**Practice Information Leaflet**

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| ***Study title:*** ­­­­­­­­­­­­­­­­­­­­­­­­ Medicines Support and SocIal Prescribing to aDdress pAtient priorities in multimorbidity (MIDAS): A cluster randomized trial in Irish general practice |

**Principal investigator’s name:** Professor Susan Smith

**Principal investigator telephone number:** 01 8961087

**Trial manager’s name:** Farah Tahsin

**Trial manager’s telephone number:** 01-8963739

**Data Controller’s/Joint Controller’s Identity:** Prof Susan Smith, Farah Tahsin

**Data Protection Officer’s Identity:** Evelyn Fox

**Data Protection Officer’s Contact Details:** evelyn.fox@tcd.ie

Your practice is being invited to take part in a research study to be carried out in Irish general practice, which is funded by the Health Research Board and based in the Department of General Practice, Trinity College Dublin supported by the Departments of General Practice at University of Galway and RCSI University of Medicine and Health Sciences in Dublin.

Before you decide if you wish to take part, please read the information provided below. You don't have to take part in this study and you can change your mind about taking part in the study any time you like.  Even if the study has started, your practice can still opt out.  You don't have to give us a reason.

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| **Why is this study being done?** |

We know that having multiple medical conditions is 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 don’t have time to review medications for each patient, or to refer them to local non-medical services and resources.

The research study aims to see how people with multiple medical conditions can best be supported in managing their health. We want to see if providing additional types of support makes a difference over a six-month timeframe.

We will be testing two types of additional support:

1. Pharmacist support to collaboratively review and optimise patient medications.

Pharmacists have expert knowledge on 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 your medications and create action plans to improve the combinations of medications you receive.

1. 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 we need to take a more holistic approach to care, taking into account people’s health and social needs. One way to do this is though having a link worker based in your GP practice who can support people with multiple medical conditions to access community-based services, and available resources

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| **Who is organising and funding this study?** |

This study is organised by the Principal Investigator Prof Susan Smith in the Department of General Practice in Trinity College Dublin. It 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 University of Galway and RCSI University of Medicine and Health Sciences in Dublin.

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| **Why am I being asked to take part?** |

Your practice is being asked to take part in this study so that your patients can be invited to join this study.

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| **How will the study be carried out?** |

This study will take place from 04 April 2024 to 01 January 2027.

It will take place in GP practices across the country, with 48 practices in total to be selected. Approximately 700 patients attending those practices will take part.

One third of practices will have pharmacist support in addition to their usual chronic condition care, one third will have link worker support in addition to their usual chronic condition care, and the remaining third will continue with their usual chronic condition care

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| **What will happen to me if I agree to take part?** |

After you contact the trial manager about your interest to take part in the study, the first step will be gathering some information about the practice. This will involve completing a set of questionnaire that will be sent out to you by the study manager. These questionnaire will give us information about your practice and patient population.

After you return these forms, what will happen depends on the group to which your practice is randomly assigned.

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

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

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

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| **What are the 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 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. There is no guarantee that your patients will benefit however.

Taking part in 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.

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| **What are the 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.

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| **What if something goes wrong when I’m taking part in this study?** |

If your practice is involved with the pharmacist or the link worker and are unhappy with the service you should contact Prof Susan Smith, as per the contact details at the end of this form.

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| **Will it cost me anything to take part?** |

No. There are practice remunerations available to cover the cost to you of participating in this study. These include the following: €2,000 per intervention practice and €1,000 per control practice, based on agreed deliverables.

Recruitment incentives (all practices): €120 per patient

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| **Is the study confidential?** |

If you consent to take part in this study, all the information you provide about your practice will be pseudo-anonymised. This means any identifying information (e.g. name, address) will be removed and a unique study ID will be assigned to you.

Your pseudo-anonymised data will be reviewed by the above named members of the research team. Only members of the research team will be able to find out your identity, however, they will only do so when they need to contact you.

All information about you will be stored electronically on a secure Trinity College Dublin server and be password protected. All information will be stored for ten years after completion of the study and then destroyed, in accordance with research best practice guidelines.

At the end of the study, the results will be published in a number of journal articles arising from this study. All the data used for these purposes will be anonymised i.e. it will not be possible to identify any individuals who have been part of the study. The anonymous study data will also be shared publicly for the good of all and it will not be possible to identify any of the individual participants.

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| **Data Protection** |

We must provide you with the following information. It is a legal requirement under data protection law for us to do so and if you have any questions please feel free to contact us about it.

1. We will be using your personal information in our research to help us study whether pharmacists or link workers can improve health outcomes for people with multiple medical conditions.
2. The relevant legal basis for processing your data is Article 9 of the General Data Protection Regulation 2016; Article 9(2)(j) Scientific Research purposes.
3. Members of the research team will have access to your data for the purposes of carrying out the scientific research.
4. Your data will be stored until the final academic paper relating to the research is published. Usually this is within a ten-year period.
5. We will take every necessary step to ensure that your information is kept safe and secure. In the unlikely event that there was a data breach, it will be dealt with in accordance with the Health Research Board Data Breach Protocols.
6. At any stage during the research you have the right to withdraw consent for the processing of the data. To do this please contact Farah Tahsin (tahsinf@tcd.ie).
7. If you are unhappy with how your data is processed or how a request to review the data we store about you is handled you have a right to lodge a complaint with the Data Protection Commissioner.
8. You have a right to request access to your data and a copy of it.
9. You have a right to have any inaccurate information about you corrected or deleted.
10. You have a right to have your personal data deleted, unless the request would make it impossible or make it very difficult to conduct the research. e.g. deleting your data at the end of a research project just before it is due to be published.
11. You have a right to data portability, meaning you have a right to move your data from one controller to another in a readable format.
12. There will be no automated decision making or profiling occurring
13. We may use your personal data to contact you about longer term follow up of this study but we will not involve you in a further studies in the future without your consent.
14. You do not have to agree to being contacted in the future about other research studies or to your data being used in other research studies. If you do agree, but change your mind at any stage, you can contact Farah Tahsin (tahsinf@tcd.ie) and ask for your data to be removed from the database. However if all the research has been completed and the data has been anonymised we won’t be able to remove your individual data.
15. When the research is complete, we will give access to anonymous data from the study to other researchers, who may be outside the EU, but only if they have approval from an ethics committee to use the data for research. We will not transfer your personal data outside of Trinity College Dublin at any stage.

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| **Where can I get further information?** |

If you need any further information now or at any time in the future, please contact:

Name: Professor Susan Smith

Address: Institute of Population Health, Russell Building, Tallaght Cross, Dublin D24 DH74

Phone No: +353 1 896 1087

Name: Farah Tahsin Study manager details: tahsinf@tcd.ie