13.3 Appendix 3 – Amendment History

This has been moved from the end of the document to the beginning to make it more accessible and more visible.

This version of the document (on the Teams site for the project) should be regarded as the working version. An official version (plus superceded versions) is stored in the project site file.

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made
1.	V1.1	20/12/22	Kate O'Donnell	Addition of Carol Emslie, Alex Osmond and Richard Byng to Research Oversight Group.
2	V1.2	11/01/23	Elspeth Rae	Corrected page numbers in introduction and corrected two small spelling errors
3	V1.3	15/02/23	Elspeth Rae	Made ROG chair signature visible Amended footers to follow version control protocol Moved this amendment control table to beginning of document
4	V1.4	22/02/2023	A Williamson	Removed all tracked changes and comments. Removed PI personal mobile phone number.
5	V1.5	28/02/2024	A Williamson	Minor amendment sent to NIHR for review- regarding WP3 workshop arrangements.
6	V1.6	07/03/2024	A Williamson	Minor amendment changes approved and DHSC acknowledgment/disclaimer

				statement included (previously omitted in error)

This protocol has regard for the HRA guidance and order of content

FULL/LONG TITLE OF THE STUDY

Developing interventions to reduce 'missingness' in health care

SHORT STUDY TITLE / ACRONYM

'Missingness' interventions

PROTOCOL VERSION NUMBER AND DATE

Protocol version 1.6 07/03/2024

RESEARCH REFERENCE NUMBERS

IRAS Number:	322353
SPONSORS Number:	MIDS171022
FUNDERS Number:	NIHR 135034

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

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

I 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; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature:

Date:
..30..../...10.../22
....

....
.....

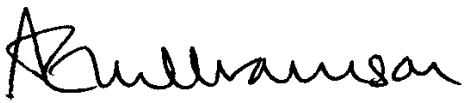
Name (please print):

Debra Stuart.

Position: Head of Research Regulation and Compliance

Chief Investigator:

Signature:



Date:
26/10/2022

Name: (please print):

‘Missingness’ interventions

Professor Andrea E Williamson

Prof Carol Emslie (Chair: ROG) 30 November 2022

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'Missingness' interventions

KEY STUDY CONTACTS

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Joint-sponsor(s)/co-sponsor(s)	N/A
Funder(s)	National Institute Health Research HSDR, Hugh Hiscock NETSCC Monitoring Team
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STUDY SUMMARY

Study Title	**Developing interventions to reduce 'missingness' in health care**
Internal ref. no. (or short title)	'Missingness' interventions
Study Design	1.Realist review 2. Qualitative realist interviews 3. Workshops to develop complex interventions
Study Participants	Experts by experience of 'missingness' in health care and professionals
Planned Size of Sample (if applicable)	2. 30 experts by experience of 'missingness' and 30 professionals 3. 8 experts by experience of 'missingness' and 8 professionals
Follow up duration (if applicable)	N/A
Planned Study Period	01/12/2022 to 28/02/2025
Research Question/Aim(s)	To develop a theoretically informed understanding of 'missingness' from patient, professional and policy perspectives with the intent of co-producing a complex intervention with multiple components for primary care to test in a future study.

FUNDING AND SUPPORT IN KIND

'Missingness' interventions

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this study)	FINANCIAL AND NON FINANCIALSUPPORT GIVEN
NIHR National Institute Health Research HSDR, Hugh Hiscock hugh.hiscock@nihr.ac.uk NETSCC Monitoring Team	**£ 728,734.63**

ROLE OF STUDY SPONSOR AND FUNDER

The sponsor – University of Glasgow- has had no role in the development of the study design, conduct, data analysis and interpretation, manuscript writing, and dissemination of results.

The funder- NIHR- have provided feedback on the funding application and have helped steer the final study design to enable the project to be funded. They will oversee that the conduct of the study follows the study protocol. However NIHR will have no input into the data analysis and interpretation, manuscript writing, and dissemination of results.

This study/project is funded by the NIHR HS&DR programme award ID 135035. The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care."

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

Study Steering Group

We are convening a small but comprehensive research oversight group for the study which includes a chair, one health service academic with complementary expertise to the chair and one public member. These will be independent colleagues with no role in the conduct of the study. This will be convened yearly over the conduct of the study. They will provide oversight on progress and advice when the study team need it.

Patient and public involvement

One of the research team members is a Public Co-I with extensive experience of engaging marginalised communities in policy and research. They are involved at each stage of the study, having helped devise the study, the programme theory. They will attend and provide input at each full research team meeting which is being held every two months and provide input as required when Work package leads require their input. Experts by experience (EPE) and professional expertise are the main focus of the qualitative and complex interventions element of the study so are embedded in the study design (see below).

We are convening a Stakeholder Advisory Group (StAG) at key time points, firstly as a small group of 4 EPE and 4 professionals to contribute to the 'missingness' programme theory and then as a larger group of 8 EPE and 8 professionals for the main focus of our interventions development. We are viewing their role as both contributing data for the study and helping shape the output accordingly so are including their contribution as part of ethics and management approval processes.

'Missingness' interventions

PROTOCOL CONTRIBUTORS

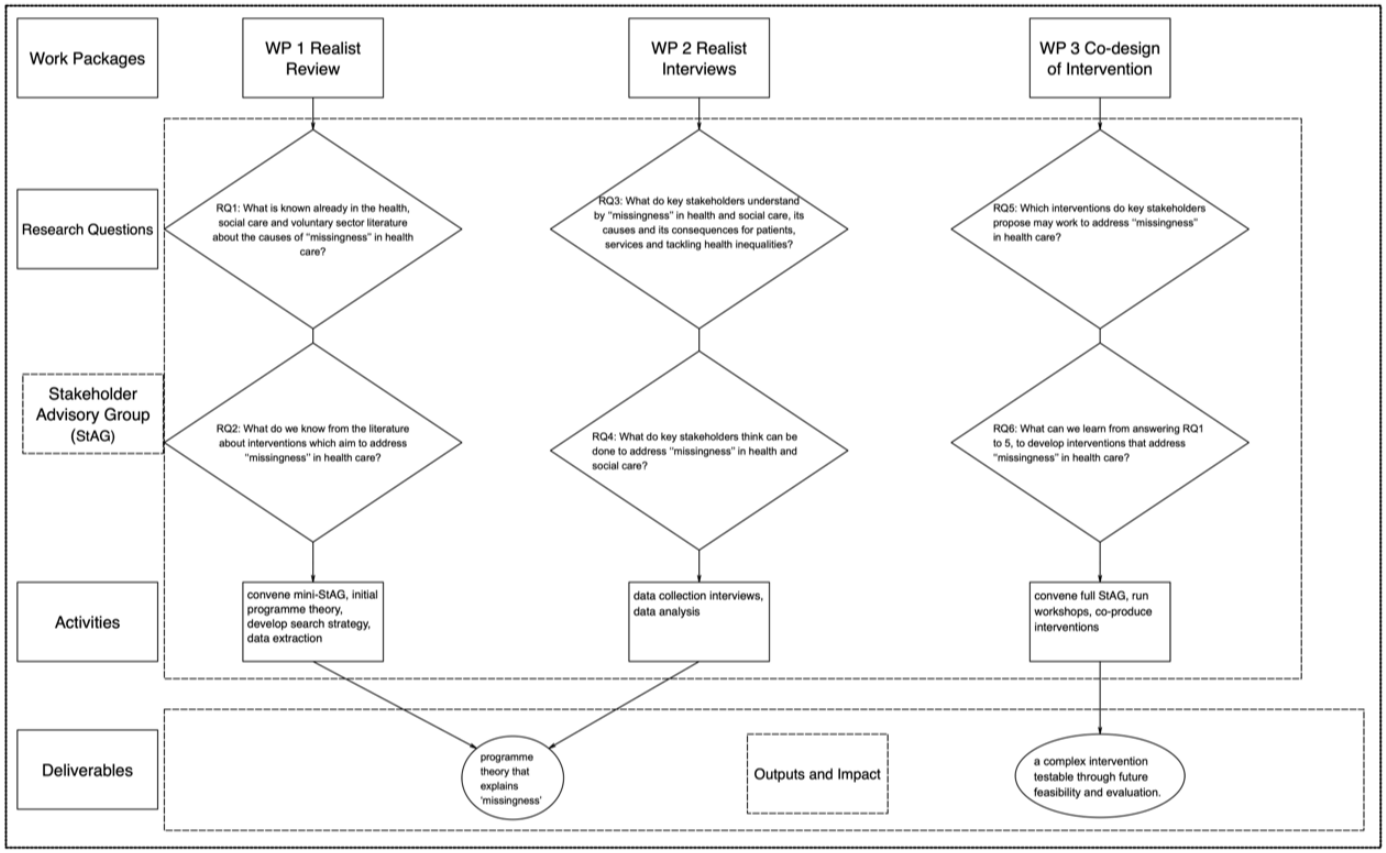
The protocol was compiled by the study team as described above. The sponsor approved the final protocol. The funder influenced the development of the study through the NIHR application process including external peer review through three stages of application and review.

The conduct of the study, data analysis and interpretation, manuscript writing, and dissemination of results is the sole responsibility of the study team. The study team will remain accountable to the study sponsor and funder by submitting regular progress reports and ensuring conduct and dissemination adheres to NIHR guidelines. The full PPI contribution is outlined in the section on PPI below. Patients and the public were involved during the conception of this study and a public Co-applicant has been involved at every stage of the study development including the protocol.

KEY WORDS: Missed appointments; missingness; engagement in care; tackling health inequalities; inclusion health, Realist review

STUDY FLOW CHART

‘Missingness’ interventions



STUDY PROTOCOL

Developing interventions to reduce 'missingness' in health care

1 BACKGROUND

Introduction

This research aims to address the problem of multiple missed appointments and low uptake of care offers in health care. This is an under-researched area, disproportionately affects the most marginalised groups in society and is associated with high levels of premature mortality(1). 'Missingness' is used to describe patterns of low engagement in health care(2).

NHS services are busy, and the patients who are invisible by their absence have, in most settings, been viewed as making an active and informed choice to be absent, leading to misconceptions that they are less needing or less worthy of care. A large-scale epidemiological study undertaken by members of the team (Williamson and Ellis) investigated patterns of missed appointments at the patient level in more than 500,000 of the Scottish general practice (GP) population, found that health need was very high and outcomes very poor when patients missed multiple GP appointments(1). This seminal, award-winning research (https://www.gla.ac.uk/researchinstitutes/healthwellbeing/news/headline_759062_en.html) interrogated patterning of attendance at the patient level rather than at the population or service level(3) for the first time at a large scale and in a general population(4). A high rate of missed GP appointments (an average of more than 2 per year) predicted very high premature death rates. Patients were more likely to have multi-morbidity, especially mental health conditions(1), experience high socio-economic disadvantage and a range of other associated factors(5, 6). Patients experienced high treatment burden and ''missingness'' in use of acute hospital services too(7).

There has been much written about the cost to the NHS of missed appointments(8) and some research conducted to address these such as evaluating mobile phone text reminders(9). However, the conceptual understanding of 'missingness' is superficial and makes no distinction between patients who miss one appointment and have low risk of a poor outcome and those who miss many and are at a much higher risk.

We define 'missingness' as the repeated tendency not to take up offers of care such that it has a negative impact on the person and their life chances. We seek to frame this across services and within the wider context of people's lives and life experiences.

We also have poor understanding of the lived experience of 'missingness' in care and hence why people may be missing from one or more service. Although challenging to study, partnership with key stakeholder organisations can overcome many of the research barriers, including access to populations, as evidenced by unpublished pilot work (conducted under the supervision of Williamson) with experts-by-experience of 'missingness'. This research will build on this work and enable us to have a sound theoretical basis, taking account of complexity, to support the identification of future interventions focussed on primary care. The identification of future interventions will be informed by input from our

expert advisory panel of stakeholders (StAG) who are comprised of both experts-by-experience and professionals from relevant settings.

Existing Evidence and how our study fits in

Previous literature reviews have described the characteristics of patients who miss appointments at the population or service level, identifying that they are more likely to be younger and come from more socio-economically deprived communities(10, 11) (12)(3). Dantas et al who examined all health care specialties in low-, middle- and high-income country health systems, highlighted that having a history of a previous missed appointment was a key factor in predicting whether a patient would go onto miss an appointment in the future(11); Parsons et al, in their review of the literature in addition to citing our Scottish epidemiological study, also found a US study focussed on diabetes patients which found having a history of 'missingness' a key risk factor(3). This suggests, therefore, that having a history of 'missingness' could be used as a means of identifying at risk groups to develop an intervention to address 'missingness'.

Previously tested interventions to reduce missed appointments in health care focus on population/service level appointment reminders, which can reduce overall service level rates of missed appointments but have not considered interventions to meet the needs of individual patients who experience 'missingness'. A Cochrane review described low/medium evidence of effectiveness that text messaging reminders as a service level intervention may make some positive difference(9). Our hypothesis is that this is because there has been no explicit targeting of interventions at 'missingness'; which takes account of the complex life circumstances, and common mechanisms across services, of engagement/disengagement experienced by people which may underpin repeatedly missing appointments. There are small- usually local un-evaluated initiatives- to increase engagement in health and care services in the UK and beyond. However they tend to be piecemeal and targeted at specific patient groups, such as patients experiencing homelessness (12)(14).

Patients who occasionally miss an appointment may find a simple text reminder helpful; however, for patients who have a pattern of missing many appointments, it is likely that more nuanced and careful consideration of both the triggers for missing appointments and what is needed to increase attendance across services may be required. This is where the gap in our knowledge is.

There is a lack of evidence about whether 'missingness' causes poor outcomes or whether poor health means people are more likely to be missing from health care. It is difficult to prove or disprove causality as the mechanisms of action are complex, likely multifactorial, influenced by the wider social determinants of health, and with a differential impact on people. For example, a person being HIV positive with a high viral load and being missing from care is more likely to lead to premature mortality than a person who has mild asthma who experiences lower quality of life as a result; however similar strategies within health care may be needed to support their engagement. An underpinning assumption of this proposed research is that these strategies will increase health and wellbeing for high-risk people and make a contribution to reducing premature mortality.

Initial focused scoping searches of MEDLINE and Web of Science (Science and Social Science Citation Indexes) were conducted in January 2022 to identify the extent of available literature on 'missingness', both in health and in wider sectors. We used keywords describing repeated missed appointments, low

engagement/uptake and attendance to explore the available existing literature with the potential to contribute data to the review. A total of 59 potentially relevant references were identified, including: studies identifying factors associated with missed appointments in a wide range of settings; studies describing interventions designed to reduce missed appointments (including reminders, different approaches to booking appointments, charges or fines, and transport options); and a small number of qualitative or mixed methods studies exploring patients' reasons for missing appointments. Outside healthcare settings, studies of absence from educational settings dominate the literature.

To augment the existing literature focused on 'missingness', we will seek to synthesise and learn from other relevant bodies of literature, including from a range of policy and practice areas that have already paid specific attention to engagement in care and understand how target groups engage or do not engage across a range of services. Our review will draw on the literature from fields such as psychology and homelessness social policy that can help us develop explanation and understandings of why, how for whom in which contexts and to what extent 'missingness' occurs for people and potential solutions. This research takes a holistic approach and draws on lived experience as well as the available literature.

2 RATIONALE

Why this research is needed now
This research aligns with the James Lind priorities for research in relation to safe care for patients with complex health needs (2019) & patient safety in primary care (2017) (13).

In 2013 practitioners working in Scotland's most socio-economically deprived communities identified there was an important knowledge gap relating to who was missing from care(14). This gap led to the epidemiological research undertaken by Williamson, Ellis et al(1, 5-7, 15, 16) which produced stark findings. This study received recognition of its importance and impact from mainstream General Practice colleagues by the morbidity and mortality paper winning the prestigious Royal College of General Practitioners (RCGP) Health Service Research paper award, 2019.

However, in order to change practice this proposed research will elucidate what we need to know to start to tackle 'missingness' at scale across multiple settings in the NHS and social care. Low engagement in care is evident across many public services, including general practice, hospital services and social work. We hypothesise that common factors are at play across different services, and that the users and providers of these services have much to learn from each other.

This research will provide evidence to support key strategic priorities across the UK including implementation of the NHS long term plan, England; through tackling health inequalities, addressing unmet health needs, increasing uptake of health screening and potentially in applying digital solutions to problems in health care(17).
It supports the UK Government focus on Inclusion Health defined as 'people who are socially excluded, typically experience multiple overlapping risk factors for poor health (such as poverty, violence and complex trauma), experience stigma and discrimination, and are not consistently accounted for in electronic records (such as healthcare databases). These experiences frequently lead to barriers in access to healthcare and extremely poor health outcomes'(18).

It remains uncertain the impact that the Covid pandemic and other organisational change will have on the way care is delivered across the health service. We know from the existing evidence that access, engagement and hence outcomes for patients are not a level playing field(2). Our proposed research will make a strong and timely addition to the evidence base about those vital aspects of care.

3 THEORETICAL FRAMEWORK

Theoretical/Conceptual Framework
We draw on the substantive theories of candidacy and structural vulnerability to develop our programme theory.

Candidacy is a sociological theory which helps us understand inequalities in access to, and utilisation of, services. It aids understanding by delineating stages in a 'candidacy journey' which include self-recognition of oneself as a legitimate candidate for a service, ease of navigation and permeability of services, the work required to disclose one's candidacy to a professional, the manner in which that disclosure is 'adjudicated' by professionals and how services are constrained or enabled by their local contexts. Mackenzie is an expert on candidacy theory having utilised it extensively in applied health and social policy settings (18) (19, 20). Structural vulnerability considers how wider social, economic and political factors intersect to influence people's health outcomes by placing them in positions of marginalisation (21). O'Donnell has experience in the application of structural vulnerability to health care access and the way in which these factors shape local operating conditions identified in the candidacy framework (21, 22). A key element of candidacy theory is the way in which structural factors play out in individual life and healthcare encounters; it is appropriate therefore that we also use the concept of structural vulnerability in our analysis.

The research design follows the new MRC Complex interventions Framework (Simpson is a lead author)(23) and the INDEX guidance(24), focussing on development of an intervention. This will be achieved by; identifying the evidence base (WP1 and 2); identifying and developing the programme theory (WP1-3) and qualitatively modelling process and outcomes using participatory methods and co-design (WP3). We will utilise the 6SQuID method of intervention development explicitly(25). This will ensure we have a strong theoretical and practical basis for our team and others in health and social care to test future interventions aimed at systems or professionals to address 'missingness' in primary health care.

'Missingness' is a complex and under-theorised problem, requiring a greater degree of understanding from multiple perspectives before potentially effective interventions can be designed. In our research, we need to be able to explain how context impacts on the phenomenon of 'missingness'. In addition, we are aware that whilst much can be learnt from the literature that is likely to be transferable to our understanding of 'missingness', to develop a future intervention, we will need to have health care specific data. For these two reasons, we have decided to choose two realist approaches: firstly, a realist review (work package (WP)1) to synthesise relevant existing literature; and, secondly, realist-informed semi-structured interviews with people with lived experience and professional key informants (WP2). Acknowledging that many of our experts-by-experience participants are likely to have experienced extreme marginalisation we will pay careful attention to the strategies needed to engage participants meaningfully and safely in the research process.

Realist review is a theory-driven approach to evidence synthesis that aims to understand and explain how, why, for whom, and in what contexts interventions work to produce their outcomes(26). It does so by using a realist logic of analysis to make sense of data drawn from published research of any study

design and grey literature. This analysis is used to develop context, mechanism and outcome configurations ('CMO Configurations' or 'CMOCs'). These configurations explain how the context (the situations around a person) affect mechanisms that cause outcomes (intended or not). Realist evaluation is a type of theory-driven approach to evaluation. In contrast to realist review, it uses primary data to develop and then confirm, refute or refine CMOCs(27). A realist logic of analysis will be used to analyse and synthesise the data both within and across the two strands of this project – namely WP1 and WP2. The two sources are secondary (WP1) and primary data (WP2). WP3 will then integrate these two sources with the input of our stakeholder advisory group (StAG) to further refine our programme theory and inform intervention development. Our stakeholder group is comprised of a diverse group of experts-by-experience, practitioners and policy makers.

4 RESEARCH QUESTION/AIM(S)

Aims and Objectives

This research is designed in three work packages (WPs) aligned to our research objectives and answering our research questions as described below.

The aim is to develop a theoretically informed understanding of 'missingness' from patient, professional and policy perspectives with the intent of co-producing a complex intervention with multiple components for primary care to test in a future study.

4.1 Objectives

To conduct a realist review (WP1) and realist interviews (WP2) with experts-by-experience and professional key informants to produce a programme theory to understand what causes 'missingness' in health care and strategies to address it.
To convene a Stakeholder Advisory Group (WP3) to refine this programme theory and devise an intervention to address 'missingness' in primary health care.

4.2 Outcome

Research Questions:
This study has six research questions (RQ):
WP1
RQ1: What is known already in the health, social care and voluntary sector literature about the causes of 'missingness' in health care?
RQ2: What do we know from the literature about interventions which aim to address 'missingness' in health care?
WP2
RQ3: What do key stakeholders understand by 'missingness' in health and social care, its causes and its consequences for patients, services and tackling health inequalities?
RQ4: What do key stakeholders think can be done to address 'missingness' in health and social care?
WP3
RQ5: Which interventions do key stakeholders propose may work to address 'missingness' in health care?
RQ6: What can we learn from answering RQ1 to 5, to develop interventions in primary care that address 'missingness' in health care?

5 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYIS

WP1: Realist review (month 1-15) – addresses RQ1 and RQ2:
The realist review will have five-steps(28) The protocol is registered on PROSPERO IDCRD42022346006 and will be published. Below for clarity the steps are shown as discrete entities. However, operationally, we will seamlessly and iteratively move between steps.

1. Developing the initial programme theory (month 1-2)
An initial (candidate) programme theory, which sets out how and why outcomes occur within an intervention, is provided below in Box 1 and is based on the collective experience of the project team including the public Co-I during the grant application stage.
A programme theory is defined as 'the description, in words or diagrams, of what is supposed to be done in a policy or programme (theory of action) and how and why that is expected to work (theory of change)' (29).
It will be further developed at an initial meeting of the project team. During this meeting the project team will further unpack the initial programme theory and map it out as a series of steps required to reach the final desired outcome, identifying intermediate outcomes that take place either sequentially or in parallel. As the project develops, for each step, the relevant and associated context and mechanism for each outcome will be developed from data identified within included documents.

Box 1: initial (candidate) 'missingness' programme theory

Our initial programme theory is that people experience 'missingness'- the repeated tendency not to take up offers of care such that it has a negative impact on the person and their life chances- because:
Identification of candidacy:
People do not view themselves as legitimate candidates for health services due to personal, socio-political and cultural reasons
Navigation of services:
People can face practical barriers to attend such as no spare money for travel costs, or credit on their phone
People can have multiple competing appointments in many services (eg DWP, housing services, criminal justice) and struggle to prioritise
Permeability of services
Services are more difficult to access like being geographically distant, eligibility not being clear, having inflexible appointment times, or long waits to get appointments or long gaps between organising and the planned appointment
Asserting candidacy
Complex and stressful life circumstances mean that people forget or place lower priority on attending appointments
Poor physical health, mental health or psychological difficulties mean that people find attending appointments difficult and at times overwhelming
People have intersectional, overlapping identities/experiences leading to felt stigma which has an impact on whether people feel worthy of care
Structural vulnerability can constrain people's decision making and how they frame their choices
Adjudication by health service (including in the past)

'Missingness' interventions

Prior negative experiences of health and social care and felt stigma mean people are less likely to trust services and take up offers of care Services are not configured so that trusted relationships with individuals or professional teams can be established or maintained **Offers of, resistance to services** Services view low engagement in care as being about 'patient choice' rather than high risk for a poor outcome, and do not view how they provide care to people through a 'missingness' lens **Operating conditions and local production of candidacy** Services do not identify people at high risk of 'missingness' so that tailored support can be offered Services do not provide tailored professional support such as engagement coordinators to consider how to make services more permeable or provide support for people to attend appointments **Factors of structural vulnerability impact on all the steps of candidacy**; these include rights and entitlement to health and social care; issues of power in relationships; health literacy; previous experiences of discrimination and stigma; impact of poverty.

2. Developing the search strategy (month 2-7)

This initial theory will be refined as the synthesis progresses using secondary data drawn from the academic and grey literature. The need to find relevant data to develop the 'missingness' programme theory will guide searching. The search strategies employed to identify literature containing relevant data will be developed iteratively, and re-visited at predetermined milestones, using different permutations and additional concepts(30, 31). Our information specialist (Duddy) will develop, refine and run the searches for this project, seeking input from the wider project team.

Our search strategies will seek to retrieve literature relevant to 'missingness' and informed by our initial programme theory. We anticipate that they will include free text and subject heading terms to describe:

- Our **population** of interest, including people from already identified 'missingness' patient groups, including people with Adverse Childhood Experiences; people experiencing severe and multiple disadvantage such as homelessness, problem substance use, mental health issues; people with cognitive impairment; young people in the care system; people with multi-morbidity, as well as others who repeatedly or persistently miss appointments or opportunities to receive care.
- Important **outcomes** for this review, including attendance and engagement with health care services.

Based on previous reviews of missed appointments (3, 11) and our team's knowledge of the wider literature areas, sources will include: MEDLINE/PubMed, Embase, Scopus, Web of Science (Core Collection), the Cochrane Library, CINAHL, PsycINFO, ASSIA, SCIE, Sociology Collection, IBSS and Google Scholar. Additional grey literature will be sought by searching ETHOS (British Library Electronic Thesis Online), ProQuest Dissertations and Theses, OpenGrey (System for Information on Grey Literature in Europe), the King's Fund Library Database, NHS Evidence. Established links with the Revolving Doors Agency, Lankelly Chase, professional networks (e.g. Royal College of GPs Health Inequalities Standing Group UK, Faculty for Homelessness and Inclusion Health UK, North American Primary Care Research Group Homelessness Special Interest Group, Doctors of the World) and

relevant NHS organisations will be drawn on to identify further grey literature including unpublished service evaluations.

Scoping searches using the PubMed and PsycINFO
On the basis of the scoping searches described above (*Existing evidence)* and our plans to broaden our searches to encompass the broader literature on engagement with health care, we anticipate that the search strategy described above is likely to retrieve sufficient literature for us to refine our programme theory. The interview study is however critical to build on what is likely to be a limited research base focused specifically on 'missingness', and particularly the relative scarcity of qualitative research in this area. If the volume of the literature retrieved by the full searches proves unmanageable, we will employ a variety of appropriate sampling strategies (e.g. theoretical sampling, maximum variation sampling, extreme case sampling) to ensure that we have sufficient focussed but relevant data for programme theory development(32). We may also consider limiting our searches to initially identify material from a UK context, and draw on wider international literature later, wherever it can help to strengthen an aspect of the programme theory.
We will subsequently use 'cluster searching' techniques to identify additional papers that might add to the conceptual richness and contextual thickness of studies initially identified within the sampling frame constructed through conventional topic-based searching(31). For example, we will aim to identify 'sibling' (i.e. directly linked outputs from a single study) and 'kinship' (i.e. associated papers with a shared contextual or conceptual pedigree) papers and reports(31). We will also conduct forward and backward citation searches, using Google Scholar and Web of Science, to identify further related papers from the wider literature.
Searching will continue until sufficient data is found 'information power'(33) to conclude that the refined programme theory is sufficiently coherent and plausible(30).

3. Selection and appraisal (month 3-8)
Citations returned from the searches will be screened against inclusion criteria set out below:

- Population groups with identified 'missingness' patterns
- or public service provision that has sought to address 'missingness' from identification to intervention
- or measurement of a positive or negative outcome relating to 'missingness'

Selection and appraisal are a two-step process:
1. Potentially relevant documents will initially be screened by title, abstract and keywords by the research associate working on WP1 (Research Associate (RA) 1). A 10% random sample will be checked by Wong (any disagreements on the boundaries will be resolved with the input of Williamson).
2. The full texts of this set of documents will be obtained and screened by RA1. RA1 will read the full text of all the documents that have been included after screening based on title and abstract. Documents will be selected for inclusion when they contain data that is relevant to the realist analysis i.e., could inform some aspect of the programme theory.

At the point of inclusion, we will also assess the rigour of each piece of data – which will be done at the level of methods used to generate the data within the included document (where necessary) and also at the level of the programme theory(34).
To illustrate how we will operationalise the assessment of rigour, if relevant data have been generated using a qualitative approach, then the trustworthiness of the data would be considered to be greater if the data was (for example) triangulated with service users, informal carers and clinicians interviewed.
Documents may still be included even if judged to be of limited rigour, as we will also be making an overall assessment of rigour at the level of the programme theory.

Again, Wong and Williamson will check a 10% random sample for consistency using the same approach. RA1 will also discuss decisions with the project team as appropriate.

During this phase initial recruitment of some members of our StAG will occur with the input of RA2. A half day workshop will be conducted with 4 experts-by-experience and 4 professionals. This will be to establish the foundations of our group, have initial input on our draft candidate programme theory of missingness, our topic guide for WP2 and planning for the wider StAG engagement in WP3.

4. Data extraction (month 5 to 12)
RA1 will upload into NVivo (a qualitative data analysis software tool) full texts of the included papers. Relevant sections of texts, which have been interpreted as relating to contexts, mechanisms and their relationships to outcomes, will be coded in NVivo. This coding will be inductive (codes created to categorise data reported in included studies), deductive (codes created in advance of data extraction and analysis as informed by the initial programme theory) and retroductive (codes created based on an interpretation of data to infer what the hidden causal forces might be for outcomes). The characteristics of the documents will be extracted separately into an Excel spreadsheet. Each new element of data will be used to refine the theory if appropriate, and as the theory is refined, included studies will be re-scrutinised to search for data relevant to the revised theory that may have been missed initially(30).

5. Data Analysis, Synthesis and Dissemination (month 10-15).
Data analysis will use a realist logic of analysis to make sense of the initial programme theory. Data for analysis will be drawn from documents that have been included in the realist review after screening against inclusion criteria. RA1 will undertake this step with support from the Project Team (PT). For example, we will have regular data analysis meetings, where the emerging findings and CMOCs (with supporting data) are presented to the PT for discussion, debate and refinement. As part of our process of analysis and synthesis a series of questions about the relevance and rigour of content within data sources will be asked(30):

- Relevance: Are sections of text within this document or transcript relevant to programme theory development?
- Rigour (judgements about trustworthiness): Are these data sufficiently trustworthy to warrant making changes to the programme theory?
- Interpretation of meaning: if relevant and trustworthy, do its contents provide data that may be interpreted as functioning as context, mechanism or outcome?
- Interpretations and judgements about CMOCs. For example, what is the CMOC (partial or complete) for the data that has been interpreted as functioning as context, mechanism or outcome?
- Interpretations and judgements about programme theory. For example, how does this particular (full or partial) CMOC relate to the programme theory? Within this same document or transcript, are there data, which informs how the CMOC relates to the programme theory?

Data to inform our interpretation of the relationships between contexts, mechanisms and outcomes will be sought across documents, because not all parts of the configurations will always be articulated in the same document. Interpretive cross-case comparison will be used to understand and explain how and why observed outcomes have occurred, for example, by comparing settings where interventions to address 'missingness' have been reported as being 'successful' against those which have not; from this

we will understand how context has influenced the results. When working through the questions set out above, where appropriate we will use the following forms of reasoning to make sense of the data: juxtaposition of data, reconciling of data, adjudication of data, and consolidation of data.

Ultimately, our analyses will be used to identify which practical intervention strategies we might be able to use to change existing contexts in such a way that 'key' mechanisms are triggered to produce desired outcomes to inform interventions development in WP3.

With the input of a professional illustrator the written 'missingness' programme theory will be transformed into cartoon-like visuals. Elements of these will be used in WP2 to aid understanding of key elements of the programme theory. This is an important way to increase active engagement for our participants who are experts-by-experience of 'missingness' and address concerns about low literacy.

WP2: Realist evaluation (month 6-19) – addresses RQ3 and RQ4:
The purpose of WP2 is to collect the necessary health and social care specific primary data needed to further develop and refine the emerging programme theory from the realist review (WP1).
Realist interviews will be conducted by our second Research Associate (RA2) to gather additional data to support, refute or refine the programme theory developed from the literature review WP1 (35) and, in particular, will explore views of emerging CMOCs. They are with two sets of key informants: experts-by-experience of 'missingness' and professionals involved in practice or policy. The emerging programme theory from WP1 will be synthesised with data from WP2 as they emerge.
Realist interviews are a sub-type of qualitative interview where the researcher does a 'show and tell' of the emerging programme theory with the participant(36) and this is connected to the participant's own experiential knowledge base.
Appropriate ethics and NHS R&D permissions will be sought from month 1 of the project.

Purpose and Rationale for primary data collection
The interviews will enable detailed exploration of the 'missingness' programme theory, embed equality, diversity and inclusivity, and potentially fill important gaps in the evidence synthesis for the intervention development. It will allow targeted exploration, with follow-up bespoke questioning, so that we can understand directly from participants how 'missingness' affects people, health, and social care delivery, and health inequalities. The interviews will facilitate an in-depth understanding of why 'missingness' occurs (its drivers within particular contexts), its implications and what can be done to address it in health and social care settings. The sampling approach (see below) will also help us to ensure that our findings have salience in all UK nations.

The interviews will identify potentially relevant data about aspects of the programme theory that have not been found in the literature including addressing the short-comings in the literature - for example interventions that participants have experienced but that have not been formally evaluated, interventions that participants have not experienced, 'softer' elements of what works that are not captured in research reports, or drivers of 'missingness' that have not been considered in existing studies but which are suggested by our conceptual framework relating to Candidacy and Structural Vulnerabilities. As the review progresses, we will explicitly identify and categorise important gaps in the existing literature that the interview data can help to fill.
Finally, the interviews are important, because the additional data they provide will enable us to develop a sufficiently in-depth understanding that will underpin our output from WP3.
The interviews will be conducted face-to-face by default with our experts-by-experience participants and remotely by default with our professional key informant participants. If required for example due to

COVID restrictions or convenience for participants, we will use videoconferencing e.g. Zoom paying attention to the ethics of research using online platforms.

Provisionally the interviews will explore the questions listed below. However, refinement of these questions may be needed, based on the findings of the programme theory developed earlier. Within a realist interview, participants are asked to provide their interpretations and perceptions of the programme theory. Care however must be taken to set the questions up in such a way that social desirability responding is minimised. As such, the questioning starts with an unfocussed discussion about the programme theory and then gradually 'drills' down into different sections of the programme theory.

Examples of 'opening' questions for 'experts-by-experience': Tell me about your experience of missing appointments in the past and those of people that you know? What was its impact on you/them? Was there anything in particular that contributed to missing appointments? Has your/their experience of missed appointments changed now? If so, what brought that change about? If not, what factors mean this continues?
Examples of questions that link to programme theory for service users: When I have spoken to other people, they have told me that X, Y or Z (illustrated visual segments) were factors that contributed to 'missingness'. What do you think? Why? Do you think X, Y or Z relates to your experiences or to people that you know? Why? Other people have also told me that A, B or C have been no help in addressing 'missingness'. What do you think? Why?

Questions for professionals will follow the same type of structure but will obviously be tailored to their perspective and experience in working with service users.

All interviews will be recorded and transcribed (we have included funding for professional transcription). For quality control, transcripts will be shared with participants either verbally or in writing and feedback elicited as to their veracity. Transcripts will then be de-identified using a participant numbering system and a record of this will be held on the secure online site file only for the customary University of Glasgow research retention period of time. RA2 will initially conduct data analysis and coding. Mackenzie will code 10% of interviews to check for consistency in coding. Explanations for alternative coding, agreed strategies and implications of early analysis will be undertaken in monthly data surgeries attended by RA2, Mackenzie and Williamson. Data analysis will take place as soon as possible after each interview and use the logic of realist analysis (see below). Anonymised data will be stored on University of Glasgow secure Network filestore and shared between the research team via Onedrive. Data will not be downloaded to computers directly.

Data Analysis
NVivo software will be used to organise the qualitative data. The process of coding the data from the transcripts of the interviews will be similar to that outlined with the secondary data (see step 5 above in WP1). In brief, coding will be inductive (e.g., if new data are found that were not represented in the programme theory), deductive (i.e., informed by the programme theory) and retroductive (based on interpretation of data to infer what the hidden causal forces might be for outcomes). The primary data provided by participants will be used to further refine the emerging programme theory (and its constituent CMOCs) from the realist review (WP1). It is useful to remind readers that the starting point for our programme theory is already conceptually rich – deriving from the concepts of Candidacy and Structural Vulnerability.
RA2 will regularly meet with members of the project team to present the analyses of the interviews. Through discussion and disputation inferences will be made about how the programme theory should

be further refined. In other words, asking the question how and why do these findings inform (if at all) the programme theory developed earlier, and what refinements (if any) do we need to make to it?

WP3: Finalising programme theory and intervention development (month13-27) addresses RQ 5 & 6

The intervention development process will follow the 6SQuID method of intervention development(25). This has six steps and we will address steps 1-4 in this project: 1. define the problem and its causes; 2. explore which causal or contextual factors are malleable and have the most potential for change; 3. identify how to bring about change (i.e. the change mechanism(s)) and 4. identify how to deliver the change mechanism(s) 5.testing and adapting the intervention; and (6) collecting sufficient evidence of effectiveness to proceed to a rigorous evaluation.

We will use data from WP1 and 2 to address step 1, 2 and 3 of 6SQuID as well as data from the workshops with our Stakeholder Advisory Group (StAG) to inform the intervention development process. The StAG will be convened to be representative experts-by-experience and key professional stakeholders (16 members) at month 14 which is the start of WP3 and utilize the input of RA1 and RA2. Membership will be drawn from expert by experience groups and key professionals identified by the evidence synthesis; experts-by-experience and professional key informant interviews; and 'missingness' programme theory as having the expertise to contribute. We judge that 8 experts-by-experience, and 8 professional key informant members is a sufficient number to ensure diversity both in terms of lived experience perspective and professional background experience and ensures balance. This minimises, along with important facilitation methods, concerns about unequal power relations.

Convening our full StAG at this stage of the research (and not earlier) is purposeful. We will have built trusted relationships with experts-by-experience during the interviews and follow up which means that when invited to join the StAG people with a more recent experience of missingness will be more likely to commit to participation, and confidence in participation will be heightened. This will ensure that participation is focussed and achievable both for our experts-by-experience, who given their likely vulnerability, some may need additional support to participate and for our professional members, some of whom will be front line service providers so time poor.

We will run four half day workshops with our full StAG. Having established trusting relationships with RA2 during the interviews the workshops will then be specifically designed to enable StAG members to build trust and relationships with each other in the group, promoting safety and high-quality participation as we together develop the intervention. These will be conducted taking availability and accessibility for our StAG members into account using a mix of in person and Zoom workshops (not hybrid)..

<u>Workshop 1</u>

This workshop will specifically look at steps 1 and 2 above. The aims will be to produce a refined 'missingness' programme theory. During the workshop we will explain to the participants how we got our findings and also what a programme theory is. We will present the emerging programme theory to the StAG using methods like our illustrated visuals to maximise participation and aid reflection. Using consensus techniques we will produce our final agreed programme theory. It is anticipated we may generate further data that will feed into the intervention development. This will be delivered online via Zoom.

<u>Workshops 2- 4</u>

In these three workshops we will focus on step 3 and 4 of 6SQUID, identifying how to bring about change and identifying how to deliver change mechanisms. The aim of the workshop is to generate potential intervention ideas based on leverage points identified earlier, data from WP2, as well as interventions already in existence identified in the other WPs. Participants will explore and critique what already exists, generate new ideas for interventions or services or adaptations of current interventions or services. For the different ideas they will consider issues like feasibility, likely acceptability, value for money, stakeholder buy-in, who might be involved in delivery etc. We will use facilitated discussion, some small group work and techniques like Charette brainstorming and Mind mapping. Workshop 2 and 3 will be delivered in person (with the option of a repeated smaller workshop for professionals who cannot attend in person). Workshop 4 will be via Zoom. Data that is collected from all of the workshops will be de-identified, coded, stored, transferred, accessed and archived in the same manner as the data generated in WP2. We will also involve StAG members in the making of short videos which will highlight our key findings about missingness and the developed intervention. This will be used in research presentations, professional training events and will be publicly available for use in teaching, training and campaigning.

By the end of the workshops, we will have developed a final 'programme theory' of the intervention too, detailing the key components, how they will be delivered, and the likely mechanisms whereby change will occur. However, given the complex nature of the problem we anticipate the intervention required will have a number of different components working at different levels of the 'system' in order to tackle the problem. An intervention programme theory could include elements like staff training and awareness raising, adequate data capture and identification of people at high risk of 'missingness', a focus on relational care, 'sticky' care, or assertive outreach. The proposed intervention may be general or targeted in specific settings or with specific patient groups. It is anticipated it (or components of it in different contexts) will form the basis of a future feasibility study.

Access and archiving

Transparent Research Practices: it is becoming typical and sometimes essential to openly share research materials and data(37). Engaging with open science practices is valuable for both quantitative and qualitative designs(38) and we will aim to engage with these practices where practical(39). This will include a project page on the Open Science Framework (https://osf.io/) that will be linked with the main project website. There are no costs associated with using this service, which will be managed by Ellis who developed recommendations and guidance for psychological science previously(40). Pages will support the sharing of materials with collaborators and partners. These might include interview protocols, anonymised data, and future publications in the form of pre-prints. We will also ensure data files use proprietary formats whenever possible (e.g., .csv or .txt) to maximise their utility for others who might not have access to specialist software(40).

6 STUDY SETTING

WP2 Study setting

Our setting and hence approach to sampling for WP2 is based on a number of factors: the vital importance of including those with direct experience of 'missingness' and of those who 'encounter' service users who are 'missing' in routine and specialist practice; the need for an evidence-based approach in identifying those groups at highest risk of 'missingness'; and differing NHS and social care organisational contexts in Scotland and England.

'Missingness' interventions

Recruitment of the StAG for WP3 will be based on purposive sampling of the groups identified from the realist synthesis.

There is no site specific activity or requirements for this study. All EPE participants are recruited via organisations out with the NHS and professional participants are being interviewed remotely or attending workshops at the University of Glasgow.

7 SAMPLE AND RECRUITMENT

7.1 Eligibility Criteria

As described above our final sampling will be guided by the realist review of the evidence in WP1.

Our eligibility criteria are:

- Adults
- With lived experience of 'missingness' in health care in Scotland or England
- Representative of population groups who experience 'missingness' as defined by our realist review
- With the capacity to participate in a research project

Or

- Professionals working in health care, voluntary sector or policy settings in Scotland or England that have professional experience of 'missingness'

7.1.1 Inclusion criteria

Specific inclusion criteria will be developed and specified based on the WP1 realist review findings.

7.1.2 Exclusion criteria

Exclusion criteria are

- people who have no experience of 'missingness' in health care
- people who lack capacity to participate in research
- professionals who have no experience of considering 'missingness' in health care in their work

7.2 Sampling

7.2.1 Size of sample

For the WP2 qualitative study we aim to recruit approximately 30 experts-by-experience and 30 professionals engaged in service delivery or planning via purposive sampling.
Team experience from multiple qualitative studies of experts-by-experience indicates that this will generate sufficient data for an in-depth analysis from lived perspectives. When combined with the findings from the realist review (WP1) we judge that we will have sufficient data for developing an intervention that is transferable across most health and social care. However, we may cease interviewing when explanatory saturation is reached.

Our StAG membership will be a purposive sample from prospective participants based on including individuals with perspectives on missingness that we have judged to be important. This membership will be built on to achieve full membership for the start of WP3. We will have 8 members in WP1 reaching 16 for WP3.

'Missingness' interventions

7.2.2 Sampling technique

Sampling of experts-by-experience: This group will be identified via stakeholder and voluntary sector organisations that reflect services or patient groups at high risk for 'missingness' groups identified in the epidemiological study and initial signals from the evidence synthesis. This includes people experiencing severe and multiple disadvantage such as problem substance use, homelessness, criminal justice system involvement; poor mental health; complex multi-morbidity; those will complex needs (which may include people who have experienced ACEs, have cognitive impairment, or been in the care system) and older people.

Sampling professionals: Approximately 30 professional key informants will be recruited from across Scotland and England and remote interviews will be conducted with them. This is to ensure that our face-to-face interview resource is targeted where it is needed most ie with experts-by-experience. This will also make best use of professionals' time.
Professional key informant sampling will provide coverage of health and social care professionals (such as GPs, GP practice staff, Inclusion Health professionals in the NHS, social care and the third sector) and relevant policy professionals for whom 'missingness' is a visible topic (for example, policy leads within local authorities and national governments). We will also add additional staff categories depending on the findings from the WP1 literature synthesis and emergent programme theory. Our outputs relating to this sample will have relevance across the UK health and social care sector.

7.3 Recruitment

Experts by experience recruitment: Mackenzie, O'Donnell and Homeless Network Scotland (HNS) have extensive expertise in conducting research with 'seldom heard' research participants, and in synergy with the clinical, professional and PPI links that Williamson and our previous and current public Co-applicant have across the UK we are confident we will recruit and appropriately support inclusive participation in the research. Williamson and HNS have well established links with a range of voluntary sector organisations in Scotland and England focussed on the care of marginalised patient groups to ensure sampling and recruitment are successful. The organisations include Homeless Network Scotland, Scottish Drugs Forum, Poverty Truth Commission Scotland, Lankelly Chase and Revolving Door. Each of these organisations have a well-supported expert by experience programme which will supplement the support we will provide to participants.
Utilising participants drawn from existing organisations will also help ensure duty of care for participants. We have estimated 5/30 participants may have additional language or communication needs requiring interpreter support and we have costed for this.

We will use additional strategies that have been found to increase engagement in research, promote active participation and ensure emotional safety for participants. This includes the researcher being in contact with the participant and providing a brief informal photo bio prior to conducting the research, providing a 'chat pack' of tea, biscuits, notepad and pens, and contacting participants after the interview to check in and hear about any further information that is required. We will use illustrated visual segments of our preliminary programme theory as visual aids in the interviews as starting points for discussion. These strategies will be further developed as the research proceeds.

Professional recruitment: Williamson, O'Donnell and Major (public Co-I) have strong links with professional organisations and services in Scotland and England due to their research and wider

NHS/academic/professional body profiles. Participants will be purposively sampled to reflect the findings from our realist review.

7.3.1 Sample identification

It is important to sample participants across Scotland and England in order to include the full range of stakeholder organisations (and hence participants) and be able to explore the range of distinct service responses in different areas of the UK. We note, for example, that some campaigning organisations in England are holistic rather than single-issue which may have important implications for both the understanding of the 'missingness' problem and its potential solutions. For example, Revolving Door Agency has reach across England and we plan to recruit participants from a range of their multiple disadvantage lived experience forums. Recruitment is focussed on diversity of participant characteristics and lived experience of services rather than geographical areas of the UK. So for example we will be seeking to sample the experience of living in a small town or rural area where provision of services tends to be generic and not at all targeted to meet the needs of diverse populations in addition to city dwellers where greater targeting may be the case.

Partner organisations

We will also specify with our partner organisations the profile of participants we would like them to recruit on our behalf beyond simply having a missingness from health care profile (eg a person known to have low literacy levels). Our draft programme theory will guide each of these levels of sampling; which organisations to involve and then the individual characteristics of potential participants from those organisations. We have already identified the majority of the organisations we will be partnering with. However, we have deliberately left space for extending this as the evidence review gets under way. Recruitment will proceed via trusted contacts within each partner organisation. We are not using Patient Identification Centres or publicity/social media directly. A professional contact within the partner organisation will connect us directly with potential participants, once they have discussed participating with them and what is involved using information from our Participant Information sheet. Research team connection will be by email or text message for the RA to then make contact with the potential participant. The persons name and contact is all the information the research team will have at recruitment.

Participants will be offered a participation recognition voucher to take part in the realist interviews (£20) and public participants in the StAG will be paid at £25 per hour the rate recommended by NIHR; travel and subsistence has been costed for.

7.3.2 Consent

Consent to participate will utilise written and oral methods. Participant information and consent forms will be in plain English format and will be shared with potential participants via email or post ahead of the planned interview date We anticipate some EPE participants will have low reading age or have no reading literacy. To ensure inclusivity, and that full consent is discussed and given the RA will read through the participant information sheet and the consent form with each EPE potential participant. If the EPE consents to take part they will then be asked to initial each section of the consent form. This may be immediately before the planned interview or , ahead of each EPE interview during other contacts as below. Interpreter support is costed for and will be utilised as required in the realist interviews. Potential participants will have the contact number for the study phone mobile and will be encouraged

to ask questions at any time in addition to in the lead up to the interview taking place. As described above it is anticipated the RA will have contact with EPE participants a number of times prior to this and there will be ample opportunity to ensure fully informed consent is obtained and maintained throughout the conduct of the study. It is anticipated this input will be much reduced for the professional participants who will be sent the participation information sheet and consent form ahead of their planned interviews.

StAG members will give informed written consent once their role has been discussed.

There is a two step recruitment process to ensure EPE participants have the capacity to participate in the research. The first is that our partner organisations will be briefed to approach potential participants that they themselves judge have capacity to participate and the recruiting researcher will then assess capacity at each step of the research process having undergone training to do so.

8 ETHICAL AND REGULATORY CONSIDERATIONS

Williamson will ensure this study will be conducted according to the UK Policy Framework for Health and Social care Research (v3.3 07/11/17) and WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI Ethical Principles for Medical Research Involving Human Subjects 1964 (as amended).The Investigators will ensure that this study is conducted in accordance with relevant regulations and with Good Clinical Practice. The protocol, informed consent form and participant information sheet will be submitted to an appropriate Research Ethics Committee (REC), and host institution(s) for written approval. The Investigator will submit and, where necessary, obtain approval from the above parties for all substantial amendments to the original approved documents.

Williamson shall submit once a year throughout the study, or on request, an Annual Progress report to the REC Committee, host organisation and Sponsor. In addition, an End of Study notification and final report will be submitted to the same parties.

Our main ethical consideration is the successful recruitment of experts-by-experience of 'missingness' given that it is likely there is a risk of 'missingness' in research studies too. Linked to this is that many of our participants are likely to have physical, mental health and social vulnerabilities. We need to take additional care when seeking consent to participate to take account of perceived power imbalances and that we are not in any way coercing people to participate. Our research team is experienced in recruiting people from vulnerable backgrounds in research and the lead PI is also an Inclusion Health clinical expert. Our research associates have been recruited with this focus of the research project in mind and are also experienced in working with marginalised participants. Williamson, O'Donnell and Mackenzie will assess and then provide any training needs identified with the research associates and provide oversight. In addition unpublished pilot work led by Williamson established that recruitment of participants is successful if conducted via relevant third sector organisations. We plan to only include third sector organisations who have robust participant support systems in place to mitigate this and provide support for participants who may find re-visiting past distressing events challenging. We have

also planned carefully to take account of building trust and relationships in the research process, and at which points in the study participation is required.

To ensure ethical and regulatory considerations are maximised we are planning to seek ethical and management permissions for our StAG participation in addition to our interview participants. This we understand is currently a grey area in terms of required permissions. However we judge due to the potential vulnerability of some EPE we should do this.

8.1 Assessment and management of risk

There are two participant groups to consider risk management of:

Firstly for **EPE participants** in the realist interviews and those who may take part in the StAG we have had to take account of the context that they may be or go onto experience difficult life experiences or health issues while taking part in the study. This may include safeguarding concerns. Williamson (the lead PI) is a senior Inclusion Health clinician in the NHS and accustomed to risk assessing potential safeguarding circumstances for patients and has overall study responsibility for this. The Leads for WP2 and 3 are senior experienced researchers who have extensive experience of handling safeguarding concerns in research. The researcher who will be in contact with participants will have same day access to advice about any concerns. A formal check-in about safety both of participants and researchers will form a part of each WP meeting and full team meeting once participant participation has commenced. Moreover our partner organisations also adhere to safeguarding best practice, have established positive relationships with participants and we will have an agreement set up with our partner organisations regarding emergency support contact if needed prior to the start of the study.

Secondly our main risk regarding **professional participation** is clinicians, managers and policy makers being able to take sufficient time out of their day to day work to participate in the research. We are seeking to mitigate this by conducting our interviews online to reduce the time commitment, by scheduling workshops far in advance so that diaries can be prioritised, and offering locum payment for primary care clinicians.

8.2 Research Ethics Committee (REC) and other Regulatory review & reports

Full REC permissions will be sought from University of Glasgow MVLS ethics committee for the participation of our experts-by-experience and professionals for all stages of the research. This is for participation in our mini StAG for WP1 the realist review; for all research interviews in WP2, and for full StAG participation in WP3 our complex interventions development. R&D permission will be obtained to enable NHS professional participation in these WPs too.

8.2.1 Regulatory Review & Compliance

This study does not involve the participation of patients or the involvement of any NHS sites.

If amendment to the study is required Williamson or her designee in agreement with the sponsor will submit information to the appropriate body in order for them to issue approval to the amendment.

'Missingness' interventions

8.2.2 Amendments

Amendments will be discussed by the research team with the Study Oversight Group and sponsor. Any amendments needed will be clearly communicated to the aforementioned parties with explanations and justifications for why an amendment is needed. The category of substantial or non- substantial will be agreed by the team with input from the afore-mentioned parties. After discussions and if approved by the aforementioned parties Williamson will then submit the application for the amendment to MVLS REC and the NHS R&D office. Agreed amendments will be communicated with MVLS REC, NHS R&D and the funder.

8.3 Peer review

This study has undergone peer review and the team responded and amended the study accordingly at the following funding submission points:

NIHR internal HS&DR committee peer review process at stage 1.

University of Glasgow Institute of Health and Wellbeing peer review by two colleagues prior to stage 2 submission.

NIHR external peer review by two colleagues at stage 2, this feedback reviewed by committee peer review.

HS&DR committee member review post stage 2.

8.4 Patient & Public Involvement

When developing the research that underpins this study the Royal College of GPs (RCGP) Scotland Patient Participation in Practice (P3) group were consulted in 2016. They are a group of expert patients who have representation from all regions of Scotland and a range of health experience backgrounds. They provide input to policy for RCGP Scotland. Williamson met with the group in person, they described patient narratives they had come across about missingness in health care. Really importantly they judged this an important topic that has not had sufficient research attention and followed this up with a written letter of support for the initial epidemiological work. While that research was being undertaken and starting to think about next steps, including this proposal, Williamson led a small unpublished pilot project in 2017. Six Inclusion Health voluntary sector professionals and people with lived experience were interviewed to hear about their experiences of 'missingness' in health care. The participants reported that 'missingness' was a recognisable and important issue for patients and for services, they described their experiences and ways to address it. Importantly this method of recruiting people with lived experience of 'missingness' via relevant partner organisations was feasible and acceptable. Williamson and colleagues have presented to or discussed the previous epidemiological work on 'missingness' with the majority of the partner organisations described in the proposal. Universally their feedback has been this is an important topic to take forward.
Frew as our previous public Co-Investigator with extensive experience of working with people with severe and multiple disadvantage including in research settings, was involved in the development of the stage 1 and stage 2 NIHR funding proposal with a particular focus on engagement strategies for people with lived experience. This helps ensure the research process is accessible and safe, and develop outputs for dissemination that will reach a wide audience - including beyond health and social care to the third sector who campaign for change on behalf of patients. Major replaced Frew as Public Co-I when Frew moved onto a new job role. Major is from the same organisation, Homeless Network Scotland. Major has also reviewed the protocol, and will participate in full team meetings which will review progress, provide data analysis input and help steer dissemination of outputs.

'Missingness' interventions

8.5 Protocol compliance

The research team agree that accidental protocol deviations can happen at any time. We will document these if they occur and report these to Williamson and the Study Oversight Group and Sponsor immediately.

Such breaches will be discussed within the project team, causes identified and actions to correct these will be developed. The action plans will then be shared with the Study oversight Group and Sponsor and we will seek their feedback, and advice and use these to improve our action plans (as needed). We will ask them to approve our planned action and once they have the project team will put these plans into action and report on progress to them. Should further action be deemed by them to be needed, we will repeat the process we have outlined above – until the breach is resolved to the satisfaction of all parties

The research team also agrees that 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.

8.6 Data protection and patient confidentiality

The research team will comply with the requirements of the Data Protection Act 1998 and is committed to upholding the six Principles underlying the General Data Protection Regulation (GDPR), the UK Data Protection Act 2018 with regards to the collection, storage, processing and disclosure of personal information.. These are set out in the description of WP2 and 3 above. Williamson is the custodian of the data.

8.7 Indemnity

Indemnity is covered by University of Glasgow as Sponsor for the study. No NHS sites are being used.

8.8 Access to the final study dataset

The full research team will have access to the anonymised data sets. Consent for data to be shared more widely if attached to future publications and/or shared via data repositories will be sought from participants as part of the study consent processes outlined above.

9 DISSEMINIATION POLICY

9.1 Dissemination policy

Within the first three months of the project the research team will produce an impact strategy drawing on the Canadian Knowledge Mobilisation Toolkit (http://www.kmbtoolkit.ca/) recommended by NIHR. This is to develop a living document that plans for what, why, how, when and how the impact of the study and its outputs will be measured, helping to develop clear pathways to impact. We will seek to maximise the impact of outputs across policy, research and practice communities in the UK (and

beyond). This is in the NHS, local and national government and in the third sector, utilising the cross sectorial expertise and profile our team members and StAG bring to the research. This will be with patients, service users, clinicians, practitioners, managers, commissioners, policy makers and campaigners using appropriate communication messages and platforms. The team will utilise its significant track record in knowledge exchange and policy engagement at local and national level.

Outputs will include*:*

1. A full report in the NIHR HS&DR Journal with details of the work undertaken, a plain English executive summary with clearly identified policy, managerial and practice implications. We will make the summary available separately as a stand-alone briefing paper for further dissemination and use all routes available to NIHR briefing documents including the CHAIN network and our own extensive professional (including Royal Colleges) and experts-by-experience networks including the partner organisations involved in the research, NHS England and OHID, NHS Scotland and PHS, and UK NHS organisations.

2. Four peer-reviewed publications in leading journals reporting the evidence synthesis protocol, its findings, the experts-by-experience and professional key informants study of 'missingness', and detailed reporting of the complex intervention, justifying and explaining our recommendations based on our gathered evidence.

3. Illustrated visuals of our final programme theory of 'missingness' having been co-produced with our StAG members will be open access and used in dissemination events, teaching and training, practice and policy change discussion for the range of stakeholder organisations across health, social care and the third sector.

4. Short videos of the key messages of our research results and the proposed intervention, involving StAG members which will be open access and used in dissemination events, teaching and training, practice and policy change discussion for the range of stakeholder organisations across health, social care and the third sector. We will use these dissemination opportunities to sense check what is likely to be implementable and to recruit some future sites for a feasibility study. It is anticipated this may lead to a future network of practice, policy and third sector colleagues interested in addressing 'missingness' in health and social care.

5. Blogs, opinion pieces, media interviews and talks delivered by our research team and StAG using our co-produced dissemination materials. All of these will be curated on our 'missingness' web page and highlighted on social media platforms. https://www.gla.ac.uk/researchinstitutes/healthwellbeing/research/generalpractice/research/serialmissedappts/

6. Presentations at relevant conferences (e.g. Society for Academic Primary Care, Royal College of General Practitioners, Faculty of Homelessness and Inclusion Health Annual Conference, North American Primary Care Research Group annual conference, UK Society of Behavioural Medicine, RCGP substance use annual conference) Four have been costed for.

The research team owns the data arising from the study (University of Glasgow policy). We are not aware of any time limits or review requirements on the publications. As per usual practice we will

acknowledge NIHR funding and our partner organisations (with permission) in publications. They do not have publication rights over the data.

Our research participants will be kept informed of the study outputs as they are produced and will have the option of accessing those that are most suitable to their context (eg academic papers for policy participants, film output for EPE participants).

Results will also be available to participants on request following publication of the Full Study Report.

The earlier section on our use of the Open Science Framework sets out our plans for making this study including its data publicly available.

9.2 Authorship eligibility guidelines and any intended use of professional writers

All members of the research team will be eligible for authorship of the final report and other peer reviewed publications. We will adhere to the CRediT scheme guidelines https://credit.niso.org/.

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'Missingness' interventions

11. APPENDICIES

11.1 Appendix 1- Required documentation

1. Briefing email to partner organisations

2.Consent form for StAG membership and realist interview participants

3. Participant information sheet for StAG membership and realist interview participants

4. Semi-structured interview schedule for realist interviews

11.2 Appendix 2 – Schedule of Procedures (Example)

This is not relevant for this study design.

13.3 Appendix 3 – Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made
1.	V1.1	20/12/22	Kate O'Donnell	Addition of Carol Emslie, Alex Osmond and Richard Byng to Research Oversight Group.
2	V1.2	11/01/23	Elspeth Rae	Corrected page numbers in introduction and corrected two small spelling errors
3	V1.3	15/02/23	Elspeth Rae	Made ROG chair signature visible Amended footers to follow version control protocol Moved this amendment control table to beginning of document