipated in methodologies depending on each subgroup, for example: design (randomized vs. non-randomized trial), population (those with physical health vs. mental health concerns), personnel delivering the intervention (community health worker vs. other lay personnel), location of studies (low-and middle-income countries vs. high-income countries), and setting (community vs. clinical or clinically-affiliated).

Patient & Public Involvement

Patients/public were not involved in choosing the methods or plans for dissemination of this protocol. However, we will seek feedback on dissemination plans for the forthcoming systematic review from our Community Health Worker Translational Advisory Board.

Ethics and dissemination

This review will analyze data from published studies only, thus it will not require Institutional Board Review. Any important protocol amendments will be documented in the

methods section of the planned systematic review manuscript. Findings will be presented at conferences and published in a peer-reviewed journal.

Discussion

We have developed a protocol for a systematic review focusing on task-shifting that will identify steps in adapting an evidence-based psychological treatment for delivery by lay/non-licensed personnel. Best practice guidelines will be developed and will have potential to provide a useful roadmap using an important dissemination strategy.

Author Contributions:
KEK: literature search, study design, writing, critical revision, referencing; LSK: study design, writing, critical revision; JP: study design, writing, critical revision; LG: study design, writing; CG: search strategy; writing; ER: literature search, writing; EL: writing; critical revision; YJ-E: writing; critical revision; JEA: writing; critical revision; AR: study design; critical revision; JT: study design; critical revision; EF: study design, literature review, writing, critical revision.

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Competing interests statement. The authors have no competing interests to disclose.

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Reporting checklist for protocol of a systematic review.

Based on the PRISMA-P guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

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		Reporting Item	Page Number
Title			
Identification	#1a	Identify the report as a protocol of a systematic review	1
Update	#1b	If the protocol is for an update of a previous systematic review, identify as such	N/A
Registration			
	#2	If registered, provide the name of the registry (such as PROSPERO) and registration number	N/A
Authors			
Contact	#3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1-2
Contribution	#3b	Describe contributions of protocol authors and identify the guarantor of the review	14
Amendments			

	#4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	13
Support			
Sources	#5a	Indicate sources of financial or other support for the review	14
Sponsor	#5b	Provide name for the review funder and / or sponsor	14
Role of sponsor or funder	#5c	Describe roles of funder(s), sponsor(s), and / or institution(s), if any, in developing the protocol	N/A
Introduction			
Rationale	#6	Describe the rationale for the review in the context of what is already known	4-6
Objectives	#7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	6
Methods			
Eligibility criteria	#8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	7-9
Information sources	#9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	9
Search strategy	#10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	9-10
Study records - data management	#11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	10-11
Study records - selection process	#11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	10-11

Study records - data collection process	#11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	10-11
Data items	#12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	10-11
Outcomes and prioritization	#13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	12
Risk of bias in individual studies	#14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	11
Data synthesis	#15a	Describe criteria under which study data will be quantitatively synthesised	12
Data synthesis	#15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I2, Kendall's τ)	N/A
Data synthesis	#15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	N/A
Data synthesis	#15d	If quantitative synthesis is not appropriate, describe the type of summary planned	12
Meta-bias(es)	#16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	11
Confidence in cumulative evidence	#17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	12

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Methodology for task-shifting evidence-based psychological treatments to non-licensed/lay health workers: Protocol for a systematic review

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ABSTRACT

Introduction: "Task-shifting" or "task-sharing" is an effective strategy for delivering behavioral health care in lower-resource communities. However, little is known regarding the actual steps (methods) in carrying out a task-shifting project. This paper presents a protocol for a systematic review that will identify steps in adapting an evidence-based psychological treatment for delivery by lay/non-licensed personnel.

Methods and analysis: A systematic review of peer-reviewed, published studies involving a non-licensed, non-specialist (e.g., community health worker, promotor/a, peer, lay person) delivering an evidence-based psychological treatment for adults will be conducted. Study design of selected articles must include a statistical comparison (e.g., RCTs, quasi-experimental trials, pre-post designs, pragmatic trials). Study selection will follow the Preferred Reporting Items for Systematic Review and Meta-analysis (PRISMA) guidelines. PubMed, the Cochrane Library, Cochrane Central Register of Controlled Trials (CENTRAL), SCOPUS, Cumulative Index to Nursing and Allied Health Literature (CINAHL), APA PsycInfo, and Google Scholar databases will be searched from 2000-2020. A narrative synthesis will be conducted for all included studies and a summary table following Proctor's framework for operationalizing implementation strategies will be included. This protocol was developed following the 2015 guidelines of PRISMA-Protocols.

Ethics and dissemination: This review will analyze data from published studies only, thus it will not require Institutional Board Review. Findings will be presented at conferences, to the broader community via Community Health Worker Translational Advisory Board and social media, and the final systematic review will be published in a peer-reviewed journal.

Key Words: Task-shifting; evidence-based psychological treatment; lay health worker; treatment delivery

Article Summary

Strengths & limitations:

- This protocol describes a planned systematic review to identify best-practices for task-shifting evidence-based psychological treatments to non-licensed/lay health workers
- We will use established operationalized terms to identify and describe implementation strategies
- Studies will be identified via a thorough search strategy using independent data extraction techniques, with risk of bias mitigation strategies
- This protocol adheres to the 17-item checklist, Preferred Reporting Items for Systematic review and Meta-analysis Protocols (PRISMA-P)
- The review will only include studies in English and focuses on non-licensed/lay health workers (e.g., not nurses or teachers), and identifies only studies examining delivery of psychological treatments (i.e., not education or other programming).

INTRODUCTION

Mental health disorders are common worldwide[1] and although there are evidence-based psychological treatments (EBPTs) that improve health outcomes, most of the people who need treatment do not receive it.[2] Mental health treatment is often provided by licensed mental health professionals in specialty settings[3]. These specialty providers may not be available due to workforce shortages, cost of care, and/or access difficulty, especially for lower-income and economically challenged populations[4], who disproportionately suffer from physical and mental health concerns[5 6].

Dissemination and implementation of EBPTs (e.g., cognitive behavioral therapy) to communities in need requires a multidimensional approach with innovative delivery methods.[7] "Task-shifting" or "task-sharing" is one notable strategy that has emerged over the past two decades, largely in low-and middle-income countries, as a method for delivering health care in lower-resource communities. As described by the World Health Organization, with task-shifting, "specific tasks are moved, where appropriate, from highly qualified health workers to health workers with shorter training and fewer qualifications in order to make more efficient use of the available human resources for health."[8]

Task-shifting has great promise in improving access to EBPTs. A recent review of 27 trials in low-and middle-income countries found that task-shifted EBPTs delivered by lay persons in primary care and community settings produced a pooled effect size of 0.49.[9] Findings from this review indicate that EBPTs can be task-shifted and maintain effectiveness, while delivered in nontraditional settings that improve scalability. Lay health workers, such as community health workers or promotor/as, are often trusted members of their communities and perform many important roles, such as delivering physical health care,[10 11] mental health care,[12-

[14] and providing pandemic-related support.[15] [16]Lay health workers help increase access to healthcare in lower-resource areas around the world. Therefore, task-shifting EBPTs to lay personnel or paraprofessionals can help reduce disparities in access to evidence-based mental healthcare, thus improving health equity[8] [17].

Task-shifted psychological treatments

Many different EBPTs have been effectively task-shifted with cultural and contextual adaptations. For example, Patel and colleagues[18] developed a task-shifted treatment program for moderately-severe to severe depression based on Behavioral Activation[19], an established EBPT. Their rigorous randomized controlled trial (RCT) in India showed that the Healthy Activity Program (HAP), delivered by non-specialist lay counselors in primary care, significantly improved patients' levels of depression (moderate effect size) and led to remission in almost two-thirds of patients treated.[18] Likewise, the "Friendship Bench" program by Chibanda and colleagues[20] was a task-shifting study conducted in Zimbabwe to address depression and common mental disorders. Their treatment program was based on Problem Solving Therapy[21], an established EBPT[22], and was delivered by lay health workers in a population with a high prevalence of people living with HIV. Results of their initial non-controlled clinical trial and a later RCT[23] showed that this approach was efficacious in reducing psychological morbidity; a large cluster RCT is now underway.[24] In both the HAP and the Friendship Bench studies, lay health workers were trained and supervised by licensed professional specialists (i.e., clinical psychologists and/or psychiatrists).

While task-shifting is a recognized method for disseminating EBPTs, the best-practice procedural steps for *how* to task-shift are unclear. A recognized problem in implementation research is that strategies are "often inconsistently labeled and poorly described … lack

operational definitions … and are part of 'packaged' approaches whose specific elements are poorly understood" (p.254)[25]. Efforts to scale up EBPTs are critical, yet there is no straightforward roadmap for how to implement task-shifting in new settings. This gap in the literature leaves interested stakeholders without clear guidance in deploying this promising implementation strategy. Therefore, we seek to operationalize such strategies used in task-shifting projects. Our research question is: *What are the best practices in task-shifting an EBPT for delivery by lay/non-licensed personnel, including methods of (a) adapting the treatment for the new delivery context; (b) training lay personnel; (c) implementing the new treatment protocol and maintaining fidelity; and (d) sustaining the task-shifted program over time?*

Objectives

This protocol outlines our specific methods and planned analyses for a systematic review. This paper adheres to the Preferred Reporting Items for Systematic review and Meta-analysis Protocols (PRISMA-P).[26] The systematic review seeks to identify specific task-shifting strategies using established definitions as described by Proctor and colleagues.[25 27] In Proctor's framework for operationalizing implementation strategies, there are 7 dimensions to consider: *The Actor, The Action, Action Target, Temporality, Dose, The Implementation Outcome Affected,* and *The Justification*. Our review will focus on identifying each of these strategies employed in task-shifting studies, operationally defined in Table 1. The most important outcome of this review is to identify best practices for conducting task-shifting implementation projects.

Dimension	***Operational definition for the planned systematic review***
Actors	Those persons delivering the implementation strategy
Actions	The methodology used to (a) adapt the treatment for the new delivery context, (b) train the lay personnel to protocol adherence, (c) implement the new treatment protocol with fidelity, and (d) sustain the new program
Action target	The focus of the task-shifting strategy, including the type of personnel delivering the intervention and the recipients
Temporality	The order/sequence of the action strategies

Dose	The amount or intensity of the actions, and how much those doses differ from standard/non-shifted EBPTs
Implementation outcome affected	Identification of which outcome—acceptability, adoption, appropriateness, feasibility, fidelity, implementation cost, penetration, and/or sustainability—is being targeted by the actions identified
Justification	Theoretical, empirical and/or pragmatic rationale for the strategies used to implement their intervention

Table 1. Dimensions and definitions of task-shifting strategies for the proposed systematic review.

Methods and Analysis

Eligibility criteria

Types of studies

Study Inclusion Criteria: 1. Studies must involve a non-licensed, non-specialist (e.g., community health worker, promotor/a, peer, lay person) who is delivering the intervention; 2. Studies must address a "behavioral health" problem, broadly defined as any psychological/mental health issue (e.g., depression, eating disorders, substance use) and/or physical health concern (e.g., chronic disease management, health behavior change, lifestyle changes, adherence) using behavioral/psychological strategies. 3. The treatment components that have been shifted must be derived from an EBPT that has been found efficacious in at least 1 prior peer-reviewed RCT (e.g., cognitive behavioral therapy, motivational interviewing, behavioral activation, interpersonal psychotherapy). 4. The studies must include a statistical comparison of some kind. The comparator condition must be any of the following: baseline functioning of participants (as in pre-post design); or in an RCT, the control group must be attentional control, a waitlist control, a non-treated group, a treatment-as-usual group, a group receiving a different form of treatment, or a group receiving treatment delivered by an expert provider (e.g., licensed psychologist). Eligible study designs also include RCTs, quasi-experimental trials, pre-post designs, pragmatic trials (e.g., using stepped wedge or cluster RCT designs). 5. Eligible studies must report evidence of effectiveness of the task-shifting strategy

(i.e., clinical outcomes) by using a study design that statistically analyzes outcomes using a comparator/control.

Study Exclusion Criteria: 1. Studies that deliver care solely using a licensed or specialist/non-lay person (e.g., nurse, educator); 2. Studies focused solely on task-shifting a primarily medical task (e.g., HIV treatment, prenatal care); 3. Studies reporting psychological/behavioral treatments that have not been previously proven effective as outlined above, or not involving treatment (e.g., screening only); 4. Patient education studies with no behavioral intervention (e.g., nutritional information only); 5. Studies not involving a comparison; 6. Descriptive studies, case reports, or exclusively qualitative studies; 7. Studies not published in a peer-reviewed journal (e.g., dissertations, poster or paper presentations, newsletter articles); 8. Books and book chapters; 9. Study protocol publications.

Types of participants

Participant Inclusion Criteria: 1. Study participants must have received a psychological/behavioral-based (i.e., non-pharmacological) intervention for a "behavioral health" problem, broadly defined as any psychological/mental health problem (e.g., depression, eating disorder, parent-child behavioral issues, substance use) and/or physical health concern (e.g., chronic disease management, lifestyle changes, adherence); 2. Study participants must have received interventions delivered by non-licensed, non-specialists; 3. Study participants must be adults age 18 years and older.

Participant Exclusion Criteria: 1. Patients treated using pharmacological, surgical, or medical procedures as the primary intervention tested in the study; 2. Participants treated exclusively by licensed health professionals (e.g., physicians, nurses).

Setting and timeframe

Inclusion Criteria for Setting and Timeframe: 1. Task-shifting research studies conducted in high-, low- and middle-income countries; 2. Studies conducted in any setting (e.g., healthcare or community settings) or region (e.g., urban, rural).

Exclusion Criteria for Setting and Timeframe: Studies conducted prior to 2000 (i.e., the approximate time when task-shifting was first reported).

Report characteristics

Information sources

The search strategy will be adapted for each of the following sources/databases: PubMed, the Cochrane Library, Cochrane Central Register of Controlled Trials (CENTRAL), SCOPUS, Cumulative Index to Nursing and Allied Health Literature (CINAHL), APA PsycInfo, and Google Scholar. The search will cover the time frame from January 2000 to July 2020. Peer-reviewed published literature will be sought and posters, dissertations, presentations; descriptive or protocol articles; books and book chapters; studies not published in English will be excluded. Unpublished studies will not be sought. The search will be re-run prior to the final analysis and any further studies identified will be retrieved for inclusion.

Search strategy

The search strategy will be developed and overseen by a medical librarian in consultation with the primary researchers throughout the review (see supplementary files for PubMed search strategy example). Medical Subject Headings and free-text terms relating to lay health workers and the implementation of task-shifting/sharing will be included (see Table 2).

Key Words	***Search Terms***
Task-Shifting	task-shifting; task-sharing; "care sharing"

Lay workers	community health worker; church; community based facilitator; community based organization; health manpower; lay counsellor; lay counselor; lay health worker; non-licensed; nonprofessional; non-specialist; nonspecialists; patient care teams; patient navigator; peer; peer-coach; peer-counsellor; peer-counselor; peer-facilitator; promotor; promotora; promotoras; promotores; self care; self management; shared care; ; traditional healer; unlicensed
EBPTs	psychological; psychological treatment; psychological intervention; empirically-supported psychological treatment; evidence-based psychological treatment; evidence-based behavioral treatment; evidence-based behavioural treatment; mental health; cognitive behavioral therapy; cognitive behavioural therapy; behavioral therapy; behavioural therapy; interpersonal therapy; acceptance and commitment therapy; psychotherapy; motivational interviewing; interpersonal therapy

Table 2. Key word search terms.

Study screening and selection

Using a coding guide and form, two reviewers will independently search titles and abstracts to remove publications not meeting inclusion criteria. Full texts will be retrieved. Multiple reports of the same study will be linked together (collated) per Cochrane guidelines (see Handbook sec 4.6.2)[28] so that the unit of interest is each study, not each article. For example, if a single study was split into separate publications such as a protocol paper, report of the actual study, a qualitative analysis on acceptability, and a follow-up, it will be counted as one study, and each of these articles will be searched for relevant data. We will examine prior reviews on the same topic and employ hand-searching of the reference lists for articles identified in the inclusion stage. We will iteratively refine our search strategy to refine the coding guide and form. We will add indexing terms as needed during the preliminary development of the inclusion article guide.

Data extraction

A data extraction chart has been developed by the team to aid in extracting the specific task-shifting steps from the included articles (see supplementary files for example of study

extraction table). Data extracted will follow established definitions as described by Proctor and colleagues.[25 27] Additional data we anticipate extracting include year of study publication; design; setting; participant demographics; geographic location of study; type of personnel delivering the intervention; demographics of personnel delivering intervention; and reported effect sizes.

Two co-authors will independently conduct data extraction and an additional author will review the data extracted for completion and accuracy. When necessary, consensus will be reached through discussions with an independent fourth author. Missing data will be sought out by contacting study investigators for unreported data and/or additional details. Data will be recorded in an Excel spreadsheet.

Assessing risk of bias

Reviewers will consider risk of bias by assessing scientific rigor used in the study design (e.g., methods of randomization; treatment allocation; control comparator). Two reviewers will independently rate risk of bias and when necessary, disagreements will be resolved by reaching consensus with a third reviewer. Risk of publication bias will be mitigated by searching as extensively as possible using diverse databases, reviewing reference lists and any related systematic reviews.

Data synthesis and analysis

Data synthesis will primarily involve descriptive statistics with tables and graphs to visually communicate findings. Descriptive statistics will be employed to categorize and tally the different types of methodologies used in task-shifting studies, based on standardized language for operationalizing implementation strategies[25], to include *actors, actions, action targets, implementation outcome affected, temporality*, *dose* and *justification*. Frequency counts and

measures of central tendency will be included. We will report effect sizes for each study. Although we are not grading evidence (i.e., incorporating all GRADE criteria[29]), we have developed strict inclusion criteria for rigor and quality as outlined above.

We will consider different subgroups of studies in our review, such as design, population, personnel delivering intervention, location of studies, and setting. Although this review is descriptive (no inferential statistical analyses are planned), different tables for each subgroup will be developed. Various subgroups are important to consider separately because differences are anticipated in methodologies depending on each subgroup, for example: design (randomized vs. non-randomized trial), population (those with physical health vs. mental health concerns), personnel delivering the intervention (community health worker vs. other lay personnel), location of studies (low-and middle-income countries vs. high-income countries), and setting (community vs. clinical or clinically-affiliated).

Patient & Public Involvement

Patients/public were not involved in choosing the methods or plans for dissemination of this protocol. However, we will seek feedback on dissemination plans for the forthcoming systematic review from our Community Health Worker Translational Advisory Board.

Ethics and dissemination

This review will analyze data from published studies only, thus it will not require Institutional Board Review. Any important protocol amendments will be documented in the methods section of the planned systematic review manuscript. Findings will be presented at conferences and published in a peer-reviewed journal.

Author Contributions:
KEK: literature search, study design, writing, critical revision, referencing; LSK: study design, writing, critical revision; JP: study design, writing, critical revision; LG: study design, writing; CG: search strategy; writing; ER: literature search, writing; EL: writing; critical revision; YJ-E: writing; critical revision; JEA: writing; critical revision; AR: study design; critical revision; JT: study design; critical revision; EF: study design, literature review, writing, critical revision.

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Competing interests statement. The authors have no competing interests to disclose.

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Supplemental Material: Example Study Extraction

Study 1 Smith & Garza (2020).	**Design:** RCT **Setting:** Primary care clinic/academic medical center **Participant demographics**: Adults age 18-65, 60% women, 45% Hispanic/Latinx; 25% White non-Hispanic/Latinx, 6% Black, 4% other **Geographic location:** Southwestern US **Effect sizes:** Between group differences: *d*=0.065 (medium), Within-group difference (Active tx): *d*=0.06 (medium)		**ACTORS**	**ACTION TARGET**	**IMPLEMENTATION OUTCOME AFFECTED**	**JUSTIFICATION**
ACTIONS, TEMPORALITY & DOSE	**Adaptations**	**Description:** Modified protocol from 6-week hour-long CBT for depression sessions in clinic to 6 modules of CBT basics delivered in homes by CHWs 1. Three one-hour focus groups 2. Modifications to CBT for depression protocol based on focus group feedback 3. Revisions of handouts and protocol	*Focus groups:* CHWs *Modifications & materials:* Research team	CBT for depression protocol and handouts	-Acceptability -Adoption -Appropriateness	*Focus groups*: Empirical & pragmatic *Modifications & materials:* pragmatic justification
	Training	4. Training developed post-focus group 5. Two half-day workshop trainings 6. Pre-post knowledge tests	Licensed Psychologists taught CHWs	Knowledge & skills of CHWs	-Feasibility	Pragmatic
	Implementation steps	7. Established competency benchmarks 8. Implementation of program 9. Random selection of recordings (20%) for fidelity to competency benchmarks 10. Feedback with weekly supervision	Licensed psychologists listened to recordings/provided supervision to CHWs	Primary care patients CHWs	-Fidelity -Uptake	Theoretical & empirical
	Sustainment	11. System hired supervising psychologist to provide weekly group supervision 12. Funding to sustain provided by clinic department	Administrators supported infrastructure change	Program - CBT for depression delivered in homes by CHWs	-Sustainability & maintenance	Pragmatic

	Search Strategy: PubMed	Results	Key Words
10	#9 NOT (telemedicine OR telehealth OR telepsychiatry)	137	
9	#8 NOT ((qualitative study [ti] OR qualitative studies [ti]) OR ((("Semi-structured" [TIAB] OR semistructured [TIAB] OR unstructured [TIAB] OR informal [TIAB] OR "in-depth" [TIAB] OR indepth [TIAB] OR "face-to-face" [TIAB] OR structured [TIAB] OR guide [TIAB] OR guides [TIAB]) AND (interview* [TIAB] OR discussion* [TIAB] OR questionnaire* [TIAB])) OR ("focus group" [TIAB] OR "focus groups "[TIAB] OR qualitative [TIAB] OR ethnograph* [TIAB] OR fieldwork [TIAB] OR "field work"[TIAB] OR "key informant" [TIAB])) OR "interviews as topic" [Mesh] OR "focus groups" [Mesh] OR narration [Mesh] OR qualitative research [Mesh] OR "personal narratives as topic"[Mesh]))	141	
8	#7 NOT ((case reports [pt] OR comment [pt] OR editorial [pt] OR letter [pt] OR news [pt]))	230	
7	#5 NOT (protocol [ti]) Filters: English, from 2000-2020	239	
6	#5 NOT (protocol [ti])	245	
5	#3 AND #4	268	
4	("psychologic"[All Fields] OR "psychological"[All Fields] OR "psychologically"[All Fields] OR "psychologization"[All Fields] OR "psychologized"[All Fields] OR "psychologizing"[All Fields]) OR (("psychologic"[All Fields] OR "psychological"[All Fields] OR "psychologically"[All Fields] OR "psychologization"[All Fields] OR "psychologized"[All Fields] OR "psychologizing"[All Fields]) AND ("therapeutics"[MeSH Terms] OR "therapeutics"[All Fields] OR "treatments"[All Fields] OR "therapy"[MeSH Subheading] OR "therapy"[All Fields] OR "treatment"[All Fields] OR "treatment s"[All Fields]) OR "psychological treatment"[All Fields]) OR (("psychologic"[All Fields] OR "psychological"[All Fields] OR "psychologically"[All Fields] OR "psychologization"[All Fields] OR "psychologized"[All Fields] OR "psychologizing"[All Fields]) AND ("intervention s"[All Fields] OR "interventions"[All Fields] OR "interventive"[All Fields] OR "methods"[MeSH Terms] OR "methods"[All Fields] OR "intervention"[All Fields] OR "interventional"[All Fields]) OR "psychological intervention") OR "empirically-supported"[All Fields] AND ("psychologic"[All Fields] OR "psychological"[All Fields] OR "psychologically"[All Fields] OR "psychologization"[All Fields] OR "psychologized"[All Fields] OR "psychologizing"[All Fields]) AND ("therapeutics"[MeSH Terms] OR "therapeutics"[All Fields] OR "treatments"[All Fields] OR "therapy"[MeSH Subheading] OR "therapy"[All Fields] OR "treatment"[All Fields] OR "treatment s"[All Fields]) OR "empirically-supported psychological treatment"[All Fields] OR ("evidence-based"[All Fields] AND ("psychologic"[All Fields] OR "psychological"[All Fields] OR "psychologically"[All Fields] OR "psychologization"[All Fields] OR "psychologized"[All Fields] OR "psychologizing"[All Fields]) AND ("therapeutics"[MeSH Terms] OR "therapeutics"[All Fields] OR "treatments"[All Fields] OR "therapy"[MeSH Subheading] OR "therapy"[All Fields] OR "treatment"[All Fields] OR "treatment s"[All Fields]) OR "evidence-based psychological treatment") OR ("evidence-based"[All Fields] AND ("behavior therapy"[MeSH Terms] OR ("behavior"[All Fields] AND "therapy"[All Fields]) OR "behavior therapy"[All Fields] OR ("behavioral"[All Fields] AND "treatment"[All Fields]) OR "behavioral treatment"[All Fields]) OR "evidence-based behavioral treatment") OR ("evidence-based"[All Fields] AND ("behavior therapy"[MeSH Terms] OR ("behavior"[All Fields] AND "therapy"[All Fields]) OR "behavior therapy"[All Fields] OR ("behavioural"[All Fields] AND "treatment"[All Fields]) OR "behavioural treatment"[All Fields]) OR "evidence-based behavioural treatment"[All Fields]) OR ("mental health"[MeSH Terms] OR ("mental"[All Fields] AND "health"[All Fields]) OR "mental health"[All Fields]) OR ("cognitive behavioral therapy"[MeSH Terms] OR ("cognitive"[All Fields] AND "behavioral"[All Fields] AND "therapy"[All Fields]) OR "cognitive behavioral therapy"[All Fields]) OR ("cognitive behavioral therapy"[MeSH Terms] OR ("cognitive"[All Fields] AND "behavioral"[All Fields] AND "therapy"[All Fields]) OR "cognitive behavioral therapy"[All Fields] OR ("cognitive"[All Fields] AND "behavioural"[All Fields] AND "therapy"[All Fields]) OR "cognitive behavioural therapy"[All Fields]) OR ("behavior therapy"[MeSH Terms] OR ("behavior"[All Fields] AND "therapy"[All Fields]) OR "behavior therapy"[All Fields] OR ("behavioral"[All Fields] AND "therapy"[All Fields]) OR "behavioral therapy"[All Fields]) OR ("behavior therapy"[MeSH Terms] OR ("behavior"[All Fields] AND "therapy"[All Fields]) OR "behavior therapy"[All Fields] OR ("behavioural"[All Fields] AND "therapy"[All Fields]) OR "behavioural therapy"[All Fields]) OR (("interpersonal"[All Fields] OR "interpersonality"[All Fields] OR "interpersonally"[All Fields]) AND ("therapeutics"[MeSH Terms] OR "therapeutics"[All Fields] OR "therapies"[All Fields] OR "therapy"[MeSH Subheading] OR "therapy"[All Fields] OR "therapy s"[All Fields] OR "therapys"[All Fields]) OR "interpersonal therapy"[All Fields] OR "interpersonal therapies"[All Fields]) OR ("acceptance and commitment therapy"[MeSH Terms] OR ("acceptance"[All Fields] AND "commitment"[All Fields] AND "therapy"[All Fields]) OR "acceptance and commitment therapy"[All Fields]) OR ("psychotherapie"[All Fields] OR "psychotherapy"[MeSH Terms] OR "psychotherapy"[All Fields] OR "psychotherapies"[All Fields] OR "psychotherapy s"[All Fields]) OR ("motivational interviewing"[MeSH Terms] OR ("motivational"[All Fields] AND "interviewing"[All Fields]) OR "motivational interviewing"[All Fields]) OR	926,979	EBPT

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3	#1 AND #2	1,019	
2	"task sharing"[All Fields] OR "task shifting"[All Fields] OR "care sharing"[All Fields]	1,491	Task-shifting
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Reporting checklist for protocol of a systematic review.

Based on the PRISMA-P guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the PRISMA-Preporting guidelines, and cite them as:

Moher D, Shamseer L, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart LA. Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) 2015 statement. Syst Rev. 2015;4(1):1.

		Reporting Item	Page Number
Title			
Identification	#1a	Identify the report as a protocol of a systematic review	1
Update	#1b	If the protocol is for an update of a previous systematic review, identify as such	N/A
Registration			
	#2	If registered, provide the name of the registry (such as PROSPERO) and registration number	N/A
Authors			
Contact	#3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1-2
Contribution	#3b	Describe contributions of protocol authors and identify the guarantor of the review	14
Amendments			

	#4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	12
Support			
Sources	#5a	Indicate sources of financial or other support for the review	13
Sponsor	#5b	Provide name for the review funder and / or sponsor	13
Role of sponsor or funder	#5c	Describe roles of funder(s), sponsor(s), and / or institution(s), if any, in developing the protocol	N/A
Introduction			
Rationale	#6	Describe the rationale for the review in the context of what is already known	4-6
Objectives	#7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	6
Methods			
Eligibility criteria	#8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	7-9
Information sources	#9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	9
Search strategy	#10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	9-10 & Suppl
Study records - data management	#11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	10-11
Study records - selection process	#11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	10-11

Study records - data collection process	#11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	10-11
Data items	#12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	10-11
Outcomes and prioritization	#13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	11-12
Risk of bias in individual studies	#14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	11
Data synthesis	#15a	Describe criteria under which study data will be quantitatively synthesised	12
Data synthesis	#15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I2, Kendall's τ)	N/A
Data synthesis	#15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	N/A
Data synthesis	#15d	If quantitative synthesis is not appropriate, describe the type of summary planned	12
Meta-bias(es)	#16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	11
Confidence in cumulative evidence	#17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	11-12

BMJ Open

Methodology for task-shifting evidence-based psychological treatments to non-licensed/lay health workers: Protocol for a systematic review

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Primary Subject Heading:	Mental health
Secondary Subject Heading:	Health services research, Public health, Global health, Evidence based practice
Keywords:	MENTAL HEALTH, PUBLIC HEALTH, Organisation of health services < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

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Methodology for task-shifting evidence-based psychological treatments to non-licensed/lay health workers: Protocol for a systematic review

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Word count: 2179

ABSTRACT

Introduction: "Task-shifting" or "task-sharing" is an effective strategy for delivering behavioral health care in lower-resource communities. However, little is known regarding the actual steps (methods) in carrying out a task-shifting project. This paper presents a protocol for a systematic review that will identify steps in adapting an evidence-based psychological treatment for delivery by lay/non-licensed personnel.

Methods and analysis: A systematic review of peer-reviewed, published studies involving a non-licensed, non-specialist (e.g., community health worker, promotor/a, peer, lay person) delivering an evidence-based psychological treatment for adults will be conducted. Study design of selected articles must include a statistical comparison (e.g., randomized controlled trials, quasi-experimental trials, pre-post designs, pragmatic trials). Study selection will follow the Preferred Reporting Items for Systematic Review and Meta-analysis (PRISMA) guidelines. Databases including PubMed, the Cochrane Library, Cochrane Central Register of Controlled Trials (CENTRAL), SCOPUS, Cumulative Index to Nursing and Allied Health Literature (CINAHL), APA PsycInfo, and Google Scholar will be searched from 2000-2020. Risk of bias will be assessed using the Cochrane Collaboration's Risk of Bias (RoB 2) tool, and publication bias will be evaluated with the Cochrane GRADE approach. A narrative synthesis will be conducted for all included studies and a summary table following Proctor's framework for operationalizing implementation strategies will be included. This protocol was developed following the 2015 guidelines of PRISMA-Protocols.

Ethics and dissemination: This review will analyze data from published studies only, thus it will not require Institutional Board Review. Findings will be presented at conferences, to the broader community via the Community Health Worker Translational Advisory Board and social media, and the final systematic review will be published in a peer-reviewed journal.

Key Words: Task-shifting; evidence-based psychological treatment; lay health worker; treatment delivery

Article Summary

Strengths & limitations:

- This protocol describes a planned systematic review to identify best-practices for task-shifting evidence-based psychological treatments to non-licensed/lay health workers
- We will use established operationalized terms to identify and describe implementation strategies
- Studies will be identified via a thorough search strategy using independent data extraction techniques, with risk of bias mitigation strategies
- This protocol adheres to the 17-item checklist, Preferred Reporting Items for Systematic review and Meta-analysis Protocols (PRISMA-P)
- The review will only include studies in English and focuses on non-licensed/lay health workers (e.g., not nurses or teachers), and identifies only studies examining delivery of psychological treatments (i.e., not education or other programming).

INTRODUCTION

Mental health disorders are common worldwide[1] and although there are evidence-based psychological treatments (EBPTs) that improve health outcomes, most of the people who need treatment do not receive it.[2] Mental health treatment is often provided by licensed mental health professionals in specialty settings[3]. These specialty providers may not be available due to workforce shortages, cost of care, and/or access difficulty, especially for lower-income and economically challenged populations[4], who disproportionately suffer from physical and mental health concerns[5 6].

Dissemination and implementation of EBPTs (e.g., cognitive behavioral therapy) to communities in need requires a multidimensional approach with innovative delivery methods.[7] "Task-shifting" or "task-sharing" is one notable strategy that has emerged over the past two decades, largely in low-and middle-income countries, as a method for delivering health care in lower-resource communities. As described by the World Health Organization, with task-shifting, "specific tasks are moved, where appropriate, from highly qualified health workers to health workers with shorter training and fewer qualifications in order to make more efficient use of the available human resources for health."[8]

Task-shifting has great promise in improving access to EBPTs. A recent review of 27 trials in low-and middle-income countries found that task-shifted EBPTs delivered by lay persons in primary care and community settings produced a pooled effect size of 0.49.[9] Findings from this review indicate that EBPTs can be task-shifted and maintain effectiveness, while delivered in nontraditional settings that improve scalability. Lay health workers, such as community health workers or promotor/as, are often trusted members of their communities and perform many important roles, such as delivering physical health care,[10 11] mental health care,[12-

[14] and providing pandemic-related support.[15] [16]Lay health workers help increase access to healthcare in lower-resource areas around the world. Therefore, task-shifting EBPTs to lay personnel or paraprofessionals can help reduce disparities in access to evidence-based mental healthcare, thus improving health equity[8] [17].

Task-shifted psychological treatments

Many different EBPTs have been effectively task-shifted with cultural and contextual adaptations. For example, Patel and colleagues[18] developed a task-shifted treatment program for moderately-severe to severe depression based on Behavioral Activation[19], an established EBPT. Their rigorous randomized controlled trial (RCT) in India showed that the Healthy Activity Program (HAP), delivered by non-specialist lay counselors in primary care, significantly improved patients' levels of depression (moderate effect size) and led to remission in almost two-thirds of patients treated.[18] Likewise, the "Friendship Bench" program by Chibanda and colleagues[20] was a task-shifting study conducted in Zimbabwe to address depression and common mental disorders. Their treatment program was based on Problem Solving Therapy[21], an established EBPT[22], and was delivered by lay health workers in a population with a high prevalence of people living with HIV. Results of their initial non-controlled clinical trial and a later RCT[23] showed that this approach was efficacious in reducing psychological morbidity; a large cluster RCT is now underway.[24] In both the HAP and the Friendship Bench studies, lay health workers were trained and supervised by licensed professional specialists (i.e., clinical psychologists and/or psychiatrists).

While task-shifting is a recognized method for disseminating EBPTs, the best-practice procedural steps for *how* to task-shift are unclear. A recognized problem in implementation research is that strategies are "often inconsistently labeled and poorly described … lack

operational definitions … and are part of 'packaged' approaches whose specific elements are poorly understood" (p.254)[25]. Efforts to scale up EBPTs are critical, yet there is no straightforward roadmap for how to implement task-shifting in new settings. This gap in the literature leaves interested stakeholders without clear guidance in deploying this promising implementation strategy. Therefore, we seek to operationalize such strategies used in task-shifting projects. Our research question is: *What are the best practices in task-shifting an EBPT for delivery by lay/non-licensed personnel, including methods of (a) adapting the treatment for the new delivery context; (b) training lay personnel; (c) implementing the new treatment protocol and maintaining fidelity; and (d) sustaining the task-shifted program over time?*

Objectives

This protocol outlines our specific methods and planned analyses for a systematic review. This paper adheres to the Preferred Reporting Items for Systematic review and Meta-analysis Protocols (PRISMA-P).[26] The systematic review seeks to identify specific task-shifting strategies using established definitions as described by Proctor and colleagues.[25 27] In Proctor's framework for operationalizing implementation strategies, there are 7 dimensions to consider: *The Actor, The Action, Action Target, Temporality, Dose, The Implementation Outcome Affected,* and *The Justification*. Our review will focus on identifying each of these strategies employed in task-shifting studies, operationally defined in Table 1. The most important outcome of this review is to identify best practices for conducting task-shifting implementation projects.

Dimension	***Operational definition for the planned systematic review***
Actors	Those persons delivering the implementation strategy
Actions	The methodology used to (a) adapt the treatment for the new delivery context, (b) train the lay personnel to protocol adherence, (c) implement the new treatment protocol with fidelity, and (d) sustain the new program
Action target	The focus of the task-shifting strategy, including the type of personnel delivering the intervention and the recipients
Temporality	The order/sequence of the action strategies

Dose	The amount or intensity of the actions, and how much those doses differ from standard/non-shifted EBPTs
Implementation outcome affected	Identification of which outcome—acceptability, adoption, appropriateness, feasibility, fidelity, implementation cost, penetration, and/or sustainability—is being targeted by the actions identified
Justification	Theoretical, empirical and/or pragmatic rationale for the strategies used to implement their intervention

Table 1. Dimensions and definitions of task-shifting strategies for the proposed systematic review.

Methods and Analysis

Eligibility criteria

Types of studies

Study Inclusion Criteria: 1. Studies must involve a non-licensed, non-specialist (e.g., community health worker, promotor/a, peer, lay person) who is delivering the intervention; 2. Studies must address a "behavioral health" problem, broadly defined as any psychological/mental health issue (e.g., depression, eating disorders, substance use) and/or physical health concern (e.g., chronic disease management, health behavior change, lifestyle changes, adherence) using behavioral/psychological strategies. 3. The treatment components that have been shifted must be derived from an EBPT that has been found efficacious in at least 1 prior peer-reviewed RCT (e.g., cognitive behavioral therapy, motivational interviewing, behavioral activation, interpersonal psychotherapy). 4. The studies must include a statistical comparison of some kind. The comparator condition must be any of the following: baseline functioning of participants (as in pre-post design); or in an RCT, the control group must be attentional control, a waitlist control, a non-treated group, a treatment-as-usual group, a group receiving a different form of treatment, or a group receiving treatment delivered by an expert provider (e.g., licensed psychologist). Eligible study designs also include RCTs, quasi-experimental trials, pre-post designs, pragmatic trials (e.g., using stepped wedge or cluster RCT designs). 5. Eligible studies must report evidence of effectiveness of the task-shifting strategy

(i.e., clinical outcomes) by using a study design that statistically analyzes outcomes using a comparator/control.

Study Exclusion Criteria: 1. Studies that deliver care solely using a licensed or specialist/non-lay person (e.g., nurse, educator); 2. Studies focused solely on task-shifting a primarily medical task (e.g., HIV treatment, prenatal care); 3. Studies reporting psychological/behavioral treatments that have not been previously proven effective as outlined above, or not involving treatment (e.g., screening only); 4. Patient education studies with no behavioral intervention (e.g., nutritional information only); 5. Studies not involving a comparison; 6. Descriptive studies, case reports, or exclusively qualitative studies; 7. Studies not published in a peer-reviewed journal (e.g., dissertations, poster or paper presentations, newsletter articles); 8. Books and book chapters; 9. Study protocol publications.

Types of participants

Participant Inclusion Criteria: 1. Study participants must have received a psychological/behavioral-based (i.e., non-pharmacological) intervention for a "behavioral health" problem, broadly defined as any psychological/mental health problem (e.g., depression, eating disorder, parent-child behavioral issues, substance use) and/or physical health concern (e.g., chronic disease management, lifestyle changes, adherence); 2. Study participants must have received interventions delivered by non-licensed, non-specialists; 3. Study participants must be adults age 18 years and older.

Participant Exclusion Criteria: 1. Patients treated using pharmacological, surgical, or medical procedures as the primary intervention tested in the study; 2. Participants treated exclusively by licensed health professionals (e.g., physicians, nurses).

Setting and timeframe

Inclusion Criteria for Setting and Timeframe: 1. Task-shifting research studies conducted in high-, low- and middle-income countries; 2. Studies conducted in any setting (e.g., healthcare or community settings) or region (e.g., urban, rural).

Exclusion Criteria for Setting and Timeframe: Studies conducted prior to 2000 (i.e., the approximate time when task-shifting was first reported).

Report characteristics

Information sources

The search strategy will be adapted for each of the following sources/databases: PubMed, the Cochrane Library, Cochrane Central Register of Controlled Trials (CENTRAL), SCOPUS, Cumulative Index to Nursing and Allied Health Literature (CINAHL), APA PsycInfo, and Google Scholar. The search will cover the time frame from January 2000 to July 2020. Peer-reviewed published literature will be sought and posters, dissertations, presentations; descriptive or protocol articles; books and book chapters; studies not published in English will be excluded. Unpublished studies will not be sought. The search will be re-run prior to the final analysis and any further studies identified will be retrieved for inclusion.

Search strategy

The search strategy will be developed and overseen by a medical librarian in consultation with the primary researchers throughout the review (see supplementary files for PubMed search strategy example). Medical Subject Headings and free-text terms relating to lay health workers and the implementation of task-shifting/sharing will be included (see Table 2).

Key Words	***Search Terms***
Task-Shifting	task-shifting; task-sharing; "care sharing"

Lay workers	community health worker; church; community based facilitator; community based organization; health manpower; lay counsellor; lay counselor; lay health worker; non-licensed; nonprofessional; non-specialist; nonspecialists; patient care teams; patient navigator; peer; peer-coach; peer-counsellor; peer-counselor; peer-facilitator; promotor; promotora; promotoras; promotores; self care; self management; shared care; ; traditional healer; unlicensed
EBPTs	psychological; psychological treatment; psychological intervention; empirically-supported psychological treatment; evidence-based psychological treatment; evidence-based behavioral treatment; evidence-based behavioural treatment; mental health; cognitive behavioral therapy; cognitive behavioural therapy; behavioral therapy; behavioural therapy; interpersonal therapy; acceptance and commitment therapy; psychotherapy; motivational interviewing; interpersonal therapy

Table 2. Key word search terms.

Study screening and selection

Using a coding guide and form, two reviewers will independently search titles and abstracts to remove publications not meeting inclusion criteria. Full texts will be retrieved. Multiple reports of the same study will be linked together (collated) per Cochrane guidelines (see Handbook sec 4.6.2)[28] so that the unit of interest is each study, not each article. For example, if a single study was split into separate publications such as a protocol paper, report of the actual study, a qualitative analysis on acceptability, and a follow-up, it will be counted as one study, and each of these articles will be searched for relevant data. We will examine prior reviews on the same topic and employ hand-searching of the reference lists for articles identified in the inclusion stage. We will iteratively refine our search strategy to refine the coding guide and form. We will add indexing terms as needed during the preliminary development of the inclusion article guide.

Data extraction

A data extraction chart has been developed by the team to aid in extracting the specific task-shifting steps from the included articles (see supplementary files for example of study

extraction table). Data extracted will follow established definitions as described by Proctor and colleagues.[25 27] Additional data we anticipate extracting include year of study publication; design; setting; participant demographics; geographic location of study; type of personnel delivering the intervention; demographics of personnel delivering intervention; and reported effect sizes.

Two co-authors will independently conduct data extraction and an additional author will review the data extracted for completion and accuracy. When necessary, consensus will be reached through discussions with an independent fourth author. Missing data will be sought out by contacting study investigators for unreported data and/or additional details. Data will be recorded in an Excel spreadsheet.

Assessing risk of bias

Reviewers will consider the quality of studies and risk of bias using the Cochrane Collaboration's Risk of Bias (RoB 2) tool,[29] incorporating considerations for evaluating psychotherapy outcome research.[30] Although the RoB 2 is focused on RCTs, it is applicable to other types of study designs (e.g., quasi-experimental, pre-post).[29] All domains will be assessed, including bias related to the randomization process, deviations from intended interventions, missing outcome data, measurement of the outcome, selection of reported result, and overall bias. Two authors will review and independently rate risk of bias in each domain as "low risk of bias," "some concerns," or "high risk of bias." When necessary, disagreements will be resolved by reaching consensus with a third reviewer.

Using the same procedures, we will evaluate publication bias by using the relevant section of the Cochrane GRADE tool[31], and also mitigate publication bias by searching as extensively as possible using diverse databases, reviewing reference lists and any related systematic reviews.

While many systematic reviews grade evidence of a particular treatment, the purpose of this review is to identify specific methods; therefore, we are restricting our search to published literature only.

Data synthesis and analysis

Data synthesis will primarily involve descriptive statistics with tables and graphs to visually communicate findings. Descriptive statistics will be employed to categorize and tally the different types of methodologies used in task-shifting studies, based on standardized language for operationalizing implementation strategies[25], to include *actors, actions, action targets, implementation outcome affected, temporality*, *dose* and *justification*. Frequency counts and measures of central tendency will be included. We will report effect sizes for each study. Although we are not grading evidence (i.e., incorporating all GRADE criteria[32]), we have developed strict inclusion criteria for rigor and quality as outlined above.

We will consider different subgroups of studies in our review, such as design, population, personnel delivering intervention, location of studies, and setting. Although this review is descriptive (no inferential statistical analyses are planned), different tables for each subgroup will be developed. Various subgroups are important to consider separately because differences are anticipated in methodologies depending on each subgroup, for example: design (randomized vs. non-randomized trial), population (those with physical health vs. mental health concerns), personnel delivering the intervention (community health worker vs. other lay personnel), location of studies (low-and middle-income countries vs. high-income countries), and setting (community vs. clinical or clinically-affiliated).

Patient & Public Involvement

Patients/public were not involved in choosing the methods or plans for dissemination of this protocol. However, we will seek feedback on dissemination plans for the forthcoming systematic review from our Community Health Worker Translational Advisory Board.

Ethics and dissemination

This review will analyze data from published studies only, thus it will not require Institutional Board Review. Any important protocol amendments will be documented in the methods section of the planned systematic review manuscript. Findings will be presented at conferences and published in a peer-reviewed journal.

Author Contributions:
KEK: literature search, study design, writing, critical revision, referencing; LSK: study design, writing, critical revision; JP: study design, writing, critical revision; LG: study design, writing; CG: search strategy; writing; ER: literature search, writing; EL: writing; critical revision; YJ-E: writing; critical revision; JEA: writing; critical revision; AR: study design; critical revision; JT: study design; critical revision; EF: study design, literature review, writing, critical revision.

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Competing interests statement. The authors have no competing interests to disclose.

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Supplemental Material: Example Study Extraction

Study 1 Smith & Garza (2020).	**Design:** RCT **Setting:** Primary care clinic/academic medical center **Participant demographics**: Adults age 18-65, 60% women, 45% Hispanic/Latinx; 25% White non-Hispanic/Latinx, 6% Black, 4% other **Geographic location:** Southwestern US **Effect sizes:** Between group differences: *d*=0.065 (medium), Within-group difference (Active tx): *d*=0.06 (medium)		**ACTORS**	**ACTION TARGET**	**IMPLEMENTATION OUTCOME AFFECTED**	**JUSTIFICATION**
ACTIONS, TEMPORALITY & DOSE	**Adaptations**	**Description:** Modified protocol from 6-week hour-long CBT for depression sessions in clinic to 6 modules of CBT basics delivered in homes by CHWs 1. Three one-hour focus groups 2. Modifications to CBT for depression protocol based on focus group feedback 3. Revisions of handouts and protocol	*Focus groups:* CHWs *Modifications & materials:* Research team	CBT for depression protocol and handouts	-Acceptability -Adoption -Appropriateness	*Focus groups*: Empirical & pragmatic *Modifications & materials:* pragmatic justification
	Training	4. Training developed post-focus group 5. Two half-day workshop trainings 6. Pre-post knowledge tests	Licensed Psychologists taught CHWs	Knowledge & skills of CHWs	-Feasibility	Pragmatic
	Implementation steps	7. Established competency benchmarks 8. Implementation of program 9. Random selection of recordings (20%) for fidelity to competency benchmarks 10. Feedback with weekly supervision	Licensed psychologists listened to recordings/provided supervision to CHWs	Primary care patients CHWs	-Fidelity -Uptake	Theoretical & empirical
	Sustainment	11. System hired supervising psychologist to provide weekly group supervision 12. Funding to sustain provided by clinic department	Administrators supported infrastructure change	Program - CBT for depression delivered in homes by CHWs	-Sustainability & maintenance	Pragmatic

	Search Strategy: PubMed	Results	Key Words
10	#9 NOT (telemedicine OR telehealth OR telepsychiatry)	137	
9	#8 NOT ((qualitative study [ti] OR qualitative studies [ti]) OR ((((("Semi-structured" [TIAB] OR semistructured [TIAB] OR unstructured [TIAB] OR informal [TIAB] OR "in-depth" [TIAB] OR indepth [TIAB] OR "face-to-face" [TIAB] OR structured [TIAB] OR guide [TIAB] OR guides [TIAB]) AND (interview* [TIAB] OR discussion* [TIAB] OR questionnaire* [TIAB])) OR ("focus group" [TIAB] OR "focus groups "[TIAB] OR qualitative [TIAB] OR ethnograph* [TIAB] OR fieldwork [TIAB] OR "field work"[TIAB] OR "key informant" [TIAB])) OR "interviews as topic" [Mesh] OR "focus groups" [Mesh] OR narration [Mesh] OR qualitative research [Mesh] OR "personal narratives as topic"[Mesh]))))	141	
8	#7 NOT ((case reports [pt] OR comment [pt] OR editorial [pt] OR letter [pt] OR news [pt]))	230	
7	#5 NOT (protocol [ti]) Filters: English, from 2000-2020	239	
6	#5 NOT (protocol [ti])	245	
5	#3 AND #4	268	
4	("psychologic"[All Fields] OR "psychological"[All Fields] OR "psychologically"[All Fields] OR "psychologization"[All Fields] OR "psychologized"[All Fields] OR "psychologizing"[All Fields]) OR (("psychologic"[All Fields] OR "psychological"[All Fields] OR "psychologically"[All Fields] OR "psychologization"[All Fields] OR "psychologized"[All Fields] OR "psychologizing"[All Fields]) AND ("therapeutics"[MeSH Terms] OR "therapeutics"[All Fields] OR "treatments"[All Fields] OR "therapy"[MeSH Subheading] OR "therapy"[All Fields] OR "treatment"[All Fields] OR "treatment s"[All Fields]) OR "psychological treatment"[All Fields]) OR (("psychologic"[All Fields] OR "psychological"[All Fields] OR "psychologically"[All Fields] OR "psychologization"[All Fields] OR "psychologized"[All Fields] OR "psychologizing"[All Fields]) AND ("intervention s"[All Fields] OR "interventions"[All Fields] OR "interventive"[All Fields] OR "methods"[MeSH Terms] OR "methods"[All Fields] OR "intervention"[All Fields] OR "interventional"[All Fields]) OR "psychological intervention") OR "empirically-supported"[All Fields] AND ("psychologic"[All Fields] OR "psychological"[All Fields] OR "psychologically"[All Fields] OR "psychologization"[All Fields] OR "psychologized"[All Fields] OR "psychologizing"[All Fields]) AND ("therapeutics"[MeSH Terms] OR "therapeutics"[All Fields] OR "treatments"[All Fields] OR "therapy"[MeSH Subheading] OR "therapy"[All Fields] OR "treatment"[All Fields] OR "treatment s"[All Fields]) OR "empirically-supported psychological treatment"[All Fields] OR ("evidence-based"[All Fields] AND ("psychologic"[All Fields] OR "psychological"[All Fields] OR "psychologically"[All Fields] OR "psychologization"[All Fields] OR "psychologized"[All Fields] OR "psychologizing"[All Fields]) AND ("therapeutics"[MeSH Terms] OR "therapeutics"[All Fields] OR "treatments"[All Fields] OR "therapy"[MeSH Subheading] OR "therapy"[All Fields] OR "treatment"[All Fields] OR "treatment s"[All Fields]) OR "evidence-based psychological treatment") OR ("evidence-based"[All Fields] AND ("behavior therapy"[MeSH Terms] OR ("behavior"[All Fields] AND "therapy"[All Fields]) OR "behavior therapy"[All Fields] OR ("behavioral"[All Fields] AND "treatment"[All Fields]) OR "behavioral treatment"[All Fields]) OR "evidence-based behavioral treatment") OR ("evidence-based"[All Fields] AND ("behavior therapy"[MeSH Terms] OR ("behavior"[All Fields] AND "therapy"[All Fields]) OR "behavior therapy"[All Fields] OR ("behavioural"[All Fields] AND "treatment"[All Fields]) OR "behavioural treatment"[All Fields]) OR "evidence-based behavioural treatment"[All Fields]) OR ("mental health"[MeSH Terms] OR ("mental"[All Fields] AND "health"[All Fields]) OR "mental health"[All Fields]) OR ("cognitive behavioral therapy"[MeSH Terms] OR ("cognitive"[All Fields] AND "behavioral"[All Fields] AND "therapy"[All Fields]) OR "cognitive behavioral therapy"[All Fields]) OR ("cognitive behavioral therapy"[MeSH Terms] OR ("cognitive"[All Fields] AND "behavioral"[All Fields] AND "therapy"[All Fields]) OR "cognitive behavioral therapy"[All Fields] OR ("cognitive"[All Fields] AND "behavioural"[All Fields] AND "therapy"[All Fields]) OR "cognitive behavioural therapy"[All Fields]) OR ("behavior therapy"[MeSH Terms] OR ("behavior"[All Fields] AND "therapy"[All Fields]) OR "behavior therapy"[All Fields] OR ("behavioral"[All Fields] AND "therapy"[All Fields]) OR "behavioral therapy"[All Fields]) OR ("behavior therapy"[MeSH Terms] OR ("behavior"[All Fields] AND "therapy"[All Fields]) OR "behavior therapy"[All Fields] OR ("behavioural"[All Fields] AND "therapy"[All Fields]) OR "behavioural therapy"[All Fields]) OR (("interpersonal"[All Fields] OR "interpersonality"[All Fields] OR "interpersonally"[All Fields]) AND ("therapeutics"[MeSH Terms] OR "therapeutics"[All Fields] OR "therapies"[All Fields] OR "therapy"[MeSH Subheading] OR "therapy"[All Fields] OR "therapy s"[All Fields] OR "therapys"[All Fields]) OR "interpersonal therapy"[All Fields] OR "interpersonal therapies"[All Fields]) OR ("acceptance and commitment therapy"[MeSH Terms] OR ("acceptance"[All Fields] AND "commitment"[All Fields] AND "therapy"[All Fields]) OR "acceptance and commitment therapy"[All Fields]) OR ("psychotherapie"[All Fields] OR "psychotherapy"[MeSH Terms] OR "psychotherapy"[All Fields] OR "psychotherapies"[All Fields] OR "psychotherapy s"[All Fields]) OR ("motivational interviewing"[MeSH Terms] OR ("motivational"[All Fields] AND "interviewing"[All Fields]) OR "motivational interviewing"[All Fields]) OR	926,979	EBPT

	(("interpersonal"[All Fields] OR "interpersonality"[All Fields] OR "interpersonally"[All Fields]) AND ("therapeutics"[MeSH Terms] OR "therapeutics"[All Fields] OR "therapies"[All Fields] OR "therapy"[MeSH Subheading] OR "therapy"[All Fields] OR "therapy s"[All Fields] OR "therapys"[All Fields]))		
3	#1 AND #2	1,019	
2	"task sharing"[All Fields] OR "task shifting"[All Fields] OR "care sharing"[All Fields]	1,491	Task-shifting
1	(("community health workers"[MeSH Terms] OR ("community"[All Fields] AND "health"[All Fields] AND "workers"[All Fields]) OR "community health workers"[All Fields] OR ("community"[All Fields] AND "health"[All Fields] AND "worker"[All Fields]) or "community health worker"[All Fields])) OR ((("church"[All Fields] OR "church s"[All Fields] OR "churches"[All Fields])) OR ((("community"[All Fields]) AND ("facilitate"[All Fields] OR "facilitated"[All Fields] OR "facilitates"[All Fields] OR "facilitating"[All Fields] OR "facilitation"[All Fields] OR "facilitations"[All Fields] OR "facilitative"[All Fields] OR "facilitator"[All Fields] OR "facilitator s"[All Fields] OR "facilitators"[All Fields])) OR "community based facilitator"[All Fields]) OR ((("community"[All Fields]) AND ("organisation"[All Fields] OR "organization and administration"[MeSH Subheading] OR ("organization"[All Fields])) OR "community based organization" [All Fields]) OR ("health workforce"[MeSH Terms] OR ("health"[All Fields] AND "workforce"[All Fields]) OR "health workforce"[All Fields] OR ("health"[All Fields] AND "manpower"[All Fields]) OR "health manpower"[All Fields]) OR ("lay"[All Fields] AND ("counsellor"[All Fields] OR "counselors"[MeSH Terms] OR "counselors"[All Fields] OR "counselor"[All Fields] OR "counseling"[MeSH Terms] OR "counseling"[All Fields] OR "counsellor s"[All Fields] OR "counsellors"[All Fields] OR "counselor s"[All Fields]) OR "lay counselor" [All Fields] OR "lay counsellor"[All Fields]) OR ("lay"[All Fields] AND ("health"[MeSH Terms] OR "health"[All Fields] OR "health s"[All Fields]) AND ("occupational groups"[MeSH Terms] OR ("occupational"[All Fields] AND "groups"[All Fields]) OR "occupational groups"[All Fields] OR "worker"[All Fields] OR "workers"[All Fields] OR "worker s"[All Fields]) OR "lay health worker" [All Fields]) OR ("non"[All Fields] AND ("licence"[All Fields] OR "licensure"[MeSH Terms] OR "licensure"[All Fields] OR "license"[All Fields] OR "licenced"[All Fields] OR "licences"[All Fields] OR "licencing"[All Fields] OR "licensed"[All Fields] OR "licenses"[All Fields] OR "licensing"[All Fields]) OR "non-licensed"[All Fields] OR "nonlicensed" [All Fields] OR "non-licenced" [All Fields] OR "nonlicenced" [All Fields]) OR ("nonprofessional"[All Fields] OR "nonprofessionals"[All Fields]) OR ("non-specialist" [All Fields] OR "non-specialists" [All Fields] OR "nonspecialist" [All Fields] OR "nonspecialists" [All Fields]) OR ("patient care team"[MeSH Terms] OR ("patient"[All Fields] AND "care"[All Fields] AND "team"[All Fields]) OR "patient care team"[All Fields] OR ("patient"[All Fields] AND "care"[All Fields] AND "teams"[All Fields]) OR "patient care teams"[All Fields]) OR ("patient navigation"[MeSH Terms] OR ("patient"[All Fields] AND "navigation"[All Fields]) OR "patient navigation"[All Fields] OR ("patient"[All Fields] AND "navigator"[All Fields]) OR "patient navigator"[All Fields]) OR ("peer" [all fields]) OR ("peer-coach" [all fields]) OR ("peer-counselor"[All Fields]) OR ("peer-counsellor"[All Fields]) OR ("peer-facilitator"[All Fields]) OR ("promotor"[All Fields] OR "promotors"[All Fields]) OR ("promotora"[All Fields] OR "promotoras"[All Fields]) OR ("promotores"[All Fields]) OR ("self care"[MeSH Terms] OR ("self"[All Fields] AND "care"[All Fields]) OR "self care"[All Fields]) OR ("self management"[MeSH Terms] OR "self management"[All Fields] OR ("self"[All Fields] AND "management"[All Fields]) OR "self management"[All Fields]) OR (("share"[All Fields] OR "shared"[All Fields] OR "shares"[All Fields] OR "sharing"[All Fields] OR "sharings"[All Fields]) AND "care"[All Fields] OR "shared care" [All Fields]) OR (("tradition"[All Fields] OR "tradition s"[All Fields] OR "traditional"[All Fields] OR "traditionals"[All Fields] OR "traditions"[All Fields]) AND ("healer"[All Fields] OR "healer s"[All Fields] OR "healers"[All Fields]) OR "traditional healer"[All Fields]) OR ("unlicensed"[All Fields]) OR ("nonphysician"[All Fields] OR "nonphysicians"[All Fields]) OR (("physician"[All Fields] AND "extender"[All Fields]) OR "physician extender"[All Fields]) OR ("CHW"[all fields])	767,391	Lay worker

Reporting checklist for protocol of a systematic review.

Based on the PRISMA-P guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the PRISMA-Preporting guidelines, and cite them as:

Moher D, Shamseer L, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart LA. Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) 2015 statement. Syst Rev. 2015;4(1):1.

		Reporting Item	Page Number
Title			
Identification	#1a	Identify the report as a protocol of a systematic review	1
Update	#1b	If the protocol is for an update of a previous systematic review, identify as such	N/A
Registration			
	#2	If registered, provide the name of the registry (such as PROSPERO) and registration number	N/A
Authors			
Contact	#3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1-2
Contribution	#3b	Describe contributions of protocol authors and identify the guarantor of the review	14
Amendments			

	#4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	12
Support			
Sources	#5a	Indicate sources of financial or other support for the review	13
Sponsor	#5b	Provide name for the review funder and / or sponsor	13
Role of sponsor or funder	#5c	Describe roles of funder(s), sponsor(s), and / or institution(s), if any, in developing the protocol	N/A
Introduction			
Rationale	#6	Describe the rationale for the review in the context of what is already known	4-6
Objectives	#7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	6
Methods			
Eligibility criteria	#8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	7-9
Information sources	#9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	9
Search strategy	#10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	9-10 & Suppl
Study records - data management	#11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	10-11
Study records - selection process	#11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	10-11

Study records - data collection process	#11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	10-11
Data items	#12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	10-11
Outcomes and prioritization	#13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	11-12
Risk of bias in individual studies	#14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	11
Data synthesis	#15a	Describe criteria under which study data will be quantitatively synthesised	12
Data synthesis	#15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I2, Kendall's τ)	N/A
Data synthesis	#15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	N/A
Data synthesis	#15d	If quantitative synthesis is not appropriate, describe the type of summary planned	12
Meta-bias(es)	#16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	12
Confidence in cumulative evidence	#17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	11-12