RESEARCH PROTOCOL

Multi-region (and multi-level) evaluation of the roll out of social prescribing link workers in primary care

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2 Study Synopsis

Title	Multi-region evaluation of the national roll out of social prescribing link workers in primary care
Background	Social prescribing links patients in primary care with sources of support within the community. With national policy implementation underway across the UK, there is now a need to understand the impact of social prescribing link worker services and how they can be developed in the future.
Aims	Our overall aim is to take a multi-regional approach to map current provision and service configuration and to assess whether access, engagement and outcomes vary by delivery model, geography and population characteristics over time. Objectives 1. To establish the key features and variations in delivery models for link worker social prescribing services within and between each region. (WP1) 2. To assess inequalities in access, uptake and engagement based on area-level and population characteristics (age, gender, ethnicity, area deprivation, availability of community assets, and rurality). (WP2) 3. To understand experience and acceptability of the referral process, the therapeutic encounter and the process of accessing and engaging with social prescribing services from a range of perspectives. (WP3) 4. To assess health and wellbeing and service outcomes, and whether outcomes vary within and between services delivered and by population characteristics (age, gender, ethnicity, area deprivation, availability of community assets, and rurality). (WP4) 5. To explore the value and economic sustainability of link workers in primary care. (WP5) 6. To ensure relevance to policy need and to maximise the impact and use of findings in decision-making processes as they occur. (WP6)
Design	Over 3 years, we will employ a multi-region mixed methods approach to map current provision and service configuration and to assess whether access, engagement and outcomes vary by delivery model, geography and population characteristics over time. The regions are: NIHR Applied Research Collaboration Greater Manchester NIHR Applied Research Collaboration North East and North Cumbria NIHR Applied Research Collaboration West NHS Greater Glasgow and Clyde NHS Lothian The rationale for taking a multi-regional approach is twofold. First, doing so represents a pragmatic and efficient use of resources. The HSDR brief called for a broader (national/multi-regional) understanding of the impact of social prescribing initiatives delivered by link workers and to do this necessitates utilisation of nationally and locally available routine data. Second, the selected regions are large and encompass multiple social prescribing link worker initiatives. They also provide sufficient variation in population age, gender and ethnicity, levels of socio-economic deprivation, geographical location and in

	distances to health and care services to understand how link worker functions are organised and funded in different settings.
Planned Sample Size	Region by region mapping of services to generate a maximum variation sample of eight case study sites for in-depth exploration. 160 qualitative interviews (WP3)
Analyses	WP1 Implementation: In Year 1, we will map services in Greater Manchester, the North East of England, Bristol and Gloucestershire, and in parts of Scotland to develop our understanding of how services are organised and funded in different settings. We will highlight key features relating to funding, organisation and delivery and taking account of characteristics that might influence access and experience of delivery. From this, we will develop a taxonomy of services and use this to select a maximum variation sample of eight case study sites for in-depth exploration in the WPs that follow. WP2 Access and Equity: In Years 2 and 3, we will examine variations in access, uptake and engagement based on area level and population characteristics (age, gender, ethnicity, area deprivation, availability of community assets, and rurality) using three datasets: Aggregate-level national analysis in England using Oxford RCGP Research and Surveillance Centre's Observatory on Social Prescribing; Individual -level national analysis using data from CPRD; Individual-level regional analysis using local service datasets. WP3 Experience and acceptability: In Years 2 and 3, will use candidacy and self-determination theory as a lens to explore the experience and acceptability of the referral process, the therapeutic encounter and the process of accessing and engaging with social prescribing services. We will do this through qualitative interviews with matched samples of referring professionals, link workers, service users and community service providers across the eight case study sites (20 matched samples per case site). WP4 Outcomes: In Years 2 and 3, will assess health and wellbeing and service outcomes, and whether outcomes vary within and between services delivered and by population characteristics (age, gender, ethnicity, area deprivation, availability of community assets, and rurality). We will examine impacts using two analytic approaches: matched comparisons of outcomes between referred and non-referred individuals using data from practice records and a national longitudinal survey; and longitudinal analysis of association between numbers of link workers and outcomes of populations targeted by link workers using data from two national surveys. WP5 Economic sustainability: In Years 2 and 3, will estimate link worker cost-effectiveness in terms of additional cost per additional person linked to social prescribing schemes and then develop a model to produce a cost utility analysis. This will be supplemented by detailed identification of costs and benefits that fall outside the scope of the NHS and Personal Social Services, consideration of whether a distributional approach substantially affects the results, and assessment of different funding models for link workers in the future.

3 Introduction

Social prescribing is a way of linking patients in primary care with sources of support within the community. It provides GPs and other health professionals with a non-clinical referral option that can operate alongside existing treatments to improve people's health and well-being.

The link worker's role is to support people referred from primary care, with social, emotional and practical needs to find solutions that will improve their health or wellbeing. This usually involves linking people to information, advice and activities, many of which are provided by the voluntary and community sector organisations. How these link worker services are locally organised and delivered varies widely across the country.

Across the UK, social prescribing models delivered by link workers are being implemented and piloted in primary care.[1, 2] In England, link workers are funded in Primary Care Networks (PCNs) as part of the England GP contract agreement to bring additional capacity to primary care.[3] In Scotland, embedding link workers in GP practices or clusters is a key priority of the 2018 Scottish General Medical Services Contract.[4]

In both countries, the aim is to strengthen connections between community resources and primary care, reduce health inequalities in areas of high socio-economic deprivation and alleviate pressures on the wider general practice team.[5]

We have a good theoretical understanding of how the link worker role could work to support access and engagement with services.[6, 7] But we also know from the existing evidence base that there are high levels of attrition and not all individuals referred actually go on to engage with support and activities provided in the community. However, qualitative studies consistently find that patients who do engage generally report positive experiences.[8, 9]

To date, research on social prescribing has evaluated the effects of individual services usually in isolation from the wider health system in which they are situated. It is well documented that this evidence base is sub-optimal and subject to a high risk of bias.[10, 11] Much existing evidence is derived from small scale studies that are limited by poor design and reporting, making it difficult to reliably judge how and in what circumstances social prescribing could deliver benefits. Few rigorous evaluations exist. Those that do have so far failed to demonstrate improved health and wellbeing for service users, but suggest that finding ways to improve access and engagement with services may lead to better overall outcomes.[12]

We know that engagement in community assets can improve health and well-being.[13] However, we do not know how people become engaged with community assets and if the link worker model will encourage engagement and or enhance access and equity.

With national policy implementation underway in both England and Scotland, there is now a need for a broader understanding of how to increase access, uptake and engagement and to understand the impact of social prescribing link worker initiatives to refine and enhance roll out.

4 Rationale for approach

The overall aim of this research programme is to provide a comprehensive assessment of the implementation, delivery and impact of link worker services to inform future policy. We plan to take a multi-regional mixed methods approach to map current provision and service configuration and to assess whether access, engagement and outcomes vary by delivery model, geography and population characteristics over time. The regions are:

NIHR Applied Research Collaboration Greater Manchester
NIHR Applied Research Collaboration North East and North Cumbria
NIHR Applied Research Collaboration West
NHS Greater Glasgow and Clyde and NHS Lothian

The rationale for taking a multi-regional approach is twofold. First, doing so represents a pragmatic and efficient use of resources. The HSDR brief calls for a broader (national/multi-regional) understanding of the impact of social prescribing initiatives delivered by link workers and to do this necessitates utilisation of nationally and locally available routine data. We are aware that a lack of data-sharing agreements and information governance more broadly can pose significant barriers to the conduct of national programmes of evaluation.[14] We believe that by grounding the evaluation in settings where the research team is active, and are part of large established research practice partnerships with links to primary, community and voluntary sector services, mitigates against this risk.

The second reason is one of geography, population reach and history. The four regions are large and encompass multiple social prescribing link worker initiatives. The regions also provide sufficient variation in population age, gender and ethnicity, levels of socio-economic deprivation, geographical location and in distances to health and care services to understand how link worker services are organised and funded in different settings. In addition, health and social care in Scotland is a devolved power and the organisation of health and social care differs from England, again offering a different perspective.

5 Study objectives

Our overall aim is to take a multi-regional approach to map current provision and service configuration and to assess whether access, engagement and outcomes vary by delivery model, geography and population characteristics over time.

Objectives

1. To establish the key features and variations in delivery models for link worker social prescribing services within and between each region. (WP1)
2. To assess inequalities in access, uptake and engagement based on area-level and population characteristics (age, gender, ethnicity, area deprivation, availability of community assets, and rurality). (WP2)
3. To understand experience and acceptability of the referral process, the therapeutic encounter and the process of accessing and engaging with social prescribing services from a range of perspectives. (WP3)
4. To assess health and wellbeing and service outcomes, and whether outcomes vary within and between services delivered and by population characteristics (age, gender, ethnicity, area deprivation, availability of community assets, and rurality). (WP4)
5. To explore the value and economic sustainability of link workers in primary care. (WP5)
6. To ensure relevance to policy need and to maximise the impact and use of findings in decision-making processes as they occur. (WP6)

6 Research plan

There are deep-rooted and persistent regional health inequalities within the UK.[15] In England, the Health and Social Care Act 2012 required all health bodies to have due regard to reducing health inequalities between the people of England and to deliver services based on need. This is mirrored in Scotland where services and systems are expected to be accessible, available appropriate and of high quality.[16] Despite this, evidence of the inverse care law where the availability of good medical care tends to vary inversely with need, persists in primary care.[17, 18]

Given a key driver of social prescribing policy is to aim to reduce health inequalities where they persist, we propose six interlinked work packages delivered over 36 months that are designed to map current provision and service configuration and to assess whether access, engagement and outcomes vary by delivery model, geography and population characteristics over time.

We will be guided by the Health Disparities Framework.[19] This framework recognises that the determinants of health inequalities are multi-level and any evaluation seeking to understand these needs to focus not only on the individual recipients of care, but on the therapeutic encounter, the providers and the ways by which services are shaped by the wider health system in which they are delivered. This multi-level exploration of implementation, access, equity and outcomes is reflected in our planned approach.

6.1 WP1 Implementation – led by Wilson

Overarching research question: What are the key features and variations in delivery models for link worker social prescribing services within and between each region?

Timeframe: 12 months - Month 1 through to 12 months

Mature: Desk research combined with sense-making consultation

Approach: In each region, we will contact the designated local lead for person and community centred approaches in each Integrated Care System (Health and Social Care Partnerships in Scotland) to help identify candidate services. We will contact the designated local lead for identified social prescribing link worker services to request documentation relating to the conception, management, design, delivery, and evaluation (where they exist). This will be supplemented by any publicly available information on delivery and by ongoing work on the development and contractual arrangements of Primary Care Networks in England being undertaken by our NIHR Policy Research Unit in Health and Social Care Systems and Commissioning.[20] For each identified service, we will seek to understand:

- The background to the development and funding of each link worker service – whether directly employed via a PCN or GP cluster or provided by a sub-contracted provider
- How each link worker service fits with other (pre-existing) services
- The priority groups for whom the service is intended, in terms of demography and needs.
- Who can make referrals and how referrals are made.
- The backgrounds, experience and expertise of employed link workers.
- The scope of activity of link workers, their connectedness with local communities and integration with primary care.

- The type of link worker service provided – i.e. 'light' (signposting) through to 'holistic' (e.g. accompanying clients to activities) and whether it is time-limited (e.g. six sessions) or open-ended.
- The services/activities/community assets people can be referred to and how they are resourced.
- The availability of routine data on referrals, encounters and outcomes including, how it is collected, stored and links to other data management systems in primary care.
- The costs of employing and supporting link workers or the costs of sub-contracts for link worker services
- The geographical and demographic characteristics of each service.
- Whether there have there been any adaptations or change of focus to the service over time
- How Covid-19 has affected service delivery, including people served and asset availability.

Where information is lacking on the above, we will supplement data sources by consulting with the leads of each local service. If necessary, and with appropriate ethical approval, will conduct interviews with providers and commissioners to provide a well-rounded perspective of how each identified service functions.

From this data, we will produce a taxonomy of link work services. We will use the Template for Intervention Description and Replication (TIDieR)[21] to provide a full and accurate description of each service, including the additional items of ‘voice’ (who was involved in preparing the description) and ‘modification’ (to convey any change in service implementation over time).[22]

The accuracy of the TIDieR descriptions will be sense-checked with representatives from each local service. The overall representativeness of the taxonomy of delivery models will be further sense-checked with our PPIE and Research Advisory Groups, and with NHSE national delivery team, Public Health Scotland and other key agencies and regional stakeholders (see WP6 Informing policy implementation).

We will use this taxonomy to develop a sampling strategy to select eight case study sites for WP2, WP3 and WP4. We will employ a maximum variation design to ensure variation in service types and taking into account of characteristics that might influence access and experience of delivery at the local level. These will include individual level and area-level characteristics, deprivation levels as measured by IMD/SIMD, urban/rural locations and the availability of community assets/activities.

6.2 WP2 Access and equity - led by Munford

Overarching research question: Are there inequalities in access, uptake and engagement based on individual-level, area-level and population characteristics (including age, gender, ethnicity, area deprivation, availability of community assets, and rurality)?

Timeframe: 24 months – from month 12 onwards

Nature: Quantitative analysis using large scale survey, population and NHS administrative data

Approach: We will examine variations in referral, uptake and engagement by individual and area level characteristics using three datasets:

1. Aggregate-level national analysis in England using Oxford RCGP Research and Surveillance Centre’s Observatory on Social Prescribing

2. Individual-level national analysis using data from Clinical Practice Research Datalink
3. Individual-level regional analysis using local service datasets

We will use quantitative analysis of service level administrative data to compare the measured characteristics of those referred, those referred but who declined the offer, and non-referred service users within and across service models and the duration of engagement. These administrative data will be supplemented with bespoke data we have already identified through stakeholder engagement and additional data that we identify during WP1. We will investigate variations in uptake and engagement based on individual level characteristics such as age, gender, ethnicity, and disability.

As well as individual level characteristics, we will investigate the effect of area-level characteristics on uptake and engagement with social prescribing support. For example, we will consider the effects of area deprivation and rurality, what schemes are currently in operation, and the availability of community assets for people to be socially prescribed to attend.

The specific research questions that we will answer using routine and bespoke data are (full descriptions of the sources of data are provided below):

- Are there groups/ populations that are more or less likely to be referred into link worker social prescribing services? What are their health profiles, do they share any characteristics, and is this influenced by local need and availability of community assets? (Stage 1 of Figure 1, see Boxes 1 and 2 of Figure 2 for characteristics to be considered.) (CPRD & Local data such as Elemental)
- Are there groups/ populations that are more or less likely to visit a link worker and have a 'therapeutic encounter', after an initial referral? Are there particular characteristics that are predictive of non-attendance to the link worker? (Stage 2 of Figure 1, see Boxes 1, 2 and 3 of Figure 2 for characteristics to be considered.)(CPRD & Local)
- Are there groups/ populations that are more or less likely to not attend and not engage with the socially prescribed advice, after the therapeutic encounter with a link worker? Are there particular characteristics that are predictive of non-attendance/participation? (Stage 3 of Figure 1, see Boxes 1, 2 and 3 of Figure 2 for characteristics to be considered.) (CPRD & Local)
- What proportion of therapeutic encounters lead to onward referrals to community services/activities? (Local/ Elemental)
- How long does a person engage with the service? Does this vary by characteristics? (Local)
- What are the characteristics of those who continue to engage with assets? (see WP3 for further exploration of engagement) (Local)

Essentially, we will analyse Stages 1 – 3 of the 'journey' described in Figure 1, particularly focussing on inequalities and observable differences based on individual, area, and service provision characteristics at each stage of the journey.

Sources of data

Aggregate-level national data in England

Data from the Oxford RCGP Research and Surveillance Centre's Observatory on Social Prescribing [23] will also be used to analyse the relationship between characteristics and referral and uptake of social prescribing. This interactive web-based dataset contains information on (i) referral to social prescribing service, (ii) social prescribing declined, and (iii) all social prescribing activity (referral and declined). Rates can be obtained based on (a) regions of England, (b) age groups, (c) deprivation, (d) ethnicity, and (e) gender. However, whilst informative, these trends mask much important individual level variation and are likely to be prone to ecological fallacy; that is aggregate – or area-level – data can lead to inferences that are not true about individuals living within those areas. A more detailed understanding of social prescribing activity – and particularly inequalities – can only be achieved with individual level data.

Box A: SNOMED Codes for social prescribing

SNOMED CT coding for social prescribing has been established to support national data collection on social prescribing referrals from primary care. The codes are as follows:

871691000000100 | Social prescribing offered (finding)

871711000000103 | Social prescribing declined (situation)

871731000000106 | Referral to social prescribing service (procedure)

Individual-level national data from Clinical Practice Research Datalink (CPRD)

We will therefore supplement the above 'macro' level analysis with a more 'micro', or individual-level focussed analysis, by using data from the Clinical Practice Research Datalink (CPRD), which now contains SNOMED codes for whether an individual has been offered a referral to a link worker (see Box A). Additionally, CPRD contains information relating to whether the individual declines the referral or whether they accept the referral. CPRD contains a rich set of information on an individual, including information about their health as well as age, gender, ethnicity, and the deprivation in the area of their home postcode. CPRD can also be linked to Hospital Episode Statistics (HES) for additional information on diagnosed conditions and use of health services, which members of our team have recently done.[24] We will use this information to assess the key predictors of (i) referral into social prescribing and (ii) whether the individual takes up the offer. CPRD is a large sample of practices in England and Scotland that has been shown to be nationally representative in terms of the key characteristics we will consider.[25, 26]

We acknowledge that it is possible that not all referrals to social prescribing will be accurately recorded in SNOMED codes. However, we believe that this will likely to be practice-level issue; some practices will use SNOMED codes and some will not. It is unlikely that a practice would use SNOMED for some people and not others. To overcome this potential limitation, we will identify practices with zero or very low rates of referrals and (i) compare their representativeness to the remaining sample that do have use of the relevant SNOMED codes and (ii) exclude the practices with zero or low referrals and examine the sensitivity of the main results.

Individual-level regional data

In addition to the CPRD and the Oxford Observatory data, we will use data from the eight case study services identified in WP1. The data sources and their availability will be mapped to services as part of the taxonomy of service models. Data sharing and processing agreements in line with Information Commissioner Office advice, will be sought for each selected case study service.

To illustrate how we will use local data, we use Greater Manchester as an example. The digital software platform *Elemental*,[27] which is an 'add-on' to electronic health records, is now used in eight out of the ten local authorities in Greater Manchester. The data are linked to electronic health records and the same information as contained in CPRD can be obtained. The data are owned by the individual local authorities in GM, and we have begun the process of obtaining data sharing agreements, facilitated by the GM Health and Social Care Partnership and the GM Combined Authority. Through conversations with Liam Gilfellon (Director of Business Development and Relationships of the Concern Group, an umbrella organisation of mental health and wellbeing groups), we have established that the *Elemental* data platform will be rolled out across Gateshead, Newcastle, and North and South Tyneside from summer 2021 onwards. Additionally, after a meeting with *Elemental* themselves, we are aware that Sirona (who cover large parts of the ARC West region) are in discussions with *Elemental* about rolling out the platform there too. Finally, NHS Lothian is planning a trial *Elemental* commencing spring 2022. WP1 will map data availability in each region and we intend to obtain similar data sharing agreements for each selected case study site. In our two Scottish areas, we know that data on referrals, demographics, engagements and health and wellbeing (SWEMWEBS) are collected at the local level.

We will compare the results from the nationally representative CPRD analysis with the region-specific analysis. *Elemental* contains richer information on social prescribing and hence will allow us to investigate the associations found at the national level further. This additional information includes: (i) who made the referral and when it was made; (ii) the reason for the referral; (iii) the link worker the individual was referred to; (iv) if and when the individual contacted the link worker; (v) what was discussed at the meeting; (vi) the link worker's recommendation(s)/referral(s); (vii) if the individual took-up the advice and visited the service they were referred to; and (viii) how long they engaged with the service. This information is reported by a combination of the medical professional, the link worker, and the individual themselves. Each individual actor can only access certain parts of the system, but we will access the anonymised data in full.

Using local data sources such as *Elemental* allows us to consider the characteristics of the referrer and the link worker. For example, it allows non-medical staff (such as social workers) to refer individuals to a link worker. Building on the work of WP1, we will analyse variations in uptake of advice and duration of engagement based on who can make referrals.

Methods

In the aggregate analysis, the key outcomes are proportions (e.g. proportion of people referred to a link worker, the proportion who attend the link worker). We will model the outcomes using fractional multinomial logistic models[28] and additionally account for confounders at the area-level (such as age structure, ethnic profile, area deprivation, rurality) We will use interrupted time series analysis to test whether there are structural breaks at the times of roll-out of link workers.[29]

In the individual-level analysis, the key outcomes are binary responses (e.g. whether referred, whether attended). We will model the outcomes using multi-level logistic regression allowing for clustering, both in terms of time effects and area effects. We will account for confounders at individual, area, and population level (e.g. people in deprived areas might have similar levels of referral for mental health advice to affluent areas. Yet the prevalence of mental health problems is much higher in deprived areas) and use these variables to examine for the existence of inequalities. For example, the parameter on the 'rural' terms will inform us if there are differences between rural and urban areas.

Figure 1: Proposed model of a generic referral pathway for social prescribing

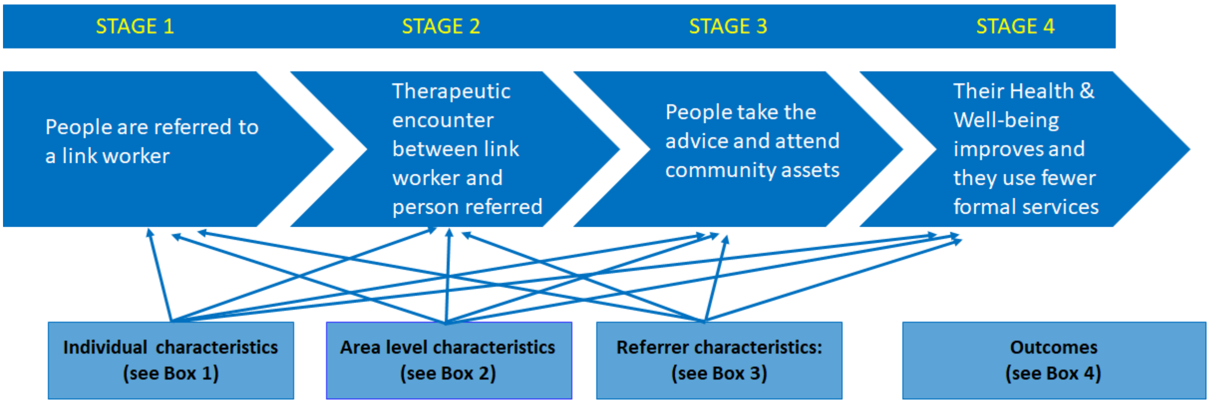

Figure 2: Characteristics to be considered (including known sources of data)

Box 1: Individual characteristics

- Age (CPRD, Local, ELSA)
- Gender (CPRD, Local, ELSA)
- Ethnicity (CPRD, Local, ELSA)
- Underlying health condition(s) (CPRD, Local, ELSA)
- Wider determinants/ social needs (Local, ELSA)
- Employment status (Local, ELSA)
- Education (Local, ELSA)
- Whether or not the person has dependents (Local, ELSA)

Box 2: Area-level characteristics

- Rurality (CPRD, Local, ELSA, through ONS)
- Deprivation (measured by IMD/SIMD) (CPRD, Local, ELSA, through ONS)
- The social prescribing schemes in use within their locality (WP1)
- The social prescribing resources ('community assets') available (WP1)

Box 3: Referrer characteristics

- Age (Local)
- Gender (Local)
- Occupation (e.g. GP, social worker, etc.) (Local)
- Other characteristics available from Local data – e.g. length of time in practice (Local)

Box 4: Outcomes

- Measures of self-reported health (APS, Local, ELSA)
- Measures of self-reported well-being (e.g. PAM; ONS 4; SWEMWEBS) (Local, ELSA)
- Use of formal services (i.e. primary care, secondary care, etc.), reliance on informal care (CPRD, Local, GPPS, ELSA)
- Work and sickness absence (Local, ELSA)
- Impairment of usual activities, role functioning (Local, ELSA)

CPRD = Clinical Practice Research Datalink; ELSA = English Longitudinal Study of Ageing (see WP4 for an overview of ELSA); GPPS = General Practice Patient Survey; IMD = Index of Multiple Deprivation; SIMD = Scottish Index of Multiple Deprivation; ONS4 = suite of four questions used by the Office for National Statistics (ONS); PAM = Patient Activation Measure; SWEMWEBS = Short Warwick-Edinburgh Mental Well-being Score.

6.3 WP3 Experience and acceptability – Led by Sanders, O'Donnell and Wyke

Overarching research question: To understand experience and acceptability of the referral process, the therapeutic encounter and the process of accessing and engaging with social prescribing services from a range of perspectives

Timeframe: 24 months – from month 13 onwards

Nature: Qualitative research (subject to Ethical approval)

Approach: In each of the eight case study sites selected in WP1, we will focus on three aspects of the pathway for social prescribing, namely the referral process, the therapeutic encounter and levels of access to and engagement with support and activities offered by social prescribing services.

Candidacy describes how people's eligibility for healthcare is determined between themselves and health services.[30, 31] It is best understood as a continually negotiated property, subject to multiple influences arising both from people, their characteristics and social contexts, and from influences on the allocation of resources and configuration of services. Access to and engagement with social prescribing services therefore represents a dynamic interplay between individuals and their current and past experience of the professionals and services with which they interact.

Self determination theory (SDT) is a psychological theory concerning human wellbeing, motivation and behaviour change,[32, 33] For new behaviours to be sustained requires the satisfaction of three innate needs: autonomy (a sense of control over one's own activities and behaviours), competence (a sense of ability to influence outcomes) and relatedness (a sense of connection to and interaction with others). Satisfaction of all three needs is necessary for an individual's actions to be 'self-determined', and that actions which are more self-determined are likely to be maintained and to lead to greater wellbeing.[32] Our team found SDT a useful theory to explain variation in patients' experience of change, or lack of change, from their engagement with the Deep End Links Worker Programme.[34] In particular, relatedness was central to the interaction with the link worker. Patients describing the greatest change also experienced a greater sense of competence and autonomy, and described more identified, and in some cases integrated, regulation of behaviour.[35]

We will use candidacy as a lens to explore the experience of different models of social prescribing and SDT to explore variations of change through engagement with the models. We will do this through qualitative interviews with matched samples of referring professionals, link workers and patients across the eight case study sites. These interviews will aim to provide in-depth understanding of the indicative questions explored in WP2 and will also seek to understand:

- How people's eligibility for social prescribing is determined between themselves and the health professionals/ services they interact with
- The nature of issues addressed (how many, what problems)
- The experience of the therapeutic encounters – the scope of link workers' work with the patient, sequencing of work and activities, follow-up and perceived success from both link workers' and patients' perspectives
- The experience of encounters used to outline:
    - Number and nature of issues

  - How issues were prioritised
  - Perceived changes or lack of changes as a result of engagement

6.3.1 Participant recruitment and data collection

We expect to conduct interviews with around five matched samples in each of the eight case study sites, resulting in 120 interviews overall (40 each with service users, referring professionals and link workers). We have ongoing experience of conducting interviews and focus groups online with underserved communities during the COVID-19 pandemic,[36, 37] and we will include flexibility to ensure we can conduct data collection online or face-to-face. This will be determined by any ongoing COVID restrictions, and choice for participants.

All interviewees will be reimbursed for their participation at appropriate rates (PSSRU and NIHR payment guidance).[38] We have budgeted for a payment for patients taking part in WP3, for giving up their time. We will pay patient participants to facilitate recruitment. Our previous experience of recruiting 'marginalised' groups - especially those with low incomes is that financial incentives are necessary. Therefore, to not have such incentives would potentially result in a sample lacking in diversity.

The eight case study sites are being selected to ensure variation in service types, populations served, and any characteristics that might influence access and experience of delivery at the local level. To ensure this variation is also reflected in the WP3 interview sample we will identify potential participants via the social prescribing provider on the basis of services they've been offered. We will explore with providers how they can assist us in facilitating the identification of potential participants (service users and or those referred, but who did not engage; referring link workers and staff in general practices) to ensure that the final sample reflects maximum diversity. We will specify the individual characteristics (i.e. age, gender, ethnicity, area deprivation, availability and use of community assets) by which we want to sample, but we will not have access to patient records at any point.

Working with providers, sampling will be iterative drawing on the emerging work on the indicative questions in WP2. We will purposively sample participants in multiple rounds starting with two sets of participants per site, to allow for iterative analysis and to inform further sampling. As suggested by our PPIE contributors and in line with our approach with DIPLOMA, we will ensure we include some service users where English is not a first language and have made provision for use of translators where needed.[39]

Exploration of the experience and acceptability of link workers from the perspective of those providing support and advice as part of the local services will also be explored in each case study. Building on existing research of the experience of the voluntary, community and social enterprise sector (VCSE),[40] and in addition to the matched sample interviews, we expect to conduct up to 40 interviews with local VCSE providers. These will focus on their experience of referral pathway communications, management of caseload, service capacity and the financial sustainability of delivery.

6.3.2 Data analysis

We will adopt an approach to the analysis that is consistent across the eight sites. Interviews will be audio-recorded with consent, transcribed and thematically analysed using a modified framework approach.[41] This produces a matrix of summarised data providing a structure for analysis and interpretation which is useful for policy research and well suited to managing large datasets such as this.[42] The coding framework will be iteratively developed as the interviews continue, through discussion at regular analysis meetings and through discussions with the PPIE group and the clinical members of the research advisory group. Coding will be guided by questions posed in the research brief, in WP2 and with reference to candidacy and SDT for interviews with service users, link workers and referring professionals. Interviews with VCSE providers will be analysed to understand the barriers and facilitators of delivering services in different environments and with a focus on sustainability of services. Overlaps and distinctions across all groups of participants and across sites will be considered through iterative analysis and constant comparison.

6.3.3 Ethical considerations

The main ethical considerations for WP3 are informed consent; confidentiality, anonymity and data protection; and risks and burdens.

6.3.3.1 Informed consent

All potential research respondents who are recruited for interviews will receive verbal and written information (participant information sheet) regarding the study and will be encouraged to ask questions prior to taking part. It will be made clear that participation is purely voluntary and respondents are able to withdraw from the study at any time, without giving a reason and if they have taken part in an interview we will not ask for return of the payment made for time (see below, section on payment of participants). We will obtain verbal consent before undertaking the telephone or Zoom interview which we will audio-record separately to the interview audio-recording. We will obtain written consent before undertaking face to face interviews. For participants for whom English is not a first language, the participant information sheet will be translated verbally and interview conducted with an appropriate translator present.

6.3.3.2 Confidentiality, anonymity and data protection

With consent, all interviews will be audio-recorded using a secure University provided encrypted audio device. We will follow the University of Manchester's standard operating procedure for taking recordings of participants for research purposes: http://documents.manchester.ac.uk/display.aspx?DocID=38446). Recordings of the consent process and interviews will be transferred from the device as soon as possible to participating Universities' secure servers (so that de-identified data is stored separately to consent data) and then deleted from the device. Transcription of audio-recordings will be undertaken by a University of Manchester approved external transcription company. Audio recordings will be uploaded to the transcription company via a secure server. We will remove any personal identifying information (such as names, places) from transcriptions once they are returned. We will securely destroy the audio-recording of each interview, once an interview has been transcribed and the research team has checked the transcription for accuracy.

Once a respondent enters the study, they will be provided with a unique identifier. This means that data including field notes, audio recordings, transcriptions and demographic data will be identified only by their unique identifier and not the name of the respondent. The 'pseudonymisation key' to the unique identifier and respondent's details (name, contact details, site and job title), will only be accessible to members of the research team and stored electronically on a University of Manchester secure server, separate to the de-identified data. Where participating University laptop computers are used, these are encrypted. Electronic data (such as digital audio-recordings, transcriptions, field notes, and demographic data) will be stored on a University of Manchester secure server, or temporarily, on other participating Universities' secure servers. Hard copies of consent forms and demographic data will be kept in a locked cabinet in a locked room on participating University premises. Once the study is finished, data will be archived securely for 10 years, after which time it will be securely destroyed.

6.3.3.3 Payment of participants

Two main considerations regarding payments relate to coercion or undue inducements. Coercion is not appropriate here as financial inducements expand rather than restrict people's options. "Undue inducements" are offers that lead people to do something to which they would normally have real objections based on risk or other fundamental values. We will explain the study clearly in leaflets and in the consent process and explain we see the payment as a way of removing barriers to participation from groups that may have limited time due to financial hardship.

6.3.3.4 Risks and burdens

There is a small chance that participants may become upset during interviews. The researchers conducting the study will receive support and training in managing this and interviews will be sensitive towards participants throughout. Should a participant become distressed during the interview, the interviewer will ask if they want to take a break. If they continue to be distressed, they will be asked if they want to stop the interview or continue at a later date. They will also be reminded that their participation is voluntary and that they are free to withdraw from the study at any time and they do not need to give a reason, even though they have been paid for their time.

Researchers may visit service users' homes to conduct interviews. In such cases, researchers will follow the employing University's standard lone worker policy, with full details of researcher visits documented in secure systems where all members of the team can access them. In all cases, there will be a nominated contact person who will be contacted both before and after interviews, who will have interviewer phone numbers (on both study phones and personal phones). The contact person will attempt to contact the interviewer after 90 minutes has elapsed if they have not been contacted. If they are unable to contact, they will escalate to first, senior member of research team, and subsequently, police. Occasionally, service may request interviews out of hours, and we will ensure that all researchers retain an appropriate contact person in such circumstances where meetings cannot be arranged in working hours.

6.4 WP4 Health and wellbeing and service outcomes - led by Munford and Wildman

Overarching research question: To assess health and wellbeing and service outcomes, and whether outcomes vary within and between services delivered and by population characteristics

Timeframe: 24 months – from month 12 onwards

Nature: Quantitative analysis using large scale survey, population and NHS administrative data

Approach: We will examine impacts using two analytic approaches:

- Matched comparisons of outcomes between referred and non-referred individuals
- Longitudinal analysis of association between numbers of link workers and outcomes of populations targeted by link worker services

The first approach will use data from CPRD and English Longitudinal Study of Ageing (ELSA). The second will use data from General Practice Patient Survey (GPPS) and the Annual Population Survey (APS). These data sources are outlined in full below.

We will conduct both an individual- and area-level analysis. These will be complementary. The individual-level analysis allows a more in-depth understanding of the health and well-being effects of link workers. However, it is dependent on data, and will therefore be more localised. The aggregate, or area-level, analysis will be nationally representative, but may suffer from ecological fallacy, as well not being able to identify individuals directly affected (only areas more affected). Ecological fallacy occurs when aggregate – or area-level – data leads to inferences that are not true about individuals living within those areas. For example, the area-level average may not be representative of any one individual living within that area.

We will perform quantitative analysis of routine service level administrative data to compare health and wellbeing and community level outcomes within and across services. We will consider Stage 4 in Figure 1, above. Outcome measures will include the NHSEI recommended measure of ONS4, as well as other routinely used measures like for example, the Short Warwick-Edinburgh Mental Well-being Score (SWEMWEBS), and the use of formal health care services (including primary, secondary, and community care). As in WP2, we will pay particular attention to possible inequalities – i.e. do certain groups of people experience greater benefits than others? And if so, why?

6.4.1 Matched comparisons of outcomes between referred and non-referred individuals

Methods

The individual level analysis will examine the changes in the health of people who have been referred into social prescribing and take up the advice relative to the changes in the health of people who have not been referred. Given the two groups are likely to be different, we will create a matched-control group of individuals who are a similar as possible to those who have been offered social prescribing. The matched controls will be identified using entropy balancing algorithms.[43] [44, 45] Entropy balancing has been shown to outperform propensity score matching when constructing pseudo-control groups at baseline. [46] We will apply double-robust estimation such that the inference can be unbiased if either of the matching process is correctly specified or the outcome equation is correctly specified.[47] Double-robust estimation can also offer increased efficiency when all the models are correctly specified.

Data sources and outcomes

We will conduct a national evaluation at the individual-level using CPRD data linked to HES, in which outcomes will include use of formal health and care services. Given the aim of the scheme was to reduce workload within primary care, the primary outcome will be measures of primary care activity and workload as defined in Hobbs et al. [48] We will additionally consider the subsequent onset and management of health conditions (including prescribed medications) as secondary outcomes. Please see page 7 for an overview of CPRD data.

We will supplement this with a more detailed set of outcome data using a range of datasets. This will allow us to uncover some of variations, or inequalities, that likely exist based on individual and area level characteristics. For example, many of the characteristics in Boxes 1 to 3 of Figure 2 are not contained within CPRD. Additional data we have identified includes a range of social prescribing specific datasets, existing longitudinal surveys, surveys relating to experiences of General Practice, and nationally representative datasets run by the Office for National Statistics.

We have identified social prescribing specific data that are available locally (e.g. *Elemental* in GM, NENC, and possibly West). Health outcomes will initially be consistent with the national CPRD analysis (i.e. use of formal health and care services and the onset and management of health conditions). However, the more in-depth regional sub-studies will also contain further health and well-being outcomes including self-assessed health, the Short Warwick-Edinburgh Mental Well-being Score (SWEMWEBS), the ONS4 questions (a series of four questions relating to self-perceived (i) satisfaction with life, feeling of worthwhile, happiness, and anxiety) and the Patient Activation Measure (PAM). The main outcome related to individual well-being will be the ONS4 suite of questions. NHS England encourages PCNs to use the ONS4 to measure the impact on patient wellbeing (See: https://www.england.nhs.uk/wp-content/uploads/2020/06/pcn-reference-guide-for-social-prescribing-technical-annex-june-20.pdf). ONS4 will be collected in the Elemental datasets in each locality and hence can be compared regionally. We will use a range of secondary well-being and health outcomes – as listed in the revised bid – to check the consistency and sensitivity of the main result on well-being.

The exact choice of outcome measure will likely vary locally, as each user/purchaser of the *Elemental* platform is free to choose the set of outcomes to collect. After discussions with *Elemental* data owners in GM and NENC, we know that ONS4, SWEMWEBS, and PAM are all collected. In Scotland, SWEMWEBS is the preferred measure of health and wellbeing. In Gloucestershire, we will seek access to data on social prescribing recorded on GP IT systems by link workers for those employed by PCNs, while data for commissioned link workers, including ONS4 and SWEMWEBS, will be available from their minimum data set. Comparison with the ‘social prescribing plus’ arts-based intervention will also be possible via a minimum data set which includes ONS4. We do not yet know the outcomes in Bristol as their discussions – through Sirona – on whether to adopt the Elemental platform are still ongoing.

Additionally, the English Longitudinal Study of Ageing (ELSA) will include a social prescribing module in the 2020-2025 waves of data and hence we will use this information too.[49] These questions will initially ask about referrals to a link worker, adherence to advice, and participation in subsequent activities. The exact questions for the social prescribing module are still being finalised and it may contain more detailed information. We are in discussion with Profs James Banks and James Nazroo who are both Co-Principal Investigators of ELSA about this module. ELSA focuses on a population group who are more likely to be referred into social prescribing schemes (adults aged 50+ years). It contains a rich set of health and well-being related outcomes, as well as very comprehensive coverage of the socioeconomic and demographic position of individuals and households and can be linked to area-level information such as availability of community assets, deprivation and rurality.

ELSA also contains detailed information on social and community engagement (e.g. involvement in local groups, visits museums, members of social groups), the frequency of social contact with friends and family, and perceived loneliness of perceived levels of positive and negative social support. The longitudinal nature of ELSA, the detailed information, and the new social prescribing module will allow a much more detailed investigation of social prescribing, particularly around engagement as well as health, loneliness, and well-being outcomes. The approximate sample size of each wave of ELSA is around 9,000 individuals, most of whom are tracked longitudinally.

6.4.2 Longitudinal analysis of area variations in numbers of link workers

With the numbers of link workers increasing over time,[1, 2] the mechanics of the roll out provides the opportunity to estimate impacts on outcomes at an area-level.

Methods
We will estimate the impact of the roll-out of link workers using a two-way fixed effects model with time varying exposure/treatment. The continuous measure of exposure/treatment will be the provision of link workers per-capita in different areas. This deviates from classical continuous treatment difference-in-differences [50, 51] as the exposure/treatment varies over both time and place; hence, we will adopt the two-way fixed-effects specification.[52]

With PCN social prescribing rolled out across England there is variation in the date at which the social prescribing intervention can be considered to be turned 'on'. Geographical variation in link worker roll-out will be used as the treatment intensity. In this case we consider intensity to be measured by the number of link workers employed within a PCN. This will be standardised to give a per-capita figure to allow for comparisons across PCNs of differing sizes.

Places that implement – or more aggressively implement – link worker social prescribing may be more pioneering, or potentially have more social problems, than other places. As a result, areas with higher clinical need may have more link workers per-capita and lower health outcomes. We will seek to adjust for this confounding in a number of ways. Our specification mitigates against this problem somewhat by using fixed effects for each area. We will also predict how many link workers per-capita we would expect in each PCN before the roll-out of link workers comes in to effect. This prediction will be obtained from data on clinical need and the level of funding available. The exact choice of predictors will be informed by available data and through discussions with stakeholders identified through WP1. In addition, we will examine whether the associations between the numbers of link workers and health outcomes are stronger for the population groups that are targeted by link workers.

The primary analysis will be a two-way fixed-effects specification with time and area varying exposure/treatment in a triple difference (or difference-in-difference-in-difference) model. We will compare the average outcomes in different areas across age groups. Particularly, we will compare the outcomes of the over 65s with younger groups and see how this varies across treatment intensity. The logic here is that, on average, social prescribing link workers are more likely to engage with older rather than younger individuals. In essence, on average, the younger members of the population can be used as a pseudo-control group, as link workers should have little direct effect on their outcomes. Health and well-being outcomes is reported, at area-level, by age groups in APS/LFS (see below). We are aware that some people in the younger age groups will engage with link workers, although the assumption is – on average – older individuals will engage more.

The area level analysis will estimate a model of the form:

$$H_{lt} = \alpha_l + \sum_{T=2020/21}^{2022/23} \pi_1^T * (over65_{lt} * LW_{lt} * \{T_{lt} = T\}) + \pi_2 X_{lt} + \delta_t + \varepsilon_i$$

In this formulation H_{lt} is the outcome of interest for area *l* at time *t*, LW_{lt} represents the number of link works per-capita in area *l* at time *t*¸ X_{lt} are area level time varying control variables in area *l* at time t and α_l and δ_t are area level and time fixed effects. Over65$_{lt}$ is a binary variable equal to one if the outcomes refer to people aged 65 years and above and equal to zero if the outcomes are for individuals aged under 65 years. The parameters of interest are π_1^T. We normalise effects to zero in the year before intervention, 2019/2020.

This specification recognises that the number of link workers per-capita varies across PCN areas and also that the effects of having link workers will (potentially) become stronger over time due to adaptation. This is particularly true if the link workers are providing targeted service responses to the social determinants of health where the impacts may take time to occur. Given the nature of the intervention, we may expect the largest effects towards the end of the observation period – so areas where more link workers have been in place longer are seeing the greatest benefits.

If we find associations between numbers of link workers per-capita and health of populations more likely to be targeted by link workers, and we do not find the same associations for populations not targeted as much by link workers, then this will provide greater credibility of the attribution of improved health to link workers.

It is likely that there will be small numbers of referred people particularly in certain areas. However, the proportion of people referred from some population subgroups – particularly ageing people and people with long-term conditions, who are explicitly targeted by social prescribing – is likely to be much larger. We will identify these subgroups and focus the analysis where the proportion referred is sufficiently large to be able to detect an effect.

At the population level, we will perform calculations on the expected proportion of the population that might be exposed to social prescribing schemes and couple this with estimates from the individual level analysis (on the effect of social prescribing at the individual level) which allows us to scale up the effects to obtain likely effect sizes at the population level. We have performed similar calculations in the DIPLOMA analysis. If the initial analysis at the area-level is not finding an effect at the population level due to the small number of people referred into this service then we will predominantly focus on the subgroups where the number, and proportion, of referred people is sufficiently large (such as the ageing population and the population of people with long-term conditions). Sample sizes in many of the datasets we have identified are suitably large to allow for detailed subgroup analyses.

Data sources and outcomes

We will use data available through the General Practice Patient Survey (GPPS). Members of our study team have experience of using GPPS at individual level, and the University of Manchester has a designated data-link person with the GPPS. The data are linked to practices, and hence we will know the social prescribing schemes in operation at the practice attended by each individual as well as their individual level outcomes and sociodemographic information. GPPS no longer contains EQ-5D, but it does still contain information on self-reported measures of health (e.g. self-assessed health, self-reported presence of health conditions, disability, use of medication, etc.) as well as detailed data on experiences and satisfaction with various aspects of GP practices, including whether they feel adequately supported to manage their conditions and needs. It also contains age, gender, ethnicity, and can be geo-linked to area deprivation, number of available community assets, and rurality.

We will also use data from the Annual Population Survey (APS) collected by the Office of National Statistics.[53] The APS is a continuous household survey covering the whole of the UK. It consists of approximately 320,000 individuals and contains sample weights to make the responses nationally representative. The APS is made up from the Labour Force Survey (LFS) as well as booster samples.

Importantly, it contains measures of self-reported health and well-being, including the ONS4 suite of well-being questions.

Additionally, we will obtain information on the aggregated use of formal health care services from NHS digital.[54] Data will include publically available data available from HES at area level and aggregated data on numbers of GP appointments (currently released at CCG-level but discussions are ongoing about releasing it at practice level through GP Extraction Service). Data on prescribing activity (type and quantity of prescriptions), available at practice level, is reported at practice level by NHS Digital.[55]

Information on control variables/confounders will be obtained from NOMIS, the official labour market statistics portal of the ONS and include the age, sex, and ethnic composition of the population, as well as measures of deprivation and rurality.[56]

Information on the number of link workers employed will be obtained from the financial claims that PCNs submit to NHSEI under the Additional Roles Reimbursement Scheme. These records are required for reimbursement, and hence reflect the number of link workers employed in each PCN.

6.5 Economic sustainability – led by Sutton

Overarching research question: To explore the value and economic sustainability of link workers in primary care.

Timeframe: 24 months – from month 12 onwards

Nature: Economic analysis using survey, population and NHS administrative data

As link workers are funded from the NHS budget, we will estimate their cost-effectiveness in terms of additional cost per additional person linked to social prescribing schemes and then develop a model to produce a cost-utility analysis. This will be supplemented by detailed identification of costs and benefits that fall outside the scope of the NHS and Personal Social Services, consideration of whether a distributional approach to cost-effectiveness substantially affects the results, and assessment of different funding models for link workers in the future.

We will draw on the findings of the other work packages to consider the costs and benefits of the funding of link workers in primary care. It will combine information on how the link worker roles are funded (WP1), with understanding from case study sites in how link workers operate and might affect costs and benefits (WP3), and estimates of uptake (WP2) and impacts on a range of outcomes (WP4). We will address the following research questions:

- Is the national funding of link workers in primary care cost-effective?
- Does cost-effectiveness vary substantially across case study sites or by type of social prescribing intervention and, if so, what are the main drivers of this variation?
- Does consideration of the contribution of link workers to reducing health inequalities have a substantial impact on the assessment of their cost-effectiveness?
- What costs and benefits of link workers occur outside the NHS?
- What are the most important evidence gaps for the assessment of cost-effectiveness of link workers in primary care?
- How could link workers be made more cost-effective?

- What ways of funding link workers could increase their cost-effectiveness?
- Based on where the costs and benefits of link workers are experienced, what is a sustainable future funding model for link workers?

As the funding for link workers in primary care is from the NHS budget, our primary analysis will be undertaken from the NHS and PSS perspective. The cost-effectiveness analysis will calculate cost per additional person linked to social prescribing schemes. Cost-utility analysis will then model cost per Quality-Adjusted Life Year.

There are likely to be costs and benefits that fall outside the NHS and PSS perspective. We will identify these through the interviews with decision-makers and in the case study sites and through discussion with the PPIE group. We will create a comprehensive list of these additional consequences and quantify them where possible. As examples, we anticipate significant consequences for the VCSE sector, the welfare system, and for informal carers.

We will obtain the direct costs of employing link workers and facilitating their work from decision-maker interviews and case study sites. In addition to these costs, we will consider the effects of link workers on the major components of NHS and PSS costs for service users, including primary care visits, prescription costs, community mental health services, and hospital visits and admissions. We will separately consider planned and unplanned elements of expenditure because local health systems may prefer to support planned expenditure on link workers to reduce the risk of future unplanned expenditure.

The effects on costs will be obtained from analysis similar to that described for outcomes in WP4, including person-level matched comparisons using CPRD and longitudinal analyses of area and time variations in numbers of link workers using national administrative datasets and population surveys. Changes in health care utilisation will be costed using national tariffs taken from NHS Reference Costs and PSSRU Unit Costs of Health and Social Care.

The primary outcome for the cost-effectiveness analysis will be the number of clients who take up the offer of a link to a social prescribing scheme. As described in WP2, this will be the additional persons placed in social prescribing schemes that are attributable to the employment of the link workers. The incremental Quality-Adjusted Life Years generated by the link workers will be obtained by creating a decision-analytic model based on data from the case study sites, the outcomes analysis in WP4, and published literature including the net-benefit analysis of community assets by Munford et al.[13] The change in life years will be estimated using CPRD linked to ONS. Because information on health-related quality of life is not available, the changes in quality of life will be modelled based on the changes in proximal outcomes available in survey datasets, including feeling supported to manage long-term conditions and self-assessed health. We will estimate their associations with health-related quality of life using historical data from the GP Patient Survey which contained these variables as well as the utility score based on the EQ-5D-5L.

A decision-analytic model will be created to combine the information on costs and benefits and to generate the incremental cost-effectiveness ratio (ICER). Bootstrapping will be used to simulate uncertainty in the ICER and sensitivity analysis will be used to identify the main influences on the ICER. Costs and benefits will be discounted at 3.5%. We will estimate cost-effectiveness and cost-utility over a time horizon of one year, five years, and over the lifetime.

We will estimate cost-effectiveness and cost-utility in each of the case study sites and identify what are the main influences on variations in the results. We will consider variations in link worker productivity, how they target highest-need clients, and whether cost-utility depends on which services clients are linked to. We will also examine whether taking account of the effect of link workers on health inequalities would substantially affect the economic considerations by undertaking distributional analysis.[57]

We will use this information on cost-effectiveness and cost-utility to make recommendations on future funding arrangements for link workers. This will include consideration of who should fund link workers and how link workers can most effectively be paid.

7 Dissemination and knowledge mobilisation (WP6)

Timeframe: Duration of project

Effective dissemination and knowledge mobilisation to improve healthcare relies on timely access to good quality and relevant research evidence and, close collaboration and on-going relationships with researchers. Our dissemination and knowledge mobilisation strategy will be based around these two core mechanisms.

To ensure relevance to policy need and to maximise the impact and use of findings, we intend to build on the successful approach of the DIPLOMA and HEDLINE studies which have actively engaged with key stakeholders at all stages of the research process to not only to ensure efficient use of NIHR resources, but also to maximise the impact and use of findings as they emerge. This WP6 is designed to facilitate this relationship and to provide timely feedback loops to policy decision making and to provide insights from the evaluation as they emerge during the life of the study.

In the HED-LINE evaluation, we consulted early with the National Delivery Team to understand the policy context for the roll out of Healthy-Living. This has proved to be incredibly helpful in refining the focus of our research to take account of strategic decision to ensure continued relevance. We intend to replicate this approach with the national delivery teams at NHSE and with other key stakeholders. Through this we will seek to understand the strategic vision for and selection of guidance and strategies to promote and support the national roll-out. This will include understanding:

- Overall aims and objectives of the strategic implementation plan
- Key performance indicators to measure ‘success’
- Any national resources and support structures
- Targeted population groups
- Any impacts from the COVID-19 pandemic

We will ensure regular contact with the national policy teams through workshops, short evidence briefings, phone and email contact. We are open to exploring ways for us to inform implementation (e.g. a DIPLOMA researcher sat on a selection panel for contractors). In addition, we will seek opportunities to share our early findings and to ensure our research takes account of any changes in planned delivery. We to plan hold a project initiation workshop to outline our work plans and propose two further workshops to share interim findings: At 12 months: sense-making workshop with the national delivery teams to discuss how the delivery models mapped in WP1 compare with provision nationally. At 24 months: feedback workshop with the national delivery teams focused on variations in population, reach and access and engagement across case sites.

Our dissemination strategy includes recognizes the need to reach audiences beyond the immediate evaluation programme. To do this we will disseminate the projects outputs through a variety of media, including conference presentations and conventional academic publications, seminars and short accessible evidence briefings for stakeholders, and plain English summaries and podcasts for patients and the public. The research team are experienced at writing for a wide range of lay and professional audiences. We will work closely with our PPIE and Research Advisory Groups to identify audiences and to maximise the utility of our dissemination. We have costed in time for patient and public contribution to dissemination, to help us create content and summaries that are as accessible as possible for as wide an audience as possible.

8 Project management

Timeframe: Duration of project

Wilson will lead the research team and provide overall project management, with mentoring from Sutton. This will include project management, WP co-ordination and delivery to time, target and budget. Specifically, project management will include:

1. Ensuring progress on the WPs, and effective co-ordination on common analyses and issues.
2. Each work package will have designated leads, and will meet with the PI at least once every two months.
3. Ensuring suitable PPIE, with relevant training and support, ongoing dialogue, and opportunities for engagement of the PPIE contributors.
4. Regular contact with nominated representative for NIHR HS&DR.
5. Reporting to the Study Steering Committee, who will provide supervision for Sponsor and Funder and ensure that the study is conducted to rigorous standards.
6. Engagement with external stakeholders (see WP6), feeding back on progress, and maximising the impact and use of findings in decision-making processes as they occur.

The Research Management Group will meet at least quarterly (more frequently at the start) and will include all of the research team plus two representatives from the PPIE group (Pat Walkington plus one other to be agreed). A Research Advisory Group will provide important clinical and ‘expert by experience’ input including awareness of new research and service developments. The group will include representatives from NHSE, Public Health Scotland as well as regional providers and commissioners and two representatives from our PPIE group. The group will meet every six months, and will be available for ad hoc advice and support as the work progresses.

Team member roles and contribution

We have the necessary methodological skills and experience to deliver. Our expertise includes use of routine datasets to support policy evaluation, large scale mixed methods evaluation of regional and national policy interventions and of social prescribing initiatives, implementation science, qualitative methodology, economic evaluation and PPIE.

Wilson (mentored by Sutton) will provide project leadership to the team, working closely with the other co-applicants. As our project model is geographically distributed, we have opted to locate researchers in each area. Our designated WP leads will coordinate local data collection and analysis efforts as follows:

WP1 Implementation: led by Wilson (supported by Kaner, Salisbury and Mercer)
WP2 Access and equity: led by Munford (supported by McLeod, Wildman and Mercer)
WP3 Engagement: led by Wyke, Sanders and O'Donnell
WP4 Outcomes led by Munford and Wildman (supported by McLeod and Mercer)
WP5 Economic sustainability led by Sutton
WP6 Informing policy led by Wilson and Sutton

We have dedicated support from researchers within all WPs, with the time requested proportionate to their involvement over the 3 years. We will expect some researchers to work flexibly across regions when required and all will engage closely with related WPs.

9 Patient Public Involvement and Engagement

Timeframe: Duration of project

In developing this application, we met with the NIHR ARC Greater Manchester Public & Community Involvement & Engagement Panel, which brings together people from different socio-economic and cultural backgrounds and under-represented communities. Panel members bring a range of skills, knowledge, voluntary and lived experience to ensure that a diverse public voice informs the research that we do and the methods we use. We discussed our research plans and ask what they would like to know about link worker models of social prescribing. Many responses mapped onto our questions:

On link workers, the Panel wanted to know more about what sort of people become link workers, how are they trained and what qualifications do they have. They also wanted to know about data confidentiality, how person centred is the care offered, how link workers connect back to the GP, and the extent to which they are embedded in the community they serve. We will ensure that these issues are addressed in our plans for WP1 and in WP3.

In terms of access, the Panel raised issues around the terminology used to describe link workers and around physical and financial access (cost of travel, distance to travel and or need for equipment) as potential barriers to engagement. They also wanted to know if the support and activities offered by social prescribing services were culturally inclusive and appropriate for the communities they serve, especially for people who may not have English as a first language. We will document support and activities offered in WP1 and intend to map explore equity and access by population characteristics in WP2 and WP3.

These issues have all been incorporated into our data collection plans. The panel asked what effort we would make to reach and involve patents who may not have English as a first language. In keeping with the guidance from INCLUDE project and our DIPLOMA and HEDLINE evaluations, we have made provision in our budget for translators (for up to 5 interviews).

The Panel have provided substantial input into the Plain English Summary and have scrutinised our plans for public involvement to ensure that NIHR national standards for public involvement in research are met.

The panel felt that our PPIE group should include representation from all four regions. Overall support will be provided by Aneela McAvoy who is PCIE manager for ARC-GM.

Due to the geographical spread, the PPIE group will meet up to nine times virtually during the project, more frequently at the start, while members establish their role. The activity will include:

1. Discussing research plans of each work package to ensure what we do is relevant Advising on suitable methods and places to recruit service users.
2. Contributing to public-facing research documents to ensure readability and appropriateness.
3. Helping identify the main messages for stakeholders and appropriate ways of disseminating them to service users and others.
4. Involvement in dissemination, for example attending a conference such as Health Service Research UK or INVOLVE, or presenting at an event.

Governance: As well as providing a public voice on study processes, members of the group will contribute to decision-making. Two of the eight members will be full members of the Research Management Group and Research Advisory Group with equal decision-making rights. This will ensure the overall management and priorities of the project benefit from a lay perspective and will allow them to feed in the views of the PPIE group, of which they will also be members.

Communications: The panel will co-produce patient-facing research documents to ensure readability and appropriateness. They will help identify the main messages for stakeholders and appropriate ways of disseminating them to patients and others. Public contributors will be involved in dissemination, for example attending a conference such as Health Service Research UK or INVOLVE, or presenting at an event.

Impact: We will ensure ongoing evaluation of all our PPIE activities using multiple methods including informal discussions with the panel members to review and evolve our approach throughout the programme. We will also use existing review form (used within ARC-GM) to ensure we collect feedback and information to report on Equality Diversity and Inclusion from wider engagement activities (e.g. community based workshops). We will devise and use an impact register to ensure we track and report on any emerging impact throughout and beyond the project.

10 Statement of Indemnity

The University of Manchester has insurance available in respect of research involving human subjects that provides cover for legal liabilities arising from its actions or those of its staff or supervised students. The University also has insurance available that provides compensation for non-negligent harm to research subjects occasioned in circumstances that are under the control of the University.

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13 Amendments to protocol

Version 2.0		
Work Package	**Nature of amendment**	**Date**
WP3 – Section 5.31	Wording Change - Added additional detail on patient reimbursement for participation	05/10/2022
WP3 – Section 5.31	Wording Change - Added additional detail on WP3 interview sampling and on how we will identify potential participants	05/10/2022
WP3 – Section 5.3.3.1	Wording Change - Clarification that if someone withdraws their consent after having taken part in an interview, we will not ask for return of the payment made for time.	05/10/2022
WP3 – Section 5.3.3.2	Wording Change - Clarification of data storage and handling procedures across participating Universities	05/10/2022
WP3 – Section 5.3.3.3	New section - Addition of rationale for payment of participants	05/10/2022