



Full/long title of study	CICADA-ME: Coronavirus Intersectionalities: Chronic Conditions and Disabilities and Migrants and other Ethnic minorities
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Chief investigator:

Dr Carol Rivas
UCL Social Research Institute
University College London (UCL)
18 Woburn Square
London WC1H 0NR

Tel: 02076126923
E-mail: c.rivas@ucl.ac.uk

Sponsor Representative:

Angela Waplington, a.waplington@ucl.ac.uk
UCLH/UCL Joint Research Office,
4th Floor, West
250 Euston Road
London
NW1 2PG

PROTOCOL VERSION HISTORY

Version Stage	Versions Number	Version Date	Protocol updated & finalised by;	Reasons for Update
Prior	1.0	01/05/2021	Dr Carol Rivas, Associate Professor	-
Prior	2.0	13/09/2021	Professor Carol Rivas	To include NHS recruitment
Current	2.1	13/12/2021	Professor Carol Rivas	NIHR-requested date and acknowledgement corrections

DECLARATIONS

The undersigned confirm that the following protocol has been agreed and accepted and that the investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the U.K. Policy Framework for Health and Social Care Research 2017 (3rd edition) (as amended thereafter), the EU General Data Protection Regulation (2016/679) and the UK Data Protection Act (2018), Sponsor SOPs and applicable Trust policies and legal frameworks.

I (investigator) agree to ensure that the confidential information contained in this document will not be used for any other purposes other than the evaluation or conduct of the research investigation without the prior written consent of the Sponsor.

I (investigator) agree to ensure that no research activity or recruitment will commence at participating research sites until the appropriate regulatory approvals and NHS confirmations of Capacity and Capability have been issued, and Sponsor green light confirmed.

I (investigator) also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest, accurate and transparent account of the study will be given. Any deviations from the study as planned in this protocol will be explained and reported accordingly.

Chief Investigator:

Signature:



..... **Date.....01/05/2021**

Print Name (in full):Carol Rivas.....

Position:Associate Professor.....

On behalf of the Study Sponsor:

Signature: **Date...../...../.....**

Print Name (in full):

Position:

STUDY SUMMARY

IDENTIFIERS	
IRAS Number	n/a
REC Reference No.	UCL IoE REC 1450 Covid-19
Sponsor Reference No.	5695004
Other research reference number(s) (if applicable)	Data Registration: Z6364106/2020/06/21 social research NIHR HS&DR project NIHR132914
Full (Scientific) title	CICADA-ME: Coronavirus Intersectionalities: Chronic Conditions and Disabilities and Migrants and other Ethnic minorities
Health condition(s) or problem(s) studied	Disabilities (various) at intersection with various factors, foregrounding ethnicity and migrant status
Study Type i.e. Cohort etc.	Mixed methods (secondary data analysis, reviews, qualitative interviews, participatory workshops, primary surveys (3 waves)
Target sample size	5,000 for surveys, 210 for qualitative work
STUDY TIMELINES	
Study Duration/length	18 months
Expected Start Date	01/05/2021
End of Study definition and anticipated date	31/10/2022
Key Study milestones, lesser ones in grey	Contract to be finalised, research staff to be recruited, SSC and two advisory groups (one being PPI) to be recruited, and first convened, dissemination plan developed, first review search, first review completed, first access to secondary cohort data, data cleaning completed for secondary data analysis, pilot of primary survey, first second and third call for 1 st wave primary survey recruitment, 1 st wave survey closure, interview patient recruitment begun, collaborator Bromley by Bow Community Centre work commenced, first interviews undertaken, interviews complete, first second and third call for 2 nd wave primary survey recruitment, 2nd wave survey closure, research workshops wave 2 designed, recruited, begun, completed, research workshops wave 3 designed, recruited, begun, completed, key informant interviews recruited, completed, participatory co-development workshops recruited, begun, completed, outputs developed, feasibility evaluation of selected outputs, closing event and final report, outputs and disseminations.
FUNDING & OTHER	
Funding	NIHR HS&DR project NIHR132914
STORAGE of SAMPLES / DATA (if applicable)	
Human tissue samples	n/a
Data collected / Storage	UCL Data Safe Haven
KEY STUDY CONTACTS	
Chief Investigator	Dr Carol Rivas UCL Social Research Institute University College London (UCL) 18 Woburn Square London WC1H 0NR Tel: 02076126923 E-mail: c.rivas@ucl.ac.uk
Study Coordinator	Lorna Collins

Sponsor	<p>Angela Waplington, a.waplington@ucl.ac.uk UCLH/UCL Joint Research Office, 4th Floor, West 250 Euston Road London NW1 2PG</p>
Funder(s)	<p>NIHR HS&DR project NIHR132914 Donna White NETSCC Monitoring Team</p> <p>National Institute for Health Research Evaluation, Trials and Studies Coordinating Centre University of Southampton Alpha House, Enterprise Road Southampton SO16 7NS Email: netpostawardsetup@nihr.ac.uk</p>
Committees	<p>Study steering group: Dr Razia Shariff, CEO Kent Refugee Action Network, Sandy Harvey David Pettinicchio, Associate Professor, Sociology, University of Dr Laura Sheard, Associate Professor, York Trials Unit</p> <p>Advisory group Lucy Mulvagh Director of Policy and Communications Health and Social Care Alliance Scotland (the ALLIANCE) Jackie Collins, The Association of Directors of Adult Social Care (ADASS) Ima Jackson, Senior Lecturer Department of Nursing and Community Health, Glasgow Caledonian University Georgia Pavlopoulou, Anna Freud Centre UCL, Educational Consultant and Neurodevelopmental Specialist, Rochelle Burgess, community health psychologist, Institute for Global Health, UCL A lay member from the PPI group</p>
Other relevant study personnel	<p>(e.g. Data Custodian and Data Processors) tbc</p>

KEY ROLES AND RESPONSIBILITIES

SPONSOR: The sponsor is responsible for ensuring before a study begins that arrangements are in place for the research team to access resources and support to deliver the research as proposed and allocate responsibilities for the management, monitoring and reporting of the research. The Sponsor also must be satisfied there is agreement on appropriate arrangements to record, report and review significant developments as the research proceeds, and approve any modifications to the design.

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CHIEF INVESTIGATOR (CI): The person who takes overall responsibility for the design, conduct and reporting of a study. If the study involves researchers at more than one site, the CI takes on the primary responsibility whether he/she is an investigator at any particular site.

The CI role is to complete and to ensure that all relevant regulatory approvals and confirmations of NHS Capacity and Capability are in place before the study begins. Ensure arrangements are in place for good study conduct, robust monitoring and reporting, including prompt reporting of incidents, this includes putting in place adequate training for study staff to conduct the study as per the protocol and relevant standards.

The Chief Investigator is responsible for submission of annual reports as required. The Chief Investigator will notify the REC and JRO of the end of the study (including the reasons for premature termination, where applicable). Within one year after the end of study, the Chief Investigator will submit a final report with the results, including any publications/abstracts to the REC and JRO.

PRINCIPLE INVESTIGATOR (PI): Individually or as leader of the researchers at a site; ensuring that the study is conducted as per the approved study protocol, and report/notify the relevant parties – this includes the CI of any breaches or incidents related to the study.

COLLABORATOR: Either someone or a group with a status as an equal partner with the core team but not a named co-applicant: (a) who works together with the core team on the research project throughout its duration or for a large part of it, or who makes frequent or substantial contributions; (b) who is responsible for one or more of the main elements of the research (e.g. the execution of some of the work, provision of training or support with output development/delivery).

KEY WORDS

disability, pandemic, networks, health and social care services, assets, ethnicity

LIST OF ABBREVIATIONS AND TERMS DEFINED

PwCD: People with Chronic Conditions or Disability.

Migrant: someone born outside the UK (as per UK policy) who intends to stay in the UK for 1+ years, including asylum seekers and refugees.

Ethnic minority: encompasses migrants and 2nd generation ethnic minorities (i.e. UK born).

Disability: We include any condition/disability, including self-diagnosis, that chronically affects daily activities (e.g. diabetes, dyslexia, chronic pain, loss of limb, depression, autism). We will record conditions, but group by Dietary and 5 UK Family Resources Survey themes: Mental, Mobility, Stamina/breathing/fatigue, Hearing/Vision loss, Developmental/intellectual. We include long Covid and other multisystemic conditions (which may belong to more than one group); our categorisation by impact not diagnosis enables a practical focus and a flexibility to changing understandings of long Covid.

Chronically: We have not tried to define this using standard definitions, to avoid excluding studies and people that do not fit their tight criteria but who/which may be relevant, but in general we mean by this that the condition has lasted for at least 12 weeks and has no defined end-point.

Long Covid: defined by NICE (1) as: *“Signs and symptoms that develop during or following an infection consistent with COVID-19, continue for more than 12 weeks and are not explained by an alternative diagnosis. It usually presents with clusters of symptoms [this may be more than 4 hence the Covid Symptom Study (<https://covid.joinzoe.com/blog>) under-reports long Covid], often overlapping, which can fluctuate and change over time and can affect any system in the body.”* According to the UCL/Oxford symptom survey (2) the most common ongoing symptoms in 201 long Covid patients (only 18% were hospitalised), were fatigue (98%), muscle ache (88%), shortness of breath (87%), and headache (83%), according with other long Covid studies.

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1 INTRODUCTION

Many people from minority ethnic groups, especially those with underlying (chronic) conditions/disabilities, face barriers to accessing networks of appropriate support, health and social care or vital 'resources', such as medicine and food. Around 50% lived in poverty in 2019; the pandemic has worsened their plight, highlighting the need for these barriers to be removed. The worst affected are both ethnic minority AND with chronic conditions/disabilities, a common group, as COVID-19 mortality statistics show. There is a largely unmet expressed need to explore the pandemic problems - and successes - these groups have experienced in relation to reduced services, inequalities, lifestyle changes or health neglect and vaccine uptake. This is especially as health and social care tries to return to normal – and also with the emergence of people newly disabled by post-Covid syndrome. We aim to develop a rich intersectional understanding of the mental and physical health, coping, access to resources, and informal and formal social and health care support experiences, and relevant assets and strengths, of minority ethnic groups at the intersection with chronic conditions/disabilities longitudinally over 18 months. This will contribute and inform evidence-based formal and informal strategies, guidelines, recommendations and easily adopted interventions for pandemic-related and future health and social care policy and practice, to mitigate inequities and improve the experiences, health and wellbeing outcomes of these groups. By 'intersectional', we mean we recognise everyone is affected differently by the pandemic, according to the intersection (interplay) of factors such as ethnicity, citizenship, age, gender, their work, and health or disability.

Our approach uses mixed methods and remote working throughout. We will survey 4,000 UK 1st and 2nd generation community-dwelling minority ethnic group members and for contrast 1000 white British, 3 times over 15 months across the UK's 4 nations. We will compare their health, social networks (who they have contact with) and how these help or hinder them, ways they cope with pandemic changes and associated access to support, care and resources. We will consider how intersectional factors affect this and determine relationships between measured variables and their trajectories.

After Survey 1 we will interview 210 people in 5 diverse sites in England about the same topics, informed by survey analyses, and probe for coping strategies and ideas to inform health and social care policy and practice. Interviewees will also describe their networks using special brief questionnaires, photos and maps.

We will find people for the study via social media, NHS clinics, charities, special patient and migrant groups, our own networks, and large databases of adults interested in health research across the UK. We will focus on migrants from the Middle East, India, Pakistan, Poland or Africa, or whose parents were born there, as the most likely to have problems (e.g. to have limited citizenship rights or to die from COVID-19). We will look at the impact of also having a chronic condition/disability including 'long covid'. We will train local lay people to help undertake these interviews remotely; a transformative community migrant-majority research-active group will be our main London co-researcher.

After each of surveys 2 and 3, interviewees will be invited to research workshops to discuss findings and more recent changes, using video vignettes built from earlier study findings.

Over the 18-month study we will hold 5 participatory sessions with people with disabilities/from ethnic minorities and key informants working together to help analyse our data and co-create solutions to issues, pragmatically including 'life hacks' and service adaptations for rapid impact. At 16 months we will interview 15-25 key informants such as support staff and community leaders to help

us put our work into immediate practice. We will also review published and informal (e.g. blog) articles about pandemic ethnic minority and disability experiences, and data from other complementary COVID-19 surveys.

Keyword frequency analysis, Framework, discourse and narrative analyses, Latent Growth Modelling, Structural Equation Modelling, systematic review methods, and social network analyses will all be used to analyse our data, which will be synthesised using tabulated evidence-to-decision methods. Findings and solutions will be shared as they emerge at each of the 3 data waves, for early benefit. We will report changes over time in experiences, outcomes and solutions. Respondent and national UK demographic data will be compared for representativeness, and transferability explored at each stage i.e. how to apply our work across the UK. Data will be presented separately and combined for ethnic minorities and people with chronic conditions and disabilities. We aim for immediate, readily implemented, relevant useful change in UK pandemic health and social care service delivery. We include training outputs, strong networks and Co-As with direct influence on policy and practice.

Fig 1: Gantt Chart of main activities

Task	Study month									
	Pre-study	1-2	3-4	5-6	7-8	9-10	11-12	13-14	15-16	17-18
Ethics and approvals										
Set up staff										
Develop and set up survey on Redcap										
Secondary text data analysis		1-	3					14	-	17
Secondary cohort data analysis		1-	3					14	-	17
Send out survey waves and complete descriptive analyses		2-	3		8-	9			15	-16
Three waves of qualitative research and basic analysis of these			3-4			9-			15	-16
Co-design workshops										
In depth qualitative analysis (discourse, narrative)			3			-				17
Statistical modelling and social network analysis		2	-	5		9	-11		15	17
Key informant interviews and proof-of-concept training programmes									16	-17
Stakeholder dissemination and interim outputs for public, policy, practice										
Launch and final event										
Writing reports and papers										
Advisory group meetings										

2 BACKGROUND AND RATIONALE

The greater risks and challenges faced by two vulnerable groups during the COVID-19 pandemic, ethnic minorities and those with underlying health conditions/disabilities (3-10) are now well recognised. Although disabled people constitute 16% of the population, they represent 59% of all COVID deaths (11). Similarly, though 13% of the UK population, 33% of critically ill COVID-19 patients are from non-white ethnic groups (8,9). One reason is the intersection of minority ethnic status or chronic poor health or disability with other inequities (**Box 1**), which persisted before the pandemic and have widened because of it. Our particular interest is in improving pandemic and longer-term networks of support and access to care, services and resources for these vulnerable populations (3-7) to enhance vaccination, social, health and wellbeing outcomes.

Notably, the pandemic has highlighted how ethnic minority and poor health/disability statuses themselves intersect (3-7,10), with calls for research on this (e.g. BMJ) (12).

First, having both chronic poor health/disability and ethnic minority status is associated with worse health than belonging to just one of these groups, even outside the pandemic, as noted for resettled refugees particularly (10,13). The emergence of post Covid syndrome, or long Covid (14,15), with a 5-week prevalence of 20% (16) has highlighted some of the issues. Anecdotal evidence suggests long Covid accounts may be more often ignored when made by people from ethnic minorities or who have a similar pre-existing disability such as complex multisystemic conditions.

Second, chronic conditions such as diabetes and cardiovascular disease are disproportionately common in some ethnic minority groups (17) - one reason for their increased risk of serious illness or death from COVID-19 (18). Considering mental health, the estimated 2% of the population who are recent refugees or undocumented migrants (13) had a considerably higher pre- pandemic prevalence of post-traumatic stress syndrome (PTSD) and depression than any other group (19) and minority ethnic groups report markedly poor pandemic mental health (20).

2.1 Rationale for theoretical framework

To improve support and care for these vulnerable people, it is critical that we specifically consider the intersection of chronic conditions/disabilities (including long Covid) WITH ethnic minority status. This is the basis of our study. We will consider health and social care and support experiences across a range of combinations of chronic condition/disability and ethnicity. As **Box 1** shows, we cannot consider these intersections in isolation, though at the core of our study, so we also explore other categories of societal difference (e.g. age, gender) that interact with health status and ethnicity under institutional and structural conditions to create specific health outcomes and experiences (21). In particular we foreground citizenship status as influencing the support available to ethnic minorities, since many recent refugees and undocumented migrants will have 'no recourse' to welfare and housing support.

Underpinning our study with intersectionality theory allows for complex nuanced insights into differences, while minimising the risks of a) essentialising some combinations as inherently problematic or b) considering the ethnicity/migrant experience as homogenous.

Our intersectional lens enables:

1. potential stratification by risk levels to inform preventative/care action
2. suggested strategies and interventions appropriate for different intersecting structural, cultural and religious needs, levels of deprivation, ages, gender and other factors shown through our research to be relevant.

Embodied experiences of chronic conditions and disabilities, being shaped in and through social interactions (including with health and social care and support) (22), are necessarily intersectional with areas of potential discrimination and oppression (**Box 1**) across the levels of Bronfenbrenner's socioecological model (SEM) (23), hence the need for a range of comparisons and involvement of multiple stakeholders in our study. This model will frame our translation of findings into clear recommendations for varied audiences and fits with the new NHS tiered Integrated Care plan (24). The model levels range from smaller, proximal settings of local influence to larger, distal settings with indirect influence. The bidirectional and dynamic nature of intersectional interactions across the levels means mutual constitutions are in constant flux, emphasising the need for a longitudinal study. Our work is also underpinned by the Consolidated Framework for Implementation Research (CFIR) (25) because, as an amalgamation of a range of existing implementation theories, it cuts across the levels of the SEM, with a comprehensive range of constructs. The CFIR is easy to operationalise, flexible (the user selects only themes from a pool of 39 that are relevant), and provides actionable

findings across multilevel implementation contexts. These theories will inform interview topic guides, and survey questions. In our analysis they will inform health and social care mapping and implementation.

Box 1 Inequities for ethnic minorities (including migrants) and those with chronic conditions/disabilities increasing their risk of poor pandemic health outcomes (4,5,13)

1. **Increased risk of isolation, abuse or neglect, poor access to informal emotional and wellbeing support**, due e.g. to national pandemic responses, stigma, changed activities, priorities, attitudes of others, a state of 'normalized absence, pathologized presence' (26).
2. **Inequitable formal treatment, support and care** from attitudinal, structural, policy, cultural, linguistic, communication and economic barriers, leading e.g. to difficulties implementing recommended COVID-19 avoidance strategies, vaccine mistrust, and risk of severe illness.
3. **Psychosocial factors raising COVID-19 risks, reducing capacity to cope** with social, economic and psychological pandemic impacts, including worries about people 'back home'.
4. **Unemployment/reduced income** (e.g. zero-hour contracts; 'no recourse' to welfare).

2.2 Existing literature and studies

2.2.1 Ethnic minorities

A US survey of ethnic minority asthma patients and doctors reported socioeconomic factors and institutional racism impacted on asthma care in the pandemic; 25% of doctors found it more challenging to care for black patients with asthma during COVID-19 (27). Another US survey showed pandemic telehealth was most used by black patients, attributed to their need to compensate for prior health and health care disparities caused by systemic racism (28). Both studies therefore support the need for our study. As of May 2021, none of 3801 recruiting studies on the NIHR site 'Be part of research' specifically considered the health/social support experiences of ethnic minority groups, and none could be found that were relevant when also looking at completed studies with an ethnicity-relevant word as a study keyword. Among jointly funded UKRI-NIHR studies, none has our focus on producing practical strategies and modifications to existing support and care that can be immediately implemented with minimal/low cost and effort, though several consider alternative aspects of the ethnic minority experience such as COVID-19 infections or migrant working, or engagement with pandemic information.

At UCL itself the following studies have direct or indirect relevance to subgroups of our participants:

- The Ubele Initiative (Lipietz, Oviedo and Ramalh) to develop a survey exploring the impacts of COVID-19 on young Black Asian and Minority Ethnic adults. The survey questions have been co-produced with the support of young researchers, social activists and change makers in their communities. It forms part of a wider research project (funded by National Lottery Community Fund) documenting these young adults' experiences of lockdowns through film, photography and other creative methods.
- The newly formed Consortium on Practices for Wellbeing and Resilience in Black, Asian and Minority Ethnic Families and Communities (Co-POWeR) led by Professor Lakhanpaul (UKRI-funded) will investigate the combined impact of Covid-19 and racial discrimination on wellbeing and resilience across BAME groups to provide a fuller picture of the vulnerabilities of these communities.
- In 2020 Mujtaba explored the pandemic experiences of Pakistani women, in an unfunded qualitative study. Similarly Nair interviewed 10 people with dementia and 10 carers from minority ethnic groups about access to services and other pandemic experiences.

Outside of the pandemic, the few studies (e.g. 29-34) of the post-resettlement lived experience of recent migrants to the UK have a different focus/intent and no formal social network analyses. There are more studies of 'cultural competence' in healthcare (e.g. by team members, 35-36) but though their findings support the need for this study, they tend to a narrow focus on settled single ethnic groups with one specific condition (and one of the condition/disability impacts we consider) and do not transfer to the current situation or cover conditions similar to long Covid.

At time of writing this protocol, several reports on vaccine uptake in ethnic minorities have been developed in draft form and a handful have been released. These are not summarised here as those in press cannot be fully represented at this time, but the study will report on these in more detail in its scoping reviews. However within UCL Cox and Lampos are undertaking a behavioural study exploring various examples of benefits and risks advertisements with vaccine hesitancy in ethnic minorities.

2.2.2 Chronic conditions or disabilities

Most articles on chronic conditions/disabilities and the pandemic have been survey or audit-based considerations of reduced non-COVID patient footfall. In a global COVID-19 survey, 17% of 548 respondent rheumatologists estimated 25% of their patients had no access to telehealth (37) showing the need for alternative strategies such as we aim to explore. Interviews with 7 disability NGO representatives in Italy highlighted bureaucratic challenges, and a lack of advice, coordinated care plans and inter-agency coordination to compensate for reduced services (38). Small COVID surveys inside and outside the UK have shown the negative impact of reduced access to treatment on patients' symptomatic control, for Parkinson's Disease (39), migraine (40), rheumatology (41) and chronic refractory neuropathic pain and their increased reliance on support networks (42). Shakespeare (LSHTM) (43) conducted in-depth telephone interviews with a range of disabled people, including parents of disabled children, with different conditions, across England and Scotland, as well as with 15 key informants, repeated at six months. This study, smaller than ours and single-method, had a different sampling frame and limited ability to consider intersectionalities. Our study goes beyond these studies of impact, to focus on strengths, assets and solutions to issues. For example, small cross-sectional analyses suggest some chronic conditions and disabilities may confer resilience to mental health or wellbeing effects of the pandemic (44,45) while a UK pandemic analysis of chronic fatigue Reddit posts reported more severe symptoms in some people but also more accessible opportunities to interact (i.e. online videocalls) (46). In the UCL UK COVID-19 Social Survey (20), which explores psychosocial health in the whole population and so has a different focus to us, 38.2% of 51,417 analysed respondents had pre-existing physical conditions (with a much narrower definition than ours), 19.9% pre-existing mental health conditions and 12% were from 'BAME' groups. This study found good support and resource access protective for pandemic mental health which has informed our study design.

Considering current studies, including jointly funded UKRI-NIHR studies, a handful are relevant.

- One, based at King's College London (Fettes, KCL), has explored how adults with a diagnosis of advanced non-small cell lung cancer, chronic obstructive lung disease (COPD) or interstitial lung disease (ILD) manage daily activities and how this changed over several months during the pandemic. This is to identify how to help to improve their independence, to guide clinical practice and service provision. This therefore has overlapping relevance with our GSS Breathlessness group of participants. Recruitment ended in February 2021. However this was a survey study with no qualitative component.
- One considers the response of organisations who provide services for refugees and asylum-seekers (through 20 interviews) against the lived experiences of the people they support (40 interviews), in Scotland and Newcastle-Gateshead, combined with a UK wide two-wave survey

specifically targeting asylum-seekers and asylum services (Hopkins, Newcastle). This focus is slightly different to ours.

- There are studies of people with intellectual disabilities (Hastings and Hatton at Warwick and Lancaster) or with dementia and their carers (Banerjee in Bristol plans over 250 telephone interviews and Clare in Exeter up to 700); these groups require specific considerations in study design and the consent process so we do not target them in recruitment, though we do not exclude them.
- A qualitative study (McHale, Birmingham) considers impacts of the legal suspension by local authorities of the application of certain provisions under the Care Act 2014 as part of COVID-19 emergency powers.
- Several small-scale studies by support groups or local clinics are in progress to consider long Covid lived experiences, and there are several larger UKRI-funded new long Covid studies specifically, due to start in 2021.

At UCL itself the following studies have direct or indirect relevance to subgroups of our participants:

- Patient Led Research for COVID-19 is a self-organized group of Long Covid patients working on patient-led research around the Long Covid experience. They are researchers in relevant fields such as participatory design, neuroscience, public policy, data collection and analysis, human-centred design, health activism – in addition to having intimate knowledge of COVID-19.
- Chatterjee's study Mitigating the inequitable effects of Covid-19 using community and cultural assets is exploring the positive as well as the negative aspects of engaging with resources and their effects on health and wellbeing in people with physical or psychological conditions, those on a low income, those who feel socially isolated and older members of the community.

In none of these studies except Chatterjee's (which does not focus on ethnicity or specifically on chronic conditions and disability) is there a focus on assets and solutions with a possible further exception of the KCL study. None considers the combination of chronic condition/disability AND minority ethnicity. All are complementary to our own study. Importantly we have been/will be in touch with researchers on new or ongoing studies that complement our own (including the above) and have planned to develop knowledge exchange networks, including links via our study websites with associated 'learning sets'.

2.3 Why this research is needed now

Over our study period there will be a need for more focus on changes in 3 specific areas of chronic health and disability, all more critical in our focal group:

1. New conditions/disabilities that develop or old ones that worsen because of reduced services and other structural consequences of the pandemic (which have widened pre-existing inequities for PwCD and minority ethnicities) (12)
2. New conditions/disabilities that develop or old ones that worsen because of lifestyle changes or neglect of health during the pandemic or pandemic responses such as shielding
3. Long Covid as an emergent chronic condition.

Our community-based mixed methods longitudinal approach is designed to consider this and inform and shape the immediate and future health and social care response particularly for ethnic minorities with chronic conditions/disability, and to take account of future pandemic impact and uncertainty. We believe there is considerable synergy and learning potential to considering both existing chronic conditions/disabilities and long Covid, since symptoms of long Covid and some existing conditions correspond and an underlying mechanism-in-common may be MCAS (47) (though there are alternative explanations (3)). In this regard our study is both unique and particularly important now for future planning considerations; the lessons we can learn from existing conditions are likely to be transferable to people with long Covid and their health and social care

and vice versa. Policymakers such as those within Public Health England (PHE), and practitioners such as clinicians and social support workers, specify an urgent need for participatory work with minority ethnic groups (15) such as we will undertake.

In this protocol we refer to People with Chronic conditions or Disabilities (which we shorten to PwCD) AND ethnic minority status (encompassing a range of citizen states) as our focal group. But our study is designed to also be independently applicable to those with long Covid, chronic condition/disability, or ethnic minority status and in our outputs we will disaggregate these data.

3 AIM AND OBJECTIVES

3.1 Aim

to contribute and inform evidence-based formal and informal strategies, guidelines, recommendations and interventions for health and social care policy and practice during and after the COVID-19 pandemic and system recovery (including any future waves), to mitigate inequities and improve the experiences and health and wellbeing outcomes of minority ethnic groups at the intersection with chronic conditions/disabilities.

To do so, we will develop a rich understanding of their mental and physical health, coping, access to resources, and informal and formal social and health care support experiences, and relevant assets and strengths, longitudinally over 18 months using mixed methods, examining variations through an intersectionality lens. Analyses, outputs, dissemination and implementation plans for these will be co-developed with key stakeholders.

Access to resources, formal and informal care, social networks and links to health/social care outcomes are foregrounded as these are protective for pandemic mental health (20,48) and the wider non-pandemic literature suggests psychological and social support factors enhance general wellbeing (49).

3.2 Objectives

Using an intersectionality lens our objectives are to:

01: Explore and compare, by location and time, survey and qualitative data on changing patterns of need. Including intersections of chronic condition/disability and ethnicity/citizenship state with UK pandemic contexts.

02: Relate pandemic coping strategies/solutions to 01 findings, including what worked well or less well, and touchpoints (where experiences might best be improved), to inform health and social care policy and practice

03: Use Social Network Analysis to explore formal and informal network issues/affordances in health and social care solutions

04: Gain insights from comparisons and relationships across our mixed methods data, rapid framework-based synthesis of the published and grey literature, and secondary analyses of UCL's Centre for Longitudinal Studies (CLS) and ActEarly COVID-19 specific surveys.

05: Contextualise and explore transferability of qualitative findings using the survey, and survey findings using CLS/ActEarly UK census data.

06: Co-create with stakeholders (including PwCD/minority ethnicities) interim/final outputs include identified strategies, interventions and touchpoints, and plans for rapid pathways to impact.

3.3 Secondary aims and objectives

The aim of the scoping reviews we conduct as part of the study is to identify, appraise and create a mapping and synthesis of reports, from a number of perspectives, on the pandemic-relevant lived experience of disability and/or ethnic minority status. This will acknowledge the rich context and different dimensions of the lived experience from the perspective of those experiencing it and the complex systems in which their experiences are played out. It will comprehensively cover all life stages and all impairment types. Where possible and meaningful to do so, it will use the GSS harmonised standards to categorise impairments. This increases comparability with government published data. It also enables a multitude of conditions to be represented within a manageable number of categories that focus on the socially and environmentally constructed barriers for people with disabilities rather than medical diagnoses. The review work will centre on and privilege the lived experience of disabled people/those from ethnic minorities although evidence will be included from other sources where relevant (e.g. friends, family, carers, third sector, community groups, statutory bodies). We adopt an assets-based approach to framing the ways removing barriers may be done.

4 STUDY DESIGN

4.1 Rationale for study design

Critically many of the pandemic health and wellbeing challenges faced by our focal group can be mitigated by small adjustments to health and social care service policy and delivery, formal networks such as community health services and informal networks such as family and friends (13). Yet this is not done; the voices of PwCD or ethnic minorities rarely feature in pandemic planning (6), are not reflected in vaccine roll-out, and there is a remarkable lack of primary data. Public Health England has called for this to be addressed in the next stages of the pandemic through **participatory research** (50), which we use. Our design includes **3 waves of a new roughly 15-minute UK survey spread over 15 months, secondary analyses of existing cohort and panel surveys, rapid scoping review and more granular reviews**. We incorporate qualitative insights from a 1-hour **interview** with 210 participants including **network/map/photo elicitation** methods, and two 2-hour remote **participatory research workshops** at later time points that roughly coincide with the survey waves, designed to minimise research burden spread over the study. Our separate **stakeholder co-create workshops** and **social network analysis** are key to implementation of outputs. An understanding of appropriate networks is vital to improving access to health/social care and support, resilience to stress and post-disaster recovery (20,49), and informing interventions based on health-related behaviours and health beliefs e.g. misinformation in the pandemic and vaccine uptake/hesitancy. We will explore how knowledge about network use may be harnessed to improve pandemic-related experience. Our study has a strong **practical focus**, important given our aim for immediate impact; it will use a **strength and assets-based mixed methods approach** to probe for resourcefulness and successful strategies/interventions used since the start of the pandemic. It includes consideration through the study of **new service delivery models** with continued use and advantage beyond the pandemic (e.g. telemedicine [51,52]). Importantly our study is **longitudinal**. Thus we will be able to explore significant relationships in the survey data we collect on mental and physical health, coping, access to resources, social and health care support, vaccine uptake and intersectional variables and also change in these over time and with varying pandemic contexts. The qualitative data will provide rich detail in what is currently uncharted terrain. We will be able to track trajectories of long Covid; international opinion is that its relapsing-remitting nature requires this (53). Data collection is planned remotely in line with pandemic recommendations.

4.2 Topics across all methods

These are as follows (in the survey based on questionnaires, mostly validated in ethnic minorities including recent migrants) and include a range of variables that the research evidence suggests are key influencers of pandemic health and wellbeing. We believe by focusing on these, we should have a big impact through small changes. We note that other variables such as access to education will also be important but are not of direct relevance in terms of our aims:

1. **Intersectionalities** (we use a recently developed framework [54])
2. **Behavioural responses** to COVID risk-reduction measures including vaccination by individuals and their formal/informal support and care networks (e.g. friends, family, community, health/social care) – to understand the context of peoples' lives, what responses are feasible or acceptable to them, and effects on their networks. This will help us build up a picture of potential assets and strengths and affordances (as well as issues).
3. **Access** to resources, formal/informal support and care, including **digital transformation**, service innovations –good support and resource access is protective for pandemic mental health (20), and it also mitigates other health issues.
4. **Social network** (formal/informal support and care networks) descriptions - (contextualising topic 2 above for network behaviours)
5. **Coping and attitudes, physical and mental health** consequences of the pandemic, why they arose and how issues can be mitigated.
6. Mental and physical wellbeing/**quality of life** as core outcomes
7. **Local/regional differences** in responses linked to policies/interventions and associated impacts
8. **Future** policy implementation that is accessible to PwCD and minority ethnic groups.

In all cases we will consider what has worked well and less well, ensuring policy-relevant comparison and synthesis across WP.

5 HOW PARTICIPANTS/DATA ARE BEING IDENTIFIED, SAMPLED AND RECRUITED

5.1 Review searching and screening

We will map and synthesise existing quantitative and qualitative evidence on the pandemic and PwCD or ethnic minorities that supports our aims.

- Given the novel and unstable nature of the pandemic, its sequelae and system recovery, this includes pre-print resources such as medRxiv and less formal sources such as blogs, Google, Reddit and Twitter searches.
- EPPI Reviewer, specialist software for systematic reviews, will be used to fast-track parts of the review process to support priority screening and automatically cluster/group studies in the mapping phase of the review. This will also be used to maintain a living review of relevant materials.
- The databases for the searches for potentially relevant studies for inclusion in the review are: Medline, Embase, CINAHL, PsycINFO, ASSIA, Sociological Abstracts, Web of Science, SCOPUS and, for grey literature, OpenGrey, ProQuest Dissertations and Theses Global, as well as the more recently developed pandemic-focussed databases such as the UCL EPPI centre's COVID-19 Living Map of Evidence, the WHO Global Research Database on COVID-19, the COVID-19 Rapid Evidence Reviews Group (CORRE), and LitCOVID. These databases bring together evidence on COVID-19 from a worldwide dataset; we will add other sources that we locate. These are considered sufficient to comprehensively cover the range of topics and disciplines implicated in this review.
- A search strategy developed for Medline will be modified for each database to derive the most meaningful search, with freetext, MeSH and subject headings for a careful balance of

sensitivity and specificity. For articles, reports, and longer texts, we will search using controlled subject headings and keywords related to our 8 topics running through the study (e.g. for topic 6 synonyms of 'wellbeing' OR 'quality of life').

- We will augment these by searches of relevant journal, professional body, governmental and third sector organisation websites, Google Advanced and Blogsearchengine.org for relevant articles and news reports published on organisational websites, a Google News search for news articles, expert recommendations, and eligible articles from Twitter links. Social media searches will be run on identified hashtags and frequent users who discuss our 8 topics, tailored by site in consultation with our PPI group. Extracts used in dissemination will be paraphrased to avoid identification.
- We will include citation and snowball searching, known expert consultation via email, related articles searches.

Initial screening will ask:

- Does this study consider PwCD and/or ethnic minorities (as related to the country of the research)?
- Is there primary data specific to PwCD and/or ethnic minorities?
- Do the data cover any of the 8 topics of interest as specified in *Section 4.2*?

5.2 CLS and ActEarly secondary data

We will undertake secondary analysis of a subset (those with chronic conditions/disabilities) of the UKRI-funded **ActEarly city collaboratory** consortium (56) COVID surveys. These complement our surveys and are similarly supported by qualitative data. ActEarly collects data of interest in two ethnically diverse areas, Bradford and East London, on physical health (including general health, health anxieties, health behaviours and mental health), relevant demographic factors, services access, and family relationships and social support. Both areas have strong reputations in applied health research with a focus on health inequalities in deprived and ethnic minority populations and deep engagement with the community and local policymakers. Inequalities are extreme in both areas, making it likely that strategies successful in mitigating the adverse impacts of COVID-19 there are likely to be transferable to other places with less extreme conditions. The initial focus of the ActEarly Covid-19 surveys has been on children, parents and pregnant women (a sample pool of just under 14,500 in Bradford (57) and a focused sample of 2000 in East London), which avoids participant research burden from our study.

CLS, part of the PI's UCL department, has run COVID-19 surveys within the nationally representative cohort studies it curates, with respondents aged 19-74: Millennium Cohort Study (born 2000-02), Next Steps (born 1989- 90), 1970 British Cohort Study, 1958 National Child Development Study, and also the MRC's National Survey of Health and Development (1946 British birth cohort). Wave 1, with over 18,000 respondents, took place in May 2020, and Wave 2, with almost 26,000 respondents, in September 2020. These included items on physical health (including COVID-19), health behaviours, demographics, mental health, social connectedness and health care, hence relevant to our aims though the fit is not as close as for ActEarly.

We will also draw on UCL's COVID-19 Longitudinal Research and Evidence Tracker which trawls for COVID-19 longitudinal research and evidence, e.g. briefing notes, reports, articles. Evidence from the tracker may provide further useful information and context.

CLS has run Covid-19 surveys embedded within sweeps of the national datasets that the CLS curates. Almost all the CLS data is available for free download at the UK Data Service, by means of an End User License, or occasionally a Special License. CLS is contained within the CI's department at UCL.

5.3 Survey (including quantitative social network analysis data)

5.3.1 Survey sampling strategy

We sample across the 4 nations of the UK. Survey sampling will be targeted at the groups of interest via selected sites and networks, ensuring diversity to encompass all conditions/disabilities and ethnic minority groups of interest, and screening questions at the start will aim to ensure purposive sampling. This is important to enable us to make relevant comparisons. We have not chosen to sample using individual patient data e.g. via electronic health records, because we wish to include people who are self-diagnosed or who perceive themselves to have a different diagnosis to the one held in the electronic record, as well as participants not registered with a GP.

5.3.2 Survey numbers and power

The primary aim of the quantitative data is to describe the trajectories of key variables and outcomes (e.g. quality of life, services access, networks), and the links between them, in ethnic minority and PwCD communities, in comparison to the White British. The longitudinal survey will not be used to test a particular treatment or focus on a single effect. Considering power in Structural Equation Modelling (SEM), the required sample size depends on several factors (58).

- First, the required sample size increases with the number of latent variables, but at a decreasing rate (i.e. the required sample size difference between a model with one versus two latent variables is larger than that between a model with three versus two latent variables).
- Second is the size of the loadings on latent variables. Required sample size decreases strongly as the loadings increase.
- Finally, power increases as the number of items used to measure each latent variable increases.

In our basic SEM, we have six core latent variables per wave:

1. quality of life,
2. control of life,
3. access to care,
4. coping mechanisms,
5. mental health, and
6. social networks.

Each will be measured by several items (the average number being more than 8). In a worst-case scenario with average loadings of around 0.5 and an item missingness of 20% (as suggested from ActEarly work), a sample size of 800 per subgroup per wave will yield useful analyses. We have four main subgroups (i.e. minority ethnic, minority ethnic+ PwCD, White British, White British + PwCD). Thus the required sample size is $800 \times 4 = 3,200$ though we aim for 5,000 for stronger data (58).

5.3.3 Survey recruitment

We will develop the final survey format with our PPI group and pilot it with N=30 before fielding it at scale.

Recruitment to the survey will begin a month after the start of the study and will be repeated for each of the three waves evenly spaced over 15 months.

- The survey is planned to remain open for a month in each wave.
- Recruitment will predominantly be by placing a survey link via social media and national networks (e.g. academic, NHS, third sector) including our existing networks and mailing lists, and large

databases of adults interested in health research across the UK. These include UCL BioResource and HealthWise Wales, the NIHR Be Part of Research, the NIHR Research Design Service Public Involvement groups and networks registries, the UKRI Mental Health Research Networks, The Covid-19 Research Involvement Group, The Covid-19 Support Group.

- NHS frontline staff in areas of often under-served groups e.g. high migrant population density will put posters up at diverse NHS sites from obstetrics to addiction centres inviting interview participants to contact us, will give out posters to interested patients and will offer copies to patients on their lists who fit the inclusion criteria - talking about the study as one led by UCL to avoid any feelings of obligations to take part by their patients. Migrants will also be reached via Medact Migrant Solidarity Group dissemination and other community groups. In all cases WHO/government pandemic restrictions and recommendations e.g. physical distancing will be adhered to.
- We will also recruit via the various social media patient and migrant groups with which we are connected and specialist third sector organisations. This enables good reach and access across the spread of chronic conditions/disabilities, ethnic minorities and citizenship states and connection with people already wishing to take part in research.
- To reach less accessible groups, such as migrants unable to complete the survey because of insufficient English, lack of resources or lack of technology access, these groups will also be invited for interview by word of mouth via existing team networks of key workers who come into continued contact with these groups as part of their daily work. These key workers will place posters inviting participation, to ensure no detracting from their daily work; the posters will include the researcher's contact details – details that will be set up specifically for the study to ensure researcher safeguarding,
- We recognise our recruitment, being non-randomised, will be biased, for example to those already interested in research participation or who are active users of third sector sites and have online access even though we will make available print copies for community groups involving participants lacking internet access. We will compare respondent demographics to whole population estimates where possible (though formal data are limited) to explore representativeness.
- Surveys will begin with informed consent/screening questions.
- Data will be collected through RedCap to ensure data security.
- The survey will be anonymised; however participants willing to be contacted for subsequent waves will need to provide their emails which will be processed via RedCap so the researchers will not see them.

5.4 Interviews (including qualitative social network analysis data)

5.4.1 Interview sampling frame

We aim for 210 interviews with purposive quota sampling (**Table 1**) for maximal diversity and sufficient numbers for rich data for each group.

Our sampling frame follows an intersectional studies approach that allows us to consider and compare assumed homogeneity across condition effects irrespective of ethnicity, and across ethnicity irrespective of condition, as a tool to tease out intersectional factors and heterogeneity. At analysis the focus may switch to other commonalities such as shared barriers or facilitators to health and social care resources.

Table 1: Interview sampling frame (cells contain numbers to be sampled)

Ethnic/national Origin	Migrant : Middle East	Migrant: sub-Saharan Africa	Migrant: Poland	Migrant: India and Pakistan	2nd Generation	White British	TOTAL
Condition effect							
<i>Mental</i>	5	5	5	5	5	5	30
<i>Mobility</i>	5	5	5	5	5	5	30
<i>Stamina/breathing/fatigue (incl. heart)</i>	5	5	5	5	5	5	30
<i>Hearing/Vision loss</i>	5	5	5	5	5	5	30
<i>Developmental/intellectual</i>	5	5	5	5	5	5	30
<i>Dietary</i>	5	5	5	5	5	5	30
<i>No condition/ disability</i>	5	5	5	5	5	5	30
TOTAL	30	30	30	30	30	30	210

5.4.2 Interview sites

We use 5 sites in England for interviews for maximal sampling diversity in migrant population density, proportion of EU to non-EU migrants, and reasons for migration (**Table 2**) to ensure project findings are transferable across the UK. We will use our 4 nations survey findings to contextualise and evaluate transferability of interview findings. This is important as we sample in England only for qualitative work due to differences in the devolved nations in responses to the pandemic and in health and social care systems. While this means some of our findings may be more relevant to NHS England, we expect principles to be similar across the four nations and will consider this in our reporting and outputs. We will ensure that within our sites we recruit from a mix of local communities well served by immigrant-specific services, and less service-rich communities.

Table 2: Relevant features of chosen sites (59)

Features Site	% of residents born abroad	non-EU residents born abroad	% of all Majority reason for coming
<i>London</i>	38%	68%	Work, asylum seekers, refugees
<i>SE England, Canterbury</i>	13.5%	58%	Work or to join family
<i>Gatehead-Newcastle</i>	13%	84%	Work or to join family
<i>W Midlands, Birmingham</i>	18%	75%	Work, also many to join family
<i>Yorkshire, Leeds</i>	10%	56%	Family

5.4.3 Recruitment to interviews

We do not use randomised sampling but recruit participants from adverts/links distributed through a range of platforms and networks, as well as local lay co-researchers for our qualitative work (see *Section 8.4*). We will rely on participant self-identification of ethnicity and condition/disability.

Posters, adverts and snowballing will target those who lack resources or technology to respond to online recruitment (60), for example via our clinical co-applicants and our collaborators. (Though many migrants or their local groups use digital technologies e.g. to contact 'home' (61), for pandemic faith meetings.)

We are collaborating with different groups at the different sites, who will help us to recruit by acting as gatekeepers and/or using their networks. This includes Born in Bradford (BiB) in Yorkshire, a long Covid centre in Gateshead, migrant charities in London and Canterbury. We have BiB staff on the team working with co-applicant Dickerson specifically for recruitment and data management support. The Bromley-by-Bow community centre will also undertake interviews using their own protocols, <https://www.bbbsc.org.uk/insights/research-and-evaluation/research-and-evaluation-bromley-by-bow-community-engagement-and-citizen-science/>, as major collaborators.

The 40-plus newly set-up long Covid specialist clinics will provide a further possibility of recruitment, for example via posters.

NHS frontline staff in areas of often under-served groups e.g. high migrant population density will put posters up at diverse NHS sites from obstetrics to addiction centres inviting interview participants to contact us, will give out posters to interested patients and will offer copies to patients on their lists who fit the inclusion criteria - talking about the study as one led by UCL to avoid any feelings of obligations to take part by their patients. Migrants will also be reached via Medact Migrant Solidarity Group dissemination and other community groups. In all cases WHO/government pandemic restrictions and recommendations e.g. physical distancing will be adhered to.

We expect to take less than four months for recruitment and interviews (which will occur in parallel).

5.5 Research workshops

The precise make-up/number of workshop groups per wave (2 and 3) will be determined from Wave 1 data. Participants will be recruited from Wave 1 interviews.

5.6 Co-Create workshops through the study

These are distinct from the research workshops though based on similar principles. Key differences are that they will:

1. include a range of other stakeholders as well as ethnic minorities with chronic conditions/disability; this requires purposive sampling.
2. contribute to analyses in addition to translating findings into practice.

Recruitment will involve the same sources as for the interviews but also other relevant networks such as service provider networks.

5.7 Key informant interviews

15-25 interviews (anticipated to take place in the 16th month of the study) (up to 5 per site) are planned with key informants as determined from earlier phases of the study: e.g. welfare, social and health care staff, settlement and ethno-specific services, the third sector and community leaders.

Recruitment plans will be determined in consultation with stakeholders in our co-create workshops and with our advisory groups.

5.8 Interventions

We have designed this study as stand-alone; some outputs can be used at once, but some intervention suggestions would need proof-of-concept/feasibility testing and trialling. We will adapt two existing training programmes, using our new evidence, and test them during the study at the 5

interview sites for proof-of-concept. These would likewise need to be properly evaluated for effectiveness/efficacy.

The feasibility evaluations will be exploratory and brief and so will use a pre-post design, with individual participants as the unit of analysis. Participants will be recruited from our study sites using the same methods as detailed in *Section 5.4*. The sampling will be purposive but the sampling frame will depend on the intervention being evaluated and the decisions of our advisory and participatory groups. For UltimateYou, participants will be professionals, for Tough Cookie they will be community members. Other brief interventions that we may decide to test will be specified in addenda to this protocol once determined.

A pragmatic sample size decision will be made depending on the nature of the intervention; for example, Tough Cookie aims for 30 participants per programme. As these are simple feasibility evaluations, they will not be powered to detect statistically significant intervention effects. Their primary objective is to determine implementation enablers and barriers and acceptability, although relevant outcome measures such as mental wellbeing will be measured at baseline and after the intervention has been completed.

5.9 Payments, rewards and recognition for study participants

Remuneration follows INVOLVE recommendations where participants are not professionals who require remuneration for invoiced time or who partake as part of their usual role. Those will be considered on a case-by-case basis.

Participants may be acknowledged by name on our websites but we will discuss the issues with them to make sure they are fully aware of these first.

Our PPI team members will be invited to be co-authors on outputs and supported in their own outputs, outputs, e.g. for the supportive journal Research for All which is free to contribute to and read and is run from the PI's department.

6 ELIGIBILITY CRITERIA

6.1 Eligibility criteria for review

6.1.1 Review inclusion criteria

- *Population* people with any form of disability, mapped onto the GSS or by diagnosis and/or any persons defined as ethnic minority within the country in which they are located
- *Phenomenon* Lived experience: Articles will include the perspectives of PwCD or ethnic minorities of any age, informal carers and healthcare professionals where this is relevant.
- *Focus* See the topics *Section 4.1*.
- *Study type*: Lived experience evidence comes from the reporting of first-hand involvement but although this is often generated through qualitative methods, quantitative data, such as from survey closed questions, might also be informative. We will therefore be open to different study types including other reviews whilst expecting the bulk of the evidence to be qualitative; we also include non-traditional forms of non-peer reviewed evidence that may not specifically be gathered into studies, such as tweets.
- *Setting* We will focus on sources relevant to UK settings but will not exclude international studies with transferable knowledge.

- *Source type* published paper, article, blog post commentary, online media (including videos and podcasts), relevant to the research questions, unpublished grey literature, public bodies / agencies, e.g. Equality and Human Rights Commission (EHRC), research bodies, e.g. Economic and Social Research Council (ESRC), trade unions. Data may need transforming for the Framework matrix.
- *Date* published between 2000 and the present day to ensure the currency of the work while enabling a broad view of developing issues to be identified.
- *Language* publications in English.

The outcomes will depend on the evidence available, and gaps in the evidence will be highlighted for future study.

Reporting will follow PRISMA guidelines, documenting exclusions decided after full-text review.

6.1.2 Review exclusion criteria

Not fitting the inclusion criteria.

6.2 Eligibility criteria for survey

The main screening question is:

Do you have or believe you have any of the following medical conditions or disabilities or do you care for someone who has?

Once we have reached our quota of 1,000 white British respondents, there will also be an ethnicity screening question.

Excluded participants are told:

You said you do not have a long-term condition or disability. If this is correct, we thank you for your interest but we are only collecting data on people with medical conditions and disabilities. Please close this webpage and we will not contact you any more about this study.

6.3 Eligibility criteria for lay interviews and research workshops

6.3.1 Main interview/ research workshops inclusion criteria

- White British comparators or Arab, Polish, Indian, Pakistani or sub-Saharan African 1st or 2nd generation refugees/migrant adults aged 18+ (undocumented, on temporary visas, indefinite leave to remain, British citizenship) (**Table 1**).

While not homogenous, these groups were chosen to be diverse but focused enough to ensure rich data and on the basis that a) 74% of refugees resettled in the UK since 2010 were Arabs and Turks, 19% sub-Saharan Africans (59) (who are also the most likely to die from COVID-19 in the UK (186)), b) recent migrants by choice were mostly born in Poland or India (59) and c) the 2nd highest UK COVID-19 mortality rates by ethnicity are for people of Pakistani origin (18).

We include skilled migration, humanitarian or family streams, the 'irregular' or undocumented, on temporary visas or first-generation migrants with indefinite leave to remain, or first or second generations with British citizenship.

- Any condition/disability, including self-diagnosis, that chronically affects daily activities. We have not defined chronicity using standard definitions, to avoid excluding studies and people

that do not fit their tight criteria but who/which may be relevant but in general we mean by this that the condition has lasted for at least 12 weeks and has no defined end-point.

6.3.2 Main interview/ research workshops exclusion criteria

- Student migrants as likely to have structured educational institution support,
- Residents of detention centres/closed facilities linked to national migration policies (e.g. new asylum- seekers/refugees, displaced or trafficked persons), as complex cases with specific considerations.

6.3.3 Notes for qualitative methods inclusions and exclusions

- We have taken care to involve a range of ethnicities and a full range of disabilities including long Covid and self-diagnoses. Our exclusions are based on relevance and safety considerations as advised when our study underwent ethics review.
- Our PPI advisers suggested we only interview participants able to communicate in English so the focus would not be on language fluency, which is a specific issue the CI has previously studied (36).
- We will be inclusive of disabilities through responsive accessibility formats.

6.4 Eligibility criteria for key informant interviews

Inclusion and exclusion criteria will be determined by our advisory and Co-create workshop members as a result of earlier analyses.

6.5 Eligibility criteria for Co-create workshops

We will seek representation from a cross-section of relevant lay and professional stakeholders; the inclusion criterion will be that participants should be stakeholders in the health and social care of PwCD from ethnic minority groups.

6.6 Eligibility criteria for interventions

We will try out adaptations of two existing training programmes, Tough Cookie for community members and Pain Relief Management for practitioners, based at our 5 sites for proof-of-concept. We may also evaluate other small interventions that involve expansion or adaptation of existing provision. Inclusion and exclusion criteria will be determined by our advisory and co-create workshop members as a result of earlier analyses.

7 CONSENT

- We will ensure that in the consent process, all participants are sufficiently knowledgeable about the research process generally, the nature and objectives of the study and possible risks associated with their participation, and understand the alternatives to taking part.
- The survey, information sheets and interviews will all incorporate signposting to sources of help and other resources to minimize harm; the act of taking part is more likely to be beneficial than harmful as it will give a voice to people that have been marginalized in the current pandemic, as more generally. Relevant groups and individuals have expressed strong interest in this study in scoping work and have contributed to its design.
- We will ensure participants know they can drop out at any time without adverse consequences.

- Participant information materials have been ethics-approved and for interviews and workshops are in print/digital form. For surveys they precede survey responses and the consent form, online. They have been piloted within relevant communities.
- Electronic methods of consent and data collection will be used unless participants require an alternative.
- All data disseminated, including data from the study that is shared in study workshops, will have all potentially identifying details excluded.
- REDCAP, UCL's Research Data Collection Service, will be used for eConsent and data collection, either for collection of all source data, or as an alternative to paper methods: <https://www.ucl.ac.uk/isd/it-for-slms/redcap-research-data-collection-service>. The Safe Haven version will be used.

7.1 Survey consent

- The survey begins with full information for fully informed consent and is opt-in.

7.2 Consent for all other (non-survey) primary work

- We will provide the opportunity for potential participants to ask questions
- Our consent process will be in English as default. All participants will be informed about the study using a plain English statement, read to them if needed. Potential participants will be informed that interviews will be in English, and it is their choice as to whether they feel able to take part. This is a well formulated and effective process in Born in Bradford. Where a participant is happy to interview in English, but feels more comfortable doing so in another language, if a researcher fluent in that language is available this will be arranged.
- Translated study documents will be made available if required specifically to ensure fully informed consent. Our focus on specific groups makes this manageable.
- PPI work suggested restricting interviews to English would not reduce the impact or usefulness of the study. Most research work undertaken by collaborators MedAct is in English. Moreover, they suggest our research will usefully determine barriers for those who might be assumed 'OK' because they are not housed in accommodation for the vulnerable and can communicate in English.
- Braille and other formats e.g. for neurodiversity will be used if needed. Consent and information documents may need to be prepared in specific formats such as special-coloured backgrounds and we will use online approaches such as Padlet or Miro accessible to participants; indeed, these are likely to increase accessibility.
- We include lay co-researchers locally, partly because they will be sensitive to local situations and contexts, particularly relevant when the country is subdivided according to COVID risk, as well as cultural needs.
- Any participant with mental ill health and distress will need advice from collaborator Abou-Saleh who undertakes migrant crisis assessments for the Helen Bamber Foundation and we provide signposting to sources of help. The ActEarly networks include service providers to whom participants could be referred if needed.
- As this study is planned to be fully remote, which supports access by people with chronic conditions/disabilities, our main concerns will be to match participant fatigue/wellness levels and to ensure frequent breaks.
- We will follow joint HRA & MHRA guidance on appropriate arrangements required: <https://www.hra.nhs.uk/about-us/news-updates/hra-and-mhra-publish-joint-statement-seeking-and-documenting-consent-using-electronic-methods-econsent/>.

8 PROCESS

8.1 Review process

Our review work will involve a two-stage process:

1. Create a systematic (living) map to describe the nature and extent of the literature in the field.
2. Undertake an in-depth analysis and synthesis on specific aspects in the map/evidence base. .

These data will give us a grounding in current research and other evidence, in a fast-moving pandemic-responsive field, to ensure we tackle our to provide themes to incorporate in the primary data collection.

In both cases:

- Two reviewers will screen titles, abstracts and full texts against inclusion criteria, with disagreements resolved by 3rd researcher.
- We will use quality assessments designed for each study type, with additional reference to the provenance and publication status of sources.
- Data will be extracted by one reviewer and checked by a 2nd.
- Data extraction will be managed in EPPI-Reviewer and will reflect the inclusion criteria and the designated aims of the review. Information will be gathered on:
 - title; author and author background(s);
 - year of publication;
 - website address;
 - access date;
 - setting;
 - source type (e.g. journal article, news report, etc.);
 - study type;
 - relevant background and impetus for the study;
 - methodological approach and specified methods;
 - participant characteristics and demographics;
 - main findings including pertinent themes;
 - strengths and limitations;
 - key relevant discussion points.

8.2 CLS and ActEarly data process

We will extract, clean and analyse data from the CLS and ActEarly datasets that relate to ethnicity and/or disability for each of the topics and outcomes of interest to our work, as outlined in *Section 4.1*.

Since October 2017 there has been monthly data at regional and national level available on NHS community service care access, <https://digital.nhs.uk/data-and-information/publications/statistical/community-services-statistics-for-children-young-people-and-adults#latest-statistics>, the Community Services Data Set. We may therefore also draw on this.

Co-applicants have led on ActEarly surveys and will provide access.

8.3 Survey process

The survey will be online but with telephone interviews (CATI) where needed.

To minimise respondent burden, each wave will be completable within approximately 15 minutes, which ActEarly and CLS work shows is acceptable for COVID- 19 surveys.

Survey study topics will be explored, based on validated questionnaires, mostly validated in migrant and ethnic minority groups as well as the dominant population (**Table 3**). Surveys in different waves will differ. First, theoretically stable concepts (e.g. tolerance to uncertainty, demographic characteristics) will be measured only in one wave. Second, key topics identified in prior wave(s), qualitative work and our co-production and engagement work running through the study may be added. But key outcome and exposure variables that we expect to change during the pandemic will be measured in all three waves to study trajectories.

Table 3: Our 8 survey topics and corresponding survey instruments/items

Topic	Questions
Intersectionalities	Demographics including year of birth, gender, ethnicity, relationship status, area code of postcode, urban/rural dwelling, accommodation type, household income, education, employment status, religiosity (62)
Behavioural responses ‘	‘Control of life’ (including COVID-19-related)
Access to resources, support, care, vaccines	QOCS-ID (63), Vulnerability Assessment Framework (64) for care needs, UK government SAGE group recommended questions (https://bit.ly/2OZN9Bf)
Social networks	Developed from the close persons questionnaire (65)
Mental and physical wellbeing/quality of life	WHOQOL-BREF-ID (63) or EURO-QOL questionnaires
Coping	Including tolerance to uncertainty, positive appraisal style, attitudes to being ill/disabled (WHO ADS (63)), health and mental health consequences (Global Mental Health Assessment Tool (66)) of the pandemic, why they arose and how issues can be mitigated
Local and regional differences	Apart from within-survey analysis, we will match respondents’ area code of postcode with area-level (i) registered COVID-19 cases, hospitalisations and deaths (ONS https://bit.ly/2NOydC8) and (ii) social distancing adherence (Google Community Mobility https://bit.ly/2AqRwyk).
Vaccines, Future policies	Freetext comment boxes

8.4 Social Networks Analysis process

The data collection on Social Networks will take place in two forms: the first is in the large-scale survey, the second as part of the qualitative interviews. The nature of social network measurement will differ in these two versions. In the survey, we will use the standard ego-centred network items that use name generators, name interpreters for a limited number of “alters” in “ego”s (the respondent’s) network, and the standard social network questions. Such social network components have been incorporated in standard large-scale surveys (e.g. General Social Survey or Understanding Society). We thus do not see any threats to feasibility of the social networks component of the large-scale survey, given that this is a standard approach which has already effectively been tested in CLS surveys, with good response. The social network component in the qualitative interviews (target n = 210) is more involved. It will include more detailed questions about the nature of support networks around “ego”, such as on the features of the relationship between the “alters” and “ego” as well as between the “alters”. To facilitate network data collection process,

we will use tailored software (i.e. Network Canvas <https://www.networkcanvas.com/>). We will pilot the Network Canvas module before fielding it to check for feasibility. We believe social support network analyses are essential in understanding the effects of the pandemic on our participants, and that collecting good quality data on social networks during the pandemic is very important. Should the Network Canvas module prove to be unfeasible we will still be able to ascertain information from simple questions, but this provides a framework to probe for all important aspects.

8.5 Interview process

Remote by default, interviews will use the method of respondents' choosing (most likely phone (60) but Teams and other remote video methods are also possible). At each site, our PPI leads will help train a lay community member to undertake interviews locally –still planned remotely – supported by 2 central qualitative researchers who will also undertake remote work. Interviews will be recorded; with video conferencing software this may include faces.

Participants will be told how to ensure their names do not appear on these recordings on screen before recording begins.

The prompt guide or interview schedule will be developed from the research objectives and the review work (see *Section 8.1*), in collaboration with our advisory groups and through participatory workshops.

Many participants are likely to depend on informal support networks for: education; health, social care, legal matters; wellbeing; social/cultural activities (49). These, formal support and third sector networks have been disrupted during the pandemic. We explore the issues through:

1. A brief questionnaire about social networks preceding the first interview – orally if needed
2. Results translated into Network Canvas software to develop ego(participant)-centric network maps that can be explored in depth in interviews
3. Participant sketch-maps of their local area and the places significant to them.

For inclusivity, important when considering people with disabilities and ethnic minority/migrant groups, participants will be asked to take smartphone photographs of significant places prior to interview. This ethnographic approach facilitates a safe social space to communicate difficult issues and has been used to explore migrant resettlement (67). We will give all participants clear instructions, with a focus on ethical issues (e.g. to avoid identifiable photos of other people). Participants with no/unsuitable phones, no internet, limited data plans will be given disposable cameras with SD cards (local researchers will arrange pandemic-safe digital data collection). Participants will be asked to take photos significant to their healthcare interactions and to their social interactions. Photos will be discussed in interview, to probe for insights, and will also be thematically analysed as data. They might for example show physical barriers to accessing a building, or a photo of a restricted gathering for a wedding or a funeral, which can be used to stimulate discussion about our key topics.

Transcription of qualitative data will be undertaken professionally with UCL preferred supplier contracts. Data will be cleaned, de-identified, stored/transferred, accessed, archived by the core research team. Coding will be undertaken by the core team, with feedback from the advisory and co-design groups.

8.6 Research workshop process

All 3 workshop sets (wave 2, wave 3, co-create) will aim for outputs relevant and implementable for the 'real world' that maintain participant voices, with tangible benefits for all.

Materials will be shared in advance, to suit accessibility needs, and discussions led by our PPI lead and PI/lead researcher.

All types of workshop will use creative approaches for engagement and participation.

Sessions will last 4 hours (2 if remote), with practical activities that empower all those attending to contribute as equals to 'negotiated' analyses/outputs. Group discussions will be summarised for reference. The research team will work on outputs/analyses to present at following workshops. Study analyses will be developed iteratively through the co-create workshops.

The wave 2 and 3 research workshops will likely be remote, e.g. using 'Teams', led by core team members, with support from the PPI group. To avoid excluding people, we will also offer repeat interviews. We will work with the UCL Centre for Collaboration and our PPI group to ensure workshops are accessible and inclusive, e.g. incorporating Padlet, Miro and other visual tools or infographics where appropriate.

Wave 2 workshops will discuss scenarios, or structured vignettes, shown as short videos recorded by community members reading scripts; content will be developed from Wave 1 data into a pandemic-relevant story, illustrated e.g. with Wave 1 photos with permission, to consider assets and strengths, issues and potential solutions. Non-identifiable verbatim phrases will enhance authenticity, with accessibility transcripts provided in advance. This approach is effective in inclusive research and suited to both remote and face to face work, so we can be flexible. Discussion will serve to check validity of previous findings and consider changes from these.

Wave 3 workshops will be similar, with updated vignettes. We will also use participatory scenario planning (68), a policy tool whereby participants are encouraged to explore alternative futures, their impacts and relevant action plans (topic 8, *Section 4.1*).

Transcription of qualitative data will be undertaken professionally with UCL preferred supplier contracts. Data will be cleaned, de-identified, stored/transferred, accessed, archived by the core research team. Coding will be undertaken by the core team, with feedback from the advisory and co-design groups.

8.7 Co-create workshop process

The Co-create workshops will involve discussion of milestone data and findings and Co-create their translation into outputs to feed into the next stages or in study outputs, depending on what is appropriate at the time each workshop is held.

To stimulate discussion and outputs we will use arts-based and participatory approaches such as those in <https://blogs.brighton.ac.uk/collaborativepoetics/resources/cp-draft-resource-pack-final-27ftb2i/> (co-authored by the CI of CICADA-ME) or <https://ccw.southdenmark.eu/> and adapted for online work, for example using Padlet or Miro.

8.8 Key informant interview process

To support implementation into policy and practice, topics include:

- perceptions of local service needs,
- area-level characteristics,
- barriers and facilitators to community member service access,
- current community-led responses,
- impacts and effects of the pandemic, and

- future planning.

Topic guides will also consider CFIR themes (25) and will also draw from other findings from the study. They will be developed with our advisory and workshop teams.

Transcription of qualitative data will be undertaken professionally with UCL preferred supplier contracts though we may also use internal UCL-approved transcription software. Data will be cleaned, de-identified, stored/transferred, accessed, archived by the core research team. Coding will be undertaken by the core team, with feedback from the advisory and co-design groups.

8.9 Interventions evaluation process

We will use a mixed methods approach for UltimateYou and Tough Cookie, collecting a range of quantitative and qualitative data. We anticipate using validated measures used in our primary surveys. The process will be developed with our advisory and workshop teams and with stakeholders in the intervention evaluations. Their evaluation may require ethical review amendment.

Other brief interventions that we may decide to test will be specified in addenda to this protocol once determined and their evaluation may require ethical review.

9 DATA ANALYSIS

9.1 Review data analysis

- We will use descriptive statistics and meta-analysis to summarise data where appropriate, and otherwise narrative synthesis.
- We will perform subgroup analyses where appropriate.
- Disaggregation will be built in where possible and useful, though in a complex systems approach this may sometimes be misleading due to system interdependencies. Systems diagrams, logic models and other approaches will be used where appropriate.

9.2 Secondary analysis of CLS and ActEarly data

These data will undergo similar analysis, where possible, to our primary survey (*Section 9.3*), to help to place it into context and to augment it.

We are not undertaking linked analysis and therefore the surveys may include some of the same respondents, which will be taken into account in data use, synthesis and reporting.

Data on population characteristics including demographics (e.g. age, sex), indicators of health status (e.g. Activities of Daily Living, frailty), and societal factors (e.g. social fragmentation, area deprivation) will be amongst those extracted.

We will look for patterns in the data.

To place our primary survey data within existing and prior national contexts and relate them to other studies, we will conduct our secondary quantitative analyses on three periods: before the pandemic (up to 01/01/20); pre-relaxation of the winter-spring 2021 lockdown in the UK (up to May 12th, 2021) and thereafter (to end of the study, with a 16-17-month update of the data analysis). Should the data

enable this, we will also subdivide the 3rd period according to the three times that our primary survey is undertaken

9.3 New survey data analysis

A descriptive statistical summary will be updated with each wave using RedCap analytical tools for rapid dissemination.

More in-depth analysis will exploit all 3 waves of the data, with these research questions (RQ):

1. How do outcomes (resource access, formal/informal care, quality of life, control of life, physical and mental health, social networks) and outcome trajectories differ by sample subgroups?
2. What are the outcomes (resource access, formal/informal care, quality of life, control of life, physical and mental health, social networks) and their trajectories in terms of intersectionalities?
3. To what extent can pandemic prevalence and adherence to social distancing at the area level explain differences in outcomes and outcome trajectories across subgroups of the sample and in terms of intersectionalities?
4. How do the outcomes inter-relate within and across survey waves, and how does this differ across groups of the sample and in terms of intersectionalities?

For **RQ1**, we will exploit the longitudinal nature of the data using Latent Growth Modelling (LGM) to estimate:

- (i) levels of network capital, quality of life, mental and physical health and other key variables, and
- (ii) change in these over time, and differences in levels and changes between those with chronic conditions versus without, white British versus ethnic minority, and citizenship versus without.

For **RQ2**, we will carry out “multiple group” analysis with separate levels and trajectories of the key variables estimated per minority, condition/ disability and citizenship intersectionality. In other words, we will vary different combinations to consider the effect of intersectionalities on outcomes.

For **RQ3**, we will include area-level matched data on pandemic prevalence and adherence to social distancing in the latent growth models as covariates, to explore the extent they can explain differences in outcomes between each subgroup, and differences compared with inter-sectional combinations.

- (i) Depending on geographical coverage and the numbers recruited, the LGM estimation could be carried out within-area, to examine the causal impact of the change in pandemic prevalence and social distancing across the waves on each key outcome, under the assumption that change in pandemic prevalence and social distancing is exogenous.
- (ii) We will examine the plausibility of this assumption and detail possible sources of endogeneity. This will be important for policy, with its unique focus on ethnic minorities and PwCD. For example, our data could help clarify why specific groups may not find it feasible to adhere to recommended behavioural responses.

Finally, for **RQ4** we will estimate a developmental cascade model, including all 3 data waves and key variables, to explore how the key variables are associated with one another, both within survey waves and over time.

We will fit the LGM models using Structural Equation Modelling (SEM); this offers useful tools for dealing with missing data due to non-response and attrition; the Full Information Maximum Likelihood estimation will be used for possible systematic missingness.

The **Social Network Module** will provide an ego(participant)-centred network, including ego's ties, their frequency, resources of the alters (others), relationship types. Further characteristics e.g. the ego network's size, density, composition, and average strength of ties will be calculated and a latent "network capital" variable created through measurement analysis within the SEM as a novel contribution.

A Confirmatory Factor Analysis will refine other survey measures.

We will use Canvas SNA software for the social network analysis and SPSS for other analyses.

9.4 Interviews data analysis

Interview data will undergo Keyword in Context (word frequency-based) analysis with software to be determined e.g. WordSmith, NVivo.

- Constructs from this will be used to develop a coding frame for Framework analysis of the workshop, interview, photo and key informant data, for general dissemination and policy-relevant themes that can be mapped to the survey for added insight. This will use NVivo.

Added to this deductive approach we will allow for inductive themes.

- Data collection and analysis will be concurrent for quick outputs and to test emerging and discordant themes and will continue until sufficient 'inductive thematic saturation' is reached.

We will undertake discourse and narrative analyses on a data subset produced from participant pairs matched on features identified as important from analysis.

We will ensure:

- credibility/internal and external validity (e.g. through exemplar data extracts, data collection triangulation, and team and participant workshop data discussions),
- transparency (with a clear audit trail), and
- reproducibility (through thick descriptions of context and analysis).

Anonymised data will be archived for secondary analyses.

9.5 Overall data synthesis

This will provide an executive overview for easy digestion by policymakers and practitioners and help show where health/social care policy and practice changes are likely to be most effective.

Synthesis will be results-based, with thematic tabulation derived from data analyses, with table columns for themes, rows giving quantitative and qualitative data.

Some data will need to be transformed (quantified or qualitisied) for tabulation e.g. network graphs. We will interrogate the tabulated data using anchor questions based on the PerSPectif framework (informed e.g. by data convergence/divergence patterns). See Section 9.1.3.

9.6 Interventions evaluation data analysis

9.6.1 Statistical analysis for interventions evaluation

- Given that these are feasibility studies with a small sample size, descriptive statistics will be used (χ^2 test and Fisher's exact test).
- Differences pre-post in all outcomes will be estimated with 95% CIs.

- The descriptive data will provide estimates of differences pre-post in means and proportions for the key outcomes.
- SPSS will be used.

9.6.2 Process evaluation for interventions

Process evaluation is an essential part of testing complex interventions and will be used to:

1. Test the intervention theory and whether the mechanisms of change operationalise as hypothesised.
2. Evaluate contextual factors that influence operationalisation of the intervention's theory/mechanisms of change and any unintended effects of these factors.
3. Evaluate whether the intervention is differentiable from 'usual practice'.
4. Evaluate implementation of the intervention, particularly 'reach' (e.g. who receives the intervention), 'dose' and completion rates, and intervention fidelity, what adaptations are undertaken and why.
5. Evaluate acceptability of the intervention to relevant stakeholders.
6. Evaluate intervention embedding and sustainability, for example, what are the barriers and facilitators to the uptake of the intervention in current care pathways.

Our process evaluation will depend on stakeholder interviews and focus groups, and session observation notes, with descriptive qualitative analysis, and inductive reasoning to determine whether the intervention requires further development and adaptation.

Transcription of qualitative data will be undertaken professionally with UCL preferred supplier contracts. Data will be cleaned, de-identified, stored/transferred, accessed, archived by the core research team. Coding will be undertaken by the core team, with feedback from the advisory and co-design groups.

10 PATIENT AND PUBLIC INVOLVEMENT (PPI)

10.1 Designing the study

In designing the study, we had a consultation as a minuted MedAct meeting item, others with small groups or individuals by email, or online by remote video chat including members of the public, and community groups. While this excluded some groups e.g. without internet, MedAct and Bromley-by-Bow contributed and are successful in engaging these groups. As a result:

- We focus on particular minority ethnic groups; the choice and implications on study design were discussed.
- PPI contributors considered citizenship status influential, which is thus included as a consideration.
- There is no agreed definition of the term 'migrant', usually differentiated from asylum seekers in terms of 'choice' (<https://www.unhcr.org/pages/49da0e466.html>; <https://www.unhcr.org/uk/5d9ed32b4>). A refugee has had their lack of choice formally ratified (<https://www.unhcr.org/uk/5d9ed32b4>). The relevance of these definitions changes over time according to our PPI work so for simplicity, despite its problems, they suggested using the term migrant to encompass all these and to mean someone who was born outside the UK and intends to stay in the UK for at least a year. Our PPI contributors will help us discuss this in our final outputs.
- PPI contributors suggested restricting interviews to English would not reduce the impact of the study but would usefully determine barriers for those who might be assumed OK because they are not in housing for the vulnerable and can communicate in English.

- The PI has undertaken work on service use in minority ethnic groups with limited English language fluency and agrees language issues need dedicated in-depth analysis and specific responses, outside the remit of this study. But as per our PPI work we will include their broader influence where relevant, following the approach of collaborators with experience in this work with relevant groups, Bromley-by-Bow and MedAct Migrants Group (most of whose research is in English).
- It was agreed translated study documents will be available if required to ensure fully informed consent and that if this approach excludes intended participants, interpreters will need to be used.
- PPI members said to monitor need for formats for disabilities e.g. Braille.
- Our PPI work suggests many potential participants will prefer a cautious remote approach even when government rules allow face to face work; they may find remote work avoids time and energy costs of travel. PPI team members have also advised us it will be a long time before they would be prepared to undertake normal research work. But we can easily revert to face-to-face work if appropriate.
- We include any self-declared chronic health condition or disability as determined through brief screening questions, including self-diagnoses as considered vital in our PPI work.
- Our PPI contributors approved the use of our six disability 'impact' categories after ensuring diet encompassed eating disorders but asked to ensure multisystemic conditions are represented by multisystemic impacts – thus the survey does not restrict people to choosing one or the most dominant condition, and does not restrict the number of effects (symptoms).

10.2 PPI through the study

PPI will continue through the study. We have taken care to involve lay people who represent our interview population in the range of ethnicities and disabilities. Our PPI team members were recruited through existing networks and also through specific condition support and third sector groups. One lay co-A has contributed to the NICE long Covid committee, but this was not a condition of their recruitment, though any call for volunteers is more likely to recruit people actively engaged in this way.

1. The PPI group will undertake standard tasks such as checking survey questions, contributing to topic guides and advising on the study.
2. Our PPI team will be involved in co-create workshops through the study as an important part of its design:
 - a. Our five co-create workshops will be led by members of our PPI working group supported by the CI and a researcher from the team trained in the methods.
 - b. Materials will be provided in advance, taking account of accessibility needs (something specified in PPI work).
 - c. Practical activities will aim to produce 'negotiated' analyses and outputs that empower all those attending to contribute as equals and that our PPI lead is comfortable with. These workshops should not be confused with our research workshops which will also use participatory approaches but with our research participants (though members of our PPI team will be invited to join in running these).
3. In each of our five recruitment areas we will train a member of our focal community to undertake interviews locally – and remotely unless it is safe to do otherwise AND this is preferred - supported by our central team which will also undertake interviews remotely.
 - a. Time has been costed in for the lay co-researchers for training as well as their remuneration for the research work they do.
 - b. At the study start, our PPI team will co-develop their memorandum of association and other

- c. documents relating to their role. They will be supported in this and asked to specify their precise training/support needs, which we will provide.
4. All PPI members and lay co-researchers will be recompensed at £150 per day spent on work, pro rata.
5. We will fully involve our PPI team in dissemination and output work with full support, and with the opportunity to write or co-author papers; the PI's' department hosts a free -for-all journal called Research for All that is an ideal platform, being fully supportive of PPI contributors.
6. PPI team members will also run training workshops at study end as outputs, with full support.

10.3 Connecting to patients/service users, carers, focal communities, the wider public

- Our PPI team with lived experience, and other stakeholders such as third sector, clinicians, social care staff, policy staff (selection to be determined in consultation with our advisory group and PPI team at start of the study), will co-create outputs to ensure their credibility and real-world relevance and to strengthen public engagement.
- Being online, at least initially, widens participation opportunities.
- An overview of early findings will be presented to participating communities more widely via collaborator platforms, to give them the opportunity to reflect upon and interrogate researchers' interpretations and analysis of the data and ideas for outputs. This will enable broader community input into the final project outputs such as empowering guidance, recommendations.
- All findings will be publicly available via our website in accessible forms for lay consumption using recommendations in the Patient Engagement Open forum (<https://bit.ly/388SFr0>) and by involving trusted community channels, such as places of worship, trusted religious leaders, community champions - possibly tapping into the infrastructure developed from COVID vaccine rollout - and community groups, including collaborators Bromley-by-Bow. This aligns with Black community comments in a meeting about vaccine uptake and UK government 2021 vaccine hesitancy guidance by the Scientific Advisory Group for Emergencies ethnicity sub-group (SAGE) (<https://bit.ly/38GLt6D>).

11 FUNDING AND SUPPLY OF EQUIPMENT

The study funding has been reviewed by the UCLH/UCL Joint Research Office, and deemed sufficient to cover the requirements of the study. The research costs for the study have been supported by NIHR HS&DR.

12 DATA HANDLING AND MANAGEMENT

The study is compliant with the requirements of General Data Protection Regulation (2016/679) and the UK Data Protection Act (2018). All investigators and study site staff will comply with the requirements of the General Data Protection Regulation (2016/679) with regards to the collection, storage, processing and disclosure of personal information, and will uphold the Act's core principles. UCL is the data controller; the UCL Data Protection Officer is <https://www.ucl.ac.uk/data-protection/>: data-protection@ucl.ac.uk The data processors are as specified at the start of the protocol.

13 ROLES AND RESPONSIBILITIES OF STUDY STEERING COMMITTEE

The study steering committee has been formed in line with NIHR guidance: <https://www.nihr.ac.uk/documents/research-governance-guidelines/12154>.

We have recruited representation from: a lay member, clinician, third sector representative, qualitative and quantitative methodologist and a social care representative.

We also have a project advisory group with a similar make-up and of similar size, and a PPI group that aims to represent the breadth and diversity of lay participants.

14 PEER AND REGULATORY REVIEW

The study has been peer reviewed in accordance with the requirements outlined by UCL.

For any amendments to the study, the Chief Investigator or designee, in agreement with the Sponsor, will submit information to the appropriate body in order for them to issue approval for the amendment. The Chief Investigator or designee will work with sites (R&D departments as well as the study delivery team) to confirm ongoing Capacity and Capability for the study.

All correspondence with the Sponsor, REC and HRA if relevant will be retained. The Chief Investigator will notify the Sponsor and REC of the end of the study.

It is the Chief Investigator's responsibility to produce the annual progress reports when required; an annual progress report (APR) will be submitted to the Sponsor and REC within 30 days of the anniversary date on which the favourable opinion was issued, and annually until the study is declared ended.

If the study is ended prematurely, the Chief Investigator will notify the Sponsor and REC, including the reasons for the premature termination.

Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the Sponsor and to the REC and HRA.

15 ASSESSMENT AND MANAGEMENT OF RISK

15.1 Potential risks to participants

- If during the study we determine that a participant has mental health or safeguarding issues, Abou-Saleh, who undertakes migrant crisis assessments for the Helen Bamber Foundation will advise and we will provide posting to sources of help. Abou-Saleh will take the appropriate steps to mitigate harm to the participant.
- Immigration concerns need assured anonymity and sensitivity.
- If a participant discloses information about intention to harm others, the sponsor will be immediately alerted and steps taken urgently to mitigate harm to others. The participant will be informed that this is being done.

15.2 Survey success

15.2.1 Survey target number risks:

- We are confident of achieving our target numbers because of our comprehensive recruitment strategy, extensive networks, prior experience with the marginalised, and the experiences of other pandemic surveys including those of co-applicants.
- We also believe the emergence of long Covid critical mass and the particular desire of people with marginalised chronic conditions such as long Covid and complex (multisystemic) comorbidity (such as Ehlers Danlos Syndromes, Chronic Fatigue, Fibromyalgia) to contribute to research to get their voices heard, means there will be a strong appetite for our survey.
- Should we over- or under-sample, we will use all the data; under-sampling may preclude within-area analyses. There are two particular risks that require mitigation:
 - Should we fail to achieve even 3,200 at wave 1, we will reduce the study design to a two-wave survey, leaving recruitment open for longer at each wave. In the worst case, we will only undertake one wave. However, we consider these mitigation scenarios highly unlikely from initial scoping and from past experience of team members for other surveys.
 - Failure to recruit enough minority ethnic participants - the above shows the minimum number needed is 1,600 BAME respondents. Several team members have considerable experience in recruiting ethnic minorities with chronic health problems and we believe minimum numbers can be reached with a four nations survey. In Dickerson's successful localised 2020 BiB survey, only 18% of 2,144 respondents were White British. We have ensured strong connections also with ethnic minority organisations that deal specifically with chronic conditions, such as collaborators MedAct and via collaborator Abou-Saleh. So we believe we will be successful in our plans. However should this not be so, we will be able to undertake useful analyses of white British data and can then explore ethnic intersectionalities within WP3 and by collapsing ethnic minority +/- the survey.

15.2.2 Survey attrition and missing data

- We will require completion of almost every question on every page for participants to proceed, so we can undertake the association analyses required. This means there should generally be no *missing* items in any measures.
- But this requirement may lead to *completion attrition*, with respondents giving up and logging off. We will try to mitigate that, with the questionnaire design which will be developed and piloted with our PPI group and N=30 others.
- There is the risk of *attrition between waves*. Participants will be asked to provide an email address on enrolling, if online. The RedCap online secure system will then automatically re-contact them for wave 2/3 follow-up questionnaires (with reminders) to explore trajectories over time. This automatic process makes for efficient and secure second and third wave recruitment to reduce the risk of missing respondents.
- Data will be anonymised prior to analysis and researchers will not directly handle email addresses; however they can control reminders. Careful design of the covering letter/page on between-wave reminders can improve return rates from those with lower levels of education or who speak languages other than English at home (71), so we have ensured these are designed with full PPI input. Lotteries appear effective in some online surveys (71) and we are including a £50 Amazon voucher as an incentive given at random.
- To handle missing data and address panel attrition and item non-response, we will use modern methods, including Full Information Maximum Likelihood, Multiple Imputation

with Chained Equations that produce unbiased estimates under assumptions of missing at random (i.e. missingness depend on observable data only) and multivariate normality; and pattern mixture models that address missing not at random (i.e. missingness may also depend on unobserved data) assuming correct model specification (72). Those techniques, under certain assumptions, ameliorate loss of statistical power due to missing data and possible biases due to systematic missingness.

15.3 Interviews

15.3.1 Risks of interview non-recruitment and attrition

We aim for sufficient participants for rich data for all our main ethnicity/disability combinations shown in **Table 1**.

Possible attrition (up to 20% based on BiB experience) between waves may require further recruitment if theme/pattern saturation is not reached.

But if many combinations provide similar data, leading to saturation, we may stop recruitment early or modify our recruitment strategy for theoretical sampling.

To reduce risks of non-recruitment and attrition, and to enable us to achieve our aims, we have considerable in-built capacity to do this work.

16 PROTOCOL COMPLIANCE

Accidental protocol deviations can happen at any time. Protocol deviations are usually an unintended departure from the expected conduct of the study protocol/SOPs, which does not need to be reported to the Sponsor. The CI will monitor protocol deviations, and if found to frequently recur, will discuss in the first instance with the Sponsor to determine re-classification and reporting requirements.

Deviations from the protocol which are found to frequently recur are not acceptable, will require immediate action and could potentially be classified as a serious breach.

A protocol violation is a breach which is likely to effect to a significant degree: –

- (a) the safety or physical or mental integrity of the participants of the study; or
- (b) the scientific value of the study.

The CI and Sponsor will be notified immediately of any case where the above definition applies via research-incidents@ucl.ac.uk or the UCL REDCAP incident reporting form.

17 RECORDING AND REPORTING OF EVENTS AND INCIDENTS

Research related events and incidents can encompass incidents that involve participants, staff or a carer/visitor during the course of the research study (e.g. a member of staff may be injured whilst administering an intervention, participants may not have been consented properly, collected data may be misplaced or stolen, data losses or breaches in confidentiality may occur, protocol violations or non-compliances with regulatory requirements or Sponsor conditions of approval, etc.). For any doubts or queries as to whether an incident is reportable or not, contact the JRO Quality Assurance team/refer to the *JRO non-CTIMP Research Incident Reporting SOP*.

Research related incidents are all unintended or unexpected events that could have led, or did lead to harm for participants, staff or members of the public during the research study. A reportable incident may significantly affect:

- a) the rights or wellbeing of a research participant
- b) the scientific value of the study
- c) the compliance of the study/research staff with relevant legislation, e.g. General Data Protection Regulation (2018), the U.K. Policy Framework for Health and Social Care Research, etc.
- d) UCL's organizational reputation, and that of participating organisations.

All events and incidents (and near misses) that occur to participants and/ or staff that are unexpected and directly related to the research study will be reported to the Sponsor via research-incidents@ucl.ac.uk or [UCL REDCAP incident reporting form](#)), and documented in a study-specific incident log (and related correspondence). This will be completed by the CI. The Sponsor will be responsible for investigating, reviewing, or escalating to a serious breach if required.

In some instances, despite risk management and mitigations, personal data breaches may occur throughout the duration of the study. GDPR broadly defines personal data breaches as a security incident that has affected the confidentiality, integrity or availability of personal data. In short, there will be a personal data breach whenever any personal data is lost, destroyed, corrupted or disclosed; if someone accesses the data or passes it on without proper authorisation; or if the data is made unavailable, for example, when it has been encrypted by ransomware, or accidentally lost or destroyed. Reporting of any data breaches will follow processes in place at UCL at the time. <https://www.ucl.ac.uk/data-protection/guidance-staff-students-and-researchers/practical-data-protection-guidance-notices/report-breach>

Personal data breaches will be immediately reported to the UCL Information Security Group (ISG) and the UCL Data Protection Officer [data-protection@ucl.ac.uk], (as per form and guidance: <https://www.ucl.ac.uk/legal-services/guidance/reporting-loss-personal-data>), and to the Sponsor via the UCL REDCAP incident reporting form (<https://redcap.slms.ucl.ac.uk/surveys/?s=NE5dypTdFo>). The following information will be provided: full details as to the nature of the breach, an indication as to the volume of material involved, and the sensitivity of the breach (and any timeframes that apply).

17.1 Complaints from research participants

In the first instance, research participant complaints (patients or healthy volunteers) will be reported to the CI/PI to investigate, as documented in the patient information sheet(s), and to the Sponsor via research-incidents@ucl.ac.uk, following the *UCL Complaints from Research Subjects about UCL Sponsored Studies and Trials* policy.

18 MONITORING AND AUDITING

The Chief Investigator will ensure there are adequate quality and number of monitoring activities conducted by the study team. This will include adherence to the protocol, procedures for consenting and ensure adequate data quality.

The Chief Investigator will inform the Sponsor should he/she have concerns which have arisen from monitoring activities, and/or if there are problems with oversight/monitoring procedures.

19 TRAINING

The Chief Investigator will review and provide assurances of the training and experience of all staff working on this study. Appropriate training records will be maintained in the study files

20 INDEMNITY ARRANGEMENTS

University College London holds insurance against claims from participants for harm caused by their participation in this clinical study. Participants may be able to claim compensation if they can prove that UCL has been negligent.

Participants may also be able to claim compensation for injury caused by participation in this study without the need to prove negligence on the part of University College London or another party. Participants who sustain injury and wish to make a claim for compensation should be advised to do so in writing in the first instance to the Chief Investigator, who will pass the claim to the Sponsor's Insurers, via the Sponsor's office.

21 ARCHIVING

UCL recognise that there is an obligation to archive study-related documents at the end of the study (as such end is defined within this protocol). The Chief Investigator confirms that he/she will archive the study master file at UCL for the period stipulated in the protocol and in line with all relevant legal and statutory requirements. Study documents will be archived for a minimum of 5 years from the study end, and no longer than 20 years from the study end.

22 PUBLICATION AND DISSEMINATION

22.1 Dissemination of outputs

Cascaded dissemination at each data wave, tailored to our key audiences, will emphasise practical solutions and implementation, and will be co-developed with key stakeholders representing our audiences. All publications will be passed by NIHR for approvals and updates.

22.2 Connecting to policy, health, social care practitioners

e.g. social workers, community health teams, clinicians, medical organisations, WHO: 2+ **articles, talks, knowledge exchange event, training, guidance, recommendations, educational case studies** on the implications of findings disseminated by e.g. Royal Colleges, **practitioner journals**.

To ensure engagement and action from shared outputs and disseminations, we will determine the best approaches through stakeholder analyses in our co-create workshops, and draw on existing networks and possibilities.

On completion of the study, the data will be analysed and tabulated and a Final Study Report prepared. This will be available from the NIHR dissemination centre.

22.3. Reporting guidelines

We will follow all relevant good reporting guidelines, such as the TIDieR checklist and Intervention Taxonomy for interventions, PRISMA for reviews, COREQ for qualitative reporting.

22.4. Authorship guidelines

All co-applicants and core researchers will be granted authorship on the final study report in line with contributions. The International Committee of Medical Journal Editors has defined authorship criteria for manuscripts submitted for publication. We will follow the CRediT (Contributor Roles Taxonomy) of 14 roles to describe how they have contributed to disseminations.

All publications will have an NIHR acknowledgement:

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23 Disclaimer

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24 REFERENCES

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25 APPENDICES

Document Name	Document Version	Document Date
Data dictionary	1.1	Sept 2020
Data management plan	1.1	7th May 2021
Ethics documents	2.1	Sept 2020