Study Title: Understanding the implementation of link workers in primary care: A realist evaluation to inform current and future policy

Short title: Understanding the implementation of link workers in primary care

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Confidentiality statement

This document contains confidential information that must not be disclosed to anyone other than the Sponsor, the Investigator Team, host organisation, and members of the Research Ethics Committee, HRA (where required) unless authorised to do so.

Conflict of interest

There are no potential conflicts of interest to declare.

Intellectual property

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1. KEY STUDY CONTACTS

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2. LAY SUMMARY

Background: Approximately one in five people see their GP with problems that are mainly social (e.g. loneliness), environmental (e.g. housing issues) or economic (e.g. worries about debt) in nature. This is why social prescribing has been introduced into primary care. Social prescribing draws on 'community assets' (e.g. local groups, organisations, charities) to assist patients with 'non-medical' difficulties.

Link workers are employed to facilitate social prescribing in primary care. The link worker meets with a patient (often more than once) to find out what is happening in that person's life and what they want to change/address. They then co-produce an action plan, based on the individual's health and well-being priorities. The action plan concentrates on linking the patient to relevant 'community assets'.

We have reviewed existing literature to develop guidance on optimising the implementation of link workers in primary care. Our review highlighted gaps in knowledge. Therefore, we will carry out some primary research to strengthen our initial recommendations.

Aims: To explore why link workers produce benefits in some settings for some individuals but not for others. We aim to understand and explain how and why link workers produce specific outcomes in certain contexts.

Design/methods: We will collect data from 6 primary care sites. Data collection will include observing link workers interacting with patients and professionals. We will examine key documents related to the link

worker's role within a setting. We will use data collected routinely by link workers. We will conduct a one off semi-structured interview with link workers, health professionals and voluntary-community sector staff. We will conduct interviews with patients close to when they first meet a link worker and 9-12 months after this meeting. This will allow us to examine how they have benefited (or not) from seeing a link worker. We will use a research approach called realist evaluation to explain what causes different outcomes from link workers seen in different contexts.

3. SYNOPSIS

Study Title	Understanding the implementation of link workers in primary care: A realist evaluation to inform current and future policy
Internal ref. no. / short title	Understanding the implementation of link workers in primary care
Sponsor	University of Oxford, Clinical Trials and Research Governance, Joint Research Office, 1st floor, Boundary Brook House, Churchill Drive, Headington, Oxford, OX3 7GB
Funder	National Institute for Health Research (HS&DR), Evaluation, Trials and Studies Coordinating Centre, University of Southampton, Alpha House, Enterprise Road, Southampton, SO16 7NS
Study Design	*Design:* A realist evaluation, composed of two work packages (WPs), will be undertaken. It will build on a programme theory we developed from a previous realist review on the topic (Tierney et al., 2020). *Data collection:* WP1 will explore the implementation of link workers in different primary care settings. A purposive sample of six cases (link workers) within six sites (geographical areas) across England will be selected. Each case site will be examined in-depth for three months. As part of this, we will interview patients who have been referred to a link worker. WP2 will involve 9-12 month follow-up semi-structured interviews with patients from WP1, to understand how they benefitted (or not), in the longer term, from seeing a link worker. A realist logic of analysis will be applied to data from each WP – initially separately and then combined – to specifically see if it confirms, refutes or calls for refining of the programme theory developed from our completed realist review. Analysis will explore connections between contexts, mechanisms and outcomes to explain how, why and in what circumstances the implementation of link workers might be beneficial to patients and/or health care delivery.
Study Participants	We will purposively sample geographical areas (our sites) and link workers within these (our cases) who will connect us to other data sources (e.g. patients and GPs). This will enable us to explore factors that our realist review emphasised as important to consider: a) at a service level, in terms of how link workers are being implemented (e.g. employed as part of an existing social prescribing service or acting alone in a Primary Care Network), and b) in terms of a Primary Care Network's patient population (e.g. age, ethnicity, faith, socio-economic status). Purposively sampling in this way will help us to explore how to refine/expand the programme theory we developed in our realist review.

	During the project, cases (link workers) will be purposively selected from differ parts of England. Sampling will occur in a sequential manner, so we can achieve variation in a) how the link worker service is set up and b) in the patient population served. Data collection and analysis from one site might indicate a particular factor that needs to be explored in more detail, so we will select the next site and case within it accordingly.
Sample Size	Six cases (link workers) around which data will be collected from approximately 102 participants in total (link workers themselves, patients, healthcare professionals, voluntary-community sector staff).
Project Duration	01 Aug 2021 to 31 Jan 2024 (30 months)
Planned Study Period	The study will run for 30 months (includes time for study set up and dissemination). WP1 will run for 12 months. Two researchers will spend three months on each case – they will be responsible for three cases each. This will involve three weeks of fieldwork for a case and nine weeks undertaking interviews with patients and healthcare professionals for that case. This will be followed by a short period of analysis. WP2 will involve 11 months of follow up data collection with patients and healthcare professionals.
Planned Recruitment Period	Recruitment for WP1 will last from Nov 2021 until Oct 2022. Recruitment for WP2 will last from Nov 2022 until Oct 2023.
Research Question	When implementing link workers in primary care to sustain outcomes – what works, for whom, why and in what circumstances?
Aims	To generate evidence-based recommendations on how to optimally implement link workers in primary care, allowing NHS patients to receive the best possible support.
Objectives	• To undertake an in-depth examination of the delivery of link workers in a purposive sample of primary care settings; • To critically exam the impact of link workers in practice, exploring if, what and how link workers deliver sustained, desired outcomes; • To compare and explain proximal outcomes (e.g. patients attending community activities or seeking advice from local organisations) and more distal ones (e.g. patients engaging more in self-care or reducing how often they see a GP); • To examine how a) models of link worker delivery and b) patient characteristics may influence the production of sustained, positive outcomes; • To integrate findings to produce detailed, real-world recommendations for those commissioning, providing or acting as link workers.

4. BACKGROUND AND RATIONALE

The purpose of the research is to understand how delivery of the link worker role can be optimised within primary care in England. Link workers are being employed within the NHS to support patients who attend a GP's surgery with what may be defined as 'non-medical' issues that affect how individuals feel physically and psychologically; things like loneliness, debt, hoarding, anxiety. Link workers form part of the drive to embed social prescribing within the NHS.

Social prescribing involves connecting patients to 'community assets' – groups, organisations, clubs, charities – that can help to address their 'non-medical' issues. Link workers act as bridge between the patient and these community assets. They help the patient to develop an action plan, which prioritises what matters to the individual in terms of their health and well-being goals, and then connects them to appropriate community assets. They might meet with the patient on more than one occasion and could use motivational techniques to encourage individuals to try or attend new things. Link workers need a good up-to-date knowledge of a range of community assets in their local area.

Interest in social prescribing has escalated due to the central place it occupies in the NHS long-term plan (NHS England, 2019a) and its role as a key component within the NHS personalised care agenda (NHS England, 2019b). There is emerging evidence that social prescribing can improve health and well-being, social contacts, and reduce service use and healthcare demand, but it should be noted that findings are mixed, with not all studies reporting positive outcomes (Bickerdike et al., 2017; Pescheny et al., 2020; Polley et al., 2017). This highlights the need to understand further when and why it works and in what circumstances. The NHS long-term plan states that by 2023/24, at least 900,000 people will be referred to social prescribing (NHS England, 2019a). Link workers will be central to meeting this aim, with resources provided for each Primary Care Network in England to have access to such an employee.

Despite social prescribing being heralded widely in key policy documents as part of the solution to growing demands on GPs and the complexity of healthcare needs (NHS England, 2019c), use of community assets to improve well-being is not novel. What is new is an aim to systematically identify and mobilise these assets to support primary care. Converting social prescribing from a concept to a tangible intervention on the ground can be challenging. It is a model of practice with multiple components – a complex intervention that has core elements alongside variable components to make it flexible and relevant to local context (NHS England, 2019c).

From this perspective of seeing social prescribing as a complex intervention, we intend to further understand its nature and impact by focusing on one important element – the link worker role. Our research will address the following question: When implementing link workers in primary care to sustain outcomes – what works, for whom, why and in what circumstances? From a realist perspective, "variations in programme performance are a crucial first step but outcome patterns considered alone are only surface 'markers' or 'traces'…the potential outward signals of inner workings of a programme in a particular manifestation" (Pawson, 2013: 17). Hence, we will not be so much interested in the % or degree to which link workers have worked, but in explaining how different outcomes are produced under different contexts.

5. AIM / RESEARCH QUESTIONS / OBJECTIVES

Aim / Research Questions / Objectives
Key question: • When implementing link workers in primary care to sustain outcomes – what works, for whom, why and in what circumstances? Sub-questions: • How are link workers being implemented and used in primary care? • What factors contribute to link workers working, for whom, why, and in what circumstances? • What impact do link workers have on patients and service use? • What is required to further optimise patient outcomes?
Aim: • To generate evidence-based recommendations on how to optimally implement link workers in primary care, allowing NHS patients to receive the best possible support.
Objectives: • To undertake an in-depth examination of the delivery of link workers in a purposive sample of primary care settings; • To critically exam the impact of link workers in practice, exploring if, what and how link workers deliver sustained, desired outcomes; • To compare and explain proximal outcomes (e.g. patients attending community activities or seeking advice from local organisations) and more distal ones (e.g. patients engaging more in self-care or reducing how often they see a GP); • To examine how a) models of link worker delivery and b) patient characteristics may influence the production of sustained, positive outcomes; • To integrate findings to produce detailed, real-world recommendations for those commissioning, providing or acting as link workers.

6. STUDY DESIGN

6.1 Methodology

Link worker services can be regarded as a complex intervention (Craig et al., 2013), comprising a range of components (e.g. educating, encouraging, empowering people), including several stakeholders (e.g. patients, voluntary-community sector, primary care staff, link workers), having variable outcomes (e.g. for patients, practices, the health service) and being implemented to meet local needs.

A realist approach is suitable to understand complex interventions, by explaining the influence of context, who might (might not) benefit, and how outcomes have arisen (Pawson, 2013). We seek to develop

workable recommendations about optimising link worker implementation within primary care. We will investigate whether, how and for whom different implementation configurations and components work.

Our study is designed as a realist evaluation. It will be theory-driven, underpinned by a realist philosophy of science. It will focus on mechanisms, and contexts required to 'trigger' them – resulting in the development, refinement and testing of context-mechanism-outcome configurations (CMOCs). CMOCs are embedded within a programme theory (a proposition about how an intervention is thought to work, under what conditions) (Pawson et al., 2005). Exploring the link worker role through a realist logic of analysis will avoid the criticism that it is "a crude oversimplification to say that interventions change behaviour; they work by providing some resource that persuades the subject to change and this is the underlying generative mechanism around which inquiry is constructed" (Pawson, 2013: 63). The starting point for the proposed research will be a programme theory we developed from a previous realist review we conducted (Tierney et al., 2020); we will expand and refine this by exploring how it relates to six link worker cases that we will study in-depth; cases will be built around six link workers, but will involve the collection of data from related sources (see below).

6.2 Sampling Strategy

Our preparatory work (realist review and consultations with key stakeholders) suggested that six sites would be enough to obtain 'maximum variation' in our sample because of the inherent diversity in the implementation of link workers in the NHS.

We will purposively sample geographical areas (our sites) and link workers within these (our cases) who will connect us to other data sources (e.g. patients and GPs). This will enable us to explore factors that our realist review emphasised as important to consider: a) at a service level, in terms of how link workers are being implemented (e.g. employed as part of an existing social prescribing service or acting alone in a Primary Care Network), and b) in terms of a Primary Care Network's patient population (e.g. age, ethnicity, faith, socio-economic status). Purposively sampling in this way will help us to explore how to refine/expand the programme theory we developed in our realist review.

Sampling of sites (areas) and cases (link workers) within them will occur in a sequential manner, so we can achieve variation in terms of how link worker services are set up (whether it is a site where link workers are directly employed by a Primary Care Network or a site where link workers are employed by voluntary organisations), and in terms of the populations served (e.g. sites with high and others with low levels of disadvantage, or with significant minority ethnic populations). Data collection and analysis from one site might indicate a particular factor that needs to be explored in more detail, so we will select the next site and case within it accordingly.

We have talked to link workers currently based in a range of areas in England. They suggested seeing between 20-50 patients a month; this number is likely to increase as the role becomes more familiar to surgery staff and patients, and as a consequence of the need for psychosocial support among patients in light of the COVID-19 pandemic. The proposed size will allow us to address the criteria in our purposive sampling strategy within the time available for the study. We believe it will prove sufficient to reach data redundancy (no longer learning new things as data collection progresses), whilst offering a diverse insight into the implementation of link workers in primary care.

6.3 Methods of Data Collection

Data will be collected using a range of methods, including qualitative 'self reports', along with corroborative (or disconfirming) data from other sources (e.g. routinely collected quantitative data such as referral rates to a link worker).

Data will be collected in GP practices and venues where the link worker works (e.g. voluntary-community sector venues). Patients will have the option to be interviewed remotely (via telephone or via Microsoft Teams) or in a private room at their GP's surgery or at the voluntary sector organisation where they meet the link worker. Professionals will be interviewed in their place of work or remotely if they prefer.

Written notes will be taken during observations and daily debrief between the link worker and researcher (see below). Audio-recordings will be made of interviews, which will be transcribed verbatim by a transcribing service approved by the study's Sponsor (the University of Oxford).

For WP1, we will focus for three months on the case (i.e. link worker) at each site. This will include three weeks of fieldwork where data will be collected in the following ways (N.B. patient interviews will be completed in the weeks following the fieldwork):

- *Non-participant observations:* During the three weeks of fieldwork at each site, we will undertake focused observations (Cruz and Higginbottom, 2013; Wall, 2015); we will adopt a targeted approach to what is observed, to address specific queries or problems that will help to further understanding of the programme theory developed in our previous realist review. What we observe may evolve as the study progresses, depending on parts of the programme theory that need expanding. However, initially we will seek to observe, in each setting, at least one meeting between a link worker and a new patient and one meeting with someone who has seen the link worker more than once (*n=12 in total*). Patients who have been observed meeting with the link worker can be invited to take part in an interview (see below). We will also observe the link worker at any meetings held with colleagues during the three weeks of fieldwork. We will use an observation grid to record what is observed.
- *Daily debriefs with link workers:* Each day, at a time convenient for the link worker, a researcher will conduct a debrief to find out what they have been doing that day. Written notes will be made by the researcher during the debriefs; no names or other identifying information will be recorded.
- *Semi-structured interviews with professionals (n=42 in total):* For each case, we will complete semi-structured interviews with the link worker, as well as with a GP, receptionist, practice manager and practice nurse from the Primary Care Network they serve. We will also interview a representative of the voluntary-community sector with whom they work, and the Primary Care Network clinical director. Interviews will address perceptions of the link worker role, how these employees function in practices, barriers and facilitators to implementation, views of the impact on patients. We will also explore, in interviews, how participants feel the link worker role has been received by colleagues.
- *Semi-structured interviews with patients* (n=60 in total): We will conduct interviews with patients in the nine weeks following fieldwork at a site. Ten patients from each site will be asked about their interactions with the link worker. This may include patients who have been observed meeting with a link worker during the fieldwork. We will seek to talk to patients who started seeing the link workers during the three week fieldwork period, in the month before then or the month after this (so they can recall what took place). These interviews will be by telephone or Microsoft Teams, or in person at their GP's surgery or the voluntary sector organisation where they meet the link worker. We will ask link workers/the practice to send a letter to eligible patients inviting them to be

part of the study, along with the participant information sheet. If someone is interested in participating, they will contact a member of the research team, who will talk them through the project and, if they are happy, arrange a date to be interviewed. During interviews we will ask patients about topics related to our programme theory, such as how they were introduced to the idea of seeing a link worker, what their first impressions were, what they found useful or not so useful from seeing a link worker. They will also be invited to complete two questionnaires - the ONS4 (which measures well-being) and the General Self-Efficacy Scale (GSE) (which assesses one's belief in being able to cope with stressful or challenging demands). We will ask them to complete these questionnaires again in their follow-up interview (WP2), exploring at this point with them any potential changes on their scores and their explanations for these.

- *Documentary reviews:* Documents related to the link worker role (e.g. flyers for patients about this service, job descriptions, referral forms, quality assessment procedures, minutes of multidisciplinary team meetings) will be collected by the researcher from the link worker during the fieldwork period. This will help to orientate the researcher to how the link worker role is being implemented locally and will act as background knowledge for the interviews.
- *Routinely collected data:* We will gather anonymised, aggregated, routinely collected data from link workers based on the social prescribing outcomes framework (NHS England, 2019c); it proposes that link workers collect procedural data (e.g. number of referrals received, type of patients referred – e.g. age, gender, ethnicity, uptake of the referral) alongside questions on well-being (the ONS4) and general self-efficacy (via the GSE). We will ask each link worker to provide routinely gathered data for the three months prior to fieldwork starting. We will also gather data on changes in patterns of GP use among these patients six months on from them first seeing a link worker. The link worker will be asked to collect this information and to send it on to the research team.

For WP2, we will conduct follow-up semi-structured interviews with patients from WP1. These will take place 9-12 months after the first interview; based on our conversations with stakeholders, we believe this follow-up period is long enough for changes to have occurred but not too long that attrition becomes problematic (e.g. people move on in life, change their contact details, die).

We will contact all 60 patients interviewed for WP1. We anticipate that at least half will be willing to be interviewed (based on previous work and discussion with stakeholders). This will provide a range of perspectives on the longer-term impact of seeing a link worker.

During interviews, we will inquire about topics to further develop aspects of our programme theory that have emerged from WP1. For example, we might ask them to talk about examples of community contacts the link worker suggested, whether they used them and whether or not they continued to access these community resources. We will also use interviews to plot the patient journey, explore any changes on the ONS4 and the GSE, identify changes in networks of support and consider the impact of seeing a link worker on interviewees' on-going well-being and healthcare usage.

6.4 Additional Methods of Data Collection for WP2

As data collection for WP1 has been undertaken, we have become aware that following up patients, as planned for WP2, may be problematic. Recruiting 10 patients from each site for WP1 has not been as easy as anticipated. This is because of the following reasons:

1. We are reliant on link workers to provide eligible patients with information about taking part in the study. As data collection for WP1 has taken place during the pandemic, this task has not necessarily

been a priority for link workers. In addition, at least one link worker left their post just after the WP1 fieldwork ended, which meant we no longer had a contact there to identify patients for us.

2. In some cases, interactions between a patient and link worker have been much shorter and less frequent than anticipated. Sometimes, link workers might only talk to the patient for a one off meeting of 15-20 minutes. Due to changes in service delivery during the COVID-19 pandemic, the majority of interactions with link workers now take place over the phone and patients have often never met the link worker face to face. These combined factors mean that their interaction with a link worker is not always memorable for patients, who may therefore not see the relevance of taking part in an interview on social prescribing, may not recall their interaction with the link worker, or are confused about the different health care and voluntary sector practitioners they have spoken to.
3. Data collection took place during the pandemic; being part of a study may not necessarily have been a priority for patients at this point, especially if experiencing other problems that brought them to the link worker in the first place.
4. We have been unable to contact a number of patients who said to the link worker that we could contact them; they have not responded to emails or telephone calls when we have tried to arrange an interview with them. This may be linked to the points made above and is also due to the nature of people referred to social prescribing who may live in challenging situations. There are examples of people who are homeless, who experience domestic abuse, substance abuse and trauma that mean they may not be readily accessible for interview.
5. At least one patient has said they do not want to take part in a follow up interview.

As a consequence of the following challenges, we anticipate that it will be difficult to interview 40 patients as planned for WP2. We have spoken to our advisory group, PPI group and steering committee about this. They agree that we need to have alternative data collection approaches in place for WP2, and made suggestions about these additional approaches. Hence, we propose that some or all of the following ***additional forms of data collection*** will be undertaken within WP2, alongside the original plan of re-contacting patients who we interviewed in WP1:

a) Ask link workers to invite patients they had seen after the field work period for WP1. A revised participant information sheet has been produced for this purpose (title: WP2 participant information sheet – service users).
b) Ask voluntary sector organisations that support social prescribing to invite people referred to their service/group by a link worker to take part in an interview with us for the study. The revised participant information sheet would cover this group (title: WP2 participant information sheet – service users).
c) Ask each GP practice involved in WP1 to put out a general call for patients who have been referred to the link worker at their practice to provide written feedback to the research team. It will be open to patients who did and did not see or speak to the link worker following this referral. Patients will be made aware of the questionnaire by their surgery through a range of routes – via practice newsletters, direct contact or other communication that the practice has with patients (e.g. online screens at the surgery). A short online questionnaire has been produced for this purpose. Implied consent will be taken when patients return a completed questionnaire. The questionnaire will ask about specific issues related to our developing analysis of data. It will be produced in JISC Online Survey – a platform approved by the University of Oxford for distributing online surveys.

d) Carry out a group interview with each practice's Patient Participation Group (PPG) – either in person or via Microsoft Teams. A participant information sheet has been produced for this purpose (title: WP2 participant information sheet – PPG).
e) Conduct a follow up interview with some of the healthcare professionals/voluntary sector providers interviewed in WP1 (1-2 for each site). A revised participant information sheet has been produced for this purpose (title: WP2 participant information sheet – professionals).

6.5 Methods of Data Analysis

A realist logic of analysis will be applied to data from each WP – initially separately and then combined, to specifically see if it confirms, refutes or calls for refining of the programme theory developed from our completed realist review. Analysis will explore connections between contexts, mechanisms and outcomes to explain how, why and in what circumstances the implementation of link workers might be (or not be) beneficial to patients and/or health care delivery.

6.6 Study Sequence and Duration

The study will last for 30 months. This includes time for study set up and dissemination. WP1 will run for 12 months. Two researchers will spend three months on each case (followed by a month of initial analysis); they will be involved with three cases each. This will involve three weeks of fieldwork for a case and nine weeks undertaking interviews with patients for that case (followed by a short period of analysis). WP2 will involve 11 months of interviews with patients (and other data collection should this be required – see above) and analysis of these data. The sequence of the study is shown in Appendix A.

7. PARTICIPANT IDENTIFICATION

7.1 Study Participants

There will be approximately 102 participants involved (patients, link workers, healthcare professionals and voluntary-community sector staff). Purposive sampling will be used to gather data from a range of perspectives. We anticipate that the amount and range of data collected will be manageable within the timeframe for the study and is also likely to bring us to the point of data redundancy.

7.2 Inclusion Criteria

- Link workers - involved in supporting patients in primary care.
- Healthcare staff working in a practice that has a link worker attached to it.
- Voluntary-community sector staff who have interacted with a link worker as part of social prescribing.
- Adult patients who have had contact with a link worker during a 3 months window - the month before the 3 weeks of fieldwork in a site, the fieldwork period and the month after fieldwork ends.
- Able to converse in English.
- Able to give informed consent.

7.3 Exclusion Criteria

- Unable to converse in English.

- Unable to give informed consent to take part.

For patients - healthcare professionals or the link worker will judge if the individual is undergoing significant psychosocial difficulties that would make it unreasonable to invite the individual to take part (e.g. there are safeguarding issues that make it inappropriate for the researcher to collect data from this patient).

STUDY ACTIVITIES

Work package	Study activity	Location	Length of involvement
WP1	Observation of link worker in meeting with 2 patients (one new, one who they have seen before)	GP's practice, voluntary-community sector venue, Microsoft (MS) Teams or by phone	Collected during the 3 weeks of fieldwork at each site
WP1	Observation of link worker at meetings they may have with health colleagues or voluntary-community sector services	GP's practice, voluntary-community sector venue, MS Teams or by phone	Collected during the 3 weeks of fieldwork at each site
WP1	Daily debrief with the link worker acting as the 'case' for the study to ask what key things they had undertaken that day	GP's practice, voluntary-community sector venue, MS Teams or by phone	20 minutes for 3 weeks (15 days in total per site)
WP1	For each site, we plan to conduct an interview with the link worker, a GP, practice manager, PCN Clinical Director, practice nurse, surgery receptionist, voluntary-community sector staff representative	GP's practice, voluntary-community sector venue, MS Teams or by phone	One off interview – lasting for 30-60 minutes, depending on how much someone has to say on the topic
WP1	For each site, we will conduct an interview with 10 patients who have seen the link worker during the fieldwork, in the month before this or the month after it	Via MS Teams or by phone or in person in a private room at their GP's surgery or at the voluntary sector organisation where they meet the link worker	One off interview – lasting for 30-60 minutes, depending on how much someone has to say on the topic
WP1	Documentary review (documents that relate to the link worker role for the site, e.g. job description, publicity material for patients)	GP's practice, voluntary-community sector venue or emailed to the researcher by the link worker	Collected during the 3 weeks of fieldwork at each site
WP1	Anonymised and aggregated routinely collected data from the link worker (e.g. on number and type of patients referred to them)	Emailed from the link worker to the researcher	This is information already collected by the link worker
WP1 and WP2	Well-being and self-efficacy questionnaires – to be completed by patients at their WP1 and WP2 interviews	Patients will be asked to complete these at the start or end of their initial and follow-up interview	The questionnaires will take about 10 minutes to complete in total
WP2	Follow-up interview with patients who took part in an interview for WP1	Via MS Teams or by phone	One off interview – lasting for 45-60 minutes
WP2	Additional forms of data collection – as listed in section 6.4	These data will be collected remotely (apart from meetings with the PPGs, which could be in person should the group wish)	These data collection activities will be one off interactions with participants

7.4 Recruitment

Link workers who are cases in the study will be asked to identify patients during the fieldwork (or who are seen in the month before then or the month after fieldwork ends). They, or a staff member from the patient's GP surgery, will send out an invitation and participant information sheet to patients on the research team's behalf (either by post, email or text message – with a link to the participant information sheet). A link to a one page summary of the study will be included in electronic versions of the participant information sheet sent via email or text message. If it is sent in the post, a copy of the full participant information sheet will be accompanied by the one page summary. The participant information sheet will ask patients who are interested in taking part to contact the research team by email or phone to express their interest. We will seek variation within the sample of patients involved. A purposive sampling approach will be used so that a range of individuals are interviewed; this may mean that not every patient expressing an interest in taking part will be interviewed. Patients interviewed in WP1 will be invited (by post, phone or email) by the researchers to take part in a follow-up interview for WP2.

We have already been talking to Clinical Commissioning Groups and services that provide link workers in Primary Care Networks about their involvement. We will ask the leads we have been talking to in these sites to identify a link worker to act as a case. We will ensure that this link worker is happy to undertake this role for the research before starting fieldwork at the site.

During the three weeks of fieldwork at a site, the researcher will invite primary care staff and staff from the voluntary-community sector that the link worker interacts with to take part in an interview. Researchers will do this by a) talking about the research at a team meeting and leaving participant information sheets for staff to take away, b) mentioning it directly to staff they meet during fieldwork and passing on to them a participant information sheet, c) providing senior staff at GP practices with posters that invite colleagues to take part in an interview, d) asking the link worker to pass on a participant information sheet to staff in healthcare or voluntary-community sector settings. The participant information sheet and posters will invite staff interested in being involved to contact the research team by email or telephone.

7.5 Informed Consent

Written versions of the participant information sheet will be presented to the participants detailing no less than: the exact nature of the study; what it will involve for the participant; any risks involved in taking part. It will state that the participant is free to withdraw from the study at any time for any reason without prejudice to future care, and with no obligation to give the reason for withdrawal.

The participant will be allowed as much time as wished to consider the information, and the opportunity to question a member of the research team to decide whether they will participate in the study.

When data are collected face-to-face, including observations with patients, written informed consent will be obtained by means of participant dated signature and dated signature of the person who obtained the informed consent. This will be a member of the research team who is suitably qualified and experienced, and has been authorised to do so by the Chief Investigators. A copy of the signed Informed consent form will be given to the participant. The original signed form will be retained at the study site.

When data are collected remotely, by telephone or via Microsoft Teams (MS Teams), verbal informed consent will be taken by the researcher. They will ask the participant the statements on the consent form and the researcher will make a written record that verbal consent has been received. A copy of this record

will be retained at the study site for three years from the end of data collection, which is only accessed by the research team.

Participants must have provided written or verbal consent, based on the latest approved version of the consent form, before any study specific activities are undertaken. All participants will receive a copy of the consent form for their records. This will be via post or a secure email.

Participants involved in any of the additional data collection approaches for WP2, listed in 6.4 above, will be asked to give verbal or written consent, after reading and discussing the participant information sheet. For questionnaire respondents, implied consent will be taken from their completion of the online questionnaire.

7.6 Subsequent Visits

Patients who are interviewed for WP1 will be invited to take part in a follow-up interview 9-12 months after their initial interview.

7.7 Discontinuation/Withdrawal of Participants from Study

During the course of the study a participant may choose to withdraw early at any time. This may happen for several reasons, including but not limited to:

- The occurrence of significant distress during study interviews
- Participant decision

In the case of withdrawal from active involvement, the participant would be withdrawn from the study. Identifiable data already collected with consent would be retained and used in the study. No further data would be collected or any other research procedures carried out on or in relation to the participant.

The Chief Investigators may discontinue a participant from the study at any time if they consider it necessary for any reason including, but not limited to:

- Ineligibility (either arising during the study or retrospectively)
- Significant non-compliance with study requirements

Withdrawal from the study for these reasons would result in the exclusion of the data for that participant from analysis. Depending on the variation and depth of data collected, this participant may have to be replaced.

The reason for withdrawal by Investigators (and by participant, if this information is volunteered) will be recorded in a study file.

7.8 Definition of End of Study

The end of study is the date of the last follow-up interview with the last patient.

8. ANALYSIS

8.1 Description of Analytical Methods

Analysis will test and refine the programme theory developed from our realist review. We will bring together data from different sources (cases, WPs) to compile context-mechanism-outcome configurations (CMOCs). For example, routinely collected data from link workers might highlight that men are less likely to take up the service than women in one of the case sites. We will use other data (e.g. from interviews) to identify mechanisms that explain this outcome. We will look across cases to see if this pattern is recurring or unique and consider contextual differences that may have accounted for its absence in other settings (because the requisite mechanism has or has not been triggered).

We will use a realist logic of analysis set out by Pawson and Tilley (1997) to bring together the different sources of data. We will apply a range of reasoning processes associated with realist analysis (Pawson, 2013) to these data – such as juxtaposing data, unpicking conflicting data, and consolidating data – to explain why differences may arise across settings, and how and why identified outcomes have occurred (or not). Our ongoing application of a realist logic of analysis will be guided by a series of questions that members of the team have used in other realist projects:

- Is this a piece of data that is relevant to programme theory development?
- If so, do its contents provide data that may be interpreted as functioning as context, mechanism or outcome?
- For data that has been interpreted as functioning as context, mechanism or outcome, which configuration (CMOC) does it belong to?
- Are there further data to inform this particular CMOC - contained within this piece of data or other sources? If so, which other sources?
- How does this particular CMOC relate to others that have already been developed?
- How does this particular CMOC relate to the programme theory?
- In light of this particular CMOC and any supporting data, does the programme theory need to be changed?

Analysis of WP1 data will begin during the first set of fieldwork. The team will meet regularly to discuss emerging data and how it informs the research question and objectives. Findings from each case will be used to refine data collection for the next one. It will also support questions asked in WP2 interviews.

We will follow RAMESES quality and reporting guidelines when conducting and reporting on this study (Wong et al., 2017). In line with standards for reporting realist research, two criteria will be used to assess data quality: a) can it contribute to theory development/refinement, and b) are methods used to produce the data credible and trustworthy? Data will be judged on the contribution they make to understanding of specific CMOCs and the overall programme theory. We will judge the rigour and trustworthiness of data collection and analysis in terms of 'fit for purpose' – do data and interpretation of it help with developing or testing or refining our CMOCs/programme theory ('relevance')? – and examining whether the piece of data used was underpinned by credible and trustworthy methods ('rigour'). Triangulation will be important here, to support with *credibility* of our interpretations, whereby different types or sources of data are used. We will also seek stakeholder feedback from our PPI group and advisory group to explore how far our interpretations make sense to a range of individuals. This will assist with *transferability*. We will establish an audit trail, documenting how we moved from raw data to final findings, helping to establish *confirmability*.

9. DATA MANAGEMENT

9.1 Access to Data

Direct access will be granted to authorised representatives from the Sponsor or host institution for monitoring and/or audit of the study to ensure compliance with regulations.

9.2 Data Recording and Record Keeping

Study data will be stored electronically as Word, NVIVO, SPSS or Excel files, apart from consent forms which will be kept as paper versions in a locked cupboard at the University of Oxford (a copy of each consent form will also be scanned, uploaded and stored on a secure shared server hosted by the University of Oxford, which is only accessible to members of the research team).

Participants will be identified by a unique study specific code in any database. Names and any other identifying details will not be included in any study data electronic file. Codes next to participants' personal information (name, age, gender, ethnicity) will be kept in a separate file – not with the research data.

As soon as the researcher is able, they will transfer the recording of an interview from the audio recorder to a secure shared server. It will be saved using the participant's study code (not their name). A copy of the recording will be sent to the transcribing service that will be working on this project with us. This company has been approved by the Chief Investigators' department to undertake this type of work for research purposes; it will be asked to sign a confidentiality agreement that includes an agreement to delete all data once it has been transcribed. Once the transcription of an interview has been received by the research team, and checked against the audio recording, this recording will be removed from the shared server. Transcripts of interview data (saved with a study identifier rather than someone's name) will be kept for three years from the end of data collection.

Results from questionnaires that patients complete (the ONS4 and the GSE) will be entered into an Excel or SPSS file (using study codes rather than participants' names) and stored on a secure server hosted by the University of Oxford for three years from the end of data collection.

Observational data and notes from the daily debriefs with the link worker will be stored on the secure server for the project and deleted three years after the end of data collection.

Consent forms will be removed from the secure server (and paper copies will be destroyed) three years from the end of data collection.

Contact details for participants will be destroyed at the end of the study, once a summary of findings has been sent to them either as a postal or electronic version.

10. QUALITY ASSURANCE PROCEDURES

The study may be monitored or audited by the Sponsor or funder. In addition, a steering committee will have oversight of the project and will be able to monitor its progress. This is to be composed of two academics, two providers of primary/social care and two PPI contributors.

11. ETHICAL AND REGULATORY CONSIDERATIONS

11.1 Declaration of Helsinki

The Investigators will ensure that this study is conducted in accordance with the principles of the Declaration of Helsinki.

11.2 Approvals

Sponsor approval will be secured for the protocol, written and verbal consent forms, participant information sheets, topic guides for interviews, templates for collecting observational data, questionnaires for patients, and posters to be displayed in primary care staff rooms advertising the study to healthcare and voluntary-community sector staff. An application will then be submitted to an appropriate Research Ethics Committee (REC), HRA (where required), and host institution(s) for written approval.

The Investigators will submit and, where necessary, obtain approval from the above parties for all substantial amendments to the original approved documents.

11.3 Other Ethical Considerations

Patients involved will be invited, during an interview, to talk about their life circumstances that resulted in them seeking support from a link worker. They will also be invited to talk about support received from this individual. Some people may find it distressing talking about these topics. The researcher will be vigilant of a patient's verbal and body language during an interview. Should someone show signs of distress, the researcher will stop the recording and ask the interviewee if they wish to continue. They will be encouraged to speak to their link worker, GP or a member of their family.

Patients will be informed in the participant information sheet that confidentiality will be maintain in terms of what they disclose, unless they say something suggesting they or someone close to them is at significant risk of harm. In such cases, the researcher would be bound to tell the individual's link worker or GP.

During the study, the impact of COVID may still be a consideration. When collecting any data in person (rather than remotely), we will observe social distancing regulations at the time in the place of data collection (e.g. GP surgery or voluntary-community sector space), and wear masks if required.

11.4 Reporting

The Chief Investigators will submit once a year throughout the study, or on request, an Annual Progress report to the REC Committee, HRA (where required), host organisation and Sponsor. In addition, an End of Study notification and final report will be submitted to the same parties.

11.5 Participant Confidentiality

The study will comply with the UK General Data Protection Regulation (GDPR) and Data Protection Act 2018, which require data to be de-identified as soon as it is practical to do so. The processing of the personal data of participants will be minimised by making use of a unique participant study number/code only on all study documents and any electronic database(s). All documents will be stored securely and only accessible by study staff and authorised personnel. The study staff will safeguard the privacy of participants' personal data.

11.6 Expenses and Benefits

Patients who are interviewed will receive a £20 gift voucher as a token of thanks for their involvement. They will receive a £20 voucher after completing an initial interview and another £20 voucher after a follow-up interview. Patients taking part in WP2 activities (see 6.4 above) will also receive a £20 voucher for their involvement, apart from those who provide written feedback in the form responding to a short online questionnaire. This will be so they can provide anonymous feedback, and because their contribution will be relatively short – 10 minutes in total.

12. FINANCE AND INSURANCE

12.1 Funding

The study has been funded by the National Institute for Health Research (Ref: NIHR130247) through a Health Services and Research Delivery (HS&DR) award.

The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

12.2 Insurance

The University of Oxford maintains Public Liability and Professional Liability insurance, which will operate in this respect.

12.3 Contractual arrangements

Appropriate contractual arrangements will be put in place with all third parties.

13. PUBLICATION POLICY

The Investigators will be involved in reviewing drafts of the manuscripts, abstracts, press releases and any other publications arising from the study. Authors will acknowledge that the study was funded by the NIHR. Authorship will be determined in accordance with the ICMJE guidelines and other contributors will be acknowledged.

14. DEVELOPMENT OF A NEW PRODUCT/ PROCESS OR THE GENERATION OF INTELLECTUAL PROPERTY

It is unclear if there will be intellectual property (IP) in terms of a new product/process from this research. However, if this does arise, ownership of IP generated by employees of the University vests in the University. The University will ensure appropriate arrangements are in place as regards any new IP arising from the trial.

15. ARCHIVING

Word documents of transcripts from interviews and notes from observations, Excel or SPSS files containing patients' responses to a questionnaire, anonymised and aggregated routinely collected data from link workers, observation and documentary data will be stored on a secure University server for three years from the end of data collection. It will be deleted from this server by the Chief Investigators at this point.

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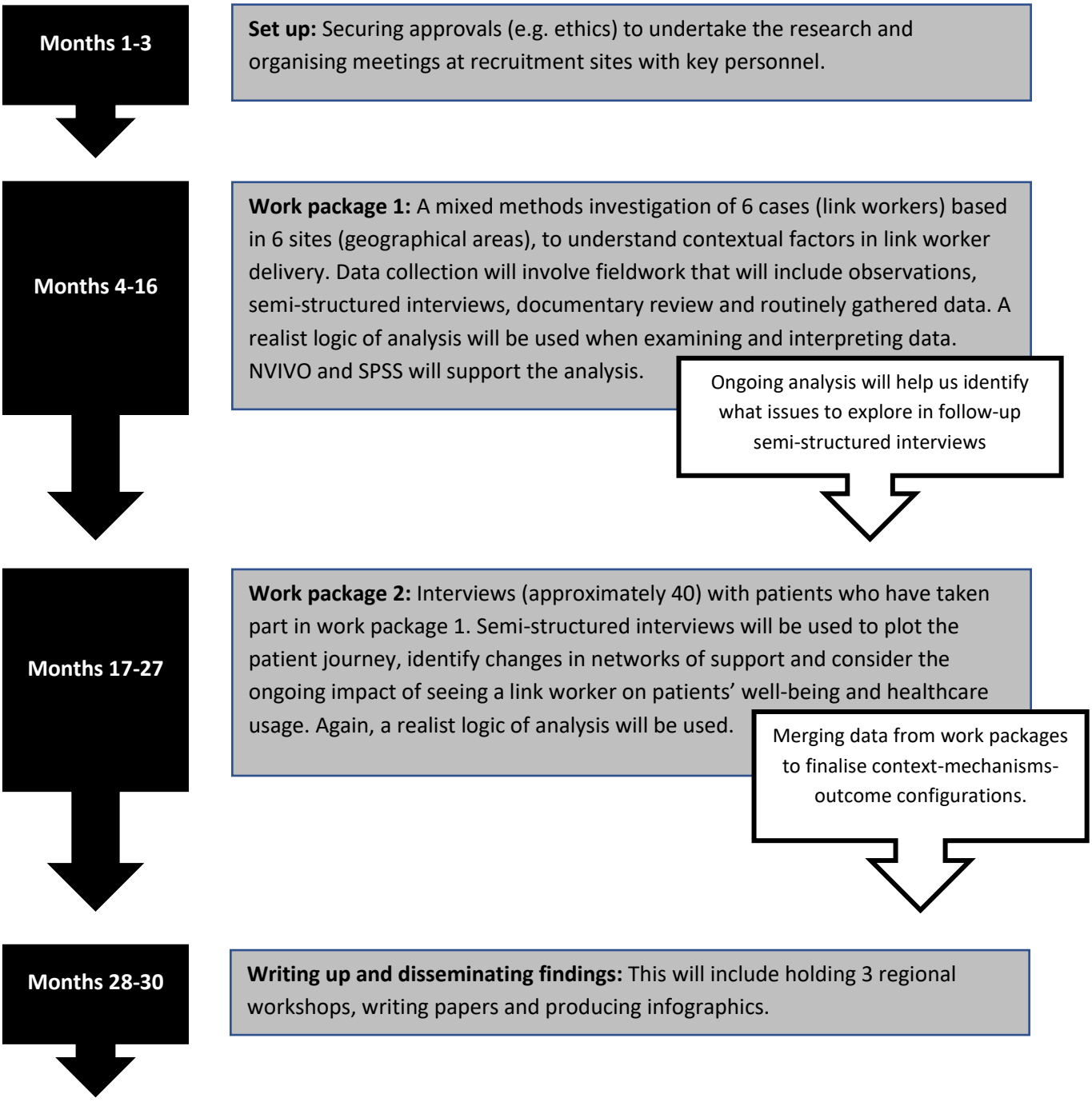
APPENDIX A: STUDY FLOW CHART



APPENDIX B: AMENDMENT HISTORY

Amendment No.	Protocol Version No.	Date issued	Author(s) of changes	Details of Changes made
1.	Version 2	Oct 21	Stephanie Tierney	Having a one page summary to accompany the full participant information sheet (either as a link in the participant information sheet, or as a hard copy with the full participant sheet if sent by post) Adding a disclaimer statement
2.	Version 3	Nov 21	Stephanie Tierney	Inviting patients who have been observed to also take part in an interview Giving patients the option to be interviewed in person should they wish (in a private room at their GP's practice or a voluntary sector organisation where they meet the link worker) – this is alongside being able to be interviewed by telephone or Microsoft Teams
3.	Version 4	April 22	Stephanie Tierney	Additional approaches to data collection in work package 2. We will employ some or all of the following additional forms of data collection as detailed in section 6.4: • Asking link workers to pass on information to patients not interviewed in WP1 to take part in a WP2 interview • Asking voluntary sector organisations to invite people referred to them by a link worker involved in WP1 to take part in an interview • Asking GP practices to invite patients to provide written feedback on their experiences of seeing a link worker or declining to see a link worker (via a link to a short questionnaire) • Carrying out a group interview with the Patient Participation Group at each site involved in the study • Conducting follow up interviews with health professionals or voluntary sector providers interviewed for WP1

List details of all protocol amendments here whenever a new version of the protocol is produced. Protocol amendments must be submitted to the Sponsor for approval prior to submission to the REC committee, and HRA (where required).