

1. Project title: *How can loneliness and social isolation be reduced among migrant and minority ethnic people? Systematic, participatory review of programme theories, system processes and outcomes*

2. Background

2.1 Description of the problem

This review addresses the need for better understanding of the causes of, and solutions to, unwanted social isolation and loneliness across varied settings; major public health issues recognised by national and local policy-makers.

Social isolation has been defined as a lack of interactions and relationships with other people—‘a deprivation of social connectedness’ [1]. Loneliness has been conceptualised and defined in a variety of ways [2,3], but is generally recognised as a complex and multidimensional emotional state related to, but distinct from, social isolation. It is linked with the quality (including meaningfulness) of social relationships and reflects a discrepancy between desired and actual social interactions [2,3]. Loneliness may also link closely to feelings of boredom, unfulfillment, detachment and lack of communication and connection to other people [3]. Isolation and loneliness affect individuals at any age or life stage, though people over 65 and under 25 report the highest rates of loneliness in the UK (e.g. in the ESS ~40% reported feeling lonely at least some of the time in the past week) [15]. Determinants of social isolation and loneliness operate at micro, meso and macro levels including individual, family, community, neighbourhood, and wider society [4]. Interventional activity with the potential to impact on social isolation and loneliness (whether positively or negatively) is therefore diverse, and there is a need for better knowledge of how the effects of initiatives ensue as they interplay with elements of wider socio-ecological systems.

The health risks of loneliness and social isolation are increasingly documented [5]. Both have been found to result in harmful effects on cognition and a range of physical and mental health problems [6-13]. Recent research suggests that loneliness and social isolation may both affect health independently through their effects on health behaviours and that social isolation may also affect health through biological processes [43]. Both loneliness and isolation have also been found to be adversely associated with aspects of functional status in older adults particularly among more disadvantaged individuals [44]. An analysis of data from the English Longitudinal Study of Ageing concluded that ‘both isolation and loneliness impair quality of life and well-being’ for older people but that only social isolation has an independent effect on mortality [11]. A recent meta-analysis estimated an average 50% increased likelihood of survival for people with stronger social relationships [14].]. Though much of the available research focuses on older people, isolation and loneliness have also been found to be associated with poor mental health and health damaging behaviours at younger ages, with pregnant and postpartum women and adolescents receiving particular attention to-date [45,46].

Migrants and people from minority ethnic backgrounds face particular risks of social isolation and loneliness. The diversity of the UK population continues to grow in terms of the range of ethnic identities and the proportion of the population identifying as non-White British. Net migration reached its highest recorded levels in the UK in 2015 [16]. Public health evidence and practice must reflect the needs of our multi-ethnic society. While the collective terms ‘migrant’ and ‘minority ethnic’ conceal heterogeneity, there is important patterning of social isolation and loneliness by migration status and ethnicity. Our own work using

qualitative and quantitative UK data confirmed important ethnic differences in patterns of social networks and interactions, with Black African women emerging as a group with low levels of social connection and support [47]. Very high rates of loneliness have been found in minority ethnic elders, particularly those with family origins in China, Africa, the Caribbean, Pakistan and Bangladesh [17]. There is also evidence of higher social isolation among ethnic minority children [4] and very high levels among new migrants, asylum seekers and refugees [19,20]. Perinatal depression is higher among some UK migrant and minority ethnic women and associated with isolation and poor support [18]. Similar findings are reported elsewhere [46,48].

These high risks among some migrant and minority ethnic groups relate in part to the concentration of risk factors that affect socioeconomically disadvantaged sections of society more generally (poverty, poor housing, unemployment) [21-23]. For instance, at neighbourhood level, minority ethnic people and migrants are more likely to reside in areas characterised by high unemployment, poverty and poor quality public spaces [24,25]. In addition, however, exclusionary processes and structures linked to migrant/minority ethnic identities present additional risks. Cumulative exposure to racial discrimination (e.g. micro-insults, fear of attack) can increase social isolation and mental ill-health [26]. Wider societal discourses and negative media portrayal can undermine a sense of belonging and self-worth [27]. For new arrivals, limited English language skills, uncertain legal status, lack of familiarity with processes and few local co-ethnicities can hamper the development of supportive social networks [20]. These aspects of lived experience relate closely to Rook's definition of loneliness as "an enduring condition of emotional distress that arises when a person feels estranged from, misunderstood or rejected by others and/or lacks appropriate social partners for desired activities, particularly activities that provide a sense of social integration and opportunities for emotional intimacy" [32 p1391]. Further, broader policy relating to housing and resettlement, immigration and entitlement to public services and welfare, will often impact differentially on social relationships by ethnicity. There is also evidence that migrant and minority ethnic people have lower access to, and poorer outcomes from, interventions aimed at tackling social isolation and loneliness. The tendency for practitioners to erroneously assume that "they look after themselves" has been documented [28,29], while questions about the importance of promoting co-ethnic versus inter-ethnic social ties for health promotion remain [30].

Chronic loneliness can be difficult to reverse, with evidence that individuals can spiral downwards through knock on effects for work, family members and use of statutory services [49]. Evidence on how to intervene effectively to prevent and reverse social isolation and loneliness therefore has the potential to (i) produce significant health gains, (ii) realise large savings to NHS and social care resources and (iii) avert wider social and economic costs. Similarly, evidence that can inform disinvestment from ineffective action could lead to cost savings. It is challenging to put precise estimates on the costs of isolation and loneliness to public services. Recent modelling estimates that chronic loneliness among older people may cost commissioners £12,000 per person, of which approximately 40% occurs within five years (GP visits, A&E visits, hospital admissions, residential care, some costs associated with depression and diabetes) [31]. A recent PHE review concluded that successful interventions can reduce use of health and social care services and are therefore typically cost saving and that broader social return on investment is expected to be high as isolation and loneliness have wide implications [4].

In sum, social isolation and loneliness are complex and widespread problems, with migrant and minority ethnic people facing some particular risks. Identifying effective and feasible interventional strategies to reduce unwanted social isolation and loneliness among diverse populations is therefore a priority for local

and national public health decision-makers and links closely the broader well-being agenda of many Local Authorities.

2.2 Existing evidence and rationale for the present review

A series of earlier reviews [2, 32-39] have usefully categorised some of the interventional approaches and confirmed that some interventions are effective in reducing social isolation and/or loneliness, particularly group-based and shared interest focused activities for older people. This project extends this earlier work in three important ways.

First, we review a wider range of interventional activity. Earlier reviews have often taken a narrow, individually-focused approach and looked exclusively at interventions specifically designed to address loneliness and/or social isolation. Recent policy and practice reports highlight the need to assess more holistic interventions (e.g. neighbourhood approaches) and to understand the impacts of initiatives in other sectors e.g. transport, housing and 'structural enablers' on isolation and loneliness [4,30].

Second, we focus on population groups that have to-date received little attention in prior reviews. No prior review has focused on the needs and experiences of migrant and/or minority ethnic people, nor have any examined inequalities or differential effects of interventions between minority and majority groups. Few have looked at ages other than older people.

Third, we take an explicitly theory-driven approach. Prior work has focused predominantly on answering simple effectiveness questions. While important, this approach pays little attention to the complex and multi-faceted nature of the problem and its potential solutions. There has been little attempt to uncover interventional logic or programme theories. Indeed, a recent review concluded that there is "urgent need to further develop theoretical understandings of how successful interventions mediate social isolation and loneliness" [39]. In particular, there has been little attention to wider structural determinants, including material disadvantage and discrimination, and how these interplay with interventional action. Earlier reviews have not sought to understand how and why interventions function differently for different people in different settings, nor the negative and inadvertent consequences that can ensue. We propose to take a systems approach, grounded in realist ontology, since this will enable a more thorough understanding of how and why interventional activity has particular outcomes, for particular people, in particular contexts.

3. Research objectives

The overall project aim is to synthesise the available evidence and produce new insight into the range of interventions addressing unwanted social isolation and/or loneliness among people identifying as migrant and/or minority ethnic, plus their logic, functioning and effects.

The primary purpose is to inform future action aiming to reduce social isolation and/or loneliness within ethnically diverse populations. We also anticipate new knowledge on how to identify opportunities within existing public health-related activity to prevent or reduce isolation/loneliness. We adopt a systems perspective [50-52], conceptualizing unwanted social isolation and loneliness as emergent properties of a system, in which processes operating at individual, family, community and population-level are intimately connected [52]. So, while our primary interest is interventions/ initiatives intended to reduce social isolation and/or loneliness, we aim to uncover broader features of socio-ecological systems that interplay with, and impact upon, these outcomes. We will increase understanding of what happens when interventions are

introduced into particular settings; exploring the system processes that ensue, particularly those that amplify or dampen intended mechanisms. We go beyond more traditional review methods to understand causal processes and potential solutions to this complex public health issue in varied settings.

3.1 Our research questions are:

Intervention outcomes:

1. What types of interventional approaches to addressing social isolation and/or loneliness among migrant and/or minority ethnic people have been developed and evaluated?
2. How effective are such interventions in reducing social isolation and/or loneliness when compared to usual or no intervention?
3. What health outcomes have been examined in relation to these interventions?
4. What negative effects have resulted from such interventions?
5. Do effects (positive and negative) of interventions vary for different people (e.g. by gender, age, income)?

Programme theory and systems functioning:

6. What 'programme theory' and assumed underlying mechanisms inform interventions?
7. What system factors increase or decrease social isolation and loneliness among migrant and/or minority ethnic people?
8. What happens when similar interventions are introduced into different contexts? What processes (both anticipated and unanticipated) ensue and how do these reflect the interplay of local and wider system elements?

Potential for roll out and sustainability:

9. What system conditions support or hamper successful and sustained implementation?
10. To what extent do current interventional approaches address the known determinants of social isolation and/or loneliness among migrant and/or minority ethnic people? Where are the gaps?
11. What are the costs associated with such interventions?
12. What implications are there for roll out at scale in the UK?

3.2 Research objectives

Steps in the project with deliverables and deadlines are as follows. A Gantt chart has also been provided.

Activity 1 (effectiveness review)

Searching and screening: months 1-4

Extraction and synthesis: months 3-7

Drafting synthesis products 1-3: months 5-7

Finalising synthesis products: months 11-13

MILESTONES:

Draft synthesis products 1-3: By month 7

Finalised synthesis products 1-3: By month 13

Activity 2 (constituting Consultation Panels)

Recruitment and briefing of Community Development/Support Workers: months 2-4

Recruitment and orientation of panel members: months 4-7

Ad hoc support to panel members: months 7-18

MILESTONES:

Recruitment and orientation of all 3 panels: By month 7

Activity 3 (Theory-driven systems review)

Extraction explicit and implicit programme theory: months 4-6

Round 1 Consultation Panel workshops: months 8-9

Supplementary search-screen-synthesise cycle 1: months 9-11

Revising system model (diagramming and text): months 12-13

Round 2 Consultation Panel workshops: months 12-13

Supplementary search-screen-synthesise cycle 2: months 14-15

Refining system models and draft synthesis products 4-6: month 15

MILESTONES:

Draft theory bundles and system diagrams: By month 11

Submission overall study protocol to PROSPERO: By month 1

Three initial Consultation Panel workshops held: By month 9

Revised system model: By month 13

Three follow-up Consultation Panel workshops held: By month 13

Draft synthesis products 4-6: By month 15

Activity 4 (integration, reporting, dissemination and knowledge translation)

Preparation of integrated report: months 14-18

Web outputs and oral dissemination: ongoing throughout

MILESTONES:

Interim report 1: By month 9

Interim report 2: By month 13

Advisory group meeting 1 (skype): month 2

Advisory group meeting 2 (face-to-face): By month 7

Advisory group meeting 3 (skype): By month 13

Advisory group meeting 4 (face-to-face): By month 16

Participatory dissemination workshop held: By month 16

Final synthesis products 4-6: By month 17

Final report: By month 18

4. Research design

4.1 Overview

We combine an effectiveness review with a participatory, theory-driven review informed by systems thinking. We integrate desk-based methods with extensive engagement via 3 Consultation Panels (CPs) throughout the project. We will produce 6 complementary evidence synthesis products:

Arising from the effectiveness review:

- 1) A typology of interventions (including detailed descriptions of components and resource inputs).
- 2) An assessment of comparative effectiveness using network meta-analysis, meta-analysis and/or narrative synthesis as appropriate.
- 3) A descriptive synthesis of the costs (and where reported cost effectiveness) of interventions.

Arising from the participatory theory-driven systems review:

- 4) A refined system model (presented visually in causal loop diagrams and in narrative form)
- 5) A qualitative meta-synthesis of factors supporting/undermining successful implementation and sustainability of interventions.
- 6) A qualitative meta-synthesis of factors that increase/decrease social isolation and loneliness among migrant and minority ethnic people mapped against existing interventional activity.

4.2 Scope

Both reviews are guided by the same over-arching research questions and have the same PICO scope. However, while the effectiveness review is confined to intervention studies, the participatory, theory-driven systems review is necessarily broader, drawing in a wide range of intervention and non-intervention studies, as well as theoretical literature, via iterative, targeted searches.

Participants

In broad terms the project is focused on individuals who trace a significant part of their family heritage outside of their current country of residence. We subscribe to a theoretical position that recognises migrant and ethnic identities as fluid and contingent. We understand associated categories not as natural, normal and fixed, but rather as resulting from processes of identification, inclusion and exclusion [53]. As such, we recognise the importance of understanding social processes that produce national or ethnic belonging; how insiders and outsiders are established [54,55]. Understanding such 'boundary work' – rather than simply taking such boundaries for granted - is clearly particularly relevant to the current projects' focus on social isolation (versus connectedness) and loneliness. However, as an evidence synthesis, this project is necessarily constrained to working with the concepts, categories and labels employed by other researchers; and to managing the great diversity in these across contexts. We will review studies that include individuals who self-identify, or are identified, as migrant and/or minority ethnic (or minority racial), of any age. Studies employing both generic (e.g. migrant, BME, BAME) and more specific (e.g. British Chinese) labels will be included. Within this broad remit, the review will aim to synthesise evidence relating to identified sub-groups that have been found to face particularly vulnerable circumstances, including: older people; pregnant and newly delivered women; recently arrived migrants; undocumented migrants; asylum seekers and refugees; children and adolescents.

Our decision to take this broad approach to defining migrants and minority ethnic peoples is informed by our own earlier work [56], and that of others [57], that demonstrates its value. Such an approach does not deny the role of particular ethnic identities in shaping people's understandings and behaviours, but can help to expose the importance of context and the varied significance of particular identities over time and space. It can serve to challenge the normalisation and essentialisation of categories and instead help to identify processes and opportunities for intervention. Including people with either a migrant and/or a minority ethnic identity is appropriate since they frequently share the experience of associated exclusion from a 'national imagined community' [58]. Furthermore, families and communities commonly comprise both those born within and outside the current country, so that the influences of migrant and minority ethnic status are often closely inter-twined. An inclusive approach defining migrant and minority status also sits well with our systems paradigm which aims to examine populations as a whole, and social processes in general, and then to evaluate the role of migration and ethnicity within them, as advocated by Dahinden and others [54]. Our synthesis will involve careful documentation of how categories and labels have been used and the extent to which prior studies have considered their (dis)utility for analysis. Our aim therefore will be to work with prior

migrant, minority and ethnic groupings but at the same time to reveal the limits of the explanatory power of particular categorisations [54].

Interventions: The interventions/initiatives to be considered are diverse. They may involve single or multi-component inputs/activities and aim to address social isolation and/or loneliness and associated health-related outcomes via a range of mechanisms. We will consider both tailored interventions that have an explicit target audience of migrant/minority ethnic people as well as more generic interventions that have included a recipient group that includes a substantial proportion of migrant/minority ethnic people. We will include interventions that have social isolation and/or loneliness as a primary or as a secondary outcome. Interventions may be implemented and operate at different levels: individual, group, or neighbourhood/settings based. Preparatory scoping work indicates that a majority of interventions are delivered by community-based and third sector organisations utilising para-professionals, peer workers and volunteers. Some interventions are delivered by healthcare professionals (e.g. psychotherapists; counsellors; nurse specialists) in primary care or community venues or by other trained professionals (e.g. trained exercise specialists; professional group facilitators). Other initiatives with the potential to impact on isolation and loneliness are area or neighbourhood based and may involve a range of actors who may or may not directly deliver inputs to individual recipients. Eligible interventions may have been delivered in diverse settings, sometimes using multiple settings simultaneously, including: by telephone; over the internet; in people's own homes; within primary care settings; within community venues; and at wider neighbourhood or community level.

Prior reviews have categorised interventions into four main strategies: improving social skills (e.g. communication); enhancing social support (e.g. befriending); increasing opportunities for social interaction (e.g. via creation of virtual and physical networks); and addressing maladaptive social cognition (e.g. CBT) [2]; and identified a range of individually-targeted inputs such as education, directed support, coping techniques, and problem-solving skills. However, it is increasingly recognised that opportunities to reduce (and indeed risks of increasing) social isolation and loneliness may arise through other types of public health activity such as addressing mental ill-health and physical inactivity [59,60]. We will include such interventions where social isolation and/or loneliness is a secondary outcome. Furthermore, broader structural and neighbourhood-wide initiatives, such as changes to transport, housing and public spaces, as well as cohesion strategies, also have the potential to increase or decrease social isolation; and may also represent important system features that moderate the impact of targeted social isolation interventions. Our review will include consideration of these initiatives where the available evidence allows pathways to social isolation and/or loneliness to be explicated.

Comparator: The review will include studies that have used a control/comparator group as well as those that have not. Control groups, where they have been used, are likely to have received no intervention. We will systematically record the control treatment/interventions where these have been used and use this information within our effectiveness review and synthesis.

Outcome: In line with the call specification, primary outcomes of interest relate to loneliness and unwanted social isolation. However, preliminary searches for this project and past reviews confirm that a wide range of outcome measures have been used in relation to both social isolation and loneliness. Common loneliness measures/tools include: UCLA Loneliness scale (10 item or 20 item) [61]; Asher Loneliness Scale (16 item or

24 item) [62]; De Jong Gierveld Loneliness Questionnaire (11 item or 6 item) [63]; Paloutzian and Ellison Loneliness Scale [64]. Studies have also employed a range of bespoke emotional and social loneliness questionnaires, as well as self-rating scales. Social isolation measures include both objective and subjective measures. For instance, individual measures of frequency of contact with family, friends, neighbours; numbers of close friends/relationships; and participation in interactive activities have been used. The Lubben Social Network Scale has been used [65, 66], as well as The Friendship Scale [67] and social disconnectedness scales [68]. Subjective measures record individual's assessment of their satisfaction with relationships with family, friends, colleagues and so on; or assess the characteristics of relationships such as trust or the provision of types of support (e.g. emotional or social support). Measures of social connectedness or association have also been recorded at the aggregate level e.g. levels of volunteering; numbers of social cooperatives/groups; civic engagement [4]. Studies may also have examined health and wellbeing measures (e.g. Warwick Edinburgh Mental Wellbeing Scale) as outcomes of interventions that address social isolation and/or loneliness. We will systematically record the outcome measures used and group these into key domains (e.g. loneliness, social isolation, general health and wellbeing) that will be considered as single outcome measures for the evidence synthesis. Within each outcome domain standardised mean differences (SMD) will be computed to allow comparison across the different subjective continuous measurement scales used in individual studies (see below). This approach is in line with previous reviews in the area [2]. Where objective summary measures (as mentioned above) have been widely reported these may also be considered in the evidence synthesis.

We will also examine the disparate conceptualisations that underpin different labels and measures and seek to integrate these to ensure that relevant evidence is not lost. We will also examine whether the cross-cultural validity of outcome measures has been considered in the reviewed studies.

Types of studies: As described more below, we will include a range of study types in both the effectiveness and the theory-driven systems review. RCTs, non-randomised comparative studies and single group before and after studies will be included in the effectiveness evidence synthesis.

4.3 Effectiveness review

Search strategy:

We will search initially for studies that report on the development, implementation and/or evaluation of relevant interventions or initiatives. We will seek studies where the target population was identified as either (i) migrant and/or minority ethnic people (however defined and labelled by authors), or (ii) a client group, population or neighbourhood diverse in terms of ethnicity/race/ migrant status. We will first search for studies where social isolation and/or loneliness was the primary outcome. Our experienced information specialist will develop a comprehensive list of search terms iteratively from scoping searches, MeSH terms and harvesting key words from recent relevant reviews conducted by team members [69]. Searches will combine terms relating to the key concepts of {migrant/minority ethnic identity}, {social isolation/loneliness} and {intervention/initiative/programme}. Preliminary scoping searches confirm that reliable indexing is an issue, so that we will need to use free text terms. Electronic databases searched will include MEDLINE, EMBASE, the Cochrane Library, PsycINFO, SCI and SSCI, CINAHL, ASSIA, and EPPI-Centre. Additionally Google Scholar will be searched for relevant articles. Recognising that the relevant literature is widely dispersed and inconsistently indexed, we will seek to maximise sensitivity as recommended by the Cochrane Handbook for Systematic Reviews of Interventions [70].

Next, we will conduct a supplementary set of searches to ensure that we also capture relevant interventions or initiatives where social isolation and/or loneliness were secondary outcomes. In order to make this exercise manageable, we will develop a list of interventional approaches that are known to have been implemented with the objective of reducing social isolation and/or loneliness. This list will be informed by: our initial searches described above and a review of prior systematic and policy-oriented reviews of social isolation/loneliness interventions. This list will be used to replace the generic {intervention/initiative/programme} search field, with a set of search terms relating to key interventional approaches (e.g. befriending/companionship; CBT/counselling; social skills/social competence; support networks/social bonds/support groups; neighbourhood cohesion; shared spaces/housing design; physical activity/exercise; and so on). Since outcomes are poorly reported and indexed in journal abstracts [98] and we anticipate that this issue will be even more acute for secondary outcomes, there is a danger of bias in the studies we include. We will therefore expand study identification methods beyond typical abstract based study selection to harness the full text searching capability of Google Scholar. We will use methods that we have previously used, involving the openly available Publish or Perish Software in populating an Excel Study Selection sheet, to retrieve full text articles that combine secondary outcomes with the phenomenon of interest and study design filter words (e.g. loneliness AND “comparative study” AND <Named intervention>) and thus extend our retrieval set. While this approach will only reduce, rather than eliminate, potential bias, it should optimise the value of the study within available resource constraints. We will ensure that our iterative process is systematic and auditable. We will identify and acknowledge any biases that remain in the Limitations of our report and any other outputs.

Complementary searches will also be conducted by forward and back citation searching of included intervention studies, and hand-searching of key journals. We will also identify relevant grey literature by: google searching using key terms (both generic and intervention-specific); searching websites of relevant policy, practice, research and advocacy organisations and contacting their research and evaluation sections by email; contacting subject experts and using subject-relevant email distribution groups; searching OpenGrey. No language, country or date restrictions will be applied for intervention studies. The search process will be recorded according to PRISMA guidelines.

Screening and selection of studies:

Initial screening for relevance on title and abstract will be by one reviewer, with any uncertain items referred to a second reviewer. A second round of full-text screening for inclusion/ exclusion will involve two reviewers applying an inclusion criteria checklist developed, piloted, refined and finalised. A third reviewer will resolve disagreements where needed. Translation of non-English language papers will be undertaken if needed. We will keep a detailed audit of the process of screening and selection.

Quality appraisal and risk of bias:

Quality assessment will involve two reviewers and use standard checklists appropriate to each research design [70, 71]. Will not exclude studies from the effectiveness review entirely on the basis of quality, rather we will adopt synthesis approaches that are most suitable for the research designs employed and also moderate the weight of evidence from less well designed/executed studies [72].

Data extraction and management:

We will develop and test an extraction template before finalising it and preparing it within EPPI-reviewer.

Two reviewers will then extract information from all the included studies, compare and agree extractions, and call on a third reviewer for consensus where needed. We will extract the following fields: Study descriptors; Study design and methods (including limitations); Participant / population characteristics (including migrant/ethnic categorisation employed); Outcome measures; Context/setting; Intervention/initiative characteristics (in detail, guided by the TiDieR framework [73]); Control group/control area characteristics and any intervention; Results - outcomes overall; sub-group analyses; Costs data.

Synthesis:

The material retrieved from our effectiveness review will be synthesised in three ways. First, we will produce a typology of interventions, indexed against a range of useful criteria e.g. mode of delivery; central mechanism; scale; mainstream or tailored for migrant/minority; and so on. Interventional components will be described in detail (e.g. qualification/grade of worker delivering), so that future decision-makers are able to impute costs. Where necessary, we will contact authors and/or delivery organisations to gather additional detail on interventional components. Second, we will summarise any directly reported costs associated with interventions, and also report these alongside the typology. Third, we will synthesise the evidence on comparative effectiveness of interventions, using an appropriate combination of narrative synthesis and statistical meta-analysis. Initial scoping suggests a high level of heterogeneity between the interventions and study populations. Suitable statistical methods will be used to account for this heterogeneity, and where statistical synthesis is not appropriate we will undertake a structured comparative approach to the analysis. Key elements of each study will be extracted in a way that optimises comparison and contrast across different interventions or different versions of the same intervention. We will draw on our own earlier work and that of others, particularly the TiDieR framework which we have used previously [99], to systematically extract and report on intervention components, context, mechanisms and outcomes. Results will be presented in narrative and tabular format.

Where appropriate (i.e. depending on the number of high quality studies that report data on specific outcomes), outcome measures of interest will be synthesised using random effects models to account for heterogeneity between studies that arises from differences in study protocols. RCT and non-randomised comparative studies will be considered for inclusion in a network meta-analysis (NMA) to allow a comprehensive analysis of all relevant interventions. Outcome measures for which there is not a connected network of evidence will be analysed using standard pairwise meta-analysis, considered separately according to study type (including single group before and after studies) as in Masi et al. [2]. Where possible, explanations for heterogeneity between studies in effects of the interventions will be explored using meta-regression, including potential moderators (e.g. gender, age, income) and potential mediators that could help to explain the process by which an intervention was effective (e.g. setting, who delivers the intervention). Sub-group analyses reported in the original studies will also be considered in the evidence synthesis. This evidence will be carried forward into the theory-driven synthesis. Random effects models will be implemented using a Bayesian framework using the software packages WinBUGS and R [74, 75].

4.4 Participatory, theory-driven systems review

General operational approach:

We will employ an iterative process of desk-based work and community consultation. We will convene three Consultation Panels (CPs) comprising lay experts, community workers and beneficiaries of social isolation

initiatives, one each in London, Sheffield, and Leicester. Preparatory work with stakeholders, and past experience, suggests that CPs will function best if they include individuals who are at a similar stage of life, rather than seeking homogeneity in terms of ethnic identity or migration history. Each CP will comprise 8-12 individuals and will be supported by a local development worker. The three panels will be comprised as follows. In Sheffield, the CP will be hosted by PACA, a community-based organisation serving a diverse neighbourhood in the north of the city and providing a range of services including activities aimed at improving people's social connections and combatting loneliness. This CP will comprise working age men and women, including parents with young children. Community development workers and volunteers engaged in delivering loneliness-related interventions to this age-group will also be members of this CP. Participants will include recent arrivals and more established migrants, as well as UK-born individuals. Likely ethnicities include: Pakistani, Bangladeshi, Roma, Polish and Black African. In Leicester, the CP will be hosted by Leicester Ageing Together, an umbrella organisation that is working with 16 local organisations to deliver initiatives focused on isolation and loneliness among older people funded by the Big Lottery. This CP will comprise people aged 50+ and community level workers engaged in older people provision. Likely ethnicities include: Indian, Pakistani, Black Caribbean, Black African. In London, the CP will be hosted by Brunel University, home to an extremely diverse student population. This CP will comprise single people aged <25 years and volunteers/workers with responsibilities around overseas student welfare. This group is likely to be very diverse in terms of ethnicity, and to comprise mainly recent migrants. Further, this group will complement the other two in that we expect participants to be financially and educationally more advantaged than those in the other two groups. We will also undertake a series of one-to-one or paired consultation exercises to capture the views of any key minority groups that remain under-represented in our three CPs. For instance, we have pre-existing links with Chinese community organisations in Sheffield, Manchester and London, and we have undertaken recent engagement and research work within the Polish community and with refugee and asylum seeker groups in Sheffield, who we will invite to participate if considered necessary to ensure the inclusion of a wider range of perspectives and experiences.

We draw on extensive past experience of engaging stakeholders in research [76,77] to develop approaches for this element of the project. The approach will be based on participatory principles set out by INVOLVE [41]. Preparatory work for this bid indicates that fairness of opportunity can be increased by allocating funding for carer or supporter costs, variation in both the timing of activities and use of familiar, public spaces. Specific engagement activities will be developed in collaboration with CP members to increase the likelihood that they meet the objectives and practical needs of researchers and panel members. Our approach is also informed by Group Model Building Methods [78,79], that emphasise the importance of adopting an iterative process of dialogue, building, testing and improvement, and the need to attend carefully to group dynamics.

Initial recruitment and orientation to the task will be undertaken by community development workers familiar to the CP members. Introductory conversations will provide some background knowledge about the modelling approach and identify any support needs. The core of the group modelling approach will take place through structured group exercises using visual and verbal methods of communication. Our team of experienced facilitators will run these sessions. Workshops will be carefully designed and planned, drawing on materials available on *Scriptapedia* as useful. Detailed note-taking and use of visual diagramming will capture CP contributions. In addition, however, our consultation to-date indicates that use of alternative ways of contributing is likely to be fruitful in encouraging diverse participation. We will therefore make provision for people to make contributions via email co-ordinated by community development workers

and/or through informal conversations by telephone, or face-to-face at familiar venues. Provision will also be made for participation in languages other than English where preferred.

Theoretical approach:

Our approach is rooted in a realist ontology which views socio-ecological systems as being comprised of large numbers of interacting actors, structures, and processes stratified into layers [80, 81, 82]. Initiatives or programmes that are intended to bring about a particular change (e.g. reducing social isolation and/or loneliness) provide physical and symbolic resources that may facilitate actors to behave and interact in new ways [83]. However, since such initiatives are introduced into pre-existing complex systems their results are varied. Viewing socio-ecological systems as stratified into levels which can be subject to empirical observation [83] provides the possibility of developing and refining explanations for observed phenomena within particular parts of a system [83, 84]. Realist ontology recognises the existence of “... *underlying entities, processes, or [social] structures which operate in particular contexts to generate outcomes of interest*” [83]; so-called mechanisms. Articulating potential context-mechanism-outcome configurations is a key tool in developing explanatory theory for why interventions/ initiatives produce particular effects, for particular people, in particular places. These ‘programme theories’ can then be tested against empirical data. A realist review thus typically involves an iterative process of developing and refining an explanation for why an outcome of interest (reduced social isolation and/or loneliness) emerges in response to deliberate action in some situations and not in others.

Our review expands this general approach by considering a wide range of interventional activity aimed at enhancing social connections and reducing loneliness that have been introduced into different levels of the system. We will also look out and beyond immediate c-m-o configurations, to examine a wider set of mechanisms and causal chains operating within the wider socio-ecological system. The value of this approach is that it does not foreclose the aspects of the system that are within view. It widens the focus beyond individual system elements to consider aspects of system structure (connections and interdependencies between system elements and subsystems) as potential objects of interventional action. The downside is that the scope could become unmanageable, and strategic prioritisation decisions will be taken as the review progresses in consultation with members of the CPs and the Advisory Group.

The evidence synthesis will be developed over three phases.

Emergent phase:

This phase equates to the ‘articulation of key theories to be explored’ step identified in early formulations of realist review method [85]. Alongside the extraction of data for the effectiveness review described above, we will undertake extraction of explicit and implicit programme theory from all the included intervention studies that target or include migrant/minority groups. In addition, we will extract explicit and implicit programme theory underpinning generic/mainstream social isolation/loneliness interventions by reviewing prior reviews.

Extracting explicit and implicit programme theory: Realist inquiry asserts that all programmes and interventions have underlying theories, whether explicit or implicit [83, 86]. We will systematically harvest explicit information on programme theory, underlying pathways, potential moderators and implementation processes, using structured extraction templates, iteratively developed, tested and refined in Excel. We will

also adopt innovative methods developed by team members [87,88], to identify implicit programme theory, underlying pathways, and potential moderators [88]. This phase will involve careful examination of different outcomes and experiences in different studies, across different settings for different people, in order to build theory about mechanisms and important elements of context. We recognise that intervention papers do not necessarily report all available and relevant data. Where deemed useful and feasible, we will contact authors to seek additional information to gain clarity on aspects such as: ethnic categorisation; sub-group analyses if available; contextual characteristics and implementation issues. A series of early causal loop diagrams (visual representations) and brief textual statements (including c-m-o propositions) will summarise early programme theories (theories about how the interventions are thought to operate in practice, including how they may operate differently for different people—for instance linked to individual personal attributes or circumstances, and how aspects of the implementation context may shape what happens).

Consultation Panel workshops 1: Next, we will convene our first round of workshops with the 3 CPs. We will use established methods for engaging stakeholders in structured analysis of systems and group modelling approaches [78,79]. Workshops will involve structured exercises to elicit both (i) open-ended exploration of experiences, causes and solutions to isolation and loneliness, and also (ii) reflection on the findings of the effectiveness review and early representations of programme theories. The workshops will elicit additional ideas about intervention components and functioning, and context, as well as system elements that impact upon isolation/loneliness that have not yet been articulated in the programme theories. We will compare and contrast insights across the 3 diverse CPs to refine the emergent programme theories (written up in memos and causal loop diagrams) and also begin to articulate system structure. The diversity of the panels will allow for exploration of how different sub-groups within the migrant and minority ethnic population may be exposed to different risk factors, have varied protective resources, and also may access and experience interventions differently. A preliminary partially formulated visual diagram informed by our early scoping work is included for illustrative purposes as an appendix. The panel workshops will identify gaps in the literature so far reviewed and inform the next stage of desk work, in which we will search, screen, extract and synthesise additional evidence that can help to further explicate programme theory and wider system structure and dynamics.

Construction phase:

Supplementary searches 1:

Purposive, iterative searches will employ search terms suggested by the first round of CP workshops, as well as earlier rounds of searching, to retrieve literature that can enable the further articulation of programme theories and system dynamics. Searching for, and screening of, the supplementary material will be informed by standards [84] and use established snowball sampling literature search techniques. We will identify clusters of related documents that will contribute richness and contextual depth [89]. Published and grey literature will be searched. We also anticipate that CPs will highlight some relevant 'grey information' [90] to be incorporated.

Screening: Qualitative, quantitative, intervention and non-intervention studies will be eligible. Appraisal will employ bespoke assessment tools for quality, relevance and richness. These tools will consider how researchers have conceptualised and operationalised constructs of ethnicity/race/migrant identity, as well as more generic quality of theory considerations (e.g. use of explicit definitions; clarity of articulation). Relevance ranking will consider country context as well as focus on system elements. Two reviewers will

rank each paper using a composite checklist, and consensus will be reached on which papers warrant inclusion, and if needed, the priority order in which extraction should occur.

Extracting evidence on system elements and relationships: The initially developed coding templates will be further refined and extended to accommodate both structured and more interpretive coding. We will extract text verbatim and also use precis as appropriate. Provision will be made for the extraction of any relevant visual representations. We anticipate a large volume of relevant studies and will therefore opt for single extraction with a sub-sample of extractions being double extracted and reviewed to promote consistency. This approach is appropriate since our synthesis and model building approach is iterative and allows us to return to included studies as often as needed to achieve consensus. Extraction will access evidence on underlying pathways, moderators, implementation processes, wider determinants of isolation and loneliness, and system elements and processes that interplay with interventional activity. We will ensure that evidence related to sub-groups (particularly by age, gender, education, language ability and migrant status) is systematically extracted to allow the identification of important differences, as well as similarities.

Synthesis: Here the value of a systems approach will be harnessed. Instead of focusing in isolation on logic chains immediate to interventions, we will locate the emerging programme theories in an interpretation of the wider system. At the same time we will follow current guidance to work back from the outcomes of interest (social isolation and loneliness) to keep the exercise focused and manageable. A combined integrative, interpretive and abductive approach [91, 92] will bring qualitative and quantitative empirical evidence together with prior theory, to identify and develop explanations for patterns and regularities in how elements of the system relate to each other (in both anticipated and unanticipated ways). We will interrogate the available material to examine the manner in which mechanisms interact with other mechanisms at different levels, under specific conditions. This should help to explain why particular concrete outcomes and processes are documented in particular circumstances for particular people. We will distinguish between structural conditions (e.g. racial discrimination) and more idiosyncratic circumstances [92]. As before, the constructed theory will be presented both textually and via causal loop diagrams (together these form the system model).

Confirmatory phase

CP Workshops 2: The first element of our confirmatory phase will involve a second round of CP workshops. These will engage CP members in structured exercises to review the current representation of system elements, connections and inter-dependencies. The panels will draw on real world contextualisation to confirm or refute the draft system and sub-system models. We will prepare accessible materials and structured exercises to support engagement. Discussions will identify overlooked elements and additional relationships, particularly processes that amplify or dampen the intended mechanisms of the interventions/initiatives [93, 94]. An integrated synthesis will draw across the insights from the 3 CPs to highlight elements of the constructed theory that are: supported, refuted, or refined/extended by CP testimony, as well as any new system characteristics not previously identified. Identified gaps and uncertainties that warrant further follow-up will be fed into a final round of targeted searching.

Assessment of evidence: A further period of desk-based work will adopt the 'Inference to Best Explanation' approach proposed by Haig [95] and applied by Eastwood et al. [92] to systematically assess the compiled evidence (from both the literature and the CPs) in relation to the constructed system model, and its sub-

elements. As recommended [92], a combination of Thagard's seven principles and the Bradford Hill criteria for causation will be used to arrive at an assessment of the 'strength' of the evidence in support of the constructed system model and each of its theory sub-elements.

Supplementary searches 2: Provision within the plan has been made for a final round of targeted searches to identify supplementary evidence that could help to further examine any system relationships for which the evidence remains weak or inconsistent. A small number of bespoke searches will be undertaken on priority areas to identify additional literature. As before, we will sift identified studies and rank them according to quality, relevance and richness. Targeted extraction will then produce additional evidence to feed into a final assessment of theories and refinement of the system model.

4.5 Final synthesis and stakeholder dissemination workshop

Using narrative, graphical, and numerical tools we will then bring together the systems and effectiveness findings into a series of project outputs in accessible formats. We will convene a dissemination workshop for around 30 participants (including local authority and CCG commissioners across relevant portfolios, representatives from PHE and NHSE, as well as VCF and community representatives) to promote engagement with and testing out of the recommendations and conclusions. The event will be participatory inviting people to examine the systems model and programme theories developed and to consider how the findings relate to their own local systems. A series of exercises will be designed to enable participants to:

- share and seek feedback on contextual claims about aspects of the system
- map local and national action against the system model to reveal (i) examples of promising practice, (ii) opportunities for more impactful deliberative action [96] and (iii) potential for modification or disinvestment
- identify avenues for mobilising the knowledge within their own decision-making structures (with or without support from the research team)

Detailed notes will be taken during the workshop and fed into the final project report.

5. Size of the available literature

In preparation for this proposal, we have conducted a series of pilot searches in order to confirm that there is an adequate volume of literature to meet the project objectives and also to inform the design of a manageable approach to searching, screening, extraction and synthesis. Screening database records for papers published 2006-16 retrieved via a search described in appendix 2 identified 56 relevant intervention studies. A grey literature search also described in appendix 2 identified a further 8 intervention studies. Of these 64 studies, 56 included information on intervention design and 51 included process evaluation data. Twenty seven studies were identified as outcome evaluations, of which 8 employed a RCT design, 3 a waiting list trial, 2 non-randomised comparative designs, 9 uncontrolled before-and-after designs, 2 a natural experiment design and 3 other designs. These scoping searches also confirmed a large volume of rich and relevant studies (>200 identified), employing both qualitative and quantitative methodologies, focused on the patterns and determinants of social isolation, social connectedness, social integration, social support and loneliness among migrant and minority ethnic people. Recent work on postnatal depression by Eastwood et al. [46] suggests there will be value of drawing in this broad body of theoretical and empirical work in developing a comprehensive understanding of the factors shaping social isolation and loneliness, and the opportunities for effective intervention.

6. Socioeconomic position and inequalities

This project focuses directly on key dimensions of socioeconomic position – migrant and minority ethnic identity. Though UK formulations of health inequalities have tended to foreground economic deprivation and class, WHO's Commission on the Social Determinants of Health (CSDH) [97] promotes a broader understanding of health inequalities as rooted in differential power and influence, associated with social status as well as income inequality, and linked to differential exposure to stress, adverse conditions, discrimination and unequal access to services. The project aims to fill recognised gaps in current knowledge that prevent informed action on health inequalities experienced by migrant and minority ethnic groups (as indicated by the recent NIHR PHR call for research on migrant health). In addition to the overall focus, the project will synthesise available quantitative and qualitative evidence on differential outcomes and processes between groups identified by other socioeconomic indicators, particularly income, employment and gender. Our theory driven, systems approach is designed to identify social processes that create disadvantaged circumstances and increased risk of isolation among particular groups, as well as opportunities to address such inequalities. Our consultation panels are also designed to ensure close attention to the role of socioeconomic position and inequalities, and to highlight ways in which current literature and interventional approaches do/do not address disadvantage. Members will represent diverse socioeconomic positions, including individuals living in marginalised circumstances.

7. Ethical arrangements

We will comply with the research ethics framework of the ESRC. We will seek guidance from the SchARR, University of Sheffield, Research Ethics Committee on whether formal research ethics approval should be sought for the Consultation Panel workshops. If formal ethics approval is not required, we will nevertheless attend carefully to principles of informed consent and participant safety by adhering to principles of good practice set out by INVOLVE [41] and the Simple Rules Toolkit of our local CLAHRC [42]. We do not anticipate needing to notify any R&D offices of the study. We will register the review with PROSPERO.

8. Project timetable and milestones:

A Gantt chart has been submitted. Milestones are identified below:

Advisory group meeting 1 (skype): By month 2
Advisory group meeting 2 (face-to-face): By month 6
Recruitment and orientation of all 3 panels: By month 6
Draft synthesis products 1-3: By month 6
Interim report 1: By month 6
Three initial Consultation Panel workshops held: By month 8
Draft system model and programme theories: By month 9
Submission overall study protocol to PROSPERO: By month 9
Finalised synthesis products 1-3: By month 12
Advisory group meeting 3 (face-to-face): By month 12
Revised system model: By month 11
Three follow-up Consultation Panel workshops held: By month 13
Interim report 2: By month 13

Draft synthesis products 4-6: By month 15
Advisory group meeting 4 (face-to-face): By month 16
Participatory dissemination workshop held: By month 16
Final synthesis products 4-6: By month 17
Final report: By month 18

We will also hold study steering group meetings as agreed with NIHR PHR.

9. Dissemination and knowledge translation

Our dissemination approach is informed by past experience of researching migrant and minority ethnic health as well as the literature on knowledge mobilisation processes. We adopt an integrated model [40], with Consultation Panels (described above and in PPI), and a Project Advisory Group (consisting of practitioners, policy-makers and academics) being central to the research design from conception through to outputs. We will produce a range of research products tailored to different audiences and will use our extensive academic, policy-practice and community networks to share the study findings with the key stakeholder groups. We will report our findings in the NIHR Public Health Research journal. We will submit two open access papers to high impact journals, one focused on the substantive findings and another on the novel methodology. We will present findings at two relevant conferences e.g. EUPHA Migrant and Minority Health and Society for Social Medicine. We will convene a dissemination workshop for around 30 participants (including local authority and CCG commissioners across relevant portfolios as well as third sector organisations and community representatives). The event will be participatory inviting people to engage with the systems model(s) developed, to consider how the findings relate to their own local systems and to identify avenues for mobilising the knowledge within their own decision-making structures. Our Advisory Group members will also link the project into important regional, national and international networks and will act as conduits for the study outputs. We will prepare a 'Bitesize' summary of the project findings for local authority officers and CCG managers (in both text and video format) and distribute this widely both face-to-face (utilising our ongoing, regular interactions at local and regional levels), via e-lists and also via a project web-page which will be linked to other pre-existing webpages with significant traffic. We will also use current links to PHE (Health Equity team) and NHSE (Equalities and Health Inequalities team) to share study findings. Wherever possible, we will engage audiences in two-way exchanges about the relevance of the findings and opportunities for translation of the findings into action. We will also develop accessible research products aimed at community members, potentially using community languages, short video and printed materials. Consultation Panel members will be involved in preparing these outputs to ensure their relevance and accessibility to community members and third sector organisations.

We will explore opportunities for taking the outputs forward into knowledge translation activities with support from the CLAHRC Y&H.

10. Expertise:

Our team is multi-disciplinary with expertise relating to the populations of focus, the substantive topic area and the research methods to be employed. All team members have contributed to previous successful evidence syntheses and to research employing participatory elements. We also bring extensive policy, practice and community networks.

Sarah Salway: Public health specialist with expertise in migrant and minority ethnic health; participatory methods; currently engaged in research using systems theory. Overall leadership; design; input to all stages of the research; management of budget, timeline and Advisory Group; lead for systems modelling methods.

Louise Preston: Information specialist; extensive experience of diverse review methods. Lead reviewer (searching, sifting, extraction and synthesis)

Katie Powell: Sociologist; expertise in health inequalities and community engagement; currently engaged in research using systems theory. Second reviewer (sifting, extraction and synthesis)

Liz Such: Social policy; experience in consultation and participatory methods; new migrants and ethnicity expertise. Design of participatory elements; Lead for Consultation Panel in Yorkshire & Humber; lead for practice and community outputs.

Raghu Raghavan: Psychologist; mental health expert; ethnic health inequalities. Lead for Consultation Panel in Midlands; input to theory building and synthesis.

Christina Victor: Public Health; recognised international expert in loneliness and social isolation including minority ethnic older people. Input to measurement issues, theory building and synthesis; lead for Consultation Panel for London and the South; lead for policy outputs.

Andrew Booth: Information and evidence synthesis expert; extensive methodological experience relating to theory driven reviews. Design of search strategy and synthesis approach; contribution to synthesis.

Jean Hamilton: Statistician; experience in Bayesian statistics and methods of evidence synthesis including network meta-analysis.

All team members will contribute to study outputs and dissemination activities.

We have extensive experience of completing complex projects on time working across institutions. We are also experienced in engaging with a range of stakeholders via appropriate formats to support research and its translation. Most co-applicants have worked together successfully on past projects including theory-driven reviews and projects involving systems thinking. The principal applicant SS will take overall responsibility for the study and will have a hands-on role in the day-to-day management and delivery of the project. SS will hold weekly meetings with LP, LS, KP and JH to coordinate activity and ensure quality across the project elements. All these team members are based in the same building enabling frequent interaction. Monthly whole team meetings will be held by Skype/Google hangout involving CV, AB and RR to ensure senior expertise is accessed as needed to guide the project. Face-to-face whole team meetings will also be held at key junctures of the project. We will establish a virtual platform to share project documentation. Responsibility for liaison with the Consultation Panels via the Community Development/Support worker will be as follows: LS (Sheffield), RR (Leicester) and CV (London). In each case, prior close relationships exist and we do not anticipate difficulties in securing efficient and appropriate practical arrangements for the

workshops and other consultation activities as needed. Each CP workshop will involve at least 3 team members, and there will be a full team debriefing afterwards to maximise learning. The timing of Advisory Group meetings has been designed to coincide with key project stages. We will also seek input from Advisory Group members via phone/email as needed during the course of the project. In addition, we anticipate the need to establish a study steering group in consultation with NIHR PHR and will arrange this appropriately following guidance from NIHR.

11. Partner Collaboration

Three partner organisations have committed to hosting Consultation Panels PACA (Sheffield), Leicester Ageing Together and Brunel University – letters of support have been included. We have also recruited a strong group of academic experts, practitioners and policy makers representing a range of organisations to a Project Advisory Group. Other partner organisations with whom we have consulted during the preparation of this proposal will contribute to the project via participation in the Consultation Panels and the stakeholder dissemination event.

No other organisations will contribute direct funding to this work.

12. Research Governance

The University of Sheffield will be the sponsor for this study. A Project Advisory Group will be convened.

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