Title: A realist synthesis to explain how, for whom and in what circumstances different community mental health crisis services work.

Short Title: MH-CREST (Mental Health-Crisis Realist Evidence SynThesis)

Study Registration: NIHR Database
Prospero CRD42019141680
IRAS 261486

Funding Source: NIHR

Principal Investigator: Dr Nicola Clibbens, School of Healthcare, University of Leeds

Co-Investigators: Professor Scott Weich, ScHARR, University of Sheffield & Sheffield Health and Social Care NHS Foundation Trust
Professor John Baker, School of Healthcare, University of Leeds & Leeds and York Partnership NHS Foundation Trust
Dr Andrew Booth, ScHARR, University of Sheffield
Mr Michael Ashman, Independent Consultant
Dr Kathryn Berzins, School of Healthcare, University of Leeds
Dr Jill Thompson, School of Nursing and Midwifery, University of Sheffield

Study Sponsor: Sheffield Health and Social Care NHS Foundation Trust

This study is funded by the National Institute for Health Research (NIHR) HS&DR programme (project reference NIHR127709). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

Abstract:

BACKGROUND: Mental health crises cause significant disruption to the lives of individuals and families and can be life threatening. The drive for community care alongside large reductions in hospital beds has led to a proliferation of community crisis services. This has resulted in service designs that can be difficult for people to access and navigate. People also report that their needs in a crisis are not always met and variation between services has been reported. It is unclear which underpinning mechanisms of crisis care are most effective, for whom and in which circumstances. Developing community crisis care interventions through the Complex Interventions Framework presents an opportunity for greater cost effectiveness if the interventions can be successfully developed, tested and implemented.

AIMS AND OBJECTIVES: The aim of this study is to identify mechanisms to explain how, for whom and in what circumstances community crisis services for adults work to resolve crises with a view to informing current and future intervention design and development. The study objectives are to:

i. Use stakeholder expertise, current practice and research evidence to develop programme theories to explain how different crisis services work to produce the outcome of resolution of mental health crises.
ii. Using a Context, Intervention, Mechanisms, Outcome framework (CIMO), to construct a sampling frame to identify subsets of literature within which to test programme theories.
iii. Iteratively consult via Expert Stakeholder Group and individual interviews with diverse stakeholders to test and refine programme theories.
iv. Identify and describe pen portraits of UK crisis services that provide exemplars of the programme theories to explain how mental health crisis interventions work in order to explore and explain contextual variation.
v. Synthesise, test and refine the programme theories, and where possible identify mid-range theory, to explain how crisis services work to produce the outcome of resolution of the crisis. Provide a framework for future empirical testing of theories in and for further intervention design and development.
vi. Produce dissemination materials that communicate the most important mechanisms needed to trigger desired context-specific crisis care outcomes, in order to inform current and future crisis care interventions and service designs.

DESIGN: A realist evidence synthesis with collection and analysis of secondary (realist synthesis) and primary data (stakeholder engagement via a series of Expert Stakeholder Groups and individual interviews).

ANALYSIS: We will analyse the data using realist logic to:

- Identify initial programme theory/ies (Objectives i, ii, iii)
- Explore application of the programme theories in different contexts (Obj. iii, iv, v)
- Explore and explain contextual variation as it relates to putative mechanisms (Obj. iii, iv, v)
- Inform current and future design and development of crisis interventions (Obj. iii, iv, v, vi)

IMPACT: This research will inform the ongoing development and evaluation of existing mental health crisis services and interventions. By taking a theory driven approach, our findings will inform commissioning, service design and delivery that is sensitive to context across diverse service designs and providers. From the perspective of patients and the public, our theory testing will provide a platform for future empirical testing to streamline service designs thereby improving access and experience of crisis care.

1. Background and rationale

Mental health crises cause significant disruption to the lives of individuals and their families and can be life threatening (1, 2). There has been a proliferation of community based services for people experiencing acute crises embodied in a complex range of service providers, service designs, referral routes and interventions. The growth of voluntary sector and multiagency crisis services and NHS crisis services has contributed to the confusing array of care pathways which can be difficult to access and navigate (3, 4). Evaluations have found that too many people are unable to access timely crisis support and are dissatisfied with the help they receive (4, 5, 6). Previous research has been largely limited to evaluating and developing the fidelity of NHS Crisis Resolution Teams (CRTs) (7, 8, 9), scoping the range of crisis services available nationally (including alternatives to hospital admission) (10, 11) and understanding the role of the voluntary sector in crisis care (12, 13). This bricolage of evidence leaves substantial gaps in our understanding about how or why these different crisis services work for people in different circumstances.

Mental health crises can be defined in different ways (12) including, as a relapse in a psychiatric condition, characterised by increased symptom severity (such as voice hearing, suicidal thoughts, and risky behaviours) and decreases in social functioning (including reduced self-care) (14, 15). Irrespective of psychiatric diagnoses, crises can also be defined as a reaction to adverse life events leading to increasing disruption for the person and their family where their usual coping strategies have failed (16). Being in a state of crisis can also be conceived as an opportunity for change and may enable people to develop new ways of coping (17).

Mental health crises are serious, sometimes life threatening and often associated with increased risks to the safety and wellbeing of the person or others (3, 18). The nature of crisis varies between individuals and has a complex aetiology linked to factors such as; general health, life stresses, treatment adherence, coping skills, and social situation including family, work, income, social support and housing (15, 19). This can result in a complex array of health problems related to mental, physical and social wellbeing that can, if people are unsupported, lead to catastrophic outcomes, such as suicide (18). Social stigma and a lack of public awareness about mental health contribute to delays in contacting services due to fear of being coerced into treatment or negatively labelled (20) and may influence how and from whom people seek help in a crisis. The complexity of service structures and referral routes may also present a barrier resulting in people failing to access the most appropriate or timely crisis care for their needs (4).

The Five Year Forward View for Mental Health (3) sets out the broad mental health policy direction and highlights the importance of effective crisis services. This was preceded by the Crisis Care Concordat (21), a national response to urgent improvement in mental health crisis care. A key part of this strategy has been the development of local plans that bring together multiple agencies through 'nationally coordinated local implementation'. The Crisis Care Concordat has influenced

improvement in crisis services including; more people being seen quickly and reporting being taken seriously and fewer people describing their care as poor or having their first contact with the police (22). Crisis services across health, social care, local government and the voluntary sector are shaped by health priorities including; increasing community based care that is close to home, available urgently across 24/7 (3,23) and situated in an appropriate in place of safety (24). Important too is the involvement of people and their family members in decisions about crisis care (1) and improved access for marginalised communities (3, 23). Allied to crisis care policy are policy priorities to reduce the rate of suicide by 10% by 2020/21 (3) and reduce pressure in both hospital bed use and accident and emergency attendances (25).

Mental Health crisis care is delivered through two main commissioned care pathways; the acute mental health care pathway (26) and the urgent care pathway (27). In theory, CRTs play a central role in coordinating crisis care, often through a single point of access service (28). The functions of CRTs has been summarised as; "1. Assessment of all patients being considered for acute psychiatric hospital admission and act as gatekeeper, 2. To initiate home treatment as an alternative to hospital admission until the crisis has been resolved, 3. To refer to other services for ongoing support, and 4. To facilitate and early discharge for those requiring a hospital admission" (19, p. 339).

In practice, implementation of CRT is highly variable; less than one-half of CRTs in England provided 24/7 services (4) , referrals varied between 42 and 430 referrals per 100,000 of the population across England (29) and some core CRT functions are inconsistently implemented (3,30). CRTs have however been shown to reduce the cost of crisis care, although estimates have varied between 17 and 30% (31, 32), and work well for many people (6, 7). But despite this, areas where CRTs fall short of expectations include; the lack of a consistent care worker; the timing, length and frequency of visits; and the interventions being too focused on risks and medicines management (33,34). The main reason for this variability is the lack of evidence for each of the specific interventions delivered by CRTs or indeed consensus about what these, or any other crisis intervention, ought to comprise.

The voluntary sector has a long history of delivering crisis care services alongside statutory care and over the past decade this has gained recognition as providing an alternative or an adjunct service as well as occupying the gaps left by statutory services (12). Voluntary sector crisis care was initially largely focused on providing alternatives to acute inpatient care (35) but this has been increasingly focused on community interventions including crisis cafes, night time drop-in services and services to improve access for marginalised communities (36). Increasingly, community crisis care is jointly funded between local government, NHS and voluntary sector organisations as evidenced in the range of investment in crisis care via NHS non-recurrent funding (24).

Currently in England, services for people experiencing a mental health crisis are very diverse, postcode dependent and use an array of different labels for services including; CRTs, specialist home treatment teams, out of hours teams, accident and emergency departments, mental health liaison teams, ambulance and paramedic services, place of safety suites, police, street triage teams, day

treatment services, crisis houses, crisis cafes, crisis drop-in services, NHS 111, NHS 999 and telehealth. For many people, the first port of call is their GP. It is unclear what each of these offer (and how provision may vary in different contexts), or which mechanisms (such as early assessment, a safe environment, peer support, advice about medication or support for family members) is most effective for whom and in which circumstances.

1.1 Why is this review needed now?

There is a drive in the UK to improve experiences of crisis care and to design services and interventions that are effective, timely, and accessible to all those in need (23) as well as addressing the need for parity with physical health (37). It is therefore vital to develop complex interventions from a theoretical understanding of the mechanisms that produce the desired outcomes and in which contexts these work best. The Crisis Care Concordat (21) identified a need for crisis care to be developed across multiple agencies including statutory and voluntary sectors; to be largely community based and to improve implementation across the UK to avoid crisis care being postcode dependent. While most attention has been focused on service providers and settings, we currently lack evidence about the mechanisms that underpin effective mental health crisis care and how these are activated to resolve crises across a range of contexts. A focus on underpinning theoretical development would enable commissioners to invest in a range of services designed to include the mechanisms that produce the best outcomes across service designs and providers.

Health services are under ongoing financial pressures, and inpatient care is undesirable to most people, expensive (29) and scarce (25). Community based crisis care presents an opportunity for cost effectiveness if the interventions can be successfully developed, tested and implemented enabling improved prediction of outcomes (38). The development of effective community crisis care may also help to alleviate pressure in the urgent care pathway particularly in accident and emergency departments.

Our pre-protocol consultations with people who have accessed community crisis care have shown that these services resemble a tangled web of overlapping services with complex referral routes and blurred functions. The stakeholders we spoke to endorsed a focus on community crisis services because they are generally preferred, they provide the respite, information and support that people ask for, and because they avoid the need to be away from home and family. Their experiences echoed the published evidence in having mixed experiences of CRTs, and lent weight to the need to improve our understanding of how services work to resolve crises. This would improve people's ability to access information about crisis care thereby improving their ability to access the right care at the right time (4). In order to make sense of this heterogeneity in crisis service design we conceptualise crisis resolution services as complex interventions as defined by the Medical Research Council (38). Complex interventions consist of multiple human responses that interact in non-linear ways to produce highly context dependent outcomes (40). Realist synthesis is a theory-driven approach for understanding existing diverse multiple sources of evidence relating to complex interventions (39, 40). Realist approaches aim to understand "What works for whom, in what circumstances, how and

why?" These approaches optimally explore how and why complex programmes involving multiple human actions and decisions, such as crisis mental health services, may or may not work (40).

2. Aims and Objectives

2.1. Aim

The aim of this study is to identify mechanisms to explain how, for whom and in what circumstances community crisis services for adults work to resolve crises with a view to informing current and future intervention design and development.

2.2. Objectives

The study objectives are to:

i. Use stakeholder expertise, current practice and research evidence to develop programme theories to explain how different crisis services work to produce the outcome of resolution of mental health crises.
ii. Using a Context, Intervention, Mechanisms, Outcome framework (CIMO), to construct a sampling frame to identify subsets of literature within which to test programme theories.
iii. Iteratively consult with stakeholders via a series of Expert Stakeholder Groups and individual interviews with diverse stakeholders to test and refine programme theories.
iv. Identify and describe pen portraits of UK crisis services that provide exemplars of the programme theories to explain how mental health crisis interventions work in order to explore and explain contextual variation.
v. Synthesise, test and refine the programme theories, and where possible identify mid-range theory, to explain how crisis services work to produce the outcome of resolution of the crisis. Provide a framework for future empirical testing of theories in the pen portraits and for further intervention design and development.
vi. Produce dissemination materials that communicate the most important mechanisms needed to trigger desired context-specific crisis care outcomes in order to inform current and future crisis care interventions and service designs.

3. Research Plan

3.1. Design and theoretical/conceptual framework

The focus of the proposed realist synthesis is to develop programme theory/ies to explain how different elements of crisis mental health care work to provide appropriate and effective responses to mental health crises. The research is conceived as a realist synthesis and draws on realist philosophical ideas to answer a generative causal question which, rather than asking

'Does 'A' lead to 'B'?', instead asks 'What is it about 'A' that results in 'B' happening, for whom and in what circumstances?' (41). Realist synthesis offers a lens through which a review team can make sense of what is occurring within a complex intervention, particularly in understanding circumstances

under which it is more or less likely to be effective through the identification and testing of programme theory/ies (39, 40, 42).

Realist programme theories are theories about what an intervention is expected to do and how it is expected to work. It is described in terms of context, mechanisms and outcomes (43). A realist approach aims to understand the interaction between an intervention and its context, mechanisms and outcomes (40). In other words, how the context (the situation around a person) affects any mechanism (the resources and human responses), to generate an outcome (intended or not) (40, 44). It is how people respond to the resources offered by an intervention that is conceptualised in realist syntheses as a 'mechanism'.

Outcomes of interventions are causally triggered by multiple context-sensitive mechanisms and they happen, not only because of what is done in an intervention, but because of the ways that people respond (40, 45). This approach is optimal to explore how and why complex programmes involving human actions and decisions, such as crisis mental health services, may or may not work, and thus to inform the theoretical development of an intervention(s) (40). The realist approach is a participative method of synthesis that allows for, and indeed capitalises on, continual testing of emergent programme theories against empirical evidence as well as data from policy documents and may be further refined using primary data (e.g. from engagement with stakeholders) (39). The involvement of consumers of healthcare in research is essential (46, 47) and the approach to involvement here will be continuous across the study (48). Our Expert Stakeholder Group (ESG) will have diverse membership (maximum of 15 people) reflecting community crisis care services across the UK, in recognition that no one person or group holds all knowledge about crisis care (49). The process of engagement described by Harris et al., (50) will inform engagement at key stages of the research to ensure that important yet potentially hidden, subtle contextual conditions are not missed (Figure 1).

Initial programme theory/ies will be developed and later refined by synthesising evidence from research and policy with data from project team members and stakeholders (via a series of four Expert Stakeholder Groups and up to 50 individual interviews). This process will begin by using this data to develop our understanding of the architecture of UK community mental health crisis interventions. A CIMO (Context, Intervention, Mechanisms, and Outcome) framework will be used to construct an initial sampling frame from which the review team will identify distinct subsets of literature with which to test programme theory/ies. These subsets will reflect different levels of success achieved within crisis mental health services (outcomes) as well as a diverse range of crisis interventions and their associated mechanisms in different contexts.

Empirical research studies will be selected and appraised based on both relevance and rigour. Studies will be included if they present data relevant to the theories being tested (relevance) and if the research supports the conclusions drawn from it by the researcher or the reviewers (rigour) (51). Relevant data will be coded within an appropriate analytical framework; either identified from the conceptual literature or created *de novo* by the project team. Data analysis and synthesis will develop

and refine the programme theory by piecing together data from different sources with a view to creating links to mid-range theory that can be used in future evaluation and development of mental health crisis interventions. "Middle (or 'mid') range… theories are delimited in their area of application and are intermediate between 'minor working hypotheses' (programme theories) and the 'all-inclusive speculations comprising a master conceptual scheme'…" (52, p. 229). Mid-range theories are therefore useful as frameworks in guiding the development of interventions and making generalisations about their application. Realist and Meta-narrative Evidence Synthesis-Evolving Standards (RAMESES) quality and reporting guidelines will be followed (40) and the protocol for the synthesis registered with PROSPERO (53).

3.2. Target population and setting

The population of interest for the review are adults aged 16 years or older, experiencing a mental health crisis. The setting is any community mental health service providing mental health crisis care for adults in a UK context; including crisis resolution teams (CRT), home treatment teams, out of hours services, A&E departments, mental health liaison services, paramedic and ambulance services, place of safety suites, police, street triage teams, crisis houses, day treatment services, intensive community services, crisis cafes, crisis drop-in services, NHS 111, NHS 999 and telehealth.

3.3 Inclusion and exclusion criteria

i. Inclusion criteria

A CIMO (Context, Intervention, Mechanisms, and Outcomes) framework will be used to construct an initial sampling frame. The initial CIMO framework is:

- Context: adult community services delivering mental health crisis care to people aged 16 years or older.
- Intervention: the mechanisms that underpin any intervention that aims to produce the outcome of resolution of mental health crisis applicable to the UK context.
- Mechanisms: the mechanism(s) triggered by each intervention will be identified by the programme theory (e.g. consistency of person/s providing intervention).
- Outcomes: individual outcomes (e.g. resolution of the crisis) and service-level outcomes (e.g. number of emergency admissions).

Distinct subsets of literature will be identified from within the sampling frame with which to test emerging theory (45). The initial sampling frame will be the starting point for the selection of 'index papers' from which key exemplar interventions will be identified. Links to associated publications will be followed up to allow us to derive a cluster of rich data including primary research, policy, practice guidance and grey literature, around each focal intervention or programme. When retrieved data suggests the presence of common mechanisms, search techniques will be refined to identify data from comparable interventions. Preliminary exploration of the literature, suggests that the team will be able to use a comprehensive sampling approach. However, if the logistics prove challenging then we will employ diverse sampling strategies (e.g. theoretical sampling, maximum variation sampling, extreme case sampling) to optimise the analytical value of the realist synthesis component; as specified by the methodology (54).

ii. Exclusion Criteria

In order to optimise the usefulness of the synthesis findings within a UK context we will exclude mental health crisis interventions undertaken in low- and middle-income countries (LMICS). We will privilege studies from the United Kingdom and Europe, (in particular Ireland, Netherlands, Belgium and Norway); followed by countries with comparable health service systems including Australia, Canada, New Zealand, and the United States, given the likely volume of research. Only materials in English Language will be assessed for inclusion.

Data sources must focus on the provision of crisis interventions applicable to a UK context for people accessing adult mental health services aged 16 years or older and they must be experiencing a crisis related to their mental health. Crises without a mental health focus and crisis services specifically commissioned for children and young people under the age of 16 years will be excluded. Acute general hospital inpatient care and acute inpatient mental health care (including acute mental health wards, psychiatric intensive care and short stay acute wards) are excluded from this review.

3.4 Search Strategy

Realist synthesis uses both iterative and purposive sampling from a wide range of evidence to develop, refine, and test theories about how an intervention works, for whom, and in what circumstances (54). Consequently, the search strategy will be developed iteratively and revisited at predetermined milestones, using different permutations and additional concepts (45, 55).

Initial searching will be guided by the need to find data to develop the programme theory/ies. The development of programme theories will include a focus on the architecture of crisis interventions and services in a UK context. This will be achieved through consultation with our Expert Stakeholder Group alongside data drawn from primary research (individual interviews with stakeholders), policy and grey literature. After initial programme theory/ies have been identified, the next step will use 'cluster searching', an innovative approach for purposive sampling, to identify 'clusters' of data from related publications. This approach will add to the conceptual richness and contextual thickness of studies initially identified within the sampling frame constructed through conventional topic-based searching (55). We will identify "sibling" (i.e. directly linked outputs from a single study) and "kinship" (i.e. associated papers with a shared contextual or conceptual legacy) papers and reports to add richness of data while preserving both rigour and relevance (55). Active pursuit of citation networks, using Google Scholar and Web of Science will be used in linking from index papers to the wider literature. These approaches enable the review to search for data specifically focused on the detail of the programme theories, specifically testing their veracity in the context of UK community crisis interventions.

Searching will continue until sufficient data is found ('theoretical saturation') to conclude that a candidate programme theory is sufficiently coherent and plausible (45). The research team with expert input from BOOTH, will develop, refine and run the searches. In addition, we will invite our

Expert Stakeholder Group to recommend potentially relevant documents and ground the review in UK crisis services using their real world experiences and expertise.

We will use the most up-to-date methodological literature when devising search strategies relating to crisis mental health services. Based on previous work and input from information specialists, sources will include: Scopus, Web of Science, EMBASE/PubMed/MEDLINE, Cochrane, CINAHL, PSYCINFO, ProQuest, Sociological Abstracts, Google Scholar, BASE (Bielefeld Academic Search Engine)/ETHOS (British Library Electronic Thesis Online)/ProQuest Dissertations and Thesis, Grey Literature in Europe (http://www.opengrey.eu/) and NHS Evidence and equivalent, external experts and charities/user groups and reference lists of relevant papers.

3.5 Review Strategy

This study uses realist synthesis, including stakeholder consultations, to address three steps within the Medical Research Council framework for Developing Complex Interventions: 1. identifying the evidence base, 2. identifying/developing theory, and 3. modelling process and outcomes (38). Realist programme theories focused on community based crisis interventions will be developed through a combination of secondary (realist synthesis) and primary (stakeholder engagement) data collection. Data from within and across both strands will be used to further develop and refine realist programme theory.

Data collected from each strand will be continually analysed to enable the emerging findings from one to inform the other, resulting in a programme theory that is developed iteratively from multiple data sources. The resulting refined realist programme theory will be used, with input from both the research team and the stakeholder group, to identify and define six diverse pen portrait sites providing working examples of programme theory within crisis services.

We plan to connect our theories back to the real world of services and the experiences of stakeholders by providing exemplar pen portraits of the theories we identify. The pen portraits will not be used to collect primary data within the scope of this protocol but will provide an important framework through which future empirical testing of theory can be conducted. The pen portraits will be defined using realist logic and may include for example, practitioner level crisis interventions, a part of any crisis service or whole crisis service designs according to the programme theories identified, and will be drawn from different types of providers from anywhere in the UK.

Whilst the identification of pen portraits is one of the final steps in the proposed research, examples from real experiences of services will form part of discussions with ESG members across the life of the research. This will support an emergent understanding of examples of context, interventions, mechanism and outcome (CIMO) in crisis services across the UK, through the iterative approach to the evidence synthesis and stakeholder consultation (via both ESG and individual interviews). The research team, in collaboration with the Expert Stakeholder Group (ESG), will utilise this data to inform the final identification of six diverse pen portraits

from across the UK that provide exemplars of the programme or mid-range theories. Representatives from the pen portrait exemplars will be invited to attend a large stakeholder dissemination event.

Theories will be expressed according to a realist 'IF-THEN-LEADING TO' logic. One example of an intervention expressed using this logic is the 'co-location of crisis services'; an approach currently being developed using NHS non-recurrent funding (24) in a number of regions in England. *'IF crisis services are co-located THEN collaboration and communication between providers improves LEADING TO people in crisis having greater choice of provider without delay in receiving an intervention.'* This example may lead to identification of pen portrait exemplars where service providers are co-located and are not co-located.

The team will configure extracted data and develop the programme theory by piecing together data from different sources (Figure 1) (40, 45). The Template for Intervention Description and Replication (TIDieR) (56) will be used to specify key elements of each intervention (e.g. by whom it is delivered, over what period and to what intensity). This process will be carried out by the research fellow BERZINS, the information specialist WONG with methodological support from BOOTH and topic experts CLIBBENS, BAKER & WEICH.

3.5.1 Expert Stakeholder Group

We have convened a pre-protocol Expert Stakeholder Group (ESG) including people with lived experience of mental health crises, carers, members of the project team, health and social care professionals, voluntary sector crisis care providers, local government representatives and health care commissioners; many of whom have already been engaged in pre-protocol development. Stakeholder engagement at pre-protocol stage pragmatically accessed expertise in the north of England. Whilst these stakeholders provided representation of an appropriate range of types of expertise from the full range of community crisis services available in the UK, they were not able to represent the breadth of different perspectives from across the UK.

In order to address this limitation, during the study set-up stage we will build our ESG membership to include representatives from across the UK. We will achieve this through firstly inviting stakeholders from the networks of the research team and pre-protocol ESG members. Recruitment of members will take place via direct contact with services and via advertisement on social media. Participants will be provided with an information sheet and asked to sign a consent form prior to participating in the group. Secondly, co-applicants THOMPSON and ASHMAN will coordinate the stakeholder group membership and ensure that it represents varied expertise, experience and location. Thirdly, we will make contact with key organisations commissioning, delivering and researching crisis mental health care to identify stakeholders including for example; crisis research expert academics at University College London, NHS England mental health crisis project lead, NHS Vanguard services such as North East Hampshire NHS and the Crisis Care Concordats for England and Wales. We will engage with services in Scotland, Wales and Northern Ireland (e.g. Edinburgh Crisis Centre, Belfast Health and

Social Care Trust, NI Direct crisis services) including voluntary sector and lived experience organisations such as Vox Scotland and Wales Alliance for Mental Health. We have planned a series of four Expert Stakeholder Groups at four stages of the research. The stakeholders will meet the objectives of the research at each of these stages as follows:

Stage 1:

- Review membership of the ESG to ensure that they reflect a varied demographic, a range of expertise, and a broad range of quality of experience of services and types of crisis services available in UK contexts (objective i)
- Following feedback from the research team, refine the initial search strategy used to identifying initial programme theories (objective i)
- Contribute to in-project dissemination through development of web pages, the first blog and social media communication (objective vi).

Stage 2: Following feedback from the research team:

- Review membership of the ESG in light of the emerging programme theories (objectives i & iii)
- Review the programme theories to test that they are plausible to the experts and refine as needed (objectives i & iii)
- Contribute to the development of the sampling frame as part of the iterative focused searches to test the programme theories (objective ii)
- Initial identification of potential pen portrait exemplars of programme theories (objective iv)
- Provide feedback on in-project dissemination and contribute to the content of web pages, a second blog and social media communication. Identify ESG members to take a lead in the development of a film as part of the dissemination strategy supported by THOMPSON & ASHMAN (objective vi).
- Identify the types of people to be sampled for individual interviews.

Stage 3: Following feedback from the research team:

- Iterative review of programme theories to test that they are plausible to the experts and refine as needed (objectives i & iii)
- Critically review and refine the emerging theoretical model of crisis services developed through testing of programme theories in the focused searches and from individual interview data. Discuss possible midrange theories to test with the experts their adequacy in explaining how crisis service work (objective v)
- Identify and define pen portrait exemplars of programme theories with a focus on explaining contextual variations (objective iv)
- ESG to feedback on development of dissemination film. Discuss and develop in-project dissemination and contribute to the content of web pages, a third blog and social media communication (objective vi).

Stage 4:

- Refine the theoretical model of crisis services with a focus on its credibility and completeness. Discuss the plausibility of identified mid-range theories with the experts (objective v)
- Finalise pen portraits providing six exemplars of the theories identified from UK crisis services (objective iv)
- Use the emerging theoretical model of crisis services to consult ESG about the development of a framework for future empirical testing and guidance for commissioners of crisis services across the UK (objectives v and vi)
- ESG to feedback on development of dissemination film. Discuss and develop in-project dissemination and contribute to the content of web pages, a fourth blog and social media communication. Plan post-project conference attendance and publication strategy. Plan the large stakeholder event (objective vi).

The processes used to achieve the above actions use the principles of community-based participatory research (57). These processes will be driven by the need to identify and test programme theories and will require a degree of flexibility due to the iterative nature of realist review methods. During ESG meetings, the use of note taking, flip charts and audio recording will be used. The stakeholder meetings may divide into smaller groups to facilitate discussion on particular topics or to create homogenous sub-groups within the heterogeneous stakeholder group membership to ensure that potentially marginalised or minority voices can be heard (50). Email and telephone communications will be used between stakeholder meetings to flexibly engage with members of the ESG and to provide information prior to ESG meetings.

Using these approaches, the stakeholders will move through the steps of the realist review alongside the research team beginning with an initial process of describing the architecture of the complex intervention, in this case community crisis services. The ESG members will provide real world data from UK contexts to answer questions according to realist logic such as "What is the intervention supposed to do?" and "How is it supposed to work?" (50). This process will inform the development of programme theories and the iterative focused evidence searches. The ESG will support the research team to refine theory and identify relevant data, using their expertise to support or challenge theories thus testing their credibility and completeness. In this way, the ESG members provide a powerful interpretive lens through which the researchers can assess the primary data in light of real-world experiences (58).

3.5.2 Individual interviews

Purposive strategies will be used to identify interviewees who will be either mental health service users and their carers or professionals from a range of organisations both health, local authority and voluntary sector. Potential participants will be invited to take part in an interview either face-to-face or by telephone. The interview is anticipated to take no more than one hour. Consent for the interview

will be taken by the signing of a consent form if it is carried out in person or by giving verbal consent if carried out by telephone. Participants will be asked for their opinion on what evidence we have found and how our thinking is developing. Depending on how the study develops they might be invited to take part in a second interview (and can agree to receive a second invitation on the consent form).

3.5.2.1 Carers and service user interview recruitment

For NHS and other service sector sites, a member of the service staff will identify potential participants and make the first approach i.e. inform potential participants of the study by distributing study related documentation to eligible participants. Potential participants will then need to contact the RA should they wish to express an interest in participating. (For voluntary sector or local authority services a similar procedures will be followed.) Potential participants recruited via social media will contact the PI directly for more information.

3.5.2.2 Health and care practitioner interview recruitment

The research team will work with R&D in Sheffield Health and Social Care NHS Trust as study sponsor to identify health and care practitioners for interview from mental health services, GP practices or other relevant health services, depending on local arrangements. Contact will also be made with health and care practitioners via local professional / practitioner networks and via the third sector organisations. We will seek representation from urban, rural, mental health, acute and ambulance trusts.

3.6 Study quality

The quality of the evidence will be screened based on relevance and rigour using a realist approach. Inclusion and exclusion will be decided by asking firstly 'does the document contain any data that can contribute to developing or testing theory (relevance)?' and secondly 'are the methods (if any) utilised to generate the relevant data trustworthy and credible (rigour)?' Selection and appraisal of the evidence is a two-step process:

i. Potentially relevant documents will initially be screened by title, abstract and key words by the information specialist WONG and research associate. A 10% random sample will be checked for consistency by the research fellow BERZINS (any disagreements on will be resolved with the input of the PI CLIBBENS)
ii. The full texts of the retained set of documents will be obtained and screened by the research fellow BERZINS and research associate. A 10% random sample will be checked for consistency by the information specialist WONG.

Relevant data from included documents will be coded in two ways; according to the programme theory (i.e. deductive coding) or by identifying new codes that emerge from the data (i.e. inductive coding). When coding, where it is possible to make such inferences, data will be coded as context, mechanism or outcome. Any data suggesting explanatory links between Context-Mechanism, Mechanism-Outcome or Context-Outcome will also be coded. These codes will cover concepts that are judged to be important and potentially relevant to the programme theory (39, 40, 45).

3.7 Data synthesis

Data will be synthesised using realist logic of analysis. Relevant data are interpreted as linking at least two of the following: context, mechanism and/or outcome within our programme theory. Data may come from included documents or from engagement with the stakeholders via ESG and individual interviews. The views of stakeholders will be sought to enable us to further support, refute or refine the previously-developed programme theory. Agreed modifications will be presented, discussed and debated at regular project team meetings and stakeholder consultations, where a particular focus will be on exploration of: data relevance, interpretation of meaning, judgements on contexts, mechanisms and outcomes, and judgements about the programme theory and rigour (42).

Data from the literature and from engagement with stakeholders (via ESG and individual interviews). will be combined to refine the realist programme theory/ies to identify; mechanisms that might operate across multiple interventions in order to 'trigger' an appropriate treatment response; and contexts related to these key mechanisms that might enhance or detract from intervention success. Programme theory will be used to identify important intervention components by:

i. Using the data from the realist synthesis and stakeholder engagement (via ESG or individual interviews). to identify the most important mechanisms within the programme theory that need to be 'triggered';
ii. Identifying links between contexts and key mechanisms;
iii. Drawing on data from the realist synthesis that provides information about the intervention strategies, and the underpinning mechanisms that can change the contexts;
iv. Identifying and defining six pen portrait sites as examples of the theories in action.

In undertaking these steps, information on how to change the contexts in such a way that key mechanisms are triggered to produce desired outcomes will be identified (40, 45). We will then identify and develop pen portraits of six UK crisis services informed by the literature, the programme theories, interviews and stakeholders. The pen portraits will provide a preliminary map of elements of crisis interventions (structured around the TIDieR Template), their mechanisms and outcomes (structured according to realist 'IF-THEN-LEADING TO' logic) in answer to the review question. The pen portraits will be developed from the theories and be based on diversity of models. The pen portraits will be used to inform future empirical testing of the programme theory beyond the scope of this protocol.

The research team will attempt to link our findings to substantive (middle-range) theories to refine our theoretical understanding of how interventions achieve their effect and how these effects may be context-dependent. These strategies will be shared at an event with a wider group of stakeholders (those involved in policy making, service commissioning and delivery, as well as public involvement representatives) to obtain detailed feedback on identified strategies. Data from this event will be used within a potential framework by which the six pen portraits can be tested through future empirical studies.

Figure 1 Flowchart of Evidence Synthesis

4 Outputs, dissemination and impact

4.3 Outputs and Dissemination

IN-PROJECT DISSEMINATION

In-project dissemination will include blogs developed in partnership between ESG and research team following each stakeholder consultation meeting. These will be shared using the faculty and school research webpages at the Universities of Leeds and Sheffield. The mental health research group at University of Leeds have developed a new mental health webpage in January 2019 (www.mentalhealthresearchinLeeds.co.uk), a project page will be embedded in this website and regularly updated with news, events and blogs.

The research team and many of the ESG members will use institutional and personal Twitter feeds to extend the reach of the blogs as well as providing an opportunity for public discussion and debate on the topic of the research (e.g @mhresearchleeds; @ScHARRMH; @UniLeedsMH; @JohnBaker_Leeds). We will work with the ESG to develop a topic for a Twitter Chat during the life of the project. We will develop an annotated slide show providing information about the project with an accessible description of the methodology.

POST PROJECT DISSEMINATION

Representatives of our ESG and research team will be consulted on the most suitable ways to disseminate new knowledge within their area of expertise to ensure widest reach and greatest accessibility.

CONFERENCES: We will begin our post-project dissemination by holding a stakeholder event involving a larger group of key stakeholders including health care commissioners, health and social care professionals and people with lived experience. This event will be advertised across the UK using

university, NHS and voluntary sector webpages and Twitter addresses. Representatives from identified pen portrait exemplar sites will be specifically invited to join the stakeholder event and asked for their specific input regarding future theory testing and evaluation. We will seek opportunities to present our findings at local (e.g. NHS Trust Research Events, national (e.g. NIHR conference events) and international conferences including those that are profession specific and research focused (e.g. International Royal College of Psychiatry conference events). We will seek permission to share our findings using summary documents and oral presentations through events delivered by established networks in crisis care (e.g. Crisis Care Concordats).

REPORTS: Our realist synthesis will be freely accessible in executive summary and full form through NIHR, universities of Leeds and Sheffield, NHS (e.g. Crisis Care Concordats) and voluntary sector web pages. We will prioritise providing reports that include guidance for commissioning crisis services in the NHS, voluntary sector and with other public services as identified by the review (e.g. Police, Housing). We will work in partnership with members of the ESG to develop a short film to share the findings from the realist synthesis. The film will provide an easy to access animated summary voiced by members of the ESG. The film will be accessed through the institutional websites. A final project blog will be produced as a summary of the project findings and shared through webpages and Twitter.

JOURNALS: A publication strategy will be developed in partnership between the research team and the ESG. The strategy will identify the type and focus of publications and will include user/carer focused publications (e.g. via INVOLVE, VoxScotland) and professional journals including those with high impact (e.g. British Journal of Psychiatry; International Journal of Nursing Studies). Our strategy will also identify the need to report methodological development (e.g. Health Information and Libraries Journal). We have included costs for one open access publication to ensure wide accessibility to the findings.

NETWORK DISSEMINATION: Members of the research team and ESG will be encouraged to disseminate knowledge through their networks using summary documents, blogs, oral presentations, film and annotated slides. This will be achieved through for example face-to-face meetings, Twitter, webpages in University, NHS or voluntary sector settings. Using all available contacts, we will promote knowledge transfer across the NHS and partner organisations. We will maximise the mobilisation of knowledge through our established links with for example The Royal Colleges of Psychiatry and Nursing, Mental Health Nursing Academics UK, The Crisis Care Concordats; NHS England, NHS Commissioning Groups, The Kings Fund as well as through connections with advisors and policymakers in the Department of Health.

4.2 Impact

The proposed study will produce the first realist evidence synthesis of crisis mental health care. We believe that our ability explain how and why crisis care works across contexts will be of value to stakeholders involved in the commissioning, delivery or receipt of such services. Our aim is to develop a theoretical framework for the development and evaluation of crisis mental health interventions for

adults in community settings. In fulfilling this aim, we will identify what is likely to be effective and conversely, what is not likely to be effective, in what contexts and for whom. This will inform service design and commissioning by identifying the mechanisms that underpin crisis care outcomes thus enabling improvements in service delivery that can be implemented across providers and in different service configurations. Our research will therefore enable decision makers to select interventions in each geography based on what is needed in order to trigger the outcome of resolution of mental health crisis across interventions, services and providers. This may improve cost effectiveness by streamlining services, and avoiding unnecessary duplication in service delivery. By improving service delivery in these ways, people experiencing a crisis will be able to access improved information about crisis services making access and navigation more straightforward. Our intentions are to use the findings from the realist evidence synthesis to inform the development and testing of the substantive theories across NHS and other crisis care settings.

5 Project Management

The lead applicant CLIBBENS will project manage the grant with project management support from co-applicants BAKER and WEICH and with specialist methodological support from BOOTH. PI CLIBBENS will provide support to ASHMAN, who provides lived experience expertise as a co-applicant. Two groups will support this research, the Research Team and an Expert Stakeholder Group (ESG). The research team will contain the Principal Investigator, all co-applicants and other research staff named in the application and will meet up monthly via teleconference (or face to face) and as required for additional meetings. There will be face-to-face meetings at the start of the project and during expert stakeholder meetings. The Research Team, led by CLIBBENS, will be responsible for running all aspects of the project and dissemination of results.

The ESG will be co-chaired by co-applicants THOMPSON and ASHMAN and the group will provide advice to the Research Team and provide feedback on the veracity of programme theory as it is developed during the project. The group will also monitor progress against milestones, provide advice, promote the project, communicate with stakeholders, and help to refine the dissemination strategy and outputs to maximise impact and knowledge mobilisation. The ESG will meet four times over the life of the project either face-to-face, or via teleconference and receive monthly written updates outside of these meetings. Expert stakeholders engaged in pre-protocol consultations have been invited to remain involved throughout the delivery of the study (50).

6. Study Timetable Table 1 Study Timetable (57)

Months	1-4 1st September2019	5-8	9-12	13-15	16-18	20 30th April 2021
	-Study set up and protocol development. -University ethical review. -Refine and conduct searches to identify initial programme theories. -First research team meeting followed by monthly update meetings and monthly update to expert stakeholder group (ESG) -First ESG meeting. -In-project dissemination	-Identify initial programme theory/ies. -Formalise model of theories to be tested. -Iteratively refine and conduct focused searches to test theories. -Screen, assess primary data sources for relevance and rigour and code using CIMO framework. -Second stakeholder group meeting. -In-project dissemination	-Collation of materials from selected primary studies to test theories and develop a draft theoretical framework. -Identify the need for further iterations of focused searches. –Interviews with stakeholders as determined by ESG e.g. service users, carers and staff from a range of services. Further tests of relevance and rigour, extraction of data and coding. -Third ESG meeting -In-project dissemination	-Revisions to emerging theoretical model through consolidation of new evidence. -Consider rival theoretical positions -Synthesis data focused on complex and inter-related elements of crisis interventions in the further refinement of theory. -Consider how emerging theoretical model relates to mid-range theory. -Fourth ESG meeting. -In-project dissemination	-Finalise synthesis of theoretical model. -Identification of pen portraits Delivery of wider stakeholder event. -Report drafting -ESG lead the making of short film.	-Submission of report, preparation of publications and dissemination activities.

7. Patient and Public Involvement

Our research places high importance on consultation as a core aspect of the methodological approach. ASHMAN is a study co-applicant and has provided expert by experience input in the development of the protocol as a member of the research team and will co-chair the ESG. The pre-protocol patient and public consultation was supported through Research Capability Funding from Sheffield Health and Social Care NHS Foundation Trust. This funding was used to consult members of the public, people with lived experience of crisis care and their carers through a focus group consultation event at The University of Leeds, a discussion with delegates at Rotherham, Doncaster and South Humber NHS Foundation Trust public consultation meeting and a number of individual consultations with

people who have used different crisis services. We have also consulted with CEOs of voluntary sector crisis services and peer support workers in crisis care.

Our research team has considerable experience working in partnership with a range of stakeholders; PI CLIBBENS has supported the development of public involvement strategy in the School of Healthcare at University of Leeds; BAKER's previous PPI work has been cited by NICE, MHRN and Involve as exemplars of good practice. THOMPSON has co-authored innovative stakeholder engagement methods and has experience of stakeholder consultation using realist methods.

8. Expertise and justification of support required

We have worked hard to keep the costs for study to the minimum required by the PI and coinvestigators to deliver the project, to supervise the information specialist and enable meaningful stakeholder engagement throughout. We have chosen a realistic 20 month duration to reflect the complexity of realist synthesis. Library and IT costs have been included, as have costs for open access publication, for the stakeholder group to make of a short film for dissemination and UK conference dissemination. ESG fees have been included including Involve rates of pay for those with lived experience and costing for the venue and catering for a larger stakeholder event as part of the post-project dissemination strategy; the remainder of the costs represent travel and expenses for the research team and expert stakeholder meetings.

8.1 Justification of costs

STAFF: CLIBBENS will be employed 20% as a first time Principal Investigator (PI), with realistic costing of professors BAKER at 10% and WEICH at 5% who will provide project management support as well as clinical and methodological expertise. BOOTH at 10% provides specialist methodological expertise to support the delivery of a realist synthesis across the project with the support of WONG, an information specialist, at 20% for the first 9 months to deliver the searches and contribute to screening and appraisal of the evidence. BERZINS, a research fellow, at 60% and a research associate at 40% provide sufficient resource for the duration of the study to ensure delivery of the extraction, coding and synthesis of data, as well as delivery of reports and dissemination. THOMPSON is realistically costed at 5% across the project to deliver the stakeholder consultations in partnership with ASHMAN who is costed at 7% across the project. EQUIPMENT: IT costs for data entry and analysis, printing and stationery, interlibrary loans and document retrieval.
DISSEMINATION: Conference attendance, open access journals and making a short film, large stakeholder event are also costed. TRAVEL: Research Team and ESG in Leeds. Dissemination event ESG & research team. CONSUMABLES: Stakeholder meeting venue and catering in Leeds. Expert stakeholder group members who are service user or carers will be paid. Catering and venue for research team meetings.

8.2 Justification of expertise and support

The research team has considerable expertise to deliver the proposed research. Research team members have significant clinical, methodological, project management and lived experience expertise. Within the team, we have national and international methodological reputation in evidence synthesis. We are involved in or have completed externally funded primary research and evidence syntheses in the field of mental health. We have specialist methodological support in realist evidence synthesis and stakeholder engagement.

CLIBBENS (PI) has clinical and methodological expertise to manage this project as first time PI with project management support from two experienced professors in the team (BAKER & WEICH). She is an experienced mental health academic delivering research focused on acute and crisis mental health and has experience of delivering externally funded evidence synthesis.
She holds an Honorary Research Contract with Sheffield Health and Social Care NHS Foundation Trust.

BAKER specialises in mental health services research with a focus on acute care, and reducing restrictive practices. He is leading COMPARE (HS&DR Project:16/53/17) with BERZINS. He is non-executive director of Leeds and York NHS Partnership Foundation Trust. WEICH specialises in mental health services research. He is collaborating on HS&DR study focused on day treatment for mental health crisis and has been chief investigator for a number of HS&DR mental health services studies. He is an Honorary Consultant Psychiatrist in Sheffield Health and Social Care NHS FT.

BOOTH is a methodology specialist in evidence synthesis, co-director of the NIHR HS&DR Sheffield Evidence Synthesis Centre and has completed realist syntheses for the NIHR on diverse service delivery topics including missed appointments, postnatal depression, new models of care, group clinical and research capacity development. He has authored the only published guidance on conducting realist research.

ASHMAN is an independent consultant providing lived experience expertise of crisis services and has been a peer support lead in the NHS, and contributed to numerous mental health evaluation projects. He is currently providing lived experience expertise to an HS&DR study focused on voluntary sector crisis services at University of Birmingham. He has chaired a service user led research group.

BERZINS is an experienced mixed methods mental health researcher and project manager, with expertise in a range of methods including evidence synthesis. Her research interests are in carer experiences and safety in mental health practice.

THOMPSON is an experienced healthcare social scientist with specific published expertise in delivering innovative stakeholder consultations in evidence synthesis including those taking a realist approach.

9 Carbon Reduction

The NIHR Carbon Reduction Guidelines have been used to inform the development of this study. Travel has been kept to a minimum with meetings being conducted via teleconferencing whenever possible. Remote working and the use of electronic documents rather than hard copies will also reduce the carbon footprint of the study. Study dissemination will use electronic methods for sharing, and downloading documents and stakeholder film.

10 Declaration of Interests

Professor Scott Weich has declared that he is a board member for NIHR Health Technology Assessment (HTA) Clinical Evaluation and Trials.

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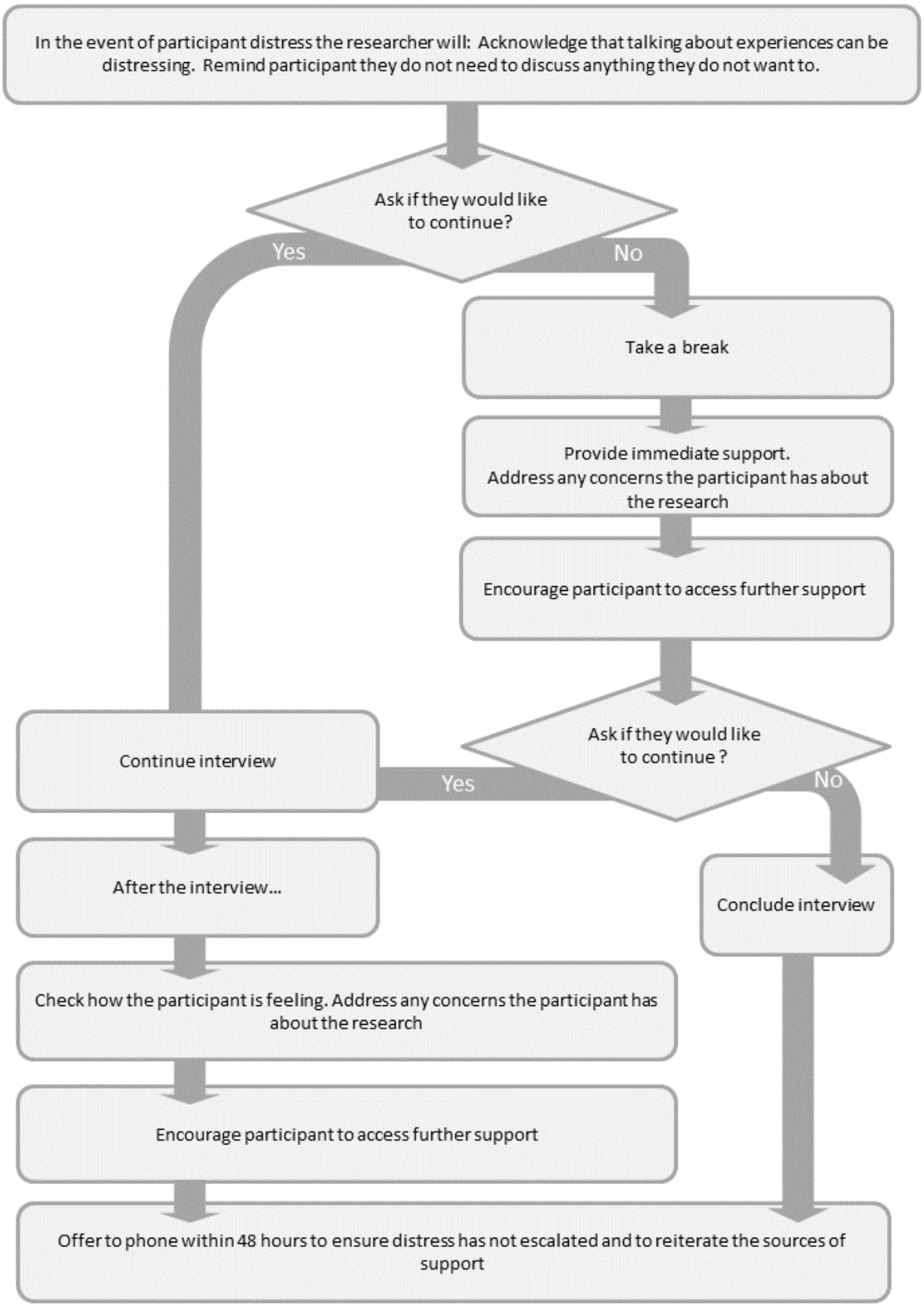
Appendix 1: Interview and Focus Group Distress Policies

Interview distress policy flowchart



Focus group distress policy flowchart