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Advancing a program theory for community-level oral health promotion programs for humanitarian migrants: A realist review protocol

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Abstract

Introduction: Humanitarian migrants often suffer from poor health, including oral health. Reasons for their oral health conditions include difficult migration trajectories, poor nutrition, and limited financial resources. Oral health promotion is crucial for improving oral health-related quality of life for humanitarian migrants. While community-level oral health promotion programs for humanitarian migrants have been implemented (e.g., in host countries and refugee camps), there is scant literature evaluating their transferability or effectiveness. Given that these programs yield unique context-specific outcomes, the purpose of this study is to understand how community-level oral health promotion programs for humanitarian migrants work, in which contexts, and why.

Methods and analysis: Realist review, a theory-driven program evaluation methodology used in evidence-based policy, incorporates a causal heuristic called context-mechanism-outcome (CMO) configurations to explain how programs work, for whom, and under which conditions. Using Pawson's five steps of realist review (clarifying scope and drafting an initial program theory; identifying relevant studies; quality appraisal and data extraction; data synthesis; and dissemination of findings.), we begin by developing an initial program theory using the references of a scoping review on the oral health of refugees and asylum seekers and through hand searching in Google Scholar. Following stakeholder validation of our initial program theory, we will locate additional evidence by searching in four databases (Ovid Medline, Ovid EMBASE, Cochrane Library, and CINAHL) to refine our initial program theory into a middle-range realist program theory. The resultant theory will explain how community-level oral health promotion programs for humanitarian migrants work, for whom, in which contexts, and why.

Ethics and dissemination: Since this study is a review and no primary data collection will be involved, institutional ethics approval is not required. The findings of this study will be disseminated in peer-reviewed journals, local and international conferences, and via social media.

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Keywords: Transients and migrants, Refugees, Oral health, Program evaluation, Realist review, Health promotion

Strengths and limitations of this study:

- This study is the first using realist review to understand how community-level oral health promotion programs work, for whom, in which contexts and why.
- The program theory resulting from this study can inform the design and implementation of successful and context-specific community-level oral health promotion programs for humanitarian migrants.
- Our research team is interdisciplinary, and we will also consult stakeholders from various relevant fields to ensure that our program theory transcends disciplines.
- Since this study is a review of existing literature, theory making is limited by the availability, richness, and quality of available evidence.

- Only studies in English and French will be included.

Introduction

Humanitarian migrants – a term we use to include refugees, asylum seekers, and internally displaced persons – are people who forcibly move away from their place of habitual residence and are in vulnerable conditions needing urgent protection.(1) At the end of 2019, there were 79.5 million humanitarian migrants displaced worldwide due to human rights violations, conflict, and persecution, including 45.7 million internally displaced persons, 26 million refugees, and 4.2 million asylum seekers.(2) Humanitarian migrants disproportionately suffer from diseases such as tuberculosis, HIV, and mental disorders and thus have a compromised health-related quality of life.(3) In addition to poor health conditions, these populations often have compromised oral health conditions for reasons such as financial constraints, limited or no access to dental care, and the legacy of their difficult migration trajectories.(4, 5) Poor oral health further reduces the quality of life of humanitarian migrants.(6)

Good oral health enables individuals to speak, chew, breathe, taste, smile, socialize and enjoy life.(7) Poor oral health can cause pain and discomfort, social and psychological problems, and loss of effective school or work hours.(8) Oral diseases such as dental caries and periodontal diseases are associated with the risk of chronic diseases such as cardiovascular diseases and diabetes through sharing common risk factors.(9) Poor oral health can compromise quality of life by causing pain, impairment of craniofacial functions such as chewing and speaking, and reduced aesthetics, leading the individual to social exclusion and stigmatization.(10) The negative sequelae of poor oral health are of the utmost importance for humanitarian migrants who are already vulnerable to fragile health, have limited finances, and lack social support.(11, 12) Enjoying good

oral health is a fundamental human right; therefore, programs and policies aiming to improve the oral health of humanitarian migrants are imperative.(13)

Many community-level oral health promotion programs have been developed and implemented to address humanitarian migrants' oral health needs. These programs intend to improve migrants' oral health via two main approaches: oral health education and dental service provision.(14) Oral health education programs aim to increase oral health knowledge of humanitarian migrants and thereby induce motivation for oral health behavior, potentially leading to improved oral health.(15-17) For example, an oral health education program in the United States provided brochures for refugee children and their caregivers to increase their knowledge of the oral health of children.(18) Another example of oral health education includes a multilingual oral health education DVD for refugees in Australia.(17)

Dental service provision programs intend to improve the oral health of humanitarian migrant populations through provision of dental care, such as dental restorations or extractions, by volunteer dentists and non-governmental organizations.(12, 19) An example is the dental restoration program for Dinka and Nuer refugees living in Nebraska, aiming to restore and replace the lower anterior teeth extracted during childhood following local cultural practices.(19) Some community-level oral health promotion programs for humanitarian migrants incorporate both oral health education and dental service provision interventions for enhanced effectiveness. For instance, an oral health promotion program for Chilean refugees in Sweden provided oral health instructional sessions as well as scaling and root planning at the baseline visit.(20)

Some programs train humanitarian migrants to work as community oral health workers (COHWs) to provide oral health education and/or basic dental services for their own community.(21, 22) COHW programs aim to account for acute shortage of dental staff in settings with inadequate

resources such as refugee camps, as well as to increase the cultural competency of the program interventions. For instance, a program in Ghana tutored volunteers of the Liberian refugee camp 'Gomoa Bududuram' as COHWs to provide preventive oral healthcare and emergency dental treatment for the camp members.(21)

Notwithstanding the presumed importance of these programs, there is scant evaluation data accompanying their descriptions in the literature. Community-level oral health promotion programs for humanitarian migrants are necessarily complex interventions as they are implemented in complex and ever-changing social situations.(23) Contrary to clinical treatments, which generally have a linear pathway of action,(23) public health programs are not finite treatments or singular schemes; they include design, implementation, regulation, and management of the services.(24) Further, the success of these programs depends on client reasoning, behaviors, and decision making, and how these elements unfold within the context of the specific program and the clients' lives.(24, 25) As a result, each program will yield unique outcomes in each specific context.

Traditionally, evaluations of community programs focus on effectiveness; that is, evaluating the effect of the intervention on its outcome. Such an approach, however, often misses the important role of contextual factors: that is, how the outcomes of a specific intervention are moderated by myriad elements within which the intervention is implemented, such as interpersonal relationships, legislations, and the infrastructure of the delivered services.(26) To render community-level oral health promotion programs most effective for humanitarian migrants, understanding the underlying causal pathways through which the contextual foundations of a program interact with the clients involved and produce program outcomes is essential.(27)

The purpose of this study is to understand how community-level oral health promotion programs for humanitarian migrants work, for whom, in which contexts, and why.

Methods

Methodology

Realist review, also referred to as 'realist synthesis,' is a theory-driven program evaluation methodology developed by Pawson and colleagues (23) to inform evidence-based policy. It employs an explanatory approach to develop an understanding of how complex programs work, for whom, under what circumstances and settings, and why (27). Using a causal heuristic called 'context-mechanism-outcome (CMO) configurations', realist reviews seek to explain how the context of a program (the conditions within which a program is implemented, such as culture, interpersonal relationships, and legislations) can impact the mechanism (e.g., participants' reasoning and responses to the program, which will depend on their values, situations, beliefs, and cognition) through which the outcome (intended and unintended) occurs (25). During the review process, CMOs are constructed and refined through an iterative examination of peer-reviewed and grey literature that can shed light on how these programs work (26). These CMOs are then incorporated and synthesized into a program theory, which explains how the programs work, in what contexts, for what populations, and why (25, 27).

A realist review begins with an initial 'rough' program theory and ends with a refined realist program theory (23). The realist philosophy is premised on the idea that all programs are 'theories incarnate' (28); the implementation of a program puts to test the theory about what can cause behavior change in the target population (29). A realist review thus begins by drafting an initial program theory, which proposes hypotheses explaining how a program works (23, 28). This initial

program theory can be drawn from existing relevant substantive theories or developed by theorizing the programs' design into a theory of action (what a program is expected to accomplish) or a theory of change (why a program is expected to work),(26) preferably populated with realist elements of context, mechanism and outcome.(26, 30) The initial program theory is then refined during the review process using the identified CMOs into a realist program theory at the middle-range level; that is, a theory that is not too abstract to detach from the context of a program and not too specific to pertain to only one program.(25, 31) The final program theory can then serve as an evidence-based tool for designing and implementing context-specific programs with optimized effectiveness.

Patient and public involvement

While patients or members of the public were not involved in the development of our protocol, we will consult and seek input from multiple stakeholders during the review process. Our stakeholders group is yet to be determined; however will include categories such as (i) internationally-renowned migrant oral health researcher, (ii) community-level oral health promotion program designer or project implementer, (iii) representative of a migrant organization; (iv) service user (humanitarian migrant); and (v) realist researcher. The involvement of the stakeholders is further explained in the methods and dissemination sections.

Objectives:

1. To develop an initial program theory explaining how community-level oral health promotion programs for humanitarian migrants work; This will be validated by stakeholders.

2. To conduct a search of databases to identify relevant data sources and elicit CMO configurations explaining the pathways through which contextual factors of these programs impact their outcomes.
3. To refine the initial program theory using the CMOs into a middle-range realist program theory with respect to community-level oral health promotion programs for humanitarian migrants. This will be validated by stakeholders.

Study design

This realist review protocol uses Pawson's five stages for conducting a realist review,(23) which are: (i) clarifying the purpose of the review and the research question and drafting an initial program theory; (ii) identifying relevant studies; (iii) quality appraisal and data extraction (iv); data synthesis; and (v) dissemination of findings. These steps are iterative, with the reviewers moving back and forth between stages.

i. Clarifying the scope of the review and drafting an initial program theory

Clarifying the scope of the review

This study contributes to the CIHR-funded Migrant Oral Health Project (MOHP)'s program of research to advance an understanding of how community-level oral health promotion programs can best help humanitarian migrants. Our team is interdisciplinary, including the following expertise: Dentistry, oral public health, social sciences, epidemiology, and health services research. We held an initial meeting to define the scope and focus of our review. The team confirmed that by humanitarian migrants, we mean refugees, asylum seekers, and internally displaced persons. Community-level oral health promotion programs are those aiming to improve the oral health conditions of humanitarian migrants through delivering interventions at the community level (rather than the individual level). For example, an oral health education program

including presentations and group discussions delivered in a community organization for newly arrived refugees can be considered a community-level oral health promotion program.

The review will commence with this broad question: How do community-level oral health promotion programs for humanitarian migrants work, for whom, in which circumstances, and why? More specific questions to be answered in this review will include:

- How do community-level oral health promotion programs for humanitarian migrants achieve their outcomes?
- How do contextual factors within which community-level oral health promotion programs for humanitarian migrants are implemented impact these programs' outcomes?
- What mechanisms are triggered by these contextual factors and how do these mechanisms lead to the observed outcomes?

Drafting an initial program theory

The next step to our realist review will be to draft an initial program theory that can explain how community-level oral health promotion programs for humanitarian migrant populations achieve their outcomes. For this aim, we will use the bibliographies of a recent scoping review on the oral health of refugees and asylum seekers conducted by MOHP team members.(14) This review singles out a number of studies incorporating the common approaches of community-level oral health promotion programs for humanitarian migrants, namely: oral health education, dental service provision, and community oral health worker programs. Two reviewers will screen the articles' bibliographies to identify studies potentially having more information about the three aforementioned types of programs. Moreover, the reviewers will conduct hand searching in Google Scholar to identify papers with more information about the pathways through which these programs lead to their outcomes or how humanitarian migrants may respond to program activities.

The reviewers will read a minimum of 10 papers and will attempt to draft a theory of action and/or a theory of change for these programs, which will then be populated by the CMO configurations identified in the papers. Following, the reviewers will complement the initial program theory with relevant substantive theories that support the observed CMO patterns in these programs.

Following, the drafted initial program theory will be shared with stakeholders for comments and feedback. We will incorporate the comments and feedback received from the stakeholders to further complete and finalize our initial program theory. This initial program theory will serve as a framework for data collection and analysis during the review process.

ii. Identifying relevant studies

Our database search aims to identify studies providing information about the causal pathways through which contextual factors in community-level oral health promotion programs for humanitarian migrants lead to the observed outcomes. With the advice and recommendations of a university-based librarian, we will conduct a comprehensive search of peer-reviewed literature in four databases: Ovid Medline, Ovid EMBASE, CINAHL, and Cochrane Library. The developed search strategy for the Ovid Medline database is shown in Table 1. The search strategy will be converted for use in the three additional databases. We will conduct all database searches on the same day. We will not include any date of publication restrictions in our searches. Language of studies will be restricted to English and French.

Grey literature search will be conducted if the database search does not yield adequate results or if more specific information is needed. We will attempt to find relevant grey literature by searching in Google using specific terms and truncations (e.g. (refugees AND oral health)). We will also specifically search websites of international and local organizations working on the oral health of

humanitarian migrants, including the World Health Organization (WHO), World Dental Federation (FDI), and the International Organization for Migration (IOM).

1. exp Refugees/
2. refugee.tw,kf.
3. refugees.tw,kf.
4. exp "Transients and Migrants"/
5. exp "Emigrants and Immigrants"/
6. "Emigration and Immigration"/
7. exp Undocumented Immigrants/
8. humanit* migra*.tw,kf.
9. asylum seek*.tw,kf.
10. internal* displac*.tw,kf.
11. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10
12. exp Oral Health/
13. exp Dentistry/
14. oral healthcare.tw,kf.
15. exp Dental Health Services/
16. exp Fluorides, Topical/ or exp Fluorides/
17. exp Mouth Diseases/
18. exp Periodontal Diseases/
19. exp Dental Caries/
20. 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19
21. (oral* adj3 health*).tw,kf.
22. (dental* or dentist* or tooth or teeth or caries or carious or periodont*).tw,kf.
23. 20 or 21 or 22
24. 11 and 23

Table 1- Search strategy for the Ovid Medline database.

A search of the bibliographies of retrieved peer-reviewed articles will also be conducted, using the snowballing method to identify other pertinent studies that were not included in our initial database searches. The same inclusion and exclusion criteria will be used to assess the eligibility of the papers identified through snowballing.

Based on the extensiveness and depth of the identified literature in the initial search, the reviewers will decide about conducting secondary searches (e.g., with modified search terms and additional

databases such as ProQuest.) Secondary searches will be conducted with the assistance of a librarian and will be aimed at identifying the elements of context, mechanism and outcome that were not identified in the initial search but are required for a complete and robust explanation of the findings.

Study selection and screening

The identified articles will be exported to EndNote reference manager(32) where duplicate articles will be removed. The remaining articles will then be uploaded to Covidence, an online tool for managing systematic reviews.(33) Two reviewers will conduct title-and-abstract screening for all identified studies. Qualifying studies from the title-and-abstract screening stage will then undergo full-text screening by the two reviewers.

The inclusion criteria for the studies in title-and-abstract and full-text screening stages will be relevance to oral health of humanitarian migrants. In realist reviews, the unit of analysis is not the entirety of a study but the evidentiary fragments in the study.(34) Therefore, the inclusion criteria for the evidentiary fragments in the full-text screening stage will be: (i) relevance to community-level oral health promotion programs for humanitarian migrant populations; (ii) rigor, which will be determined after relevance.

We will endeavor to locate all papers that qualify for full-text screening; those not located will be excluded. At the full-text screening stage, articles will be excluded if (i) they combine populations within the sample such that the results cannot be disaggregated (e.g. immigrants pooled with humanitarian migrants); or (ii) they do not uniquely address oral health (i.e., if oral health is merged with general health such that the data cannot be disaggregated, the study will be excluded.)

The reviewers will use a Microsoft Excel(35) spreadsheet for the full-text screening stage in which they will indicate the title, authors, journal, year of publication, the type of paper (e.g., whether it is an original article, a commentary, or other), as well as the decision on including or excluding the papers and the reason behind this decision.

iii. Quality appraisal and data extraction

Quality appraisal

In realist reviews, rigor depends on two criteria: trustworthiness (how much the data used to draw inferences can be trusted) and coherence (whether the data is consistent with those of other relevant data sources.)(30) While the rigor of data is often based on the plausibility of the methods through which the results were generated,(26) in realist reviews, data can be drawn from any part of a paper, not just the results section.(25) Since the information used in different parts of a paper will have been generated through specific means and methods serving specific purposes, using standard checklists to make judgements about the rigor of the whole body of the paper may not be appropriate, as these checklists may only account for a small portion of the relevant data in the paper.(36) The most important decision to be made about data quality is the contribution each paper can make to the construction and refinement of the program theory, usually stemming from the 'pieces' of data and not the entire body of the paper.(34) Furthermore, sometimes circumstantial data identified in less rigorous studies can contribute to constructing a convincing theory.(30) Therefore, following the recommendations of Realist And Meta-narrative Evidence syntheses: Evolving Standards (RAMESES) training materials,(26) for each identified piece of data, the reviewers will note any issues that could impact its rigor and quality. These issues will be considered in developing and refining the program theory.

Data extraction

Two reviewers will carefully read the included papers in full and extract the parts of the data that can contribute to our theory development and refinement. When confusion or concern arises (e.g., lack of adequate information), the reviewers will contact the authors of the papers to request additional information or clarification.

We will indicate each paper's characteristics in a Microsoft Excel spreadsheet. The following information will be included: (i) bibliographic details: title, author, journal and year of publication; (ii) study type and design; and (iii) target population, intervention, and type of program. A Microsoft Word table (37) will be used to chart the following information from the papers: (i) the relevant data; (ii) CMOs; (iii) pertinence to theory; and (iv) rigor notes. The extraction templates will be refined as necessary.

iv. Data Synthesis

Underlying mechanisms are often implicit in data and may not necessarily appear at the empirical level.(25) For example, the participants' reasoning occurs in their minds and might not be explicit in the data. Therefore, mechanisms need to be identified using 'retroduction,' an analytic technique to uncover hidden causal factors lying behind the identified patterns and the changes to those patterns.(38) Retroduction encompasses unearthing causal mechanisms using induction (developing theories from empirical evidence), deduction (testing theories against evidence), and abduction (creative thinking).(38, 39)We will iteratively read and extract elements of context and outcome from the papers. Following, mechanisms relating the contextual factors to the outcomes will be elicited to construct CMOs, explaining how a program can yield different outcomes in different contexts. These CMOs will be used to test and refine the initial program theory to form

a middle-range realist program theory, explaining how community-level oral health promotion programs for humanitarian migrants work and in what contextual settings.

We will consult our stakeholder group regarding the final program theory; Their comments and feedback will be applied to further improve and finalize the final realist program theory.

Ethics and dissemination

v. Dissemination of findings

The findings of this review will be reported according to the principles of 'RAMESES publication standards for realist synthesis',(40) which outline the key elements to include in the abstract, introduction, methods, results, and discussion section of a realist review. With the advice and input from the stakeholders, we will make recommendations regarding how to implement community-level oral health promotion programs for humanitarian migrants most effectively.

Two manuscripts will be written to report the findings of this study, one encompassing the initial program theory, and another reporting the refined realist program theory regarding how community-level oral health promotion programs for humanitarian migrants work. The manuscripts will be submitted for publication in peer-reviewed journals. The findings of this review will also be presented in oral and poster format in scientific local and international conferences. Moreover, we will disseminate the findings of this review through the MOHP website and via social media.

Ethics approval

Since this study is a review and synthesis of the literature, and that our consultations with stakeholders will not include primary data collection, institutional ethics approval is not required.

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Authors' contributions:

MEM and BN conceptualized the study. NEA and NSN developed and piloted the search strategies. NEA designed and drafted the realist review protocol, which was critically reviewed and revised by MEM, NSN and BN. All authors have approved the final version of the manuscript.

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Competing interests: The authors declare no conflict of interests for this study.

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Advancing a program theory for community-level oral health promotion programs for humanitarian migrants: A realist review protocol

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Abstract

Introduction: Humanitarian migrants often suffer from poor health, including oral health. Reasons for their oral health conditions include difficult migration trajectories, poor nutrition, and limited financial resources. Oral health promotion is crucial for improving oral health-related quality of life of humanitarian migrants. While community-level oral health promotion programs for humanitarian migrants have been implemented (e.g., in host countries and refugee camps), there is scant literature evaluating their transferability or effectiveness. Given that these programs yield unique context-specific outcomes, the purpose of this study is to understand how community-level oral health promotion programs for humanitarian migrants work, in which contexts, and why.

Methods and analysis: Realist review, a theory-driven literature review methodology, incorporates a causal heuristic called context-mechanism-outcome (CMO) configurations to explain how programs work, for whom, and under which conditions. Using Pawson's five steps of realist review (clarifying scope and drafting an initial program theory; identifying relevant studies; quality appraisal and data extraction; data synthesis; and dissemination of findings.), we begin by developing an initial program theory using the references of a scoping review on the oral health of refugees and asylum seekers and through hand searching in Google Scholar. Following stakeholder validation of our initial program theory, we will locate additional evidence by searching in four databases (Ovid Medline, Ovid EMBASE, Cochrane Library, and CINAHL) to test and refine our initial program theory into a middle-range realist program theory. The resultant theory will explain how community-level oral health promotion programs for humanitarian migrants work, for whom, in which contexts, and why.

Ethics and dissemination: Since this study is a review and no primary data collection will be involved, institutional ethics approval is not required. The findings of this study will be disseminated in peer-reviewed journals, local and international conferences, and via social media.

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Keywords: Transients and migrants, Refugees, Oral health, Program evaluation, Realist review, Health promotion

Strengths and limitations of this study:

- This study is the first using realist review to understand how community-level oral health promotion programs for humanitarian migrants work, for whom, in which contexts and why.
- The program theory resulting from this study can inform the design and implementation of successful and context-specific community-level oral health promotion programs for humanitarian migrants.

- Our research team is interdisciplinary, and we will also consult stakeholders from various relevant fields to ensure that our program theory transcends disciplines.
- Since this study is a review of existing literature, theory making is limited by the availability, richness, and quality of available evidence.
- Only studies in English and French will be included, which might lead to the exclusion of potentially relevant literature available in other languages.

Introduction

Humanitarian migrants – a term we use to include refugees, asylum seekers, and internally displaced persons – are people who forcibly move away from their place of habitual residence and are in vulnerable conditions needing urgent protection.(1) At the end of 2020, there were 82.4 million humanitarian migrants displaced worldwide due to human rights violations, conflict, and persecution, including 48 million internally displaced persons, 26.4 million refugees, and 4.1 million asylum seekers.(2) Humanitarian migrants disproportionately suffer from diseases such as tuberculosis, HIV, and mental disorders and thus have a compromised health-related quality of life.(3) In addition to poor health conditions, these populations often have compromised oral health conditions for reasons such as financial constraints, limited or no access to dental care, and the legacy of their difficult migration trajectories.(4, 5) Poor oral health further reduces the quality of life of humanitarian migrants.(6)

Good oral health enables individuals to speak, chew, breathe, taste, smile, socialize and enjoy life.(7) Poor oral health can cause pain and discomfort, social and psychological problems, and loss of effective school or work hours.(8) Oral diseases such as dental caries and periodontal diseases are associated with the risk of chronic diseases such as cardiovascular diseases and diabetes through sharing common risk factors.(9) Poor oral health can compromise quality of life by causing pain, impairment of craniofacial functions such as chewing and speaking, and reduced aesthetics, leading the individual to social exclusion and stigmatization.(10) The negative sequelae

of poor oral health are of the utmost importance for humanitarian migrants who are already vulnerable to fragile health, have limited finances, and lack social support.(11, 12) Enjoying good oral health is a fundamental human right; therefore, programs and policies aiming to improve the oral health of humanitarian migrants are imperative.(13)

Many community-level oral health promotion programs have been developed and implemented to address humanitarian migrants' oral health needs. These programs intend to improve migrants' oral health via two main approaches: oral health education and dental service provision.(14) Oral health education programs aim to increase oral health knowledge of humanitarian migrants and thereby instigating a change in oral health behavior, potentially leading to improved oral health.(15-17) For example, an oral health education program in the United States provided brochures for refugee children and their caregivers to increase their knowledge of the oral health of children.(18) Another example of oral health education programs includes a program providing a multilingual oral health education DVD for refugees in Australia.(17)

Dental service provision programs intend to improve the oral health of humanitarian migrant populations through provision of dental care, such as dental restorations or extractions, by volunteer or remunerated dentists, dental students, and non-governmental organizations.(12, 19, 20) An example is the dental restoration program for Dinka and Nuer refugees living in Nebraska, aiming to restore and replace the lower anterior teeth extracted during childhood following local cultural practices.(19) Some community-level oral health promotion programs for humanitarian migrants incorporate both oral health education and dental service provision interventions for enhanced effectiveness. For instance, an oral health promotion program for Chilean refugees in Sweden provided oral health instructional sessions as well as scaling and root planning at the baseline visit.(21)

Some programs train humanitarian migrants to work as community oral health workers (COHWs) to provide oral health education and/or basic dental services for their own community.(22, 23) COHW programs aim to account for acute shortage of dental staff in settings with inadequate resources such as refugee camps, as well as to increase the cultural competency of the program interventions.(16, 20) For instance, a program in Ghana tutored volunteers of the Liberian refugee camp 'Gomoa Buduburam' as COHWs to provide preventive oral healthcare and emergency dental treatment for the camp members.(22)

Notwithstanding the presumed importance of these programs, there is scant evaluation data accompanying their descriptions in the literature. Community-level oral health promotion programs for humanitarian migrants are necessarily complex interventions implemented in complex and ever-changing social situations.(24, 25) Contrary to clinical treatments, which generally have a linear pathway of action,(24) public health programs are not finite treatments or singular schemes; they include design, implementation, regulation, and management of the services.(26) Further, the success of these programs depends on client reasoning, behaviors, and decision making, and how these elements unfold within the context of the specific program, the clients' lives, and the wider setting.(26, 27) As a result, each program will yield unique outcomes in each specific context.

Traditionally, evaluations of community programs focus on effectiveness; that is, evaluating the effect of the intervention on its outcome. Such an approach, however, often misses the important role of contextual factors: that is, how the outcomes of a specific intervention are moderated by myriad elements within which the intervention is implemented, such as interpersonal relationships, legislations, and the infrastructure of the delivered services.(28) To render community-level oral health promotion programs most effective for humanitarian migrants, understanding the

underlying causal pathways through which the contexts interact with the clients involved to produce program outcomes is essential.(29)

The purpose of this study is to understand how community-level oral health promotion programs for humanitarian migrants work, for whom, in which contexts, and why.

Methods

Methodology

Realist review, also referred to as 'realist synthesis,' is a theory-driven literature review methodology developed by Pawson and colleagues(24) to inform evidence-based policy. It employs an explanatory approach to develop an understanding of how complex programs work, for whom, under what circumstances and settings, and why.(29) Using a causal heuristic called 'context-mechanism-outcome (CMO) configurations', realist reviews seek to explain how the context (particular aspects of the conditions within which a program is implemented, such as individuals, culture, interpersonal relationships, and legislations) can impact the mechanism (e.g., participants' reasoning and responses to the program resources, which will depend on their values, beliefs, and cognition) through which the outcome (intended or unintended) occurs.(27) During the review process, CMOs are constructed and refined through an iterative examination of peer-reviewed and grey literature that can shed light on how these programs work.(28) These CMOs are then incorporated and synthesized into a program theory, which explains how the programs work, in what contexts, for what populations, and why.(27, 29)

A realist review begins with an initial 'rough' program theory and ends with a refined realist program theory.(24) The realist philosophy is premised on the idea that all programs are 'theories incarnate';(30) the implementation of a program puts to test the theory about what can cause

behavior change in the target population.(31) A realist review thus begins by drafting an initial program theory, which proposes hypotheses explaining how a program works.(24, 30) This initial program theory can be drawn from existing relevant substantive theories or developed by theorizing the program into a theory of action (what a program is expected to accomplish) or a theory of change (why a program is expected to work),(28) preferably populated with realist elements of context, mechanism and outcome.(28, 32) The initial program theory is then tested and refined during the review process using the identified CMOs into a realist program theory at the middle-range level; that is, a theory that is not too abstract to detach from the context of a program and not too specific to pertain to only one program.(27, 33) The final program theory can then serve as an evidence-based tool for designing and implementing context-specific programs with optimized effectiveness.

Patient and public involvement

While patients or members of the public were not involved in the development of our protocol, we will consult and seek input from multiple stakeholders during the review process. Our stakeholders group is yet to be determined; however will include categories such as (i) internationally-renowned migrant oral health researcher, (ii) community-level oral health promotion program designer; (iii) program director; (iv) service provider (oral health educator or dental service provider); (v) service user (humanitarian migrant); and (vi) realist researcher. The involvement of the stakeholders is further explained in the methods and dissemination sections.

Objectives:

1. To develop an initial program theory explaining how community-level oral health promotion programs for humanitarian migrants work. This initial program theory will be shared with the stakeholders for feedback.

2. To conduct database and complementary searches to identify relevant data sources and elicit CMO configurations which will be used to test the initial program theory.
3. To refine the initial program theory using the CMOs into a realist program theory at the middle-range level. The refined theory will be shared with the stakeholders for feedback.

Study design

This realist review protocol uses Pawson's five stages for conducting a realist review,(24) which are: (i) clarifying the purpose of the review and the research question and drafting an initial program theory; (ii) identifying relevant studies; (iii) quality appraisal and data extraction (iv); data synthesis; and (v) dissemination of findings. These steps are iterative, with the reviewers moving back and forth between stages.

i. Clarifying the scope of the review and drafting an initial program theory

Clarifying the scope of the review

This study contributes to the CIHR-funded Migrant Oral Health Project (MOHP)'s program of research to advance an understanding of how community-level oral health promotion programs can best help humanitarian migrants. Our team is interdisciplinary with expertise in both quantitative and qualitative methods, and includes the following domains: Dentistry, oral public health, social sciences, epidemiology, and health services research. During our initial meeting, the team confirmed that by humanitarian migrants, we mean refugees, asylum seekers, and internally displaced persons. Community-level oral health promotion programs are those aiming to improve the oral health conditions of humanitarian migrants through delivering interventions at the community level (rather than the individual level). For example, an oral health education program including presentations and group discussions delivered in a community organization for newly arrived refugees can be considered a community-level oral health promotion program.

The review will commence with this broad question: How do community-level oral health promotion programs for humanitarian migrants work, for whom, in which circumstances, and why? More specific questions to be answered in this review will include:

- How do community-level oral health promotion programs for humanitarian migrants achieve their outcomes?
- Which contextual factors impact these programs' outcomes and how?
- What mechanisms are triggered by these contextual factors and how do these mechanisms lead to the observed outcomes?

Drafting an initial program theory

The next step to our realist review will be to draft an initial program theory explaining how community-level oral health promotion programs for humanitarian migrant populations achieve their outcomes. For this aim, we will use the bibliographies of a recent scoping review on the oral health of refugees and asylum seekers conducted by MOHP team members.(14) This review singles out a number of studies incorporating the common approaches of community-level oral health promotion programs for humanitarian migrants, namely: oral health education, dental service provision, and community oral health worker programs. Moreover, the reviewers will conduct hand searching in Google and Google Scholar to identify papers with more information about the pathways through which these programs lead to their outcomes, how contexts may impact these pathways, or how humanitarian migrants may respond to program activities, including those published after our team's scoping review. A potential search strategy for these databases would be ("refugee" OR "internally displaced" OR "internal displacement" OR "asylum seeker" OR "refugee claimant" OR "migrant" OR "humanitarian migrant") AND ("oral health" OR "dental" OR "dentistry" OR "teeth" OR "tooth").

One reviewer will screen the articles' bibliographies with the assistance of another reviewer to identify studies potentially having more information about the three aforementioned types of programs. The reviewers will read a minimum of 10 papers and will attempt to draft a theory of action and/or a theory of change for these programs, which will then be populated by the CMO configurations identified in the papers. Following, the reviewers will look for substantive theories relating to the observed CMO patterns in the initial program theory.

The drafted initial program theory will then be shared with stakeholders for comments and feedback. We will consult with stakeholders regarding which CMOs to prioritize in our review and will ask for additional evidence. In accordance with our available time and resources for this project,(34) we will select up to 10 CMOs for testing in our realist review process. We will incorporate the comments and feedback received from the stakeholders to further complete and finalize our initial program theory. This initial program theory will serve as a framework for data collection and analysis during the review process.

ii. Identifying relevant studies

Our searches at this stage will be guided by the initial program theory and will aim to identify data sources to test the CMOs in the initial program theory. With the advice and recommendations of a university-based librarian, we will conduct a systematic search of peer-reviewed and grey literature in five databases: Ovid Medline, Ovid EMBASE, CINAHL, ProQuest and PsychInfo. The developed search strategy for the Ovid Medline database is shown in Table 1. The search strategy will be converted for use in the four additional databases. We will conduct all database searches on the same day. We will not include any date of publication restrictions in our searches. Language of studies will be restricted to English and French.

1. exp Refugees/
2. refugee.tw,kf.
3. refugees.tw,kf.
4. exp "Transients and Migrants"/
5. exp "Emigrants and Immigrants"/
6. "Emigration and Immigration"/
7. exp Undocumented Immigrants/
8. humanit* migra*.tw,kf.
9. asylum seek*.tw,kf.
10. internal* displac*.tw,kf.
11. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10
12. exp Oral Health/
13. exp Dentistry/
14. oral healthcare.tw,kf.
15. exp Dental Health Services/
16. exp Fluorides, Topical/ or exp Fluorides/
17. exp Mouth Diseases/
18. exp Periodontal Diseases/
19. exp Dental Caries/
20. 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19
21. (oral* adj3 health*).tw,kf.
22. (dental* or dentist* or tooth or teeth or caries or carious or periodont*).tw,kf.
23. 20 or 21 or 22
24. 11 and 23

Table 1- Search strategy for the Ovid Medline database.

We will conduct searches in Google and Google Scholar to identify additional relevant resources for testing the initial program theory. Some search strategies used at this stage are mentioned in table 2.

Search type	Search aim	Example	Search strategy
Searches for relevant community-level oral health promotion programs for	To identify relevant CMOs for testing the initial program theory	Dental service provision programs	("refugee" OR "internally displaced" OR "internal displacement" OR "asylum seeker" OR "refugee claimant" OR "migrant" OR "humanitarian migrant") AND ("oral health" OR "dental" OR "dentistry" OR "teeth" OR

humanitarian migrants			"tooth") AND ("service" OR "treatment" OR "restoration" OR "care" OR "examination" OR "prevention" OR "preventive" OR "dentist" OR "clinic")
Searches for specific CMOs	To identify more detailed descriptions of elements of context, mechanism, outcome and their interactions in a specific CMO	Context: Experience of war	(("refugee" OR "internally displaced" OR "internal displacement" OR "asylum seeker" OR "refugee claimant" OR "migrant" OR "humanitarian migrant") AND ("oral health" OR "health" OR "dental" OR "dentistry" OR "teeth" OR "tooth") AND ("war" OR "conflict" OR "persecution" OR "violence" OR "trauma" OR "traumatic")
Searches for substantive theories	To identify substantive theories that support the refined CMOs, allowing them to be abstracted to the middle-range level	Self-efficacy	("self-efficacy" OR "empowerment" OR "empower" OR "confidence")

Table 2 – Complementary searches in Google and Google Scholar

A search of the bibliographies and citations of retrieved peer-reviewed articles will also be conducted through reference searching and citation searching(35) to identify other pertinent studies that were not included in our initial database searches.

Based on the extensiveness and depth of the identified literature in our searches, the reviewers will decide about conducting additional searches (e.g., with modified search terms and/or additional databases.) Additional searches will be conducted with the assistance of a librarian and will be aimed at identifying the specific elements of context, mechanism, outcome and their interactions mentioned in our initial program theory to provide more detailed and specific explanations of our CMOs. In case there is insufficient data regarding oral health programs for humanitarian migrants,

we will draw on literature from other domains (e.g. health) or other target populations (e.g. immigrants) if we realize that they have the same mechanisms at play.(34)

Study selection and screening

The identified articles will be exported to EndNote reference manager(36) where duplicate articles will be removed. One reviewer will conduct title-and-abstract and full-text screening for the identified resources, which will be checked by a second reviewer.

The inclusion criteria for the studies in title-and-abstract and full-text screening stages will be (i) relevance to the initial program theory and its CMOs; and (ii) containing information about contexts, mechanisms, outcomes and/or their interactions. Resources containing only descriptive information about outcomes will be excluded.

Unlike Cochrane systematic reviews, realist reviews do not aim to be comprehensive; rather, the aim is to establish an equilibrium between comprehensiveness and saturation.(28) Therefore, we will stop our searches when we have obtained enough evidence to support, refute, or refine our initial program theory.

iii. Quality appraisal and data extraction

Quality appraisal

In realist reviews, the unit of analysis is not the entirety of a study but the evidentiary fragments in the study.(37) While the rigor of data is often based on the plausibility of the methods through which the data were generated,(28) in realist reviews, data can be drawn from any part of a paper, not just the results section.(27)Therefore, using standard checklists to make judgements about the rigor of the whole body of the paper may not be appropriate, as these checklists may only account for a small portion of the relevant data in the paper.(38) The most important decision to be made

about data quality is the contribution each paper can make to the construction and refinement of the program theory, usually stemming from the 'pieces' of data and not the entire body of the paper.(37)

Rigor in realist reviews refers to the credibility, plausibility and trustworthiness of the methods used to generate data and depends on two criteria: trustworthiness (how much the methods used to obtain data are plausible and can be trusted) and coherence (whether the data is consistent and logical with explanatory breadth.)(32, 37) Since the information used in different parts of a paper will have been generated through specific means and methods serving specific purposes, assessing the rigor of the methods used to generate each data fragment might prove overwhelming or impossible and is not recommended by realist researchers (Westhorp, G, 2021, personal communication). Furthermore, sometimes circumstantial data identified in less rigorous data sources can contribute to constructing a convincing theory.(32, 37) Therefore, instead of evaluating and rating data quality, we will attempt to identify sufficient data to construct plausible program theories underpinned by coherent arguments.(32)

Data extraction

We will use MaxQDA,(39) a software used for qualitative data analysis for data extraction and analysis. This software will allow us to iteratively refine our codes.(40) One reviewer will read the included papers in full and extract parts of the data that can contribute to our theory development and refinement, which will be checked by a second reviewer. When confusion or concern arises (e.g., lack of adequate information), the reviewers will contact the authors of the papers to request additional information or clarification.

We will indicate each paper's characteristics in a Microsoft Excel spreadsheet. The following information will be included: (i) bibliographic details: title, author, journal and year of publication; (ii) study type and design; and (iii) target population, intervention, and type of program.

iv. Data analysis and synthesis

The data analysis process will involve identifying elements of context, mechanism, outcome, and their interrelationships in the data fragments.(25) Both quantitative and qualitative data types can be used for identifying any of these elements (Westhorp, G, 2021, personal communication). For instance, to identify mechanisms, qualitative data obtained from interviews can be a pathway to identifying participants' reasoning, while a multiple-choice question in a questionnaire survey can be used for the same purpose (ibid).(25) Outcomes can be identified through quantitative data, while in certain cases, such as identifying unintended outcomes, qualitative data might prove useful (ibid).(25) Contexts can be identified using quantitative categorical variables or qualitative data such as participant quotes in interviews or the constant comparative technique (ibid). While contexts are rarely the exact same as the categorical variables in quantitative studies or the theme titles in qualitative studies, they can provide clues for the reviewers and guide the inquiry regarding contexts (ibid).

Underlying mechanisms are often implicit in data and may not necessarily appear at the empirical level.(27) For example, the participants' reasoning occurs in their minds and might not be explicit in the data. Therefore, mechanisms need to be identified using 'retroduction,' an analytic technique to uncover hidden causal factors lying behind the identified patterns and the changes to those patterns.(41) Retroduction encompasses unearthing causal mechanisms using induction (developing theories from empirical evidence), deduction (testing theories against evidence), and abduction (creative thinking).(41, 42)

Identifying the interactions between the elements of context, mechanism and outcome is of the utmost importance in realist reviews and has been emphasized by realist researchers.(43) The accompaniment of terms relating to the elements of context, mechanism or outcome may indicate a possible interrelationship between them (Westhorp, G, 2021, personal communication). Conjunction terms such as "and", "so" and "but" can also indicate a relationship between these elements (ibid).

The identified CMOs will be used to test and refine the initial program theory. Relevant formal theories supporting these CMOs will be sought to advance our realist program theory at the middle-range level, allowing our findings to be transferable to similar contexts.(33, 44)

We will consult our stakeholder group regarding the final program theory; Their comments and feedback will be applied to further improve and finalize the final realist program theory.

Ethics and dissemination

v. Dissemination of findings

The findings of this review will be reported according to the principles of 'RAMESES publication standards for realist synthesis',(45) which outline the key elements to include in the abstract, introduction, methods, results, and discussion section of a realist review. With the advice and input from the stakeholders, we will make recommendations regarding how to implement community-level oral health promotion programs for humanitarian migrants most effectively.

Two manuscripts will be written to report the findings of this study, one encompassing the initial program theory, and another reporting the refined realist program theory regarding how community-level oral health promotion programs for humanitarian migrants work. The manuscripts will be submitted for publication in peer-reviewed journals. The findings of this

review will also be presented in oral and poster format in scientific local and international conferences. Moreover, we will disseminate the findings of this review through the MOHP website and via social media.

Ethics approval

Since this study is a review and synthesis of the literature, and that our consultations with stakeholders will not include primary data collection, institutional ethics approval is not required.

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Authors' contributions:

MEM and BN conceptualized the study. NE and NMN developed and piloted the search strategies. NE designed and drafted the realist review protocol, which was critically reviewed and revised by MEM, NMN and BN. All authors have approved the final version of the manuscript.

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