

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

Submission date 29/10/2019	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 10/12/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 01/07/2024	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Multimorbidity, defined as 2 or more chronic conditions, is increasing in prevalence and affects 66.2% of patients over 50 attending primary care in Ireland. It is associated with increased health care use, fragmented care and poorer health outcomes. There is a link between social deprivation and multimorbidity. 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. This study is a randomised controlled trial to test the effectiveness of link workers based in primary care in improving health outcomes for people with multimorbidity. We plan to test whether a link worker can improve physical and mental health and reduce healthcare usage and costs

Who can participate?

Adults who have 2 or more chronic conditions, are living in the community, have capacity to consent to take part in research and attending a participating GP practice serving an area of deprivation are eligible to participate. This study will be conducted in general practice surgeries serving areas of deprivation in Dublin, Cork and Limerick, Ireland. Areas of deprivation will be defined by the Pobal HP deprivation index. The Pobal HP Deprivation Index is Ireland's most widely used social gradient metric, which 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. In addition, practices will serve at least 1000 patients under the general medical services scheme, which is means-tested and entitles people with lower incomes to free medical care

What does the study involve?

The study involves testing the effectiveness of a link worker based in general practices supporting people with their health and social care needs. Participants in this study will be invited to meet with a link worker to discuss their health and social needs and develop a plan to

improve their health and well-being. The link worker will support participants over a three month period to achieve their plan by helping them to access community resources. The link worker might also support participants with accessing housing or social welfare and coordinating or accessing healthcare

What are the possible benefits and risks of participating?

There is some evidence that people who meet with link workers find it helpful. Some studies have shown reduced anxiety and increased levels of physical activity. There is no guarantee that any individual participant will benefit, however.

Taking part in this study will help us to know if link workers should be funded in GP practices and so taking part in the study may help others to access a link worker in future.

The risks from taking part in this study are minimal. Participants might find that meeting the link worker takes up a lot of their time or is not helpful for them. They might not be able to go to some of the activities the link worker suggests because it is inconvenient or expensive and this could be disappointing

Where is the study run from?

Department of General Practice, Royal College of Surgeons, Ireland

When is the study starting and how long is it expected to run for?

March 2020 to June 2021

Who is funding the study?

1. Health Research Board
2. Health Service Executive, Ireland

Who is the main contact?

Dr Bridget Kiely, bridgetkiely@rcsi.com

Contact information

Type(s)

Public

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

CDA 2343

Study information

Scientific Title

Use of link workers to provide social prescribing and health and social care coordination for people with complex multimorbidity in socially deprived areas. A randomized controlled trial, process and economic evaluation

Acronym

LinkMM

Study objectives

The aim of the study is to improve health and well being compared to usual care by addressing social determinants of health, improving coordination of care and connecting people with resources in their community

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 07/08/2019, Irish College of General Practitioners Research Ethics Committee (ICGP, 4-5 Lincoln Place, Dublin 2, Ireland; colleen.oneil@icgp.ie; +353 (0)1-6763705), ref: n/a

Study design

Randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Quality of life

Participant information sheet

Not available in web format please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Multimorbidity

Interventions

The intervention will be a link worker based in a general practice that serves an area of social deprivation. A link worker is a non-health or social care professional and usually has training in coaching or behaviour change as well as 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 to support them to access services within the community to improve their health and well-being. This process is commonly referred to as social prescribing. Social Prescribing refers to the process of accessing non-medical interventions; it is a mechanism for linking people with non-medical sources of support within the community to improve physical, emotional and mental wellbeing.

The link worker will invite participants to attend an initial meeting that will involve a baseline assessment of health and social needs and devising a plan to meet a set of personalised goals to improve health and wellbeing. Over a three month period, the link worker will support participants to achieve their goals by encouraging them to engage with community resources, help them to coordinate their health care or assist them with housing or welfare issues.

Patients on five or more medications identified via a computerised search on electronic health records and meeting inclusion criteria will be invited to participate by their GP. Those who consent will be asked to complete baseline data before they are randomised to the intervention group or waitlist control. The intervention group will receive support from the link worker as described above over a three month period. The control group will receive usual care from their GP for the three month period and then they will be invited to meet with the link worker once where they will complete a goal setting exercise and receive a personalised list of community resources that could help them to achieve their goals.

Randomisation will be conducted using a computer-generated random sequence of numbers, conducted by an independent researcher using a process overseen by the trial statistician. Randomisation will take place following initial baseline data collection to avoid bias in trial participation based on awareness of allocation. Blocked randomisation will be used to achieve equal numbers of intervention and control participants in each GP practice.

An observational study on all participants at nine months will involve a final round of data collection and will examine changes in outcomes over time

Intervention Type

Other

Primary outcome measure

Measured at baseline, three months, and nine months:

1. Health related quality of life as measured by EQ5DL
2. Mental health as measured by the Hospital Anxiety and Depression Scale

Secondary outcome measures

Measured at baseline, three months, and nine months:

1. Patient reported outcome measures
 - 1.1. Activities of daily living as measured by the Frenchay Activity Index
 - 1.2. Self-efficacy as measured by the Patient Activation Measure

- 1.3. Burden of treatment measured by Multimorbidity Burden of Treatment Questionnaire
- 1.4. Social connectedness as measured by the Social Connectedness Scale
2. Health care utilisation in the previous 3 months (data from primary care electronic health records except for use of allied health professionals) to include number of visits to the GP, number medications prescribed, number ED attendances, number and duration hospital admissions, number visits to allied health professionals.
3. Cost to patients (transport costs, fees to attend community resources)
4. Cost to practices (time spent supporting linkworker and referring patients, room hire costs)

Overall study start date

01/11/2019

Completion date

30/06/2021

Eligibility

Key inclusion criteria

1. >18 years age
2. On 5 or more regular medications
3. Have 2 or more chronic conditions
4. Living in the community
5. Attending a general practice serving a deprived area

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

600

Total final enrolment

240

Key exclusion criteria

1. Psychiatric/psychological morbidity/cognitive impairment that would remove the capacity for informed consent
2. Terminal illness likely to lead to death or major disability during the study follow-up period.
3. Living in residential care

Date of first enrolment

01/03/2020

Date of final enrolment

11/12/2020

Locations

Countries of recruitment

Ireland

Study participating centre

Department of General Practice, Royal College of Surgeons, Ireland

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Sponsor information

Organisation

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Sponsor type

University/education

Website

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ROR

<https://ror.org/01hxy9878>

Funder(s)

Funder type

Government

Funder Name

Health Research Board

Alternative Name(s)

Health Research Board, Ireland, An Bord Taighde Sláinte, HRB

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

Ireland

Funder Name

Health Service Executive, Ireland

Results and Publications

Publication and dissemination plan

The end study results will be published in a peer review journal and presented at international conferences.

A summary report will be distributed to the Social Prescribing Network Ireland.

A policy brief will be prepared and submitted to the Health and Wellbeing Department of the Health Service Executive.

A press release will be issued to media.

The Public Patient Involvement group advising on this research will be consulted regarding how best to disseminate results to people with multimorbidity.

Intention to publish date

01/06/2024

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a publicly available repository. Data will be stored for 7 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, the data controller will be responsible for deleting the files containing the key to pseudonymised data, and ensuring any personal identifiable data has been deleted. 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). The ISSDA provides a number of professional curation and management services to depositors, including preservation of data (updating of data formats, and are planning to implement Digital Object Identifiers (DOIs) for datasets and documentation. The ISSDA requires metadata to

adhere to the DDI standard, hence this standard will be used for reporting metadata associated with this study. 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

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		28/06/2024	01/07/2024	Yes	No