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Supporting people living with multiple long-term conditions (multimorbidity) to manage their medicines and link to community resources: a randomised trial in Irish general practice

Submission date 21/03/2024	**Recruitment status** Recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 26/03/2024	**Overall study status** Ongoing	
Last Edited 18/08/2025	**Condition category** Other	

Plain English summary of protocol

Background and study aims

Multiple medical conditions are challenging for patients and can lead to worse health outcomes. Research suggests that two of the key challenges are the management of multiple medications, and ensuring that patients are supported to see improvements in their daily activities. GPs are often aware of this but often do not have time to review medications for each patient or refer them to local non-medical services and resources. This research study aims to see how people with multiple medical conditions can best be supported in managing their health and if providing additional types of support makes a difference over a 6-month timeframe. The study will be testing two types of additional support: (1) Pharmacist support to collaboratively review and optimise patient medications and (2) a link worker supporting social prescription. Pharmacists have expert knowledge of how medications for multiple conditions work together and how combinations can be altered to reduce the overall number of medications. There is evidence that this helps reduce the burden on patients, and it helps to ensure patients are taking the best medicines with the least side effects. In this group, a pharmacist will work with the patient and GP to review their medications and create action plans to improve the combinations of medications they receive. A link worker is a professional who usually has training in coaching or behavioural change and an extensive knowledge of local community resources. They support people to identify their health and social needs and access community resources to improve health and well-being, a process commonly referred to as social prescribing. A link worker will be based in some GP practices and will help people with complex problems identify and meet their health and social care priorities, by supporting them to access community resources. To improve the care for people living with multiple medical conditions, a more holistic approach to care is needed, taking into account people's health and social needs. One way to do this is through having a link worker based in GP practices who can support people with multiple medical conditions to access community-based services, and available resources.

Who can participate?
Adults aged over 18 years old enrolled in the Chronic Disease Management (CDM) Programme in one of the GP practices that are participating in this trial, living with 2 or more chronic conditions, and taking at least 10 regular medicines.

What does this study involve?
This study will happen in 48 diverse GPs across Ireland, which will be divided by chance into one of three groups. Each practice will be assigned to either pharmacist support (MyComrade), link worker support (LinkMM) or to continue with care as usual acting as a comparison. Eligible patients in these practices will be asked by GP nurses to join the study when they attend their chronic disease management review. If interested, they will sign consent and some questionnaire. Afterwards, a GP nurse may arrange for pharmacist or link worker support depending on the practice.

If a practice has been assigned to test pharmacist support, the patients in that practice will be invited to attend online training by the research team and meet with their GP-based pharmacist to arrange how best to deliver the intervention in your practice.

If a practice has been assigned to test link worker support, the patients in that practice will be invited to attend online training by the research team and meet with the link worker to arrange how best to deliver the intervention in their practice.

If a practice has been assigned to test usual care, the patients in that practice will not be invited to any additional appointments and the practice will continue to deliver care as usual for the six months of the study.

What are the potential benefits and risks of participating?
Potential benefits:
Recent research in Ireland showed that for those taking lots of different medications, a review with a pharmacist reduced the overall number they had to take and therefore reduced the burden on the patient. There is also potential that the review could help to identify medicines patients no longer need or that are causing side effects.

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. However, there is no guarantee that they will benefit.

This study will help us to know if pharmacists and/or link workers should be funded in GP practices and so taking part in the study may help others to access a practice-based pharmacist or link worker in future.

Potential risks:
The risks from taking part in this study are minimal as both interventions are available in other settings and are designed to enhance usual care.

Where is the study run from?
Discipline of Public Health and Primary Care, Institute of Population Health, School of Medicine, Trinity College Dublin

When is the study starting and how long is it expected to run for?
April 2023 to January 2027

Who is funding the study?
The study is funded by the Health Research Board, as part of their Definitive Interventions and Feasibility Awards. The study is supported by the Departments of General Practice at the University of Galway and RCSI University of Health Sciences in Dublin. Funding body and Reference: Health Research Board HRB DIFA-2003-002

Who is the main contact?
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Study website
https://primarycaretrials.ie/midas-2/

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Health Research Board HRB DIFA-2023-002

Study information

Scientific Title
Medicines and Social Prescribing to aDdress pAtient priorities in multimorbidity (MIDAS): a multi-arm definitive cluster randomised trial in Irish general practice

Acronym
MIDAS

Study objectives
Background:
Patients living with multimorbidity are likely to experience a high medication and psychosocial burden in managing their conditions which can lead to worse health outcomes. However, there is limited evidence on the type of interventions that can address this patient population's medical and psychosocial needs. There is some evidence that undertaking structured medication reviews in primary care settings and connecting patients with available social and community-based resources and services can improve this patient population's health outcomes and experience of care. This study aims to evaluate the clinical and cost-effectiveness of two multimorbidity interventions designed to support GPs managing medicines (MyComrade) and to support patients addressing their priorities (LinkMM) to improve patients' health outcomes, experience of care and well-being.

Study Hypothesis:
Medication reviews and social prescribing embedded within routine primary care of patients with multimorbidity improve health outcomes, and experience of care for patients and is cost-effective to implement compared to standard care.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 29/08/2023, Irish College of General Practice (ICGP) (ICGP, 4/5 Lincoln Place, Dublin 2, D02 XR68, Ireland; +353 (01) 6763705; Info@icgp.ie), ref: ICGP_Rec_2023_016

Study design
Multi-arm (definitive) cluster-randomized trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
GP practice, Medical and other records

Study type(s)
Other, Quality of life, Treatment

Participant information sheet
Patient information material can be found at https://primarycaretrials.ie/midas-patientinvitationletter/

Health condition(s) or problem(s) studied
Patients living with multimorbidity (defined as two or more conditions and taking 10 or more regular medicines)

Interventions
This three-arm cluster randomised trial has two intervention arms: (1) MyComrade, and (2) LinkMM, and a control arm. Aligning with the cluster randomisation trial procedure, the recruited practices will be allocated to intervention 1 (n = 16), intervention 2 (n = 16) or control groups (n = 16) by the trial statistician using minimisation. The trial statistician will not know the participating practices. Minimisation variables will include practice size (number of GP sessions per week: 0 to 15, 16 to 30, and 31 or more) and location (urban, rural, or mixed).

Intervention 1 (MyComrade):
MyComrade aims to conduct medication reviews for patients with multimorbidity to optimise the medication regimen and minimise potentially inappropriate prescribing. For this intervention, a pharmacist will work with the patients and GPs to review their medications and create action plans to improve the combinations of medications they receive. Intervention practices will receive MyComrade intervention training either face-to-face from research team members or using pre-recorded material, depending on practice preference. The training sessions will be audio-recorded to allow assessment of fidelity in terms of content and duration.

Intervention 2 (LinkMM):
LinkMM aims to address patient priorities through the referral of a patient with multimorbidity to a link worker based in their general practice who meets with them to review their priorities and goals and provide social prescribing to local community resources. The link worker continues providing support to the patient through in-person or remote contact for as long as needed within the 6-month intervention period. Link worker training and ongoing support are provided by the research team, a function which would be required for system-wide implementation.

Comparison:
The control arm will receive usual GP care, with no additional support for medicines reviews or addressing patient priorities. In a multi-arm trial, it is important to pre-specify all comparisons. The primary comparisons will be Intervention 1 (MyComrade) vs Control, and Intervention 2 (LinkMM) vs Control. These interventions target different outcomes, so a direct MyComrade vs LinkMM comparison is not appropriate.

A description of usual care in Ireland:
Irish general practice is a complex mix of private and public care. Eligibility to free GP care is

based on income thresholds. Approximately 40% of adults and all those over 70 are eligible for free GP visits and therefore eligible for the Chronic Disease Management (CDM) Programme. The CDM Programme was established in 2020 and aims to prevent and manage chronic diseases using a population approach. This programme is for adult patients who are entitled to free GP care and have a diagnosis of one or more diabetes, asthma, chronic obstructive pulmonary disease and/or cardiovascular disease, including heart failure, heart attack (angina), stroke and irregular heartbeat (atrial fibrillation).

Main trial practice and patient recruitment:
Practice recruitment will occur through the HRB Primary Care Clinical Trials Network Ireland, GP networks associated with the Trinity College Dublin Network and the University of Galway. In addition, promotion will also occur through the various Irish College of General Practice (ICGP) networks (e.g. national webinars) and relevant social media (e.g. GP Buddy).

Patient recruitment:
The recruitment process will be:
1. When inviting CDM patients for review, the practice team will screen for MIDAS-eligible patients.
2. Potentially eligible patients being invited for the GP Nurse (GPN) visit (a minimum of a week in advance of their appointment), will be sent a standard text with a link to a Patient Information Leaflet (PIL), or posted out in advance of their appointment. This will ensure patients have time to consider the study before they are formally invited to participate in the GPN visit.
3. Eligible patients attending the GPN visit will receive a paper copy of the PIL, have an opportunity to ask questions, complete the consent form and complete the baseline questionnaire.
4. As per the national Health Research Regulations and Research Ethics Guidance in Ireland, the PIL will highlight that patients will be able to withdraw from the study at any time, without having any impact on their ongoing care in the practice.
5. Practice teams will keep detailed records of recruitment processes to ensure selection bias is avoided.
If they consent to participate, baseline data will be collected before practice randomisation, to minimise any bias that could arise if participants were aware of the allocation status of their practice. The sample size calculation allows for some practice variability in recruitment and based on a conservative estimate of patient consent to participate of 30%, it is anticipated that practices will complete recruitment of 12-16 patients in 6-8 weeks. Practices that fail to recruit sufficient numbers of patients will not proceed to randomisation, although there is a contingency to extend the recruitment period for those close to recruiting the minimum number of eligible patients.

Practice allocation and randomisation:
Following baseline data collection, practices will be allocated by an independent statistician using minimisation. Minimisation variables will include practice size (number of GP sessions per week: 0 to 15, 16 to 30, and 31 or more) and location (urban, rural, or mixed).

Intervention delivery:
Intervention delivery will commence in each intervention practice following practice allocation and will continue over the following 6 months as needed for each patient. This aligns with how each intervention would be delivered in routine care.

Intervention Type
Mixed

Primary outcome measure

The following primary outcome measures are assessed at baseline and 6 months:
1. The number of medicines per patient in the MyComrade arm measured using data recorded in patients' medical records to count the number of medicines stopped and started per patient reviewed
2. Patient capability and well-being in the LinkMM arm measured using the ICEpop CAPability measure for Adults (ICECAP-A)

Secondary outcome measures

Current secondary outcome measures as of 23/05/2025:
The following secondary outcome measures are assessed in both MyComrade and LINKMM arms at baseline and 6 months follow-up:
1. Patient-Reported Outcomes:
1.1. Quality of life is measured using the EQ-5D-5L questionnaire at baseline and 6 months.
1.2. Mental health is measured using the Short Warwick-Edinburgh Mental Well-being Scale (SWEMWBS) at baseline and 6 months.
1.3. Treatment burden is measured using the Treatment Burden Questionnaire at baseline and 6 months.
1.4. Patient experience of care is measured using the Patient Assessment of Chronic Illness Care (PACIC) questionnaire at baseline and 6 months.
1.5. Patient activation is measured using the Patient Activation Measure (PAM) at baseline and 6 months.
2. Medication-Related Outcomes:
2.1. Medicines outcomes are measured using patient records at baseline and 6 months.
2.2. Number of repeat medications is measured as a numeric count of medications using patient records at baseline and 6 months.
2.3. Potentially inappropriate prescribing (PIP) is measured as a count of flagged prescriptions identified by research pharmacists through review of repeat prescriptions in patient records at baseline and 6 months.
2.4. High-risk prescriptions are measured as a count of flagged prescriptions identified by research pharmacists through review of repeat prescriptions in patient records at baseline and 6 months.
3. Healthcare Utilisation:
3.1. General practitioner (GP) use is measured as the number of in-person and virtual GP visits using patient records at baseline and 6 months.
3.2. GP nurse visits are measured as the number of visits using patient records at baseline and 6 months.
3.3. Emergency department visits are measured using the number and dates of visits from patient records and self-report (in the previous 6 months) at baseline and 6 months.
3.4. Hospital admissions are measured using the number and rates of admission, length of stay, and time to first/re-admission using patient records and self-report (in the previous 6 months) at baseline and 6 months.
3.5. Outpatient department visits are measured using the number of visits from patient records and self-report at baseline and 6 months.
3.6. Community support visits are measured as the number of visits to social/community services using patient records and self-report at baseline and 6 months.
3.7. Other primary care use (e.g., Allied Health) is measured as the number of visits and type of service using patient records and self-report at baseline and 6 months.
4. Cost Data:
4.1. Healthcare utilisation costs are measured based on service usage data (as above) using patient records at baseline and 6 months.

4.2. Patient costs are measured as self-reported travel and occupational costs at baseline and 6 months.
4.3. Staff costs are measured using calculated costs per hour/day based on HSE salary grades for GPs, nurses, secretaries, and pharmacists at baseline and 6 months.
4.4. Medication costs are measured using drug prices listed in the Primary Care Reimbursement Service (PCRS) reimbursement files and patient records at baseline and 6 months.

Previous secondary outcome measures:
The following secondary outcome measures are assessed in both MyComrade and LINKMM arms at baseline and 6 months follow-up:
1. Medicines and mental health outcomes measured using the Short Warwick-Edinburgh Mental Wellbeing Scale (SWEMWBS) questionnaire
2. Patient experience of care measured using the Patients Assessment Chronic Illness Care (PACIC) questionnaire
3. Patient activation measured using the Patient Activation Measure (PAM) questionnaire
4. Health-related quality of life measured using the EQ 5D 5L
5. Mortality and Healthcare utilisation measured using data recorded in the patient's medical record to calculate the number of GP and hospital visits

Overall study start date
04/04/2023

Completion date
30/01/2027

Eligibility

Key inclusion criteria
1. Adults enrolled in the Chronic Disease Management (CDM) Programme
2. Living with two or more chronic conditions
3. Taking at least 10 regular medicines

Participant type(s)
Patient

Age group
Mixed

Lower age limit
18 Years

Sex
Both

Target number of participants
The total sample size was estimated based on the two primary outcomes. Based on these estimations, the study aims to recruit 48 GP practices and 672 patients across the three arms of the trial (approximately 16 practices and 224 patients per arm of the trial)

Key exclusion criteria

Current participant exclusion criteria as of 24/04/2025:
1. Unable to provide informed consent based on language or serious cognitive impairment
2. Limited life expectancy (less than the intervention duration and follow-up period)

Previous participant exclusion criteria:
1. Unable to provide informed consent based on language or serious cognitive impairment
2. Have participated in a link worker social prescribing intervention in the previous three years
3. Have met with a GP-based pharmacist in the previous three years
4. Limited life expectancy (less than the intervention duration and follow-up period)
5. Residing in nursing homes and residential care facilities or who are housebound, as these people will not be attending their GP for an in-person CDM review.

Date of first enrolment
22/04/2024

Date of final enrolment
30/10/2025

Locations

Countries of recruitment
Ireland

Study participating centre
Trinity College Dublin
College Green
Dublin 2
Ireland
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Sponsor information

Organisation
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Sponsor type
University/education

Website
https://www.tcd.ie/research/support/sponsorship.php

ROR
https://ror.org/02tyrky19

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

Results and Publications

Publication and dissemination plan
We will ensure the effective dissemination and knowledge transfer of the MIDAS study outputs to all relevant stakeholders throughout the study duration, to ensure uptake of the study results by local, national and international audiences. A targeted strategic Dissemination, Communications and Exploitation Plan will be developed by the research team. This will identify targeted audiences, including:

(1) Researchers with focus on academic publications to allow sharing of research methods, study findings and transfer to other contexts, nationally and internationally;
(2) Patients/patient groups
(3) The media and general public
(4) Primary care clinicians and care providers
(5) Policy makers and healthcare funders including key national and global decision-makers for better management of multimorbidity, and to plan the communication material. Particular policy stakeholders include the Irish College of General Practitioners, the Health Service Executive (HSE) Medicines Management Programme, HSE Primary Care Division and the HSE Social Prescribing within the Health and Well Being Directorate.

Dissemination strategy:

MIDAS team members believe that we have an ethical obligation to ensure that research findings are disseminated in a timely manner after completion of the study and parallel process and health economic evaluations. We will address the need for different approaches for each target audience. Dissemination to patients and the public will include brochures, newsletters and social networks. Academic and policy dissemination will include scientific presentations, stakeholder workshops, peer-reviewed publications, policy briefs, dissemination campaigns and related press releases. Dissemination to all target audiences will be facilitated through the development of a dedicated MIDAS website where in addition to scientific text, project findings designed for a lay audience will be written and accessible.

Accessibility:

All findings of the project and materials for replication of the MIDAS interventions (MyComrade and LinkMM) will be open access and freely available to anyone wishing to use them to facilitate future system-wide implementation of the two interventions more widely in our study country and in additional countries across Europe. Project materials (e.g. developed training resources for pharmacists and link workers) will be deposited in an appropriate open access repository which will assign a DOI (with a Creative Commons licence allowing for sharing and adaptation), and/or published alongside publications as supplementary materials.

We will also develop a formal publication plan by Month 6 of the study. This will be based on the Open Access Gold Route and all research outputs will be published in fully open access journals. We will publish protocols for the main trial, the process evaluation and the health economic evaluations in open access journals or in the HRB Open Research, where appropriate. To maximise and expedite reach, we will deposit preprint manuscripts at time of submission and accepted/post-print manuscripts in our institutional repository as soon as allowed.

Intention to publish date
31/01/2027

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be stored in a public available repository.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		20/06/2025	24/06/2025	Yes	No