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Theory of change for the delivery of talking therapies by lay workers to survivors of humanitarian crises in low-income and middle-income countries: protocol of a systematic review

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ABSTRACT

Introduction  There is a severe shortage of specialist mental healthcare providers in low-income and middle-income countries (LMICs) affected by humanitarian crises. In these settings, talking therapies may be delivered by non-specialists, including lay workers with no tertiary education or formal certification in mental health. This systematic review will synthesise the literature on the implementation and effectiveness of talking therapies delivered by lay workers in LMICs affected by humanitarian crises, in order to develop a Theory of Change (ToC).

Methods and analysis  Qualitative, quantitative and mixed-methods studies assessing the implementation or effectiveness of lay-delivered talking therapies for common mental disorders provided to adult survivors of humanitarian crises in LMICs will be eligible for inclusion. Studies set in high-income countries will be excluded. No restrictions will be applied to language or year of publication. Unpublished studies will be excluded. Seven electronic databases will be searched: MEDLINE, Embase, PsycINFO, PsycEXTRA, Cochrane Library, ClinicalTrials.gov. Contents pages of three peer-reviewed journals will be hand-searched. Sources of grey literature will include resource directories of two online mental health networks (MHPSS.net and MHIinnovation.net) and expert consultation. Forward and backward citation searches of included studies will be performed. Two reviewers will independently screen studies for inclusion, extract data and assess study quality. A narrative synthesis will be conducted, following established guidelines. A ToC map will be amended iteratively to take into account the review results and guide the synthesis.

Ethics and dissemination  Findings will be presented in a manuscript for publication in a peer-reviewed journal and disseminated through a coordinated communications strategy targeting knowledge generators, enablers and users. PROSPERO registration number  CRD42017058287.

INTRODUCTION

Background
Mental health and humanitarian crises

A humanitarian crisis is a natural or man-made disaster characterised by ‘a serious disruption of the functioning of a community or a society causing widespread human, material, economic or environmental losses which exceed the ability of the affected community or society to cope using its own resources, necessitating a request to national or international level for external assistance’.1 The number of people affected by humanitarian crises has nearly doubled in the past decade.2 As of 2017, almost 129 million people are in need of humanitarian assistance.3 By 2030, the share of the global poor living in fragile and conflict-affected situations is estimated to reach 46%.4 The mental health consequences of humanitarian crises, compounded by the cyclical relationship between poverty and mental illness,5 are pressing challenges in low-income and middle-income countries (LMICs), where the mental health workforce shortage already exceeds 230000 workers.6 In a multisite study of LMIC populations affected by armed conflict, the prevalence of common mental disorders (CMDs), excluding alcohol and substance use disorders, ranged from 23.6% (Ethiopia) to 60.5% (Algeria).7 A global meta-analysis of surveys carried out in postconflict populations estimated rates...
of 15%–20% for depression and post-traumatic stress disorder (PTSD) alone, mirroring projections from other crises.\(^8\) While the evidence from LMICs is weak, the WHO recognises that both the prevalence and risks associated with drug and alcohol use may also be elevated in humanitarian settings.\(^10\)

The mental healthcare needs of survivors of humanitarian crises are significant, yet specialist care in LMICs is often weakest in the aftermath of a crisis.\(^12\) For example, Liberia and Sierra Leone—two West African countries which have both experienced years of protracted violence and a recent Ebola outbreak—each has just one trained psychiatrist currently practising.\(^13\) Researchers and policy makers are therefore responding to the escalating number of humanitarian crises in LMICs by developing and testing non-specialist mental health interventions in order to produce evidence-based guidelines.\(^11\)\(^15\)–\(^18\)

### Lay-delivered talking therapies

Talking therapies are psychological interventions that are delivered primarily through dialogue between a provider and an individual recipient or group of recipients.\(^19\) Several meta-analyses have shown that talking therapies can be effective for the treatment of CMDs in populations affected by humanitarian crises,\(^20\)\(^21\)\(^22\)\(^23\)\(^24\) including survivors of torture and mass violence.\(^22\)\(^24\) Consequently, talking therapies are recommended in much of the normative guidance on mental health and psychosocial support (MHPSS), such as the Inter-Agency Standing Committee (IASC) guidelines on MHPSS in emergencies and the Sphere Handbook.\(^15\)\(^16\)

There is also a growing body of evidence indicating that talking therapies can be delivered effectively by non-specialist mental healthcare providers in LMICs.\(^25\)–\(^30\) However, less is known about the delivery of talking therapies by lay workers, a subset of non-specialists with no tertiary education or formal professional or paraprofessional certification in mental health.\(^31\) This is a challenge in humanitarian settings, where even non-specialist health professionals such as nurses and general practitioners are often spread thin. In 2014, the WHO called for partnerships with governmental and non-governmental organisations to develop and test scalable psychological interventions, including lay-delivered talking therapies, in communities affected by adversity.\(^18\) As a result of this initiative, Problem Management Plus has since been manualised and trialled in Kenya using community health workers with high school diplomas.\(^17\)\(^32\)

### Rationale

While new research into scalable psychological interventions is expected to contribute significantly to the evidence base for lay-delivered talking therapies in LMICs, there is still a need to take stock of the existing literature. Several recent systematic reviews of psychological interventions for survivors of humanitarian crises are limited to controlled trials,\(^20\)\(^23\)\(^24\)\(^33\) although others do include uncontrolled studies and,\(^34\)\(^35\)\(^37\) in some cases, qualitative or mixed-methods studies as well.\(^21\)\(^22\)\(^38\)–\(^42\) Many of these reviews have identified examples where talking therapies are delivered by non-specialists who could be classified as lay workers; however, few differentiate between lay workers and other non-specialists, despite lay workers’ comparatively low level of qualification.

The psychological interventions included in recent reviews are not only delivered by different types of workers (eg, lay workers vs other non-specialists); frequently, they are also delivered in different formats (eg, group vs individual sessions), with different durations and frequencies (eg, single vs multiple sessions), in different environments (eg, acute vs protracted crisis), to different populations (eg, refugees vs internally displaced persons) and target different disorders (eg, PTSD vs depression). Given the diversity of approaches used to implement psychological interventions in different contexts and the scarcity of resources for mental health research in LMICs,\(^33\) it is especially important that new research be guided by a clear understanding of what has already been tested, how, where and for whom. There has not yet been a review that synthesises the available literature from LMICs on the delivery of talking therapies to survivors of humanitarian crises by lay workers specifically.

We therefore propose to undertake a narrative synthesis of qualitative, quantitative and mixed-method studies of the implementation or effectiveness of lay-delivered talking therapies for adult survivors of humanitarian crises in LMICs. One key output will be a Theory of Change (ToC) describing the general pathway by which these interventions seek to achieve impact (ie, a reduction in mental health-related morbidity), as well as the variety of approaches that have already been used to implement
these interventions to different subpopulations and in different contexts.

Aims and objectives

Aim
The review aims to describe the current state of the research literature on the implementation and effectiveness of lay-delivered talking therapies targeting CMDs among survivors of humanitarian crises in LMICs.

Objectives
1. to conduct a systematic review of qualitative, quantitative and mixed-methods studies on this topic
2. to identify key similarities and differences among the studies identified, using techniques of narrative synthesis
3. to develop a ToC specific to this topic, by mapping common interventions, indicators, assumptions, rationales and outcomes onto a pathway of change.

METHODS AND ANALYSIS

This systematic review protocol was developed in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocol guidelines and registered with the International Prospective Register of Systematic Reviews (PROSPERO; CRD42017058287).\(^{44,45}\) The protocol in PROSPERO will be updated to reflect any amendments.

Eligibility criteria

Participants
We will consider studies that provide treatment to adults (≥18 years) who have first-hand experience of a humanitarian crisis that occurred during their lifetime, including former soldiers and prisoners. We use Warren et al\(^{5}\)’s definition of a humanitarian crisis, referenced previously, which may refer to either an acute or protracted crisis. Our scoping search revealed that exposure to protracted crises is not always described in text, perhaps because these crises extend over long periods of time and may come to be accepted as the status quo in some countries. For studies that do not explicitly describe a humanitarian crisis in text, we will refer in the first instance to the list of protracted crises compiled by the Food and Agriculture Organization of the United Nations and then contact corresponding authors for clarification in case of any lingering ambiguity (see the Selection process section).\(^{46}\)

We will exclude studies of interventions provided primarily to children or adolescents (<18 years), adults who were not alive at the time of the disaster (ie, exposure was before birth), and individuals who were incarcerated or serving in the military at the time of study.

Interventions
We include talking therapies (eg, cognitive behavioural therapy, narrative exposure therapy) delivered by lay workers, which we define as psychological therapies involving talking in person with a trained lay worker, either one-on-one or in a group format. We adopt the definition for lay worker proposed by Lewin et al\(^{47}\) as ‘any health worker carrying out functions related to healthcare delivery; trained in some way in the context of the intervention; and having no formal professional or para-professional certificated or degree tertiary education’.

In order to be considered for inclusion, interventions should explicitly target one or more CMDs. As the authors are unaware of any universal definition of CMDs, we include the following categories from the 2016 International Classification of Diseases that are most relevant to survivors of humanitarian crises: depressive and other mood disorders (excluding manic episode and bipolar affective disorder); phobic, dissociative, somatoform, obsessive-compulsive and other neurotic disorders; adjustment disorders and reactions to severe stress, including PTSD; and alcohol and substance use disorders. Studies including subthreshold cases of CMDs may be included, provided that the intervention is delivered for the express purpose of treating CMD symptoms.

We will exclude self-help therapies, telephone and computerised therapies, and any other intervention in which the main mode of delivery is not inperson dialogue with a trained lay worker. We will also exclude Psychological First Aid and other general psychoeducation or psychosocial interventions that do not provide an evidence-based talking therapy.\(^{48}\)

For the purposes of this review, evidence-based talking therapies will be identified using the criteria for empirically supported therapies outlined by Chambless and Hollon. Accordingly, the therapeutic component of the intervention should at minimum meet one of the three criteria for ‘probably efficacious treatments’, as shown in Table 1.\(^{49,50}\) If, at the stage of full-text screening, the evidence base for a given therapy is not obvious from the text, reviewers will conduct a brief literature search.
in order to make a final judgement. If the literature identified is insufficient to make a judgement, then the corresponding author will be contacted to clarify (see the Selection process section).

Comparators
No comparator is required for a study to be considered for inclusion. In the case of between-subject designs, no restrictions on type of comparator will be applied.

Outcomes
Studies must report one or more patient outcomes or implementation outcomes of a relevant intervention targeting CMDs in order to be considered for inclusion. Outcomes may be measured quantitatively or described qualitatively. We will adopt the three categories of patient outcomes used by van Ginneken et al.\textsuperscript{26 51} and the eight categories of implementation outcomes outlined by Proctor et al.,\textsuperscript{52} as shown in box 1.\textsuperscript{26 51 52}

Study designs
Qualitative, quantitative and mixed-method studies evaluating the implementation or effectiveness of relevant interventions are eligible for inclusion. Study designs that do not comply with these criteria (eg, ecological or prevalence studies) will be excluded.

Setting
We will include studies conducted in LMICs, based on the classification of the World Bank during the financial year in which the study was published. Studies of interventions delivered to refugees from LMICs will be excluded if the interventions are delivered in a high-income country setting.

Report characteristics
To be considered for inclusion, the study must be published by the time the search has concluded. No restrictions on language will be applied. The research group responsible for this review at the London School of Hygiene & Tropical Medicine includes Albanian, Arabic, English, French, German, Hindi, Portuguese, Punjabi and Spanish speakers, who may assist with screening. If necessary, we will recruit additional bilingual screeners from among the highly diverse staff and student population at the school. Studies in languages other than English that are deemed fit for inclusion will be translated into English by a bilingual translator with experience using medical terminology in both languages. The translation will then be used as the source material for quality appraisal and data extraction.

Information sources
Searches in the following bibliographic databases were performed in May 2017: Ovid MEDLINE(R) (1946–2017), Embase (1974–2017), PsycINFO (1806–2017), PsycEXTRA (1908–2017), Global Health (1910–2017) and Cochrane Library (all years). We will also search the trial registry ClinicalTrials.gov. Additional approaches to identify literature will include forward and backward citation searches of included literature, screening of included studies of existing systematic reviews on related topics, and hand searches of contents pages of the following

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### Table 2

<table>
<thead>
<tr>
<th>Terminology</th>
<th>Definitions</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outcomes (ie, ‘Pre-conditions’ or ‘Milestones’)</td>
<td>The intended results of the interventions; things that do not exist now, but need to exist in order for the logical causal pathway not to be broken.</td>
<td>Change in knowledge, attitudes and skills of lay health workers to enable them to successfully deliver talking therapy.</td>
</tr>
<tr>
<td>Long-term</td>
<td>The final outcome the programme is able to change on its own</td>
<td>Reduced prevalence of CMDs in the population receiving talking therapy.</td>
</tr>
<tr>
<td>Ultimate (ie, ‘Impact’ or ‘Goal’)</td>
<td>The real-world change you are trying to affect</td>
<td>Reduced prevalence of CMDs among survivors of humanitarian crises.</td>
</tr>
<tr>
<td>Interventions (ie, ‘Strategies’)</td>
<td>The different components of the complex intervention</td>
<td>Training of lay workers on the delivery of talking therapy.</td>
</tr>
<tr>
<td>Indicators</td>
<td>Things you can measure and document to determine whether you are making progress towards, or have achieved, each outcome</td>
<td>Reduction in symptom severity for CMDs.</td>
</tr>
<tr>
<td>Rationale</td>
<td>Key beliefs that underlie why one outcome… (leads to) the next, and why you must do certain activities to produce the desired outcome</td>
<td>Humanitarian responders need to be educated about signs and symptoms of CMDs in order for CMDs to be detected during crises.</td>
</tr>
<tr>
<td>Assumptions</td>
<td>An external condition beyond the control of the project that must exist for the outcome to be achieved</td>
<td>Task-sharing with lay workers is socially and politically acceptable.</td>
</tr>
</tbody>
</table>

CMD, common mental disorders.
journals: *Conflict and Health, International Journal of Mental Health Systems* and *World Psychiatry*. We will also contact a minimum of 15 experts from academic research institutions, United Nations agencies and non-governmental organisations working on MHPSS in LMICs affected by humanitarian crises. Finally, resource directories of mental health networks including the Mental Health Innovation Network (MHIN, mhinnovation.net/innovations) and the MHPSS Network (mhpss.net/resources) will be searched to identify relevant grey literature, such as reports of programme evaluations. The search strategy was developed, piloted and refined in consultation with a qualified information specialist and informed by published systematic reviews on related topics. 26 30 The search strategy was further adjusted for syntax and search terms for use in different databases; however, it has not been optimised for other languages besides English.

**Search strategy**

A scoping search identified five key domains that were then used to develop the search strategy: LMICs, talking therapies, lay workers, CMDs and humanitarian crises.

For each domain, relevant subject headings and search terms are combined with Boolean operators. Subject headings are exploded where relevant. Suitable wild cards are used to adjust for variations in spelling and pluralisation of individual search terms. Search terms, headings and syntax have been adjusted for each database. No restrictions were placed on language, year of publication or publication status in the search strategy. The search strategy for MEDLINE is presented in online supplementary appendix 1.

**Study records**

**Data management**

The reference management software EndNote V.X7.5 will be used to manage bibliographies, citations and references throughout the review. Data extraction sheets will be stored as Word documents in Microsoft Word 2016. NVivo V.11 will be used to organise, analyse and synthesise extracted data.

**Selection process**

Two reviewers will independently screen all titles and abstracts, and assess full-text articles against the inclusion criteria. A third reviewer will be engaged to resolve discrepancies between the two reviewers at any point in the screening and assessment process. If disagreements persist, we will contact study authors to seek additional information. Up to two attempts will be made to contact...
the corresponding author at 2-week intervals. If there is no response after 2 weeks, the study will be excluded. The number of excluded full-text articles and reasons for exclusion will be recorded and presented in a flow diagram.

Data collection process
A data extraction sheet will be developed, piloted and refined with particular attention to the working draft of the ToC map to be agreed at an early stage of the narrative synthesis (see the Developing a theoretical model section). One reviewer will extract data from all included studies. A second reviewer will verify the extracted items. A third reviewer may be engaged to resolve disagreement. As in the selection process, if there are missing data, study authors will be contacted at 2-week intervals. If there is no response after two attempts, the data will be recorded as missing.

Data items
As described above, the data extraction sheet will be finalised after the working draft of the ToC map is agreed (see the Developing a theoretical model section). At a minimum, we expect the data extraction sheet to include the following items:

1. publication details (title, author(s), publication year and journal/source)
2. study details (country, setting, target population, target condition, study design, patient outcomes, implementation outcomes, results)
3. intervention details (type of talking therapy, description of talking therapy, type of lay worker responsible for delivery, qualification(s)/training of lay workers).

Study quality
Quality will be assessed using the Effective Public Health Practice Project (EPHPP) Quality Assessment Tool for Quantitative Studies and the Critical Appraisal Skills Programme (CASP) Qualitative Research Checklist. The EPHPP tool produces a global rating of ‘strong’, ‘moderate’ or ‘weak’, for each study. Although the CASP checklist does not produce a global rating, the reviewers will take into consideration the criteria from the checklist in order to assign a global rating of ‘strong’, ‘moderate’ or ‘weak’ to each qualitative study as well, in order to enable disaggregation by study quality in the narrative synthesis (see the Assessing robustness section). For mixed-methods studies, both tools will be applied separately. The EPHPP and CASP ratings will then be taken into consideration by the reviewers when assigning a single global rating.

Two reviewers will conduct these assessments independently. Any disagreements will then be resolved through discussion until consensus is reached. If disagreement persists, a third reviewer will be consulted. As the aim of the synthesis is to describe the current state of the literature, studies will not be excluded on the basis of quality.

Data synthesis
Methods of narrative synthesis will be used for the purposes of this analysis, following guidance produced by Popay et al for the Economic and Social Research Council UK Methods Programme (2006). A narrative synthesis is ‘an approach to the systematic review and synthesis of findings from multiple studies that relies primarily on the use of words and text to summarise and explain the findings of the synthesis’ (p5). A narrative synthesis is desirable where the included studies are not similar enough to allow for a specialist synthesis (eg, meta-analysis or meta-ethnography), as is expected to be the case in this review. Popay et al divide a narrative synthesis into four main elements:

1. developing a theoretical model of how the intervention works, why and for whom
2. preliminary synthesis
3. exploring relationships in the data
4. assessing the robustness of the synthesis.

Developing a theoretical model
As Popay et al note, a ToC ‘is concerned with how the intervention works, why and for whom’ (p12). Although reviewers are increasingly being encouraged to use ToC, there is no universal definition of ToC and little guidance on the development of ToC maps for systematic reviews. Therefore, this review will adopt the definition proposed by De Silva et al in an influential methods paper commonly cited by researchers conducting ToC-driven evaluations of complex mental health interventions:

‘ToC is ‘a theory of how and why an initiative works’…It is visually represented in a ToC map which is a graphic representation of the causal pathways through which an intervention is expected to achieve its impact within the constraints of the setting in which it is implemented.’

The ToC map for this review will include five of the core components (table 2) identified by De Silva et al.

Outcomes will be mapped onto a causal pathway, and indicators attached to the corresponding outcomes. The interventions that lead to each outcome, the rationale for why each outcome leads to the next and the assumptions attached to each outcome will also be mapped onto the causal pathway.

The ToC map for MHPSS interventions published in a previous review by Bangpan et al will serve as the initial point of departure for ToC development. This ToC draws on the IASC guidelines on MHPSS in emergency settings as well as prior reviews of MHPSS. However, as the authors note, ‘there is no single theory of change that can be applied for all possible types of MHPSS programme’ (p3). This ToC is not specific to psychological therapies or lay-delivered interventions, nor does it follow the same conventions as De Silva et al. Therefore, it will first be adapted by the lead reviewer, drawing on seven existing reviews of non-specialist-delivered
psychological therapies and psychological therapies for populations affected by humanitarian crises in LMICs identified during our scoping review. A second reviewer with knowledge of the relevant literature will critically evaluate this adapted ToC map, and a working draft will be agreed between the two reviewers. A third reviewer will be consulted in case of disagreement.

This ToC map will then be amended iteratively by two reviewers working collaboratively, as described in figure 1, in order to incorporate the results of the review.

**Preliminary synthesis**

We will conduct a summative content analysis of the full texts of included studies. Using the working draft of the ToC map and data extraction sheet to derive the initial categories, a draft coding framework will be developed and amended iteratively by two reviewers during a preliminary phase of data immersion. The two reviewers will agree on a final coding framework after discussing their individual drafts, develop a shared codebook and then double-code the data deductively. Through this process, qualitative data can be transformed into quantitative data and used to calculate summary statistics. Any discrepancies in coding between the two reviewers will be discussed and referred to a third reviewer, if necessary, for resolution. A similar process was recently used by another ToC-driven synthesis published by the Campbell Collaboration.62 63

**Exploring relationships**

Relationships will initially be explored by tabulating the quantitative data from the preliminary synthesis, in order to identify any notable patterns (eg, which lay workers have delivered which talking therapies). Then, idea webbing and conceptual mapping will be employed, as recommended by Popay et al.55 This will involve visual diagramming of the various ToC components captured through the context analysis as well as the insights recorded previously in memos. The resulting diagrams will be compared with the working draft of the ToC map, which will then be amended as necessary, in order to take into account the observed relationships. While the two reviewers involved in coding will be mainly responsible for this process, any amendments to the ToC will be discussed and agreed by all reviewers.

**Assessing robustness**

Summary statistics will be presented for each component of the ToC map, based on the quantitative data generated through the content analysis. These statistics will indicate, for example, how many studies report on a particular outcome or use a particular intervention, and will be disaggregated by study design and quality. This will enable the reviewers to critically assess the quality and quantity of studies underpinning the ToC, and to suggest areas where new research is needed.

The ToC map will be circulated to the corresponding authors of the included studies and to the experts consulted during the literature search, for feedback. The reviewers will also be asked to critically reflect on the process of conducting the synthesis, both independently through a written log maintained by the reviewers throughout the process and also at the conclusion of the process through group discussion.

**LIMITATIONS**

Based on our initial scoping review, we expect to identify a small number of controlled studies, with substantial heterogeneity. As such, we do not believe that a meta-analysis will be appropriate, and have instead proposed a narrative synthesis, the results of which are primarily qualitative and therefore transferable, but never generalisable. The resulting ToC, for example, would need to be locally adapted before it could be meaningfully used to inform the design of a study.

Further, the exclusion of unpublished literature limits the transferability of the results, particularly to non-research contexts. While studies are not excluded on the basis of language, the search terms for this review have not been optimised for languages other than English. This could also limit transferability to non-Anglophone contexts.

Finally, our motivation for conducting this review is to provide a fine-grained synthesis of the literature on a more narrowly defined category of interventions than is commonly used in systematic reviews of psychological interventions for survivors of humanitarian crises. Accordingly, we have excluded several groups of people (ie, children and adolescents, people who are incarcerated or serving in the military) who are likely to have different needs from the general adult population and who commonly access services through institutions (eg, schools, prisons, military hospitals) as opposed to general community-based programmes. We would recommend that future reviews target these vulnerable and often underserved groups, who can also benefit from talking therapies.

**ETHICS AND DISSEMINATION**

This research relies on previously collected and anonymised data and does not require ethical approval. We plan to present our results in a manuscript to be submitted for publication in a peer-reviewed journal. We will make use of existing links with MHIN, a partnership between the Centre for Global Mental Health and the WHO, and with the Center for Humanitarian Health and Center for Global Health of Johns Hopkins University, in order to develop and execute a knowledge exchange strategy involving generators (eg, researchers, innovators), enablers (eg, media, advocacy groups) and users (eg, policy makers, service users). This will include the dissemination of knowledge exchange products (eg, webinars, policy briefs, research summaries) both online and at live events such as meetings and conferences. The aim of this strategy is to help inform the rapidly
growing global research agenda on scalable psychological interventions for populations affected by adversity.

**Contributors** GKR, JKB and JE contributed to the conceptualisation of the review. GKR and AB wrote the manuscript draft and developed the search strategy. JKB and JE revised and edited the manuscript draft and search strategy. All authors approved the manuscript.

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