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# BMJ Open

## Link workers providing social prescribing and health and social care coordination for people with multimorbidity in socially deprived areas (The LinkMM trial): Protocol for a pragmatic randomised controlled trial.

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## Title

Link workers providing social prescribing and health and social care coordination for people with multimorbidity in socially deprived areas (The LinkMM trial): Protocol for a pragmatic randomised controlled trial.

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Abstract

Introduction

Link workers are non-health or social care professionals based in primary care who support people to develop and achieve a personalised set of health and social goals by engaging with community resources. Link workers have been piloted in areas of deprivation, but there remains insufficient evidence to support their effectiveness. Multimorbidity is increasing in prevalence but there are limited evidence-based interventions. This paper presents the protocol for a randomised controlled trial that will test the effectiveness of link workers based in general practices in deprived areas in improving health outcomes for people with multimorbidity.

Methods and analysis

The protocol presents the proposed pragmatic randomised controlled trial, involving 10 GP practices and 600 patients. Eligible participants will be community dwelling adults with multimorbidity ( $\geq$ two chronic conditions) identified as being suitable for referral to a practice-based link worker.

Following baseline data collection, patients will be randomised into intervention group that will meet the linkworker over a three-month period, or a ‘wait list’ control that will receive usual GP care.

Primary outcomes are health related quality of life as assessed by EQ5D-5L and mental health assessed by HADS. Secondary outcomes will be based on the core outcome set for multimorbidity. Data will be collected at baseline and on RCT completion at 3 months using questionnaires self-completed by participants and GP records.

Parallel process and economic analyses will be conducted to explore participants' experiences and examine cost-effectiveness of the link worker intervention

## Ethics and Dissemination

Ethical approval has been granted by the Irish College of General Practitioners Ethics committee. The findings will be published in peer-reviewed journals.

## Registration

This trial is registered on ISRCTN

Title: Use of link workers to provide social prescribing and health and social care coordination for people with complex multimorbidity in socially deprived areas

Trial ID: ISRCTN10287737

Date registered: 10/12/2019

Link: <https://www.isrctn.com/ISRCTN10287737>

## Article Summary

- The LinkMM study is a pragmatic RCT examining the effectiveness of a practice-based link worker intervention for patients with multimorbidity
- Link workers will be based in general practices in urban deprived settings and will deliver social prescribing and support social care coordination

- The use of a wait-list control within practices allows for randomisation and a parallel control group but limits intervention duration as control patients are also offered a brief version of the intervention on study completion
- An economic analysis will determine the cost-effectiveness of the intervention

Keywords

Link worker, social prescribing, multimorbidity, complex intervention, primary care, general practice, social deprivation.

Word Count 4878

Introduction

Multimorbidity, defined as the presence of 2 or more chronic conditions, is recognised as a significant challenge for patients and health care systems, particularly in primary care and in areas of social deprivation (1). Within the broader multimorbidity population there are people with higher numbers of conditions involving multiple body systems with related polypharmacy, which is referred to as complex multimorbidity (2). Multimorbidity and complex multimorbidity are estimated to affect 66.2% and 11% respectively of people over 50 attending Irish General Practice (3). Complex multimorbidity is associated with increased health care utilisation and costs. People with complex multimorbidity experience more fragmented care, poorer mental health and have worse outcomes (4, 5). There are higher proportions of patients with complex combinations of physical and mental health conditions in deprived areas (4). This is reflected in higher consultation rates and has ramifications throughout the health system. Ten percent of patients with four or more conditions account

for 34% of unplanned emergency admissions and 47% of preventable unplanned admissions (6). People living in deprived areas develop multimorbidity 11 years earlier (4) and experience worse quality of life compared to those with multimorbidity in less deprived areas (7). It is not clear why this is, but there is growing evidence that people with multimorbidity in areas of deprivation have reduced self-efficacy and capacity for self-management due to psychosocial stressors, poorer mental health, increased burden of treatment and lower perceived social support (8) (9) (10) (11-13).

There is as yet, limited evidence to indicate which interventions for multimorbidity have a significant impact on health outcomes or health service utilisation (14). One potential intervention to address the complex mix of psychosocial issues and multimorbidity in areas of deprivation is the use of link workers in primary care. A link worker is a non-health or social care professional who usually has training in coaching or behaviour change as well as an extensive knowledge of local community resources. They work with people referred to them by healthcare services to identify their health and social care needs and support them to access services within the community to improve their health and well-being, a process commonly referred to as social prescribing (15). The Glasgow Deepend Linkworker programme describes the principle behind the link worker intervention as *"a catalyst to hope and self-determination, using the strong relationships with patients that exist in general practice. If patients with complex needs feel supported, they would be more likely to respond to information on ways to improve their health"* (16). The current study builds on this work using a similar intervention approach with link workers embedded in practices in deprived urban areas.

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Although link workers providing social prescribing have been gaining popularity in the UK and there have been a number of pilots in Ireland (17, 18), few have been formally evaluated. A recent review of link worker provided social prescribing in the UK found limited evidence to support the effectiveness and concluded that there was a lack of evidence for how, for whom and when social prescribing was effective (19). A recent quasi-experimental evaluation of the Glasgow Deep End Links worker programme found some impact on mental health scores for patients and staff morale in GP practices and concluded that larger, longer studies, with randomisation at the individual patient level were needed (20).

The Deep End Ireland GP group, a network of practices based in areas of deprivation, prepared a Report on link workers in Ireland that outlined its potential to address the psychosocial burden faced by their patients and the impacts of upstream social determinants of health that GPs often encounter but can have little impact on in practice (21).

To inform the implementation of the intervention and evaluation processes a short uncontrolled pilot study was conducted in one practice with 12 patients. This confirmed the feasibility of intervention delivery and led to refinements in patient selection and data collection processes. (Ref, paper in submission process with the Journal of Comorbidity)

This study aims to evaluate a link worker intervention in primary care on health outcomes for people with complex multimorbidity in socially deprived areas. Secondary aims are to examine the impact on staff morale and conduct a mixed methods process evaluation and economic evaluation of the intervention, exploring direct and indirect costs.

## Methods

This protocol is presented using the SPIRIT recommendations for the reporting of a protocol for an interventional trial (22).

### Study design

This will be a pragmatic RCT to evaluate a link worker intervention in improving health outcomes for people with multimorbidity attending primary care in socially deprived areas compared to wait list controls who receive usual care. It will be reported in accordance with the CONSORT guidance for randomised controlled trials (23). The economic analysis will be a cost utility analysis from the perspective of the public health care system and will be carried out in accordance with the guidance produced by the Health and Information Quality Authority Ireland (24).

A parallel mixed methods process evaluation will be conducted in line with the Medical Research Council guidance on evaluating complex interventions (25). The process evaluation protocol will be informed by the MRC framework for process evaluations (26). A full protocol for the process evaluation will be published in an open access source.

### Study settings

This study will be conducted in urban general practices serving areas of deprivation in four cities (Dublin, Cork, Limerick and Waterford) within the Republic of Ireland. Serving areas of deprivation will be defined as providing general practice care to at least two small areas identified as disadvantaged or below by The Pobal HP Deprivation index(27) and provide services to at least 1,000 patients under the General Medical Services (GMS) scheme. The Pobal HP deprivation index is Ireland's most widely used social gradient metric and scores

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each small area (50 – 200 households) in terms of affluence or disadvantage. The index uses information from Ireland’s census, such as employment, age profile and educational attainment, to calculate this score (27). The GMS scheme provides medical care to approximately 40% of the Irish population. It is predominantly means-tested and provides eligible patients with free general practitioner visits, free hospital care and free medications (except for a prescription levy, currently €2.50 per item to a maximum of €25).

Eligibility Criteria

Participants

Participants will be community dwelling adults aged over 18, who have two or more chronic conditions (multimorbidity), attend a GP that provides care for patients living in an area of deprivation and have been identified by their GP as having potential to benefit from a link worker intervention. As this is a pragmatic trial we are seeking to replicate conditions in real work practice where GPs would refer to a link worker based on need.

Exclusion criteria include psychiatric/ psychological morbidity or cognitive impairment that would impair capacity for informed consent, a terminal illness likely to lead to death or major disability during the study follow-up period, living in residential care, already participating in a similar programme or had previously participated in the pilot study.

Practices

Ten practices in the Deep End Ireland group will be invited to participate (28). Membership of the group is open to any practice that identifies as working in an area of deprivation. In addition, practices must have a GMS list of >1000 patients, serve at least two small areas defined as disadvantaged or below by the Pobal HP deprivation index 2016 and have space to

host a link worker on site. Practices that are taking part in another link worker project will be excluded.

## Recruitment and Randomisation

Each practice will be asked to recruit 60 participants, giving a total of 600 patients.

Recruitment will begin one month before the start date of the intervention and will be phased for logistical reasons with 20 participants being recruited each month in each practice.

Eligible participants will be identified by their GPs, based on being prescribed five or more medications as a proxy for multimorbidity. This proxy is being used because of significant variation in coding practices for chronic conditions in Ireland and lack of a code for multimorbidity. A finder tool in the electronic record, previously developed for another multimorbidity study (29), will generate this list of patients. Previous research has indicated that medication count is a suitable proxy measure for multimorbidity (6) The GP team will screen this list of patients with multimorbidity to identify all patients who they would refer to a link worker and thus create a register of potentially eligible patients. This process is based on our pilot study findings and is designed to reflect real world conditions where GPs refer patients they identify as having a psychosocial need that would benefit from a social prescribing approach to a link worker. Once this register of potentially eligible patients is created, GPs will be supported to select a random sample of 60 potential participants. They will then be asked to double check that the selected participants meet the inclusion criteria and ensure none of the exclusion criteria apply. GPs will also be asked to document the reasons why each of the selected patients would be referred to a link worker using a standardised list of options. This list will include reasons for referral identified from other studies and known proxies for psychosocial need such as frequent attendance and will also

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allow GPs to record free text additional reasons. This process will improve transparency around referral decision making and provide additional data on types of patients referred for link worker supports and is summarised in Figure 1.

A letter of invitation, patient information leaflet, consent and baseline questionnaires will be sent to eligible participants and GP teams will follow up with phone calls to explain the study and see if potential participants require assistance completing the baseline questionnaires. Once they have consented, a member of the research team can assist them with baseline data collection either face to face at the practice or over the phone.

Randomisation will take place following baseline data collection to avoid allocation bias. Randomisation will be carried out by an independent researcher and overseen by the trial statistician using a computer-generated sequence. Patients will be stratified by practice and age and allocation will be blocked using random permuted blocks of sizes 2 and 4 to ensure balanced numbers of intervention and control patients in each practice.

The independent researcher will inform the research team of allocations. The research team will contact the participants by phone to inform them of their allocation and what to expect. The research team will inform the relevant link worker by phone who has been allocated to the intervention group. A letter will be sent to the GP practice informing them of the participants involvement in the trial and their allocation. Due to the nature of the intervention it is not possible to blind participants, link workers or GPs to the allocation. Blinding will be implemented at the data analysis stage.

## Intervention

The link worker intervention (LinkMM) is based on the Glasgow Deep End Links worker project which had a quasi-experimental cluster design (30). Our intervention is shorter than the Glasgow project to facilitate the wait list control study design and it does not include practice subsidies for developing in practice activities beyond hosting the link worker. The LinkMM intervention is a complex intervention with the following components:

- Link worker training and support
- GP training
- Compilation and mapping of local health and social care community resources
- Link worker participant meetings and follow up
- Financial supports to practices

### Link worker training and support

To inform the implementation of link worker social prescribing project the lead researcher attended Social Prescribing Network Ireland meetings and engaged with local social prescribing projects to explore the nature of the link worker role and appropriate job specifications, training, communication with GPs and engaging with community resource providers. In keeping with the literature, empathy and an ability to listen were identified as important link worker skills (31). Given the limited training time available, a background in health or social care and experience of working with disadvantaged communities were essential criteria for applicants to the role.

Resources from the Alliance website(32) (the community organisation who had delivered the link worker intervention in the Glasgow Deep End Links Worker project) were referenced to

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develop a 40 hour training plan with input from local social prescribing providers and based on the experience of our pilot study link worker, who had significant experience in health and social care and working with disadvantaged communities. Link workers will be employees of the research host institution rather than the general practices and will be line managed by the trial project manager. They will have monthly check-ins with the project manager and bimonthly peer support meetings and review sessions. Any clinical concerns regarding participants will be raised with the individual’s GP. If for whatever reason they are unable to access the individual’s GP link workers can seek support from the principal investigator (SMS), an experienced GP.

GP training

GP practices will receive training on site or via video-link on trial processes including selecting and recruitment processes, including the potential reasons a patient might be referred to a link worker. The link worker role will be explained.

Compilation and mapping of local health and social care community resources

The research team will have identified some key local resources for each area in advance of the link worker taking up their post. The link workers will have allocated time during their induction period to map out local resources using a template developed during the pilot. This will however be an ongoing process depending on the needs of participants. In the context of the ongoing Covid-19 pandemic, online and individual resources will also be identified for those unable to attend group activities.

Link worker participants meetings and follow up

Following randomisation, intervention group participants will be referred to the link worker straight away and invited to meet with them at least once, with at least 60 minutes scheduled for this initial appointment. At the initial meeting the link worker will explain their role and explore the participants' health and social care priorities and produce a joint plan to address these. This will include a range of activities and community resources that participants may choose to attend to improve their health and well-being. The link worker will offer to follow up and support participants to attend these activities during the three-month trial period. Support will be tailored to the individual's need and can vary from a check-in phone call to accompanying someone to a community centre or appointment. There will be no change to the participants usual clinical care. At the end of the intervention period the link worker will provide a summary to the participant's GP, outlining the plan and resources they accessed to help achieve it. All link worker activity will be captured in a specifically designed client management database, including details of the initial assessment, priority health and social issues, goals set, community resources referred to and attended, number of follow ups and the type of support provided.

The link worker will be based in the GP practice and meetings with participants will primarily be in the GP practice. The link worker will be able to liaise with participant's GPs should they have any specific concerns about an individual. Link workers will also share knowledge on local community resources with GPs during monthly meetings with practice staff.

#### Financial supports to practices

Practices will receive a stipend to cover one session a week of GP time to allow for time spent on recruitment and supporting the link worker intervention. An additional grant will cover

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any room hire and equipment costs that the practice may incur as a result of hosting the link worker.

Control

The RCT will have a wait list control. During the 3-month intervention period the control group will receive usual care from their GP. On completion of the intervention, the control group will be invited to a one-off meeting with the link worker, during which they will have an opportunity to identify their needs and be provided with a list of suggested resources tailored to their needs and a booklet of community resources.

Outcomes

A wide range of outcomes will be used to assess intervention effectiveness and mechanism of action in line with the MRC framework for evaluating complex interventions (25). Outcomes are based on the pilot study findings and on the Core Outcome Set for Multimorbidity research (33). In line with the National Institute for Health Care Excellence an additional measure of capability and wellbeing, the ICE-CAP A (ICEpop CAPability measure for Adults) (34) will be used alongside the EQ5D-5L to capture the wider social benefits to the individual that are expected with this type of intervention.

Primary Outcomes

- Health related quality of life as measured by EQ5D-5L (35)
- Mental health as measured by Hospital Anxiety and Depression Scale (36)

Secondary Outcomes

Patient reported outcome measures

- Capability and wellbeing as measured by the ICE-CAP A (34)
- Activities of daily living as measured by the Frenchay Activity Index (37)
- Self-management as measured by the Patient Activation Measure (38)
- Burden of treatment measured by Multimorbidity Burden of Treatment Questionnaire (39)

### Health care utilisation

Data from primary care electronic health records, in the previous 3 months unless otherwise specified:

- Number of GP attendances
- Number of practice nurse attendances
- Number and type of regularly prescribed medications
- Number of out of hours GP attendances
- Number of Emergency Department attendances
- Number of hospital admissions (emergency) and length of stay
- Number of attendances to public health nurse and allied health professionals (self reported)
- Number of hospital outpatient visits

### Sample Size

A sample size of 600 participants in total has been calculated based on our two primary outcomes. Using a HADs Anxiety score of 10.9, a standard deviation of 5.1 and a minimally clinically important difference of 1.5 (based on a similar Scottish population study (40)); for 90% power with approx. 20% loss to follow up, 600 patients are needed. Similar calculations

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for HRQoL, using 0.316 SD units in EQ5D (based on a similar Scottish population (40)), for 90% power and presuming approx. 20% loss to follow up, we need a sample of 510 patients. We will recruit the larger number of 600 patients (300 in each study arm).

Data Collection

Data collection will be at baseline pre-randomisation and at three months from initial invitation to the intervention group to meet with the link worker. This will be prior to the control group meeting once with the link worker and receiving a truncated version of the intervention.

Patient reported outcome measures will be self-reported using standardised paper-based questionnaires, which will be posted to participants. Data on patient costs and community resources accessed, will be self-reported using a specifically designed questionnaire. A member of the research team will assist participants to fill in paper-based forms if there are literacy issues.

The health care utilisation data on GP visits, Out of Hours GP visits, prescribed medications and ED attendances will be extracted from health care records by a member of the research team. Allied health professional visits, hospital admissions and outpatient attendances will be self-reported as these are not currently captured in a timely and reliable way in GP health care records.

On completion of the RCT, we also plan to conduct an observational study on all participants at nine months from the intervention group receiving an invitation to meet with the link worker to examine changes in outcomes over this longer time period.

## Data management

Paper questionnaires will be returned by post to the research team in the Department of General Practice, RCSI, who will be responsible for manual data entry into pre designed excel spreadsheets. All participants will provide informed consent for the processing of their data. Data will be pseudonymised with the use of a unique study ID. All data will be stored in secure encrypted institutional network drives accessible only to named members of the research team. A comprehensive data management plan is in place which had been reviewed by the trial steering committee.

A Trial Steering Committee (TSC) comprising an independent chair and three other independent members, one of whom is a lay member representing the patient and public perspective, has been established and will oversee the progress of the trial and adherence to the study protocol.

Unintended consequences will be monitored during the trial using self-reporting by participants, reporting by link workers during planned supervision and reporting by GPs. GPs will receive instructions on how to report any adverse events on concerns they have to the trial manager during their training on the intervention. In addition, the trial manager will check in on a monthly basis with practices to get updates on any recruitment, implementation challenges and adverse events. Unintended consequences will also be explored as part of the process evaluation.

## Planned Statistical analysis

Descriptive statistics will be used to describe recruited participants and to investigate comparability of trial groups at baseline. For primary and secondary outcomes, the primary

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analyses will be ‘intention-to-treat’ (ITT) including all randomised participants, all retained in the group to which they were allocated and using last observation carried forward (LOCF) for missing values. The primary analysis will be adjusted for baseline scores and stratification variables, age and practice. Secondary analyses will include further adjustment for any variables displaying imbalance between the groups at baseline. We will also conduct a per-protocol (PP) analysis. The PP population will consist of those randomised to the intervention group who met with the link worker at least once. We will also conduct pre-planned subgroup analyses based on gender and age (above and below 65 years of age). All analyses will use appropriate (that is, linear or poisson) regression models with results presented as point estimates (difference in means or incident rate ratios), 95% confidence intervals and p-values. Stata 15 will be used for all data analysis (41).

Economic Evaluation

The health economic evaluation will consist of a trial-based cost utility analysis of the proposed intervention. The evaluation will be undertaken in a manner consistent with guidelines issued by the Health Information and Quality Authority (HIQA) in Ireland [42]. Evidence collected on direct costs of the intervention from the trial, community resource use and health outcome measures will provide the basis for the evaluation over the trial follow-up period. With respect to costing, a publicly funded health service perspective will be adopted. That is, resource use associated with delivery of the proposed intervention will be measured and costed, as will other health service resource use by patients over the course of the trial. For the cost utility analysis, effectiveness will be evaluated in terms of quality adjusted life years (QALYs), which will be estimated based on responses to the EuroQol EQ-5D-5L instrument [35].

An incremental analysis will be undertaken to provide information on the marginal costs and effects of the intervention relative to the control through the calculation of incremental cost effectiveness ratios (ICERs). The statistical analysis will be conducted in accordance with current guidelines for economic evaluation alongside cluster RCTs [42].

Probabilistic sensitivity analysis will be performed using the range of uncertainties from the statistical analysis of the trial. This allows the expected value of perfect information (EVPI) to be calculated. In this case given that the data will come from a single trial this will help to inform whether longer follow up is worth considering before investing in the intervention.

A cost effectiveness acceptability curve (CEAC) will be produced to examine the probability of the intervention being cost effective at different cost effectiveness thresholds. Incremental cost effectiveness ratio (ICER) per QALY gained will be presented along with a scatter plot, CEAC and EVPI.

### Process Evaluation

A mixed methods process evaluation is planned and we will publish a separate protocol outlining the methods for this evaluation, to be submitted to HRB Open research

### Public and Patient Involvement (PPI) and implementation advisory group

This study has public and patient involvement through a multimorbidity patient advisory group and an implementation advisory group. The patient advisory group are patients with multimorbidity who meet quarterly to discuss issues arising with research projects on multimorbidity funded through the Health Research Board Collaborative Doctoral Award (BK is a PhD student on this programme). The specific input of the PPI groups is outlined in the pilot study paper (Ref, paper in submission process with the Journal of Comorbidity) but in

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summary it included co-design of patient information leaflets, input on patient outcome selection and questionnaire design.

The implementation advisory group consists of GPs working in deprived areas, with and without experience of social prescribing and a project manager from a well established social prescribing project in a deprived inner city area in Dublin.

Discussion

This trial will provide some of the most robust results to date on link workers. As a recent systematic review on link worker interventions concluded there is insufficient evidence “to judge either success or value for money” and “future evaluations must be comparative by design and consider when, by whom, for whom, how well and at what cost” interventions are for (19). While previous projects have not specified strict inclusion criteria and have often focused on younger patients with mental health problems (42), we are focusing on multimorbidity, which is predicted to increase in prevalence and is known to be a particular challenge in areas of deprivation. This will contribute to evidence on who is most likely to benefit from link workers and social prescribing as well as providing robust effectiveness and economic data.

A recent systematic review of the self-management characteristics of patients with complex health needs concluded that tailored self-management support is required for people in areas of socioeconomic deprivation to address the social norms that accept poorer health, social isolation and socioeconomic insecurity (43). Link workers are one intervention that could provide this kind of support. Governments are recognising this and link workers are

specifically mentioned in the UK NHS Long Term Plan and funding provided to primary care clinical commissioning groups for one link worker per 30,000 population (44). An all-party Committee on the Future of Health Care in the Irish Parliament agreed on a plan for healthcare reform in Ireland in 2017, called Slaintecare (45). This is now being implemented through the Department of Health and Children and it emphasises a shift towards care in the community and empowering people to manage their own health (46). Social prescribing is recognised as one way to achieve this. The Department of Health announced a Slaintecare Integration Fund programme in 2019 which is funding a range of projects evaluating interventions that reflect Slaintecare priorities, including this study. Social Prescribing is also being supported by the Irish national Health Service Executive (HSE) with a number of funded pilots (17, 18). However, the lack of robust evaluation is recognised and the HSE are in the process of developing an evaluation framework. The results of this trial and process evaluation will be timely in informing national policy about the role-out of link workers and social prescribing nationally.

### Strengths

While there have been a number of smaller trials and quasi-experimental studies this trial will be the first large scale pragmatic randomised trial of a link worker and social prescribing intervention. This will overcome the previous challenge of finding suitable controls in non-randomised trials (20, 47) and provide some of the most robust results to date on link workers. Furthermore, this will be the first multimorbidity trial with a link worker type intervention and this intervention addresses the challenge of identifying a generic intervention that works across all conditions, as recommended in the Cochrane review of interventions for multimorbidity (14).

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Limitations

Our study is restricted to urban deprived areas. Rural areas provide unique challenges and have less concentrated deprivation, which would affect costs and recruitment timelines. While deprivation in Ireland is concentrated in urban areas the results of this trial may not be applicable to more rural locations. Due to the nature of the funding and the wait list control design our intervention is only three months in duration and this may be too short a time to both deliver and show a significant difference in outcomes. While the intervention period is shorter than the Glasgow Deep End Linksworke model, it is in keeping with pilot projects in Ireland where link workers supported people over a 6-8 week period (42). In order to better understand the mechanisms of impact of the intervention we are collecting a range of measures, but a lengthy questionnaire may be off putting to potential participants, especially those who are most deprived, leading to a biased sample. The levels of patient engagement in the pilot study however are encouraging and the further input from our patient advisory group and expert panel of GPs on recruitment strategies and materials should mitigate against this.

Conclusion

This pragmatic randomised controlled trial will add to the evidence base for link workers and social prescribing at a time when there is considerable national and international interest in rolling out this intervention more widely. The trial will provide evidence on the effectiveness of link workers based in primary care in deprived areas for people with multimorbidity. The economic evaluation will provide a cost per QALY gained which will be important for policy makers going forward.

## Ethics Approval

Ethical approval has been granted by the Irish College of General Practitioners Ethics committee. This includes a Data Management Plan and Data Impact Assessment Form to ensure adherence to GDPR and Health Research Regulations.

## Consent and confidentiality

Fully informed consent will be obtained from all participants. Confidentiality will be maintained by pseudonymisation of data using a unique study ID. Only named members of the research team will have access to individuals personal contact data and will only access it to communicate with participants regarding the trial. All data will be stored in secure password protected files with named access only.

## Data availability

Data will be stored for seven years in line with RCSI data management policy and shared at the time of publication where facilities permit and under ethical and data protection requirements. Once final data analysis has been undertaken and peer reviewed publications secured, anonymised data arising from this study may be accessed by contacting the PI and data may be placed on publicly accessible sites such as the Irish Social Science Data Archive (ISSDA). Researchers who wish to access the data can submit a request to the ISSDA and can use the data for research or teaching purposes with appropriate attribution and citation.

## PPI

This study is supported by the HRB CDA in Multimorbidity PPI panel, convened in May 2019.

Dissemination

The end study results will be published in peer-reviewed journals and will be open access. A full report will also be submitted to funders. The results will also be disseminated to relevant stakeholders and participating GP practices. The PPI panel will be consulted on how best to disseminate results to people with multimorbidity.

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Author contributions

Bridget Kiely is the Lead researcher for the pilot project and RCT and completed initial draft and contributed to manuscript drafts and approved the final draft. Barbara Clyne gave advice on methodology for the pilot and main RCT and contributed to manuscript drafts and approved the final draft. Mark Murphy contributed to manuscript drafts and approved the final draft. Patrick O'Donnell contributed to manuscript drafts and approved the final draft. Fiona Boland is the lead statistician for project, gave advice on randomization methods and planned statistical analysis. She also contributed to manuscript drafts and approved the final draft. Deirdre Connolly contributed to manuscript drafts and approved the final draft. Eamon O Shea is the lead economist and advised on economic methods and analysis plans. Susan Smith conceptualized the original research question and trial methodology and will act as corresponding author. All authors reviewed and approved the final draft.

Competing Interests

The authors declare that they have no competing interests.

## Funding

This trial is jointly funded by the Health Research Board Ireland (Grant reference HRB CDA 2018 Reference CDA-2018-003) and the Department of Health Slaintecare Integration Fund (Grant reference PCC-ID24). The funders did not have any role in the design of this study.

For peer review only

Figure 1 Process for selection and recruitment of participants

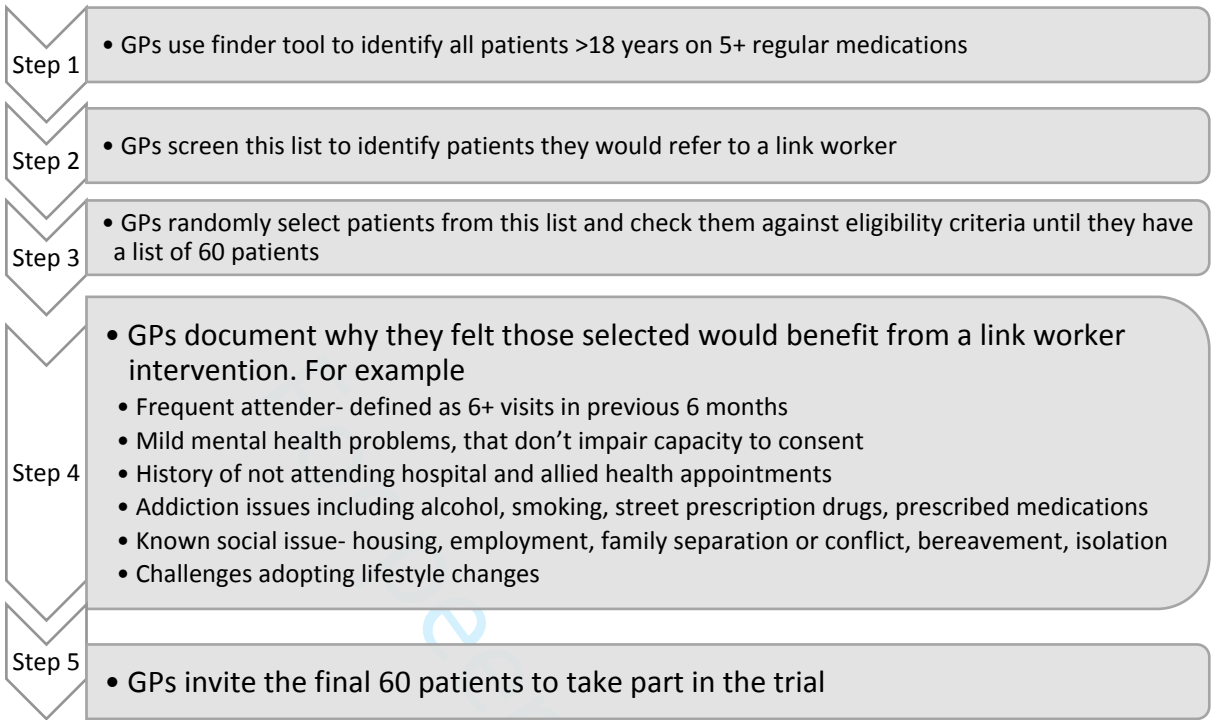


Figure. Example template of recommended content for the schedule of enrolment, interventions, and assessments.\*

	STUDY PERIOD						
	Enrolment	Post-allocation					Close-out
TIMEPOINT**	-1 month	M1	M2	M3	M4	M5	M6
<b>ENROLMENT:</b>							
Eligibility screen	X						
Informed consent and baseline data collection phase 1 recruitment	X						
Informed consent and baseline data collection phase 2 recruitment		x					
Informed consent and baseline data collection phase 3 recruitment			x				
Allocation phase 1 recruitment	x						
Allocation phase 2 recruitment		x					
Allocation phase 3 recruitment			x				
<b>INTERVENTIONS:</b>							
Intervention group first phase recruitment meet with link worker		←→					
Intervention group second phase recruitment meet with link worker			←→				
Intervention group third phase recruitment meet with link worker				←→			
Control group received truncated version of intervention]						←→	
<b>ASSESSMENTS:</b>							
Follow up current use and cost of community					x		

<b>resources, patient reported outcome measures Phase 1 recruitment</b>							
<b>Follow up current use and cost of community resources, patient reported outcome measures Phase 2 recruitment</b>						x	
<b>Follow up current use and cost of community resources, patient reported outcome measures Phase 3 recruitment</b>							x
<b>Health care utilisation</b>	x				x	x	x

\*Recommended content can be displayed using various schematic formats. See SPIRIT 2013 Explanation and Elaboration for examples from protocols.

\*\*List specific timepoints in this row.

# BMJ Open

## Link workers providing social prescribing and health and social care coordination for people with multimorbidity in socially deprived areas (The LinkMM trial): Protocol for a pragmatic randomised controlled trial.

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2020-041809.R1
Article Type:	Protocol
Date Submitted by the Author:	18-Nov-2020
Complete List of Authors:	Kiely, Bridget; Royal College of Surgeons in Ireland Department of General Practice, Department of General Practice Clyne, Barbara; Royal College of Surgeons in Ireland Department of General Practice, Department of General Practice Boland, Fiona; Royal College of Surgeons in Ireland Department of General Practice, HRB Centre For Primary Care Research, Division of Population Health Sciences (PHS) O'Donnell, Patrick; University of Limerick Graduate Entry Medical School, Connolly, Deirdre; Trinity College, Occupational Therapy O'Shea, Eamon; National University of Ireland Galway, School of Business and Economics Smith, Susan; Royal College of Surgeons in Ireland Department of General Practice, General Practice
<b>Primary Subject Heading</b>:	General practice / Family practice
Secondary Subject Heading:	Health services research
Keywords:	PRIMARY CARE, PREVENTIVE MEDICINE, SOCIAL MEDICINE

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## Note from the Editors: Instructions for reviewers of study protocols

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Since launching in 2011, BMJ Open has published study protocols for planned or ongoing research studies. If data collection is complete, we will not consider the manuscript.

Publishing study protocols enables researchers and funding bodies to stay up to date in their fields by providing exposure to research activity that may not otherwise be widely publicised. This can help prevent unnecessary duplication of work and will hopefully enable collaboration. Publishing protocols in full also makes available more information than is currently required by trial registries and increases transparency, making it easier for others (editors, reviewers and readers) to see and understand any deviations from the protocol that occur during the conduct of the study.

The scientific integrity and the credibility of the study data depend substantially on the study design and methodology, which is why the study protocol requires a thorough peer-review.

*BMJ Open* will consider for publication protocols for any study design, including observational studies and systematic reviews.

Some things to keep in mind when reviewing the study protocol:

- Protocol papers should report planned or ongoing studies. The dates of the study should be included in the manuscript.
- Unfortunately we are unable to customize the reviewer report form for study protocols. As such, some of the items (i.e., those pertaining to results) on the form should be scored as Not Applicable (N/A).
- While some baseline data can be presented, there should be no results or conclusions present in the study protocol.
- For studies that are ongoing, it is generally the case that very few changes can be made to the methodology. As such, requests for revisions are generally clarifications for the rationale or details relating to the methods. If there is a major flaw in the study that would prevent a sound interpretation of the data, we would expect the study protocol to be rejected.

Title

Link workers providing social prescribing and health and social care coordination for people with multimorbidity in socially deprived areas (The LinkMM trial): Protocol for a pragmatic randomised controlled trial.

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## Abstract

### Introduction

Link workers are non-health or social care professionals based in primary care who support people to develop and achieve a personalised set of health and social goals by engaging with community resources. Link workers have been piloted in areas of deprivation, but there remains insufficient evidence to support their effectiveness. Multimorbidity is increasing in prevalence but there are limited evidence-based interventions. This paper presents the protocol for a randomised controlled trial that will test the effectiveness of link workers based in general practices in deprived areas in improving health outcomes for people with multimorbidity.

### Methods and analysis

The protocol presents the proposed pragmatic randomised controlled trial, involving 10 GP practices and 600 patients. Eligible participants will be community dwelling adults with multimorbidity ( $\geq$ two chronic conditions) identified as being suitable for referral to a practice-based link worker.

Following baseline data collection, patients will be randomised into intervention group that will meet the linkworker over a one-month period, or a 'wait list' control that will receive usual GP care.

Primary outcomes are health related quality of life as assessed by EQ5D-5L and mental health assessed by HADS. Secondary outcomes are based on the core outcome set for multimorbidity. Data will be collected at baseline and on intervention completion at 1 month using questionnaires self-completed by participants and GP records.

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Parallel process and economic analyses will be conducted to explore participants’ experiences and examine cost-effectiveness of the link worker intervention

Ethics and Dissemination

Ethical approval has been granted by the Irish College of General Practitioners Ethics committee. The findings will be published in peer-reviewed journals.

Registration

This trial is registered on ISRCTN

Title: Use of link workers to provide social prescribing and health and social care coordination for people with complex multimorbidity in socially deprived areas

Trial ID: ISRCTN10287737

Date registered: 10/12/2019

Link: <https://www.isrctn.com/ISRCTN10287737>

Strengths and Limitations

- The LinkMM study is a pragmatic RCT examining the effectiveness of a practice-based link worker intervention for patients with multimorbidity.
- The focus on people with multimorbidity builds the evidence base for generic interventions that work across all conditions in multimorbidity.

- The short intervention and follow up period allows for a wait list control design and is consistent with the duration of real world link worker interventions, but may be too short to show a meaningful difference in outcomes.
- The large number of patient reported outcomes is consistent with the Medical Research Council guidance on evaluating complex interventions, but may be off putting to people with lower literacy levels, creating challenges for recruitment and potential threats to generalisability for very vulnerable adults with multimorbidity.
- Parallel process and economic analysis will add to our understanding of the implementation of this type of intervention and determine the cost-effectiveness of the intervention

## Keywords

Link worker, social prescribing, multimorbidity, complex intervention, primary care, general practice, social deprivation.

Word Count 4878

## Introduction

Multimorbidity, defined as the presence of 2 or more chronic conditions, is recognised as a significant challenge for patients and health care systems, particularly in primary care and in areas of social deprivation (1). Within the broader multimorbidity population there are people with higher numbers of conditions involving multiple body systems with related

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polypharmacy, which is referred to as complex multimorbidity (2). Multimorbidity and complex multimorbidity are estimated to affect 66.2% and 11% respectively of people over 50 attending Irish General Practice (3). Complex multimorbidity is associated with increased health care utilisation and costs. People with complex multimorbidity experience more fragmented care, poorer mental health and have worse outcomes (4, 5). There are higher proportions of patients with complex combinations of physical and mental health conditions in deprived areas (4). This is reflected in higher consultation rates and has ramifications throughout the health system. Ten percent of patients with four or more conditions account for 34% of unplanned emergency admissions and 47% of preventable unplanned admissions (6). People living in deprived areas develop multimorbidity 11 years earlier (4) and experience worse quality of life compared to those with multimorbidity in less deprived areas (7). It is not clear why this is, but there is growing evidence that people with multimorbidity in areas of deprivation have reduced self-efficacy and capacity for self-management due to psychosocial stressors, poorer mental health, increased burden of treatment and lower perceived social support (8) (9) (10) (11-13).

There is as yet, limited evidence to indicate which interventions for multimorbidity have a significant impact on health outcomes or health service utilisation (14). One potential intervention to address the complex mix of psychosocial issues and multimorbidity in areas of deprivation is the use of link workers in primary care. A link worker is a non-health or social care professional who usually has training in coaching or behaviour change as well as an extensive knowledge of local community resources. They work with people referred to them by healthcare services to identify their health and social care needs and support them to access services within the community to improve their health and well-being, a process commonly referred to as social prescribing (15). The Glasgow Deepend Linksworker

programme describes the principle behind the link worker intervention as *“a catalyst to hope and self-determination, using the strong relationships with patients that exist in general practice. If patients with complex needs feel supported, they would be more likely to respond to information on ways to improve their health”* (16). The current study builds on this work using a similar intervention approach with link workers embedded in practices in deprived urban areas.

Although link workers providing social prescribing have been gaining popularity in the UK and there have been a number of pilots in Ireland (17, 18), few have been formally evaluated. A recent review of link worker provided social prescribing in the UK found limited evidence to support the effectiveness and concluded that there was a lack of evidence for how, for whom and when social prescribing was effective (19). A recent quasi-experimental evaluation of the Glasgow Deep End Links worker programme found some impact on mental health scores for patients and staff morale in GP practices and concluded that larger, longer studies, with randomisation at the individual patient level were needed (20).

The Deep End Ireland GP group, a network of practices based in areas of deprivation, prepared a Report on link workers in Ireland that outlined its potential to address the psychosocial burden faced by their patients and the impacts of upstream social determinants of health that GPs often encounter but can have little impact on in practice (21).

To inform the implementation of the intervention and evaluation processes a short uncontrolled pilot study was conducted in one practice with 12 patients. This confirmed the feasibility of intervention delivery and led to refinements in patient selection and data collection processes. (Ref, paper in submission process with the Journal of Comorbidity)

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This study aims to evaluate a link worker intervention in primary care on health outcomes for people with complex multimorbidity in socially deprived areas. Secondary aims are to examine the impact on staff morale and conduct a mixed methods process evaluation and economic evaluation of the intervention, exploring direct and indirect costs.

Methods

This protocol is presented using the SPIRIT recommendations for the reporting of a protocol for an interventional trial (22).

Study design

This will be a pragmatic RCT to evaluate a link worker intervention in improving health outcomes for people with multimorbidity attending primary care in socially deprived areas compared to wait list controls who receive usual care. It will be reported in accordance with the CONSORT guidance for randomised controlled trials (23). The economic analysis will be a cost utility analysis from the perspective of the public health care system and will be carried out in accordance with the guidance produced by the Health and Information Quality Authority Ireland (24).

A parallel mixed methods process evaluation will be conducted in line with the Medical Research Council guidance on evaluating complex interventions (25). The process evaluation protocol will be informed by the MRC framework for process evaluations (26). A full protocol for the process evaluation will be published in an open access source.

## Public and Patient Involvement (PPI)

This study has public and patient involvement through a multimorbidity patient advisory group. The patient advisory group are patients with multimorbidity who meet quarterly to discuss issues arising with research projects on multimorbidity funded through the Health Research Board Collaborative Doctoral Award (BK is a PhD student on this programme). The specific input of the PPI groups is outlined in the pilot study paper (Ref, paper in submission process with the Journal of Comorbidity) but in summary it included co-design of patient information leaflets, input on patient outcome selection and questionnaire design.

## Implementation Advisory Group

The implementation advisory group consists of GPs working in deprived areas, with and without experience of social prescribing and a project manager from a well established social prescribing project in a deprived inner city area in Dublin.

## Study settings

This study will be conducted in urban general practices serving areas of deprivation in four cities (Dublin, Cork, Limerick and Waterford) within the Republic of Ireland. Serving areas of deprivation will be defined as providing general practice care to at least two small areas identified as disadvantaged or below by The Pobal HP Deprivation index(27) and provide services to at least 1,000 patients under the General Medical Services (GMS) scheme. The Pobal HP deprivation index is Ireland's most widely used social gradient metric and scores each small area (50 – 200 households) in terms of affluence or disadvantage. The index uses information from Ireland's census, such as employment, age profile and educational attainment, to calculate this score (27). The GMS scheme provides medical care to approximately 40% of the Irish population. It is predominantly means-tested and provides

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eligible patients with free general practitioner visits, free hospital care and free medications (except for a prescription levy, currently €2.50 per item to a maximum of €25).

Eligibility Criteria

Participants

Participants will be community dwelling adults aged over 18, who have two or more chronic conditions (multimorbidity), attend a GP that provides care for patients living in an area of deprivation and have been identified by their GP as having potential to benefit from a link worker intervention. As this is a pragmatic trial we are seeking to replicate conditions in real work practice where GPs would refer to a link worker based on need. There will be no predefined conditions, other than the conditions should be chronic, that is lasting or expected to last more than 6 months.

Exclusion criteria include psychiatric/ psychological morbidity or cognitive impairment that would impair capacity for informed consent, a terminal illness likely to lead to death or major disability during the study follow-up period, living in residential care, already participating in a similar programme or had previously participated in the pilot study.

Practices

Ten practices in the Deep End Ireland group will be invited to participate (28). Membership of the group is open to any practice that identifies as working in an area of deprivation. In addition, practices must have a GMS list of >1000 patients, serve at least two small areas defined as disadvantaged or below by the Pobal HP deprivation index 2016 and have space to

host a link worker on site. Practices that are taking part in another link worker project will be excluded.

## Recruitment and Randomisation

Each practice will be asked to recruit 60 participants, giving a total of 600 patients.

Recruitment will begin one month before the start date of the intervention and will be phased for logistical reasons with 20 participants being recruited each month in each practice.

Eligible participants will be identified by their GPs, based on being prescribed five or more medications as a proxy for multimorbidity. This proxy is being used because of significant variation in coding practices for chronic conditions in Ireland and lack of a code for multimorbidity. A finder tool in the electronic record, previously developed for another multimorbidity study (29), will generate this list of patients. Previous research has indicated that medication count is a suitable proxy measure for multimorbidity (6) The GP team will screen this list of patients with multimorbidity to identify all patients who they would refer to a link worker and thus create a register of potentially eligible patients. This process is based on our pilot study findings and is designed to reflect real world conditions where GPs refer patients they identify as having a psychosocial need that would benefit from a social prescribing approach to a link worker.. Once this register of potentially eligible patients is created, GPs will be supported to arrange the list in random order and select the first 30 potential participants to invite. They will then be asked to double check that the selected participants meet the inclusion criteria and ensure none of the exclusion criteria apply. GPs will also be asked to document the reasons why each of the selected patients would be referred to a link worker using a standardised list of options. This list will include reasons for referral identified from other studies and known proxies for psychosocial need such as

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frequent attendance and will also allow GPs to record free text additional reasons. This process will improve transparency around referral decision making and provide additional data on types of patients referred for link worker supports and is summarised in Figure 1.

The research team will update the GP practices on a fortnightly basis of who has returned consent forms. The GPs will be encouraged to remind anyone who had verbally agreed to take part during the phone call stage, but not yet returned a consent form to do so. At monthly intervals the GPs will be asked to invite another 30 patients from the randomly ordered list of potential participants until the total of 60 participants has been reached. Recruitment will end 10 weeks before the end of the study to allow for sufficient time for baseline data collection, randomisation and delivery of the intervention. The expected recruitment rate is 60% based on the quasi-experimental evaluation of the Glasgow linkworker project (20) where 50% of potential participants were recruited and our own pilot where 70% of invited participants returned consent and baseline questionnaires.

A letter of invitation, patient information leaflet, consent and baseline questionnaires will be sent to eligible participants and GP teams will follow up with phone calls to explain the study and see if potential participants require assistance completing the baseline questionnaires. One in six Irish adults are functionally illiterate and so it is assumed that at least this number will require their GP to verbally explain the study and need assistance with completion of the baseline questionnaires (30). Once they have consented, a member of the research team can assist them with baseline data collection either face to face at the practice or over the phone. Randomisation will take place following baseline data collection to avoid allocation bias. Randomisation will be carried out by an independent researcher and overseen by the trial

statistician using a computer-generated sequence. Patients will be stratified by practice and age and allocation will be blocked using random permuted blocks of sizes 2 and 4 to ensure balanced numbers of intervention and control patients in each practice.

The independent researcher will inform the research team of allocations. The research team will contact the participants by phone to inform them of their allocation and what to expect. The research team will inform the relevant link worker by phone who has been allocated to the intervention group. A letter will be sent to the GP practice informing them of the participants involvement in the trial and their allocation. Due to the nature of the intervention it is not possible to blind participants, link workers or GPs to the allocation. Blinding will be implemented at the data analysis stage.

## Intervention

The link worker intervention (LinkMM) is based on the Glasgow Deep End Links worker project which had a quasi-experimental cluster design (30). Our intervention is shorter than the Glasgow project to facilitate the wait list control study design and it does not include practice subsidies for developing in practice activities beyond hosting the link worker. The LinkMM intervention is a complex intervention with the following components:

- Link worker training and support
- GP training
- Compilation and mapping of local health and social care community resources
- Link worker participant meetings and follow up
- Financial supports to practices

### Link worker training and support

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To inform the implementation of link worker social prescribing project the lead researcher attended Social Prescribing Network Ireland meetings and engaged with local social prescribing projects to explore the nature of the link worker role and appropriate job specifications, training, communication with GPs and engaging with community resource providers. In keeping with the literature, empathy and an ability to listen were identified as important link worker skills (31). Given the limited training time available, a background in health or social care and experience of working with disadvantaged communities were essential criteria for applicants to the role.

Resources from the Alliance website(32) (the community organisation who had delivered the link worker intervention in the Glasgow Deep End Links Worker project) were referenced to develop a 40 hour training plan with input from local social prescribing providers and based on the experience of our pilot study link worker, who had significant experience in health and social care and working with disadvantaged communities. Link workers will be employees of the research host institution rather than the general practices and will be line managed by the trial project manager. They will have monthly check-ins with the project manager and bimonthly peer support meetings and review sessions. Any clinical concerns regarding participants will be raised with the individual’s GP. If for whatever reason they are unable to access the individual’s GP link workers can seek support from the principal investigator (SMS), an experienced GP.

GP training

GP practices will receive training on site or via video-link on trial processes including selecting and recruitment processes, including the potential reasons a patient might be referred to a link worker. The link worker role will be explained.

### Compilation and mapping of local health and social care community resources

The research team will have identified some key local resources for each area in advance of the link worker taking up their post. The link workers will have allocated time during their induction period to map out local resources using a template developed during the pilot. This will however be an ongoing process depending on the needs of participants. In the context of the ongoing Covid-19 pandemic, online and individual resources will also be identified for those unable to attend group activities.

### Link worker participants meetings and follow up

Following randomisation, intervention group participants will be referred to the link worker straight away and invited to meet with them at least once, with at least 60 minutes scheduled for this initial appointment. At the initial meeting the link worker will explain their role and explore the participants' health and social care priorities and produce a joint plan to address these. This will include a range of activities and community resources that participants may choose to attend to improve their health and well-being. The link worker will offer to follow up and support participants to implement their plan. It is expected that support will broadly fall into one of four categories, informational (supplying information on resources, directing to websites etc. ), instrumental (making an appointment on behalf of a participant or accompanying them to an appointment), appraisal (helping participants to make changes using behaviour change techniques such as motivational interviewing) or emotional (listening and encouraging when participants face challenges) (34). As support is tailored to the needs of the individual it will vary. All link worker activity will be captured in a specifically designed client management database, including details of the initial assessment, priority health and social issues, goals set, community resources referred to and attended, number of follow ups

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and the type of support provided, as per the categories outlined above. This will be fully reported in a parallel process evaluation and briefly described in the main trial report. There will be no change to the participants usual clinical care. At the end of the intervention period the link worker will provide a summary to the participant’s GP, outlining the plan and resources they accessed to help achieve it.

The link worker will be based in the GP practice and meetings with participants will primarily be in the GP practice. The link worker will be able to liaise with participant’s GPs should they have any specific concerns about an individual. Link workers will also share knowledge on local community resources with GPs during monthly meetings with practice staff.

Financial supports to practices

Practices will receive a stipend to cover one session a week of GP time to allow for time spent on recruitment and supporting the link worker intervention. An additional grant will cover any room hire and equipment costs that the practice may incur as a result of hosting the link worker.

Control

The RCT will have a wait list control. During the 3-month intervention period the control group will receive usual care from their GP. On completion of the intervention, the control group will be invited to a one-off meeting with the link worker, during which they will have an opportunity to identify their needs and be provided with a list of suggested resources tailored to their needs and a booklet of community resources.

## Outcomes

A wide range of outcomes will be used to assess intervention effectiveness and mechanism of action in line with the MRC framework for evaluating complex interventions (25). Outcomes are based on the pilot study findings and on the Core Outcome Set for Multimorbidity research (33). In line with the National Institute for Health Care Excellence an additional measure of capability and wellbeing, the ICE-CAP A (ICEpop CAPability measure for Adults) (34) will be used alongside the EQ5D-5L to capture the wider social benefits to the individual that are expected with this type of intervention.

### Primary Outcomes

- Health related quality of life as measured by EQ5D-5L (35)
- Mental health as measured by Hospital Anxiety and Depression Scale (36)

### Secondary Outcomes

#### Patient reported outcome measures

- Capability and wellbeing as measured by the ICE-CAP A (34)
- Activities of daily living as measured by the Frenchay Activity Index (37)
- Self-management as measured by the Patient Activation Measure (38)
- Burden of treatment measured by Multimorbidity Burden of Treatment Questionnaire (39)

#### Health care utilisation

Data from primary care electronic health records, in the previous month unless otherwise specified:

- Number of GP attendances
- Number of practice nurse attendances
- Number and type of regularly prescribed medications
- Number of out of hours GP attendances
- Number of Emergency Department attendances
- Number of hospital admissions (emergency) and length of stay
- Number of hospital outpatient visits

Sample Size

A sample size of 600 participants in total has been calculated based on our two primary outcomes. Using a HADs Anxiety score of 10.9, a standard deviation of 5.1 and a minimally clinically important difference of 1.5 (based on a similar Scottish population study (40)); for 90% power with approx. 20% loss to follow up, 600 patients are needed. Similar calculations for HRQoL, using 0.316 SD units in EQ5D (based on a similar Scottish population (40)), for 90% power and presuming approx. 20% loss to follow up, we need a sample of 510 patients. We will recruit the larger number of 600 patients (300 in each study arm).

Data Collection

Data collection will be at baseline pre-randomisation and at one month from initial invitation to the intervention group to meet with the link worker. This will be prior to the control group meeting once with the link worker and receiving a truncated version of the intervention.

Patient reported outcome measures will be self-reported using standardised paper-based questionnaires, which will be posted to participants. Data on patient costs and community resources accessed, will be self-reported using a specifically designed questionnaire. A

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3 member of the research team will assist participants to fill in paper-based forms if there are  
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9 The health care utilisation data on GP visits, Out of Hours GP visits, prescribed medications  
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11 and ED attendances will be extracted from health care records by a member of the research  
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17 On completion of the RCT, we also plan to conduct an observational study on all participants  
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19 at nine months from the intervention group receiving an invitation to meet with the link  
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21 worker to examine changes in outcomes over this longer time period.  
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## 24 25 Data management

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27 Paper questionnaires will be returned by post to the research team in the Department of  
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29 General Practice, RCSI, who will be responsible for manual data entry into pre designed excel  
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31 spreadsheets. All participants will provide informed consent for the processing of their data.  
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33 Data will be pseudonymised with the use of a unique study ID. All data will be stored in secure  
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35 encrypted institutional network drives accessible only to named members of the research  
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37 team. A comprehensive data management plan is in place which had been reviewed by the  
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39 trial steering committee.  
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46 A Trial Steering Committee (TSC) comprising an independent chair and three other  
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48 independent members, one of whom is a lay member representing the patient and public  
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50 perspective, has been established and will oversee the progress of the trial and adherence to  
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52 the study protocol.  
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56 Unintended consequences will be monitored during the trial using self-reporting by  
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58 participants, reporting by link workers during planned supervision and reporting by GPs. GPs  
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will receive instructions on how to report any adverse events on concerns they have to the trial manager during their training on the intervention. In addition, the trial manager will check in on a monthly basis with practices to get updates on any recruitment, implementation challenges and adverse events. Unintended consequences will also be explored as part of the process evaluation.

Planned Statistical analysis

Descriptive statistics will be used to describe recruited participants and to investigate comparability of trial groups at baseline. For primary and secondary outcomes, the primary analyses will be ‘intention-to-treat’ (ITT) including all randomised participants, all retained in the group to which they were allocated and using last observation carried forward (LOCF) for missing values. The primary analysis will be adjusted for baseline scores and stratification variables, age and practice. Subsequent models will adjust for multimorbidity severity. We will also conduct a per-protocol (PP) analysis. The PP population will consist of those randomised to the intervention group who met with the link worker at least once. We will also conduct pre-planned sub-group analyses based on gender and age (above and below 65 years of age). All analyses will use appropriate (that is, linear or poisson) regression models with results presented as point estimates (difference in means or incident rate ratios), 95% confidence intervals and p-values. Stata 15 will be used for all data analysis (41).

Economic Evaluation

The health economic evaluation will consist of a trial-based cost utility analysis of the proposed intervention. The evaluation will be undertaken in a manner consistent with guidelines issued by the Health Information and Quality Authority (HIQA) in Ireland [42].

Evidence collected on direct costs of the intervention from the trial, community resource use and health outcome measures will provide the basis for the evaluation over the trial follow-up period. With respect to costing, a publicly funded health service perspective will be adopted. That is, resource use associated with delivery of the proposed intervention will be measured and costed, as will other health service resource use by patients over the course of the trial. For the cost utility analysis, effectiveness will be evaluated in terms of quality adjusted life years (QALYs), which will be estimated based on responses to the EuroQol EQ-5D-5L instrument [35].

An incremental analysis will be undertaken to provide information on the marginal costs and effects of the intervention relative to the control through the calculation of incremental cost effectiveness ratios (ICERs). The statistical analysis will be conducted in accordance with current guidelines for economic evaluation alongside cluster RCTs [42].

Probabilistic sensitivity analysis will be performed using the range of uncertainties from the statistical analysis of the trial. This allows the expected value of perfect information (EVPI) to be calculated. In this case given that the data will come from a single trial this will help to inform whether longer follow up is worth considering before investing in the intervention.

A cost effectiveness acceptability curve (CEAC) will be produced to examine the probability of the intervention being cost effective at different cost effectiveness thresholds. Incremental cost effectiveness ratio (ICER) per QALY gained will be presented along with a scatter plot, CEAC and EVPI.

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Process Evaluation

A mixed methods process evaluation is planned and we will publish a separate protocol outlining the methods for this evaluation, to be submitted to HRB Open research

Discussion

This trial will provide some of the most robust results to date on link workers. As a recent systematic review on link worker interventions concluded there is insufficient evidence “to judge either success or value for money” and “future evaluations must be comparative by design and consider when, by whom, for whom, how well and at what cost” interventions are provided (19). While previous projects have not specified strict inclusion criteria and have often focused on younger patients with mental health problems (42), we are focusing on multimorbidity, which is predicted to increase in prevalence and is known to be a particular challenge in areas of deprivation. This will contribute to evidence on who is most likely to benefit from link workers and social prescribing as well as providing robust effectiveness and economic data.

A recent systematic review of the self-management characteristics of patients with complex health needs concluded that tailored self-management support is required for people in areas of socioeconomic deprivation to address the social norms that accept poorer health, social isolation and socioeconomic insecurity (43). Link workers are one intervention that could provide this kind of support. Governments are recognising this and link workers are specifically mentioned in the UK NHS Long Term Plan and funding provided to primary care clinical commissioning groups for one link worker per 30,000 population (44). An all-party

Committee on the Future of Health Care in the Irish Parliament agreed on a plan for healthcare reform in Ireland in 2017, called Slaintecare (45). This is now being implemented through the Department of Health and Children and it emphasises a shift towards care in the community and empowering people to manage their own health (46). Social prescribing is recognised as one way to achieve this. The Department of Health announced a Slaintecare Integration Fund programme in 2019 which is funding a range of projects evaluating interventions that reflect Slaintecare priorities, including this study. Social Prescribing is also being supported by the Irish national Health Service Executive (HSE) with a number of funded pilots (17, 18). However, the lack of robust evaluation is recognised and the HSE are in the process of developing an evaluation framework. The results of this trial and process evaluation will be timely in informing national policy about the role-out of link workers and social prescribing nationally.

### Strengths

While there have been a number of smaller trials and quasi-experimental studies this trial will be the first large scale pragmatic randomised trial of a link worker and social prescribing intervention. This will overcome the previous challenge of finding suitable controls in non-randomised trials (20, 47) and provide some of the most robust results to date on link workers. Furthermore, this will be the first multimorbidity trial with a link worker type intervention and this intervention addresses the challenge of identifying a generic intervention that works across all conditions, as recommended in the Cochrane review of interventions for multimorbidity (14).

### Limitations

Our study is restricted to urban deprived areas. Rural areas provide unique challenges and have less concentrated deprivation, which would affect costs and recruitment timelines.

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While deprivation in Ireland is concentrated in urban areas the results of this trial may not be applicable to more rural locations. Due to the nature of the funding and the wait list control design our intervention is only three months in duration and this may be too short a time to both deliver and show a significant difference in outcomes. While the intervention period is shorter than the Glasgow Deep End Linkworker model, it is in keeping with pilot projects in Ireland where link workers supported people over a 6-8 week period (42). In order to better understand the mechanisms of impact of the intervention we are collecting a range of measures, but a lengthy questionnaire may be off putting to potential participants, especially those who are most deprived, leading to a biased sample. The levels of patient engagement in the pilot study however are encouraging and the further input from our patient advisory group and expert panel of GPs on recruitment strategies and materials should mitigate against this. The method in which participants are selected may result in a selection bias, with GPs selecting participants based on the GPs perception of psychosocial needs. This is however the way such an intervention would be implemented in real world clinical practice, and so the trial is designed to be pragmatic. To better understand why GPs have selected participants they will be asked to document a reason and this will be reported to provide greater transparency into the selection of participants.

Conclusion

This pragmatic randomised controlled trial will add to the evidence base for link workers and social prescribing at a time when there is considerable national and international interest in rolling out this intervention more widely. The trial will provide evidence on the effectiveness of link workers based in primary care in deprived areas for people with multimorbidity. The economic evaluation will provide a cost per QALY gained which will be important for policy makers going forward.

## Ethics Approval and Dissemination

Ethical approval has been granted by the Irish College of General Practitioners Ethics committee. This includes a Data Management Plan and Data Impact Assessment Form to ensure adherence to GDPR and Health Research Regulations.

The end study results will be published in peer-reviewed journals and will be open access. A full report will also be submitted to funders. The results will also be disseminated to relevant stakeholders and participating GP practices. The PPI panel will be consulted on how best to disseminate results to people with multimorbidity.

## Consent and confidentiality

Fully informed consent will be obtained from all participants. Confidentiality will be maintained by pseudonymisation of data using a unique study ID. Only named members of the research team will have access to individuals personal contact data and will only access it to communicate with participants regarding the trial. All data will be stored in secure password protected files with named access only.

## Data availability

Data will be stored for seven years in line with RCSI data management policy and shared at the time of publication where facilities permit and under ethical and data protection requirements. Once final data analysis has been undertaken and peer reviewed publications secured, anonymised data arising from this study may be accessed by contacting the PI and data may be placed on publicly accessible sites such as the Irish Social Science Data Archive

(ISSDA). Researchers who wish to access the data can submit a request to the ISSDA and can use the data for research or teaching purposes with appropriate attribution and citation.

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Author contributions

Bridget Kiely is the Lead researcher for the pilot project and RCT , completed the initial draft, contributed to manuscript drafts, approved the final draft and will act as corresponding author. Barbara Clyne gave advice on methodology for the pilot and main RCT and contributed to manuscript drafts and approved the final draft. Fiona Boland is the lead statistician for project, gave advice on randomization methods and planned statistical analysis. She also contributed to manuscript drafts and approved the final draft. Patrick O'Donnell contributed to manuscript drafts and approved the final draft. Deirdre Connolly contributed to manuscript drafts and approved the final draft. Eamon O Shea is the lead economist and advised on economic methods and analysis plans. Susan Smith conceptualized the original research question and trial methodology. All authors reviewed and approved the final draft.

Competing Interests

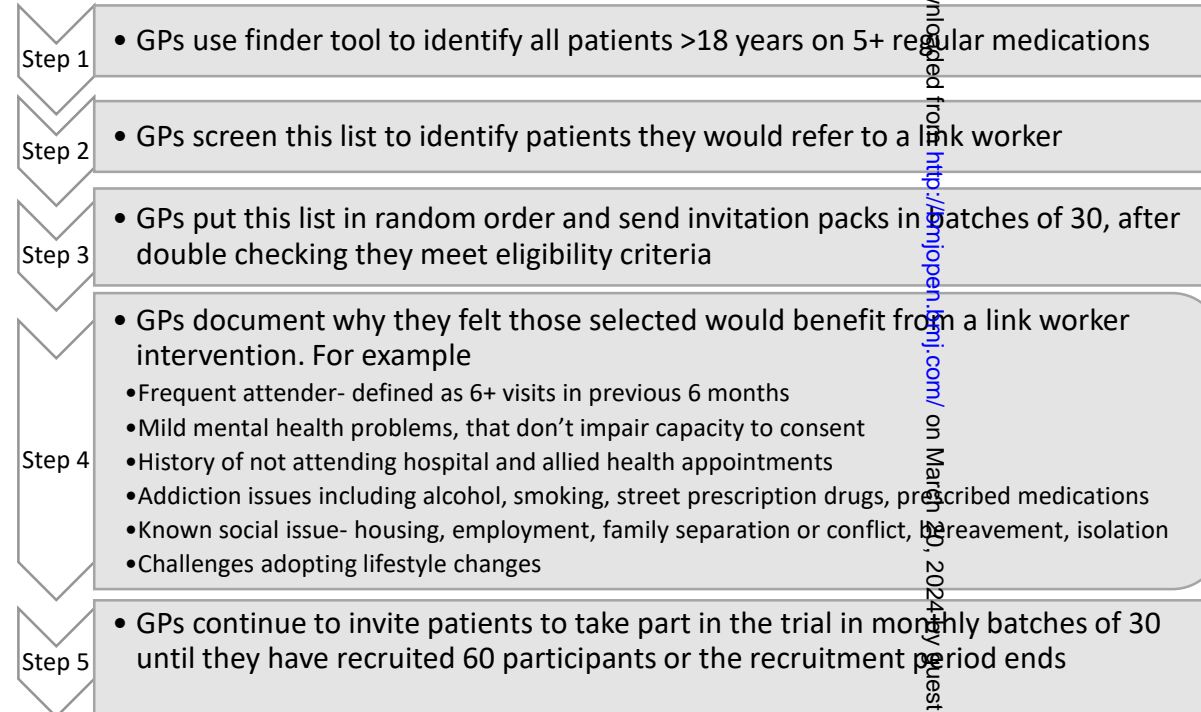
The authors declare that they have no competing interests.

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Figure Legends

Figure 1- Process for selection and recruitment of participants





SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents\*

Section/item	Item No	Description	Page No
<b>Administrative information</b>			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	3
	2b	All items from the World Health Organization Trial Registration Data Set	3
Protocol version	3	Date and version identifier	4
Funding	4	Sources and types of financial, material, and other support	27
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1, 27
	5b	Name and contact information for the trial sponsor	27
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	27
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	18
<b>Introduction</b>			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4, 5, 6, 7

	6b	Explanation for choice of comparators	15
Objectives	7	Specific objectives or hypotheses	7
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	7
<b>Methods: Participants, interventions, and outcomes</b>			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	7, 8
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	8, 9
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	11, 12, 13, 14
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	n/a
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	n/a
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	15
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	15,16
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	See Spirit Figure

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Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	16
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	9

**Methods: Assignment of interventions (for controlled trials)**

Allocation:

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	11
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	11
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	11
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	11
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	11

**Methods: Data collection, management, and analysis**

Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	15
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	15

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	17
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	18
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	18
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	18
<b>Methods: Monitoring</b>			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	18
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	n/a
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	18
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	n/a
<b>Ethics and dissemination</b>			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	23

Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	23
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	23
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	See Consent Form in supplementary data
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	23
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	27
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	24
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	n/a
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	23
	31b	Authorship eligibility guidelines and any intended use of professional writers	27
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	23
<b>Appendices</b>			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Supplementary materials

Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a
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\*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "[Attribution-NonCommercial-NoDerivs 3.0 Unported](#)" license.

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# BMJ Open

## Link workers providing social prescribing and health and social care coordination for people with multimorbidity in socially deprived areas (The LinkMM trial): Protocol for a pragmatic randomised controlled trial.

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Manuscript ID	bmjopen-2020-041809.R2
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Date Submitted by the Author:	01-Dec-2020
Complete List of Authors:	Kiely, Bridget; Royal College of Surgeons in Ireland Department of General Practice, Department of General Practice Clyne, Barbara; Royal College of Surgeons in Ireland Department of General Practice, Department of General Practice Boland, Fiona; Royal College of Surgeons in Ireland Department of General Practice, HRB Centre For Primary Care Research, Division of Population Health Sciences (PHS) O'Donnell, Patrick; University of Limerick Graduate Entry Medical School, Connolly, Deirdre; Trinity College, Occupational Therapy O'Shea, Eamon; National University of Ireland Galway, School of Business and Economics Smith, Susan; Royal College of Surgeons in Ireland Department of General Practice, General Practice
<b>Primary Subject Heading</b>:	General practice / Family practice
Secondary Subject Heading:	Health services research
Keywords:	PRIMARY CARE, PREVENTIVE MEDICINE, SOCIAL MEDICINE

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## Title

Link workers providing social prescribing and health and social care coordination for people with multimorbidity in socially deprived areas (The LinkMM trial): Protocol for a pragmatic randomised controlled trial.

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Abstract

Introduction

Link workers are non-health or social care professionals based in primary care who support people to develop and achieve a personalised set of health and social goals by engaging with community resources. Link workers have been piloted in areas of deprivation, but there remains insufficient evidence to support their effectiveness. Multimorbidity is increasing in prevalence but there are limited evidence-based interventions. This paper presents the protocol for a randomised controlled trial that will test the effectiveness of link workers based in general practices in deprived areas in improving health outcomes for people with multimorbidity.

Methods and analysis

The protocol presents the proposed pragmatic randomised controlled trial, involving 10 GP practices and 600 patients. Eligible participants will be community dwelling adults with multimorbidity (≥two chronic conditions) identified as being suitable for referral to a practice-based link worker.

Following baseline data collection, patients will be randomised into intervention group that will meet the linkworker over a one-month period, or a ‘wait list’ control that will receive usual GP care.

Primary outcomes are health related quality of life as assessed by EQ5D-5L and mental health assessed by HADS. Secondary outcomes are based on the core outcome set for multimorbidity. Data will be collected at baseline and on intervention completion at 1 month using questionnaires self-completed by participants and GP records.

Parallel process and economic analyses will be conducted to explore participants' experiences and examine cost-effectiveness of the link worker intervention

## Ethics and Dissemination

Ethical approval has been granted by the Irish College of General Practitioners Ethics committee. The findings will be published in peer-reviewed journals.

## Registration

This trial is registered on ISRCTN

Title: Use of link workers to provide social prescribing and health and social care coordination for people with complex multimorbidity in socially deprived areas

Trial ID: ISRCTN10287737

Date registered: 10/12/2019

Link: <https://www.isrctn.com/ISRCTN10287737>

## Strengths and Limitations

- The LinkMM study is a pragmatic RCT examining the effectiveness of a practice-based link worker intervention for patients with multimorbidity.
- The focus on people with multimorbidity builds the evidence base for generic interventions that work across all conditions in multimorbidity.

- The short intervention and follow up period allows for a wait list control design and is consistent with the duration of real world link worker interventions, but may be too short to show a meaningful difference in outcomes.
- The large number of patient reported outcomes is consistent with the Medical Research Council guidance on evaluating complex interventions, but may be off putting to people with lower literacy levels, creating challenges for recruitment and potential threats to generalisability for very vulnerable adults with multimorbidity.
- Parallel process and economic analysis will add to our understanding of the implementation of this type of intervention and determine the cost-effectiveness of the intervention

Keywords

Link worker, social prescribing, multimorbidity, complex intervention, primary care, general practice, social deprivation.

Word Count 4878

Introduction

Multimorbidity, defined as the presence of 2 or more chronic conditions, is recognised as a significant challenge for patients and health care systems, particularly in primary care and in areas of social deprivation (1). Within the broader multimorbidity population there are people with higher numbers of conditions involving multiple body systems with related

polypharmacy, which is referred to as complex multimorbidity (2). Multimorbidity and complex multimorbidity are estimated to affect 66.2% and 11% respectively of people over 50 attending Irish General Practice (3). Complex multimorbidity is associated with increased health care utilisation and costs. People with complex multimorbidity experience more fragmented care, poorer mental health and have worse outcomes (4, 5). There are higher proportions of patients with complex combinations of physical and mental health conditions in deprived areas (4). This is reflected in higher consultation rates and has ramifications throughout the health system. Ten percent of patients with four or more conditions account for 34% of unplanned emergency admissions and 47% of preventable unplanned admissions (6). People living in deprived areas develop multimorbidity 11 years earlier (4) and experience worse quality of life compared to those with multimorbidity in less deprived areas (7). It is not clear why this is, but there is growing evidence that people with multimorbidity in areas of deprivation have reduced self-efficacy and capacity for self-management due to psychosocial stressors, poorer mental health, increased burden of treatment and lower perceived social support (8) (9) (10) (11-13).

There is as yet, limited evidence to indicate which interventions for multimorbidity have a significant impact on health outcomes or health service utilisation (14). One potential intervention to address the complex mix of psychosocial issues and multimorbidity in areas of deprivation is the use of link workers in primary care. A link worker is a non-health or social care professional who usually has training in coaching or behaviour change as well as an extensive knowledge of local community resources. They work with people referred to them by healthcare services to identify their health and social care needs and support them to access services within the community to improve their health and well-being, a process commonly referred to as social prescribing (15). The Glasgow Deepend Linkswor

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programme describes the principle behind the link worker intervention as *“a catalyst to hope and self-determination, using the strong relationships with patients that exist in general practice. If patients with complex needs feel supported, they would be more likely to respond to information on ways to improve their health”*. The current study builds on this work using a similar intervention approach with link workers embedded in practices in deprived urban areas.

Although link workers providing social prescribing have been gaining popularity in the UK and there have been a number of pilots in Ireland (16, 17), few have been formally evaluated. A recent review of link worker provided social prescribing in the UK found limited evidence to support the effectiveness and concluded that there was a lack of evidence for how, for whom and when social prescribing was effective (18). A recent quasi-experimental evaluation of the Glasgow Deep End Links worker programme found some impact on mental health scores for patients and staff morale in GP practices and concluded that larger, longer studies, with randomisation at the individual patient level were needed (19).

The Deep End Ireland GP group, a network of practices based in areas of deprivation, prepared a Report on link workers in Ireland that outlined its potential to address the psychosocial burden faced by their patients and the impacts of upstream social determinants of health that GPs often encounter but can have little impact on in practice (20).

To inform the implementation of the intervention and evaluation processes a short uncontrolled pilot study was conducted in one practice with 12 patients. This confirmed the feasibility of intervention delivery and led to refinements in patient selection and data collection processes. (Ref, paper in submission process with the Journal of Comorbidity)

This study aims to evaluate a link worker intervention in primary care on health outcomes for people with complex multimorbidity in socially deprived areas. Secondary aims are to examine the impact on staff morale and conduct a mixed methods process evaluation and economic evaluation of the intervention, exploring direct and indirect costs.

## Methods

This protocol is presented using the SPIRIT recommendations for the reporting of a protocol for an interventional trial (21).

### Study design

This will be a pragmatic RCT to evaluate a link worker intervention in improving health outcomes for people with multimorbidity attending primary care in socially deprived areas compared to wait list controls who receive usual care. It will be reported in accordance with the CONSORT guidance for randomised controlled trials (22). The economic analysis will be a cost utility analysis from the perspective of the public health care system and will be carried out in accordance with the guidance produced by the Health and Information Quality Authority Ireland (23).

A parallel mixed methods process evaluation will be conducted in line with the Medical Research Council guidance on evaluating complex interventions (24). The process evaluation protocol will be informed by the MRC framework for process evaluations (25). A full protocol for the process evaluation will be published in an open access source.

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Public and Patient Involvement (PPI)

This study has public and patient involvement through a multimorbidity patient advisory group. The patient advisory group are patients with multimorbidity who meet quarterly to discuss issues arising with research projects on multimorbidity funded through the Health Research Board Collaborative Doctoral Award (BK is a PhD student on this programme). The specific input of the PPI groups is outlined in the pilot study paper (Ref, paper in submission process with the Journal of Comorbidity) but in summary it included co-design of patient information leaflets, input on patient outcome selection and questionnaire design.

Implementation Advisory Group

The implementation advisory group consists of GPs working in deprived areas, with and without experience of social prescribing and a project manager from a well established social prescribing project in a deprived inner city area in Dublin.

Study settings

This study will be conducted in urban general practices serving areas of deprivation in four cities (Dublin, Cork, Limerick and Waterford) within the Republic of Ireland. Serving areas of deprivation will be defined as providing general practice care to at least two small areas identified as disadvantaged or below by The Pobal HP Deprivation index and provide services to at least 1,000 patients under the General Medical Services (GMS) scheme. The Pobal HP deprivation index is Ireland’s most widely used social gradient metric and scores each small area (50 – 200 households) in terms of affluence or disadvantage. The index uses information from Ireland’s census, such as employment, age profile and educational attainment, to calculate this score (26). The GMS scheme provides medical care to approximately 40% of the Irish population. It is predominantly means-tested and provides eligible patients with free

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3 general practitioner visits, free hospital care and free medications (except for a prescription  
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5 levy, currently €2.50 per item to a maximum of €25).  
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## 8 9 Eligibility Criteria

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16 Participants will be community dwelling adults aged over 18, who have two or more chronic  
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18 conditions (multimorbidity), attend a GP that provides care for patients living in an area of  
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20 deprivation and have been identified by their GP as having potential to benefit from a link  
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22 worker intervention. As this is a pragmatic trial we are seeking to replicate conditions in real  
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24 work practice where GPs would refer to a link worker based on need. There will be no  
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26 predefined conditions, other than the conditions should be chronic, that is lasting or expected  
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28 to last more than 6 months.  
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37 Exclusion criteria include psychiatric/ psychological morbidity or cognitive impairment that  
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39 would impair capacity for informed consent, a terminal illness likely to lead to death or major  
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41 disability during the study follow-up period, living in residential care, already participating in  
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43 a similar programme or had previously participated in the pilot study.  
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### 48 Practices

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51 Ten practices in the Deep End Ireland group will be invited to participate (27). Membership  
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53 of the group is open to any practice that identifies as working in an area of deprivation. In  
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55 addition, practices must have a GMS list of >1000 patients, serve at least two small areas  
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57 defined as disadvantaged or below by the Pobal HP deprivation index 2016 and have space to  
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host a link worker on site. Practices that are taking part in another link worker project will be excluded.

Recruitment and Randomisation

Each practice will be asked to recruit 60 participants, giving a total of 600 patients.

Recruitment will begin one month before the start date of the intervention and will be phased for logistical reasons with 20 participants being recruited each month in each practice.

Eligible participants will be identified by their GPs, based on being prescribed five or more medications as a proxy for multimorbidity. This proxy is being used because of significant variation in coding practices for chronic conditions in Ireland and lack of a code for multimorbidity. A finder tool in the electronic record, previously developed for another multimorbidity study (28), will generate this list of patients. Previous research has indicated that medication count is a suitable proxy measure for multimorbidity (6) The GP team will screen this list of patients with multimorbidity to identify all patients who they would refer to a link worker and thus create a register of potentially eligible patients. This process is based on our pilot study findings and is designed to reflect real world conditions where GPs refer patients they identify as having a psychosocial need that would benefit from a social prescribing approach to a link worker. Once this register of potentially eligible patients is created, GPs will be supported to arrange the list in random order and select the first 30 potential participants to invite. They will then be asked to double check that the selected participants meet the inclusion criteria and ensure none of the exclusion criteria apply. GPs will also be asked to document the reasons why each of the selected patients would be referred to a link worker using a standardised list of options. This list will include reasons for referral identified from other studies and known proxies for psychosocial need such as

frequent attendance and will also allow GPs to record free text additional reasons. This process will improve transparency around referral decision making and provide additional data on types of patients referred for link worker supports and is summarised in Figure 1.

The research team will update the GP practices on a fortnightly basis of who has returned consent forms. The GPs will be encouraged to remind anyone who had verbally agreed to take part during the phone call stage, but not yet returned a consent form to do so. At monthly intervals the GPs will be asked to invite another 30 patients from the randomly ordered list of potential participants until the total of 60 participants has been reached. Recruitment will end 10 weeks before the end of the study to allow for sufficient time for baseline data collection, randomisation and delivery of the intervention. The expected recruitment rate is 60% based on the quasi-experimental evaluation of the Glasgow linkworker project (19) where 50% of potential participants were recruited and our own pilot where 70% of invited participants returned consent and baseline questionnaires.

A letter of invitation, patient information leaflet, consent and baseline questionnaires will be sent to eligible participants and GP teams will follow up with phone calls to explain the study and see if potential participants require assistance completing the baseline questionnaires. One in six Irish adults are functionally illiterate (29) and so it is assumed that at least this number will require their GP to verbally explain the study and need assistance with completion of the baseline questionnaires. Once they have consented, a member of the research team can assist them with baseline data collection either face to face at the practice or over the phone.

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Randomisation will take place following baseline data collection to avoid allocation bias. Randomisation will be carried out by an independent researcher and overseen by the trial statistician using a computer-generated sequence. Patients will be stratified by practice and age and allocation will be blocked using random permuted blocks of sizes 2 and 4 to ensure balanced numbers of intervention and control patients in each practice.

The independent researcher will inform the research team of allocations. The research team will contact the participants by phone to inform them of their allocation and what to expect. The research team will inform the relevant link worker by phone who has been allocated to the intervention group. A letter will be sent to the GP practice informing them of the participants involvement in the trial and their allocation. Due to the nature of the intervention it is not possible to blind participants, link workers or GPs to the allocation. Blinding will be implemented at the data analysis stage.

Intervention

The link worker intervention (LinkMM) is based on the Glasgow Deep End Links worker project which had a quasi-experimental cluster design (30). Our intervention is shorter than the Glasgow project to facilitate the wait list control study design and it does not include practice subsidies for developing in practice activities beyond hosting the link worker. The LinkMM intervention is a complex intervention with the following components:

- Link worker training and support
- GP training
- Compilation and mapping of local health and social care community resources
- Link worker participant meetings and follow up
- Financial supports to practices

### Link worker training and support

To inform the implementation of link worker social prescribing project the lead researcher attended Social Prescribing Network Ireland meetings and engaged with local social prescribing projects to explore the nature of the link worker role and appropriate job specifications, training, communication with GPs and engaging with community resource providers. In keeping with the literature, empathy and an ability to listen were identified as important link worker skills (31). Given the limited training time available, a background in health or social care and experience of working with disadvantaged communities were essential criteria for applicants to the role.

Resources from the Alliance website(32) (the community organisation who had delivered the link worker intervention in the Glasgow Deep End Links Worker project) were referenced to develop a 40 hour training plan with input from local social prescribing providers and based on the experience of our pilot study link worker, who had significant experience in health and social care and working with disadvantaged communities. Link workers will be employees of the research host institution rather than the general practices and will be line managed by the trial project manager. They will have monthly check-ins with the project manager and bimonthly peer support meetings and review sessions. Any clinical concerns regarding participants will be raised with the individual's GP. If for whatever reason they are unable to access the individual's GP link workers can seek support from the principal investigator (SMS), an experienced GP.

### GP training

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GP practices will receive training on site or via video-link on trial processes including selecting and recruitment processes, including the potential reasons a patient might be referred to a link worker. The link worker role will be explained.

Compilation and mapping of local health and social care community resources

The research team will have identified some key local resources for each area in advance of the link worker taking up their post. The link workers will have allocated time during their induction period to map out local resources using a template developed during the pilot. This will however be an ongoing process depending on the needs of participants. In the context of the ongoing Covid-19 pandemic, online and individual resources will also be identified for those unable to attend group activities.

Link worker participants meetings and follow up

Following randomisation, intervention group participants will be referred to the link worker straight away and invited to meet with them at least once, with at least 60 minutes scheduled for this initial appointment. At the initial meeting the link worker will explain their role and explore the participants’ health and social care priorities and produce a joint plan to address these. This will include a range of activities and community resources that participants may choose to attend to improve their health and well-being. The link worker will offer to follow up and support participants to implement their plan. It is expected that support will broadly fall into one of four categories, informational (supplying information on resources, directing to websites etc. ), instrumental (making an appointment on behalf of a participant or accompanying them to an appointment), appraisal (helping participants to makes changes using behaviour change techniques such as motivational interviewing) or emotional (listening and encouraging when participants face challenges) (33). As support is tailored to the needs

of the individual it will vary. All link worker activity will be captured in a specifically designed client management database, including details of the initial assessment, priority health and social issues, goals set, community resources referred to and attended, number of follow ups and the type of support provided, as per the categories outlined above. This will be fully reported in a parallel process evaluation and briefly described in the main trial report. There will be no change to the participants usual clinical care. At the end of the intervention period the link worker will provide a summary to the participant's GP, outlining the plan and resources they accessed to help achieve it.

The link worker will be based in the GP practice and meetings with participants will primarily be in the GP practice. The link worker will be able to liaise with participant's GPs should they have any specific concerns about an individual. Link workers will also share knowledge on local community resources with GPs during monthly meetings with practice staff.

#### Financial supports to practices

Practices will receive a stipend to cover one session a week of GP time to allow for time spent on recruitment and supporting the link worker intervention. An additional grant will cover any room hire and equipment costs that the practice may incur as a result of hosting the link worker.

#### Control

The RCT will have a wait list control. During the 1-month intervention period the control group will receive usual care from their GP. On completion of the intervention, the control group will be invited to a one-off meeting with the link worker, during which they will have an

opportunity to identify their needs and be provided with a list of suggested resources tailored to their needs and a booklet of community resources.

Outcomes

A wide range of outcomes will be used to assess intervention effectiveness and mechanism of action in line with the MRC framework for evaluating complex interventions (24). Outcomes are based on the pilot study findings and on the Core Outcome Set for Multimorbidity research (34). In line with the National Institute for Health Care Excellence an additional measure of capability and wellbeing, the ICE-CAP A (ICEpop CAPability measure for Adults) (35) will be used alongside the EQ5D-5L to capture the wider social benefits to the individual that are expected with this type of intervention.

Primary Outcomes

- Health related quality of life as measured by EQ5D-5L (36)
- Mental health as measured by Hospital Anxiety and Depression Scale (37)

Secondary Outcomes

Patient reported outcome measures

- Capability and wellbeing as measured by the ICE-CAP A (35)
- Activities of daily living as measured by the Frenchay Activity Index (38)
- Self-management as measured by the Patient Activation Measure (39)
- Burden of treatment measured by Multimorbidity Burden of Treatment Questionnaire (40)

Health care utilisation

Data from primary care electronic health records, in the previous month unless otherwise specified:

- Number of GP attendances
- Number of practice nurse attendances
- Number and type of regularly prescribed medications
- Number of out of hours GP attendances
- Number of Emergency Department attendances
- Number of hospital admissions (emergency) and length of stay
- Number of hospital outpatient visits

## Sample Size

A sample size of 600 participants in total has been calculated based on our two primary outcomes. Using a HADs Anxiety score of 10.9, a standard deviation of 5.1 and a minimally clinically important difference of 1.5 (based on a similar Scottish population study (30)); for 90% power with approx. 20% loss to follow up, 600 patients are needed. Similar calculations for HRQoL, using 0.316 SD units in EQ5D (based on a similar Scottish population (30) ), for 90% power and presuming approx. 20% loss to follow up, we need a sample of 510 patients. We will recruit the larger number of 600 patients (300 in each study arm).

## Data Collection

Data collection will be at baseline pre-randomisation and at one month from initial invitation to the intervention group to meet with the link worker. This will be prior to the control group meeting once with the link worker and receiving a truncated version of the intervention.

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Patient reported outcome measures will be self-reported using standardised paper-based questionnaires, which will be posted to participants. Data on patient costs and community resources accessed, will be self-reported using a specifically designed questionnaire. A member of the research team will assist participants to fill in paper-based forms if there are literacy issues.

The health care utilisation data on GP visits, Out of Hours GP visits, prescribed medications and ED attendances will be extracted from health care records by a member of the research team.

On completion of the RCT, we also plan to conduct an observational study on all participants at nine months from the intervention group receiving an invitation to meet with the link worker to examine changes in outcomes over this longer time period.

Data management

Paper questionnaires will be returned by post to the research team in the Department of General Practice, RCSI, who will be responsible for manual data entry into pre designed excel spreadsheets. All participants will provide informed consent for the processing of their data. Data will be pseudonymised with the use of a unique study ID. All data will be stored in secure encrypted institutional network drives accessible only to named members of the research team. A comprehensive data management plan is in place which had been reviewed by the trial steering committee.

A Trial Steering Committee (TSC) comprising an independent chair and three other independent members, one of whom is a lay member representing the patient and public

perspective, has been established and will oversee the progress of the trial and adherence to the study protocol.

Unintended consequences will be monitored during the trial using self-reporting by participants, reporting by link workers during planned supervision and reporting by GPs. GPs will receive instructions on how to report any adverse events on concerns they have to the trial manager during their training on the intervention. In addition, the trial manager will check in on a monthly basis with practices to get updates on any recruitment, implementation challenges and adverse events. Unintended consequences will also be explored as part of the process evaluation.

### Planned Statistical analysis

Descriptive statistics will be used to describe recruited participants and to investigate comparability of trial groups at baseline. For primary and secondary outcomes, the primary analyses will be 'intention-to-treat' (ITT) including all randomised participants, all retained in the group to which they were allocated and using last observation carried forward (LOCF) for missing values. The primary analysis will be adjusted for baseline scores and stratification variables, age and practice. Subsequent models will adjust for multimorbidity severity. We will also conduct a per-protocol (PP) analysis. The PP population will consist of those randomised to the intervention group who met with the link worker at least once. We will also conduct pre-planned sub-group analyses based on gender and age (above and below 65 years of age). All analyses will use appropriate (that is, linear or poisson) regression models with results presented as point estimates (difference in means or incident rate ratios), 95% confidence intervals and p-values. Stata 15 will be used for all data analysis (41).

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Economic Evaluation

The health economic evaluation will consist of a trial-based cost utility analysis of the proposed intervention. The evaluation will be undertaken in a manner consistent with guidelines issued by the Health Information and Quality Authority (HIQA) in Ireland (23). Evidence collected on direct costs of the intervention from the trial, community resource use and health outcome measures will provide the basis for the evaluation over the trial follow-up period. With respect to costing, a publicly funded health service perspective will be adopted. That is, resource use associated with delivery of the proposed intervention will be measured and costed, as will other health service resource use by patients over the course of the trial. For the cost utility analysis, effectiveness will be evaluated in terms of quality adjusted life years (QALYs), which will be estimated based on responses to the EuroQol EQ-5D-5L instrument [35].

An incremental analysis will be undertaken to provide information on the marginal costs and effects of the intervention relative to the control through the calculation of incremental cost effectiveness ratios (ICERs).

Probabilistic sensitivity analysis will be performed using the range of uncertainties from the statistical analysis of the trial. This allows the expected value of perfect information (EVPI) to be calculated. In this case given that the data will come from a single trial this will help to inform whether longer follow up is worth considering before investing in the intervention.

A cost effectiveness acceptability curve (CEAC) will be produced to examine the probability of the intervention being cost effective at different cost effectiveness thresholds. Incremental cost effectiveness ratio (ICER) per QALY gained will be presented along with a scatter plot, CEAC and EVPI.

## Process Evaluation

A mixed methods process evaluation is planned and we will publish a separate protocol outlining the methods for this evaluation, to be submitted to HRB Open research

## Discussion

This trial will provide some of the most robust results to date on link workers. As a recent systematic review on link worker interventions concluded there is insufficient evidence “to judge either success or value for money” and “future evaluations must be comparative by design and consider when, by whom, for whom, how well and at what cost” interventions are provided (18). While previous projects have not specified strict inclusion criteria and have often focused on younger patients with mental health problems (42), we are focusing on multimorbidity, which is predicted to increase in prevalence and is known to be a particular challenge in areas of deprivation. This will contribute to evidence on who is most likely to benefit from link workers and social prescribing as well as providing robust effectiveness and economic data.

A recent systematic review of the self-management characteristics of patients with complex health needs concluded that tailored self-management support is required for people in areas of socioeconomic deprivation to address the social norms that accept poorer health, social isolation and socioeconomic insecurity (43). Link workers are one intervention that could provide this kind of support. Governments are recognising this and link workers are specifically mentioned in the UK NHS Long Term Plan and funding provided to primary care clinical commissioning groups for one link worker per 30,000 population (44). An all-party

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Committee on the Future of Health Care in the Irish Parliament agreed on a plan for healthcare reform in Ireland in 2017, called Slaintecare (45). This is now being implemented through the Department of Health and Children and it emphasises a shift towards care in the community and empowering people to manage their own health (46). Social prescribing is recognised as one way to achieve this. The Department of Health announced a Slaintecare Integration Fund programme in 2019 which is funding a range of projects evaluating interventions that reflect Slaintecare priorities, including this study. Social Prescribing is also being supported by the Irish national Health Service Executive (HSE) with a number of funded pilots (16, 17). However, the lack of robust evaluation is recognised and the HSE are in the process of developing an evaluation framework. The results of this trial and process evaluation will be timely in informing national policy about the role-out of link workers and social prescribing nationally.

Strengths

While there have been a number of smaller trials and quasi-experimental studies this trial will be the first large scale pragmatic randomised trial of a link worker and social prescribing intervention. This will overcome the previous challenge of finding suitable controls in non-randomised trials (19, 47) and provide some of the most robust results to date on link workers. Furthermore, this will be the first multimorbidity trial with a link worker type intervention and this intervention addresses the challenge of identifying a generic intervention that works across all conditions, as recommended in the Cochrane review of interventions for multimorbidity (14).

Limitations

Our study is restricted to urban deprived areas. Rural areas provide unique challenges and have less concentrated deprivation, which would affect costs and recruitment timelines.

While deprivation in Ireland is concentrated in urban areas the results of this trial may not be applicable to more rural locations. Due to the nature of the funding and the wait list control design our intervention is only one month in duration and this may be too short a time to both deliver and show a significant difference in outcomes. While the intervention period is shorter than the Glasgow Deep End Linkworker model, it is in keeping with pilot projects in Ireland where link workers supported people over a 6-8 week period (42). In order to better understand the mechanisms of impact of the intervention we are collecting a range of measures, but a lengthy questionnaire may be off putting to potential participants, especially those who are most deprived, leading to a biased sample. The levels of patient engagement in the pilot study however are encouraging and the further input from our patient advisory group and expert panel of GPs on recruitment strategies and materials should mitigate against this. The method in which participants are selected may result in a selection bias, with GPs selecting participants based on the GPs perception of psychosocial needs. This is however the way such an intervention would be implemented in real world clinical practice, and so the trial is designed to be pragmatic. To better understand why GPs have selected participants they will be asked to document a reason and this will be reported to provide greater transparency into the selection of participants. Overall this pragmatic randomised controlled trial will add to the evidence base for link workers and social prescribing at a time when there is considerable national and international interest in rolling out this intervention more widely.

## Ethics Approval and Dissemination

Ethical approval has been granted by the Irish College of General Practitioners Ethics committee. This includes a Data Management Plan and Data Impact Assessment Form to ensure adherence to GDPR and Health Research Regulations.

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The end study results will be published in peer-reviewed journals and will be open access. A full report will also be submitted to funders. The results will also be disseminated to relevant stakeholders and participating GP practices. The PPI panel will be consulted on how best to disseminate results to people with multimorbidity.

Consent and confidentiality

Fully informed consent will be obtained from all participants. Confidentiality will be maintained by pseudonymisation of data using a unique study ID. Only named members of the research team will have access to individuals personal contact data and will only access it to communicate with participants regarding the trial. All data will be stored in secure password protected files with named access only.

Data availability

Data will be stored for seven years in line with RCSI data management policy and shared at the time of publication where facilities permit and under ethical and data protection requirements. Once final data analysis has been undertaken and peer reviewed publications secured, anonymised data arising from this study may be accessed by contacting the PI and data may be placed on publicly accessible sites such as the Irish Social Science Data Archive (ISSDA). Researchers who wish to access the data can submit a request to the ISSDA and can use the data for research or teaching purposes with appropriate attribution and citation.

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## Author contributions

Bridget Kiely is the Lead researcher for the pilot project and RCT , completed the initial draft, contributed to manuscript drafts, approved the final draft and will act as corresponding author. Barbara Clyne gave advice on methodology for the pilot and main RCT and contributed to manuscript drafts and approved the final draft. Fiona Boland is the lead statistician for project, gave advice on randomization methods and planned statistical analysis. She also contributed to manuscript drafts and approved the final draft. Patrick O'Donnell contributed to manuscript drafts and approved the final draft. Deirdre Connolly contributed to manuscript drafts and approved the final draft. Eamon O Shea is the lead economist and advised on economic methods and analysis plans. Susan Smith conceptualized the original research question and trial methodology. All authors reviewed and approved the final draft.

## Competing Interests

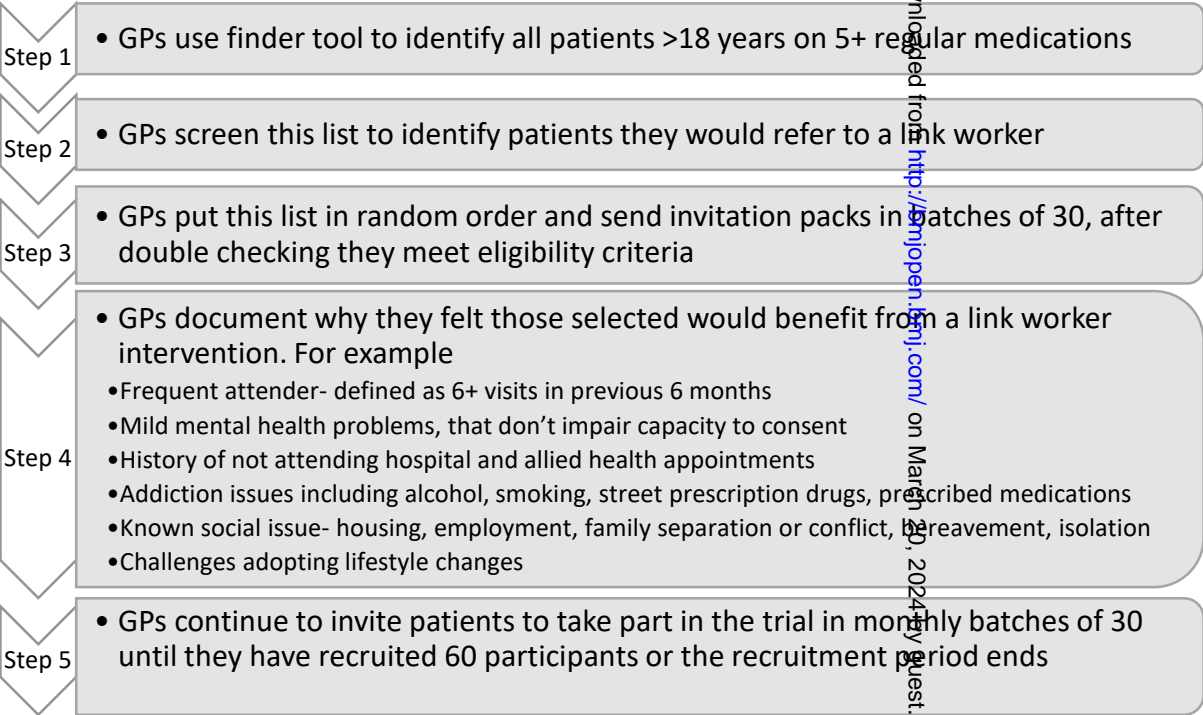
The authors declare that they have no competing interests.

## Funding

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## Figure Legends

Figure 1- Process for selection and recruitment of participants





## SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents\*

Section/item	Item No	Description	Page No
<b>Administrative information</b>			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	3
	2b	All items from the World Health Organization Trial Registration Data Set	3
Protocol version	3	Date and version identifier	4
Funding	4	Sources and types of financial, material, and other support	27
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1, 27
	5b	Name and contact information for the trial sponsor	27
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	27
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	18
<b>Introduction</b>			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4, 5, 6, 7

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	6b	Explanation for choice of comparators	15
Objectives	7	Specific objectives or hypotheses	7
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	7
<b>Methods: Participants, interventions, and outcomes</b>			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	7, 8
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	8, 9
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	11, 12, 13, 14
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	n/a
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	n/a
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	15
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	15,16
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	See Spirit Figure

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	16
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	9

## Methods: Assignment of interventions (for controlled trials)

### Allocation:

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	11
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	11
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	11
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	11
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	11

## Methods: Data collection, management, and analysis

Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	15
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	15

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Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	17
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	18
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	18
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	18
<b>Methods: Monitoring</b>			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	18
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	n/a
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	18
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	n/a
<b>Ethics and dissemination</b>			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	23

Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	23
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	23
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	See Consent Form in supplementary data
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	23
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	27
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	24
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	n/a
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	23
	31b	Authorship eligibility guidelines and any intended use of professional writers	27
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	23
<b>Appendices</b>			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Supplementary materials

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Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a
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\*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "[Attribution-NonCommercial-NoDerivs 3.0 Unported](#)" license.

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