

# Anticipatory Care Planning Intervention for Older Adults at Risk of Functional Decline: Study protocol for a Primary Care Cluster Feasibility Randomised Trial

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**Study protocol**

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# Abstract

**Background** The treatment and management of long-term health conditions is the greatest challenge facing health systems around the world today. Innovative approaches to patient care in the community such as Anticipatory Care Planning (ACP), which seek to help with the provision of high-quality comprehensive care to older adults at risk of functional decline, require evaluation. This study will evaluate one approach that will include primary care as the setting for Anticipatory Care Planning. **Methods** This study will help to determine the feasibility for a definitive randomised trial to evaluate the implementation and outcomes of an ACP intervention. The intervention will be delivered by specially trained registered nurses in a primary care setting with older adults identified as at risk of functional decline. The intervention will comprise of: a) information collection via patient assessment; b) facilitated informed dialogue between the patient, family carer, general practitioner and other healthcare practitioners; and, c) documentation of the agreed support plan and follow-up review dates. Through a structured consultation with patients and their family carers, the nurses will complete a mutually agreed personalized support plan. **Discussion** This study will determine the feasibility for a full trial protocol to evaluate the implementation and outcomes of an (ACP) intervention in primary care to assist older adults aged 70 years of age or older and assessed as at risk of functional decline. The study will be implemented in two jurisdictions on the island of Ireland which employ different health systems but which face similar health challenges. This study will allow us to examine important issues, such as the impact of two different healthcare systems on the health of older people and the influence of different legislative interpretations on undertaking cross jurisdictional research in Ireland.

## Background

The delivery of high quality, comprehensive care for older adults is becoming an increasing challenge for health systems around the world due to the ageing of society, increasing levels of multimorbidity with complex polypharmacy, shortages of healthcare providers, and rising healthcare costs [1-5]. Within the healthcare landscape primary care is increasingly seen as the optimal context to deliver care for people with complex care needs because it is accessible, efficient and can address inequalities related to socioeconomic deprivation. However, the current approach in primary care is seen as reactive, fragmented and does not fully meet the often complex needs of older adults [3, 6, 7]. A transition toward the provision of more proactive care in primary care has been proposed [3, 6, 7]. Proactive primary care requires a timely start to the identification and management of a patient's long-term conditions or chronic illnesses. This process can be facilitated using Anticipatory Care Planning (ACP) to meet a patient's wishes and needs, relieve symptoms, and prevent future symptoms and problems. A core aspect of anticipatory care is personalized care planning [8] which aims to ensure that an individual's values and health concerns inform the way their long-term conditions are managed. Instead of focusing on a standardized set of disease management processes determined by health professionals, this personalized approach encourages patients to select treatment goals and to work with clinicians to determine their specific needs for treatment and support. When considering the introduction of ACP in primary care there is a

need to identify information about strategies for patient risk stratification, which service components or service innovations are beneficial and, which are redundant.

This study examines one approach to the provision of ACP in a primary care setting. Using a randomized design, it will determine the feasibility of undertaking a definitive trial to evaluate the implementation and outcomes of an ACP intervention in primary care. The intervention is designed to assist older adults identified as being at risk of functional decline by developing a personalized support plan. The outcomes from this feasibility cluster randomised controlled trial (cRCT) will allow us to determine the methodological and statistical considerations required to move forward with the definitive trial. Furthermore, we will be able to examine potential improvements in care for older persons at risk of functional decline such as: improved ability to assess care needs and respond appropriately; enhance decision making among patients regarding their care; and, improve communication between patients, their family carers and healthcare providers on identified goals of care. In addition, this study will help us to determine if it is possible and appropriate to position the intervention within a primary care setting. It should also be noted that the study includes a cross border approach, with primary care settings in the Republic of Ireland and Northern Ireland (a region within the United Kingdom). This provides an opportunity to identify optimal system delivery supports for effective implementation in different healthcare systems and their potential impact on the delivery and outcomes of the ACP intervention.

## **Methods/design**

### **Study overview**

In order to examine the feasibility of this ACP intervention we will perform a feasibility cluster randomized controlled trial (cRCT) where 8 general practitioner (GP) practices will be randomly assigned at a 1:1 ratio (4 practices per group) to the intervention (ACP) or usual care alone. The randomisation will be stratified by jurisdiction (Northern Ireland and the Republic of Ireland) and, in the Republic of Ireland, by county (Cavan and Louth). GP practices will be randomly allocated to the intervention or usual care arms of the study before the screening of patients for signs of functional decline. An overview of the trial is presented in Figure 1 and we follow the SPIRIT checklist (additional file 2).

### **Recruitment of study centres**

Practices in Northern Ireland will be recruited via the Northern Ireland Clinical Research Network (Primary Care), an initiative which aims to facilitate the completion of clinical trials within the National Health Service (NHS). In the Republic of Ireland, informal and formal networks such as the national Health Research Board (HRB) Primary Care Trials Network will assist recruiting general practices located in the border counties of Louth and Cavan.

The allocation of general practices to intervention or control will not be revealed until the practice has formally entered the trial, thereby maintaining allocation concealment. A general practice will be ready for randomisation when it has completed the screening of its patient list to identify those who are eligible for the study. Each general practice will have a 50% probability of being allocated to the intervention or to the control group, with two intervention and two control practices being identified in each jurisdiction. The random allocation to intervention or control group will be undertaken when all four general practices in the relevant jurisdiction have completed screening and are ready for randomisation.

**Randomisation.** As a first step, the trial administrator will order the GP practices alphabetically and use this order to code the four practices in Northern Ireland and the four practices in the Republic of Ireland. The trial administrator will inform the co-applicant methodologist when all four practices in Northern Ireland or the Republic of Ireland are ready for randomisation and send him their codes, along with an indication of whether the practice is urban or rural. The methodologist, who will be blind to the identity of the practice, will then use the random number function in Microsoft Excel to assign a random number for each code. In each jurisdiction, the urban and the rural practice with the lowest number will be allocated to the intervention group and the other two practices will be allocated to the control group. The methodologist will send the allocations to the trial administrator, who, by linking the alphabetic code to the relevant practice, will know which group each practice has been allocated to. The trial administrator will inform the research nurse of the allocations and will then inform each practice of their allocation.

**Setting.** The project will be implemented across two healthcare systems: Northern Ireland and the Republic of Ireland. Northern Ireland is a region within the United Kingdom that provides an integrated health and social services model of care, under the NHS, which is free to the user at the point of delivery. The Republic of Ireland has a mixed public-private healthcare system with all persons resident in the country entitled to receive hospital care through the publicly funded health care system. In addition, the General Medical Services (GMS) card, which is available to all persons aged  $\geq 70$  years and those under 70 years who meet a certain income threshold, facilitates the use of the majority of health services free of charge, including GP practice visits as well as inpatient, emergency and outpatient services in public hospitals. In this group, medication charges incur a small co-payment (€2.50 per item) to a maximum of €25 per family per month [9]. Those not eligible to receive a medical card must pay for primary care following each visit. In addition, the two jurisdictions differ in their stage of adopting a national aging strategy and implementation of integrated health and social care [6-7].

## Study population and recruitment

Overall, a total of 64 patients will be recruited (32 per randomised group), with 8 patients recruited from each participating general practice. The inclusion criteria are: 1) aged  $\geq 70$  years; 2) in receipt of a valid general medical services (GMS) card in the Republic of Ireland, or registered for NHS primary care services in Northern Ireland; 3) have two or more chronic medical conditions (multimorbidity); 4) prescribed four or more regular medications; and 5) able to complete an English language postal questionnaire. The exclusion criteria are: 1) receiving specialist palliative care; 2) a record of assessed cognitive impairment at the level that would impact their ability to complete screening postal questionnaire, outcome measures and participate in a patient care conference(s) (defined as Mini Mental State Examination (MMSE)  $\leq 20$ ); 3) experiencing a psychotic episode at the time of recruitment; or, 4) hospitalised long-term, in a nursing home, homeless or in sheltered accommodation.

**Patient screening.** The GP practice manager will conduct a search employing the study eligibility criteria on the practice's electronic health record system to identify potential study participants. Eligible patients will be sent a letter from their GP informing them about the project and inviting them to complete the PRISMA 7 questionnaire. This is a seven item-screening questionnaire that includes items related to age, gender, mobility, need for assistance in activities of daily living and the availability of informal support [10]. It identifies frailty, is suitable for postal completion and is considered a best practice tool recommended by NHS England to case find at-risk patients for frailty in general practice. Individuals who obtain a score of  $>3$  are identified as being at risk of functional decline [11-12]. If patients do not respond to an initial invitation letter, one follow-up reminder will be mailed seven to ten days later.

**Patient enrolment.** The study methodology is designed to identify individuals who will screen as at risk of functional decline. Initially, patients who screen as 'at risk' would receive a letter from their GP inviting them to participate in the study. Patients who reply that they agree to be contacted will be telephoned by a research assistant, who would seek their consent by telephone. Allocation to the intervention versus usual care group will be communicated to the study participant by a member of the research team after consent has been obtained and the baseline-standardised interview completed. If more than one eligible participants is identified in any one household, all will be eligible for enrolment into the study and, if enrolled, would receive the same study allocation. Following consent, study nurses will commence arrangements to visit the study participants in the intervention group. Changes to enrolment procedures in the Republic of Ireland were made in response to ethical review in that jurisdiction. These changes related to patient screening and require patients who meet the study inclusion criteria to be assessed for risk of functional decline through a 3 step process; 1) GP staff generate a pseudonymised list of potential participants via the GP electronic health record system search, identifying candidates who have two or more chronic medical conditions; four or more regular prescribed medications and, the availability of an informal caregiver if recorded; 2) identified candidates will be reviewed by their own GP to confirm suitability for inclusion in the study; and, 3) eligible patients will then be sent a letter from their GP

providing information about the study and inviting them to complete the PRISMA 7 questionnaire that will also include a 'consent to be contacted' statement. Patients who do not respond to the initial GP's letter may be contacted using the same methodology on one additional occasion. If there is no response at this stage, they will not be contacted again. Patients return the completed pseudonymised PRISMA 7 to the research team who will then score it. The research team will then send the GP practice staff the unique code assigned to the completed PRISMA 7 questionnaire. These staff will link the patient's name, telephone number and address to the assigned code. Patients who do not screen as 'at risk' on the basis of their answers on the PRISMA 7 questionnaire will receive a letter from the GP explaining that they do not meet the criteria to participate in the study and thanking them for their time. The GP practice manager will provide the research team with the name and telephone number of patients who do screen as at risk and have consented to be contacted by them. A member of the research team will then telephone the patient to discuss the study and answer any questions they have. If a patient is interested in participating in the study, the researcher will arrange to meet with them to complete the written informed consent process and administer baseline questionnaires.

**Sample.** A total of 64 patients (32 per randomised group) will be enrolled into the study. This will comprise eight patients per GP practice, and random selection will be used if more than eight patients are available in a practice. This size of sample is recommended to allow the standard deviation of the continuous outcome EQ-5D-5L [13] to be determined at a sufficient level of accuracy while minimizing the number of patients required in the pilot [14, 15].

**Nurse training:** The framework for this intervention comprises personalised care and support planning. To ensure a personalised care approach in the ACP intervention, registered nurses from both jurisdictions complete a training program that was designed to orientate the nurses to the intervention and study procedures. This training lasts three days and is facilitated by a clinician, who is acknowledged as an expert in the field. It covered a range of topics including: an overview of the study; principles and practise of personalised care; shared-decision making; conducting a holistic assessment using the Easy-Care Assessment instrument; [16] and, completing a medication review facilitated by a clinical pharmacist.

## **The intervention group**

As a first step in the intervention, the study nurse will contact the patient by telephone to schedule an initial home visit. During that visit, the study nurse will complete an ACP assessment with the aid of a medical summary provided by the GP practice. This will include details of the patient's health conditions and currently prescribed medications. The ACP assessment will be conducted using the EASY-Care assessment tool to ensure a personalised holistic approach is used and this assessment will be

supplemented with a medication review. A personalised care approach will encourage discussion with the patient and their family carer about present and future care and patient goals. The patient will be asked to prioritise any concerns they have in order to guide the research nurse in the development of a person centred care plan.

Following the initial home visit, the study nurse will draft a structured summary report of the assessment that will include patient goals, preferences for care, identified problems and an action list. The study nurse will forward the medications review to the study pharmacist who will conduct a desk-based evaluation based on established guidelines [17] to determine medication management considerations to be brought forward to the patient's GP. Subsequent to the pharmacist review, the study nurse will finalize the summary report and will meet with the patient's GP who will be informed through a structured format of the patients identified goals and wishes, the results of the patient assessment, the problem list and recommended actions. The GP will review, provide feedback and confirm their agreement with the suggested plan of care.

Following the GP consultation, the study nurse will, depending on the complexity of the identified care needs or functional needs of the patient, either meet with the patient and family carer again or contact them by telephone. During this meeting or telephone call the study nurse will confirm and discuss the patient's identified priorities and then initiate a discussion of identified options for support. While the number and frequency of visits will vary depending on the complexity of a patient's needs, it is expected that participants in the intervention group will receive up to five hours of nursing contact over ten weeks. This will include the initial home visit to complete the holistic assessment, meetings with the GP, contacts with other health and social care providers and any follow-up home visits and telephone contacts.

**Usual care group.** Patients in the usual care group will not receive the ACP intervention but will receive usual care from their GP. The PRISMA 7 score and the explanation of this score will not be shared with the GP in this group. Similar to participants in the intervention group, usual care participants will complete study questionnaires with the help of a research assistant at baseline, ten weeks and six months following enrolment.

## **Data collection**

The RE-AIM conceptual framework will guide considerations for this evaluation of the ACP intervention [18-20]. Four of the five factors included in the RE-AIM framework apply to the parameters of this feasibility cRCT study: 1) Reach - describes the number, proportion and representativeness of general

practices and patients who participate in the initiative; 2) Effectiveness – describes the impact of the intervention on outcomes; 3) Adoption – examines the willingness of General Practises exposed to the intervention who are willing to initiate the intervention; and 4) Implementation – explores the fidelity of the intervention protocol and the consistency of its implementation across primary care practises and jurisdictions. In most cases, the Maintenance component of the RE-AIM Framework refers to on-going implementation into routine care and is therefore beyond the scope of this feasibility study.

### **Patient standardized interview (RE-AIM Effectiveness factor)**

On obtaining consent from the patient to participate in the study, a baseline patient standardized interview will be conducted by a trained project research assistant in the patient's own home. In order to assess the impact of the intervention, all patients will participate in the individual standardized survey interviews at baseline, and at their 10 week and 6 month follow-up. Home interviews last approximately one hour.

### **Baseline measures**

Information on variables expected to predict responsiveness to the intervention (demographic factors, social support, medical conditions, prescribed medications, and cognitive impairment) will be obtained during the initial (baseline) home interview with the research assistant.

**a) Demographic data.** Demographic data will include age, gender, education, living arrangements, income and economic resources.

**b) The Medical Outcomes Study Social Support Survey (MOS)** [21] which is a 20-item instrument designed for use with chronically ill patients, will be used to assess four categories of social support: tangible support, affectionate support, positive social interaction, and informational support. Respondents use a Likert-type scale to rate each item ranging from 'None of the Time' to 'All of the Time'. Psychometric properties of the measure are sound. It has demonstrated good reliability, internal consistency and construct validity.

### **Outcome Measures**

To evaluate the ACP intervention, a mixed-methods approach consisting of both quantitative measurement and qualitative interviews will be applied. All quantitative outcome measures will be assessed at baseline, 10 weeks and 6 months. All selected measures have been used with this population in previous research as both outcome and observational measures (22-24).

### **Primary outcome measures (RE-AIM – effectiveness factor)**

**a) EQ-5D-5L** [13] is a widely used self-reported generic measure of health related quality of life that has been validated in different patient populations. The 5-level version contains the same dimensions as the earlier 3-level version but has been designed to provide greater reliability and sensitivity.

**b) Center for Epidemiological Studies Depression Scale (CES-D)** [25] is a 20-item scale that has been used extensively with older adults. Respondents use a 4 point scale to rate how they have felt in the past week in relation to symptoms associated with depression.

### **Secondary outcome measures (RE-AIM - effectiveness factor)**

**a) The Patient Assessment of Chronic Illness Care (PACIC) Scale** [26] is a 20 item scale was designed to assess, from the patient's perspective, the receipt of patient-centered care and self-management behaviors.

**b) Health Economic Evaluation.** The health economic analysis in this feasibility study will consist of a trial-based economic evaluation and will incorporate both cost effectiveness analysis and cost utility analysis to compare the ACP Intervention versus usual care in general practice. The basic tasks of the evaluation are to identify, measure, value and compare the costs and outcomes of the alternatives being considered. This feasibility study will report on the process to identify the appropriate resource use items to be included and on the appropriate methods for collecting this data. Further, the study will consider the feasibility of conducting the incremental analyses and report on the potential cost effectiveness data generated. Evidence collected on resource use and outcome measures alongside the study will provide the basis for the analysis over the follow up period. With respect to costing, a health service perspective will be adopted. Resource use associated with delivery of the ACP intervention will be measured and costed. Other resource use to be captured will include usage of medications, primary care, community care, and hospital care services. For the cost effectiveness analysis, the ACP intervention and usual care will be compared on the basis of the effectiveness data for the primary outcomes of interest. For the cost utility analysis, effectiveness will be evaluated on the basis of Quality Adjusted Life-Years (QALYs) which will be estimated using data obtained with the EuroQol EQ-5D-5L survey instrument [13]. The health economic analysis will employ the standard approach for the comparison of alternative treatment strategies in terms of costs and health outcomes. An incremental analysis will be undertaken to provide information on the marginal costs and effects of the ACP intervention relative to usual care through the

calculation of incremental cost effectiveness ratios and incremental net benefits. Uncertainty in the incremental analyses will be explored using cost effectiveness acceptability curves.

**c) The Katz Index of Independence in Activities of Daily living [27]** is a well-established measure of performance. It describes what the person actually does, rather than what they are capable of doing. It assesses six activities: ability to bathe, dress, toilet, transfer, feed yourself and maintain bowel and bladder continence. A 3-category scoring model is used for each activity.

**d) Generalized anxiety disorder (GAD) [28]** is an established measure which asks patients how often in the last 2 weeks they had been bothered by seven anxiety related symptoms. It is a valid and efficient tool for screening for generalized anxiety and assessing its severity.

**e) Medication management [29]** will be assessed following the medication review conducted by the study nurse in collaboration with the study pharmacist. We will report the proportion of patients who receive recommendations from the pharmacist following their medications review. We will assess the mean number of suggested changes to prescribed medications.

**2. Tracking intervention patterns and intensity (RE-AIM Implementation)** Records will be maintained describing the patterns and intensity of care provided to each participant in the ACP intervention group. Nurses will maintain logs to record the amount of time spent with each participant including home visits, phone calls, and consultations with family physicians and other professionals.

### **3. Process Evaluation (RE-AIM - Adoption)**

In addition to the collection of quantitative data, a qualitative approach will also be pursued. User perceptions on the appropriateness, benefits, and convenience of the ACP intervention will be recorded through interviews. Patient acceptability of the ACP intervention will be assessed using several additional questions embedded in the semi-structured interview schedule conducted at the 10 week follow-up for the 32 participants in the ACP intervention group (n=32). These questions will assess perceptions about the intervention in terms of: (a) the overall intervention; (b) its component parts (the patient meetings, assessment, patient education on advance care planning); (c) implementation (was the home environment suitable for meetings); (d) whether the contents reviewed in the meetings were useful; and (e) suggestions for refining the intervention in future. The five study nurses will be interviewed on aspects of the intervention to review: (a) what experience a registered nurse should have to fulfill the position; (b) training requirements; (c) how to build relationships with participants; (d) if the home environment was suitable for the meetings; (e) if the ACP model fitted into the running of a GP practice; (f) their best and worst experience related to ACP meetings; and (g) any recommendations they would make to improve the ACP intervention. GP practice staff (GPs and associated healthcare providers e.g. practice nurse and practice manager) (estimate n = 12) will be interviewed to examine their perceptions on the

appropriateness, benefits, and convenience of the ACP intervention. In addition, community health professionals (estimate n = 12) will be interviewed to identify any facilitators and barriers at the regional healthcare system level that may influence the manner in which the ACP intervention is implemented.

#### **4. Metrics to be collected (RE-AIM - Reach).**

Records will be maintained that will collect indicators on: (a) number of eligible participants identified on the GP patient list; (b) number of potential participants found to be ineligible and reasons why; and (c) number of eligible participants who do not consent to participate and reasons for non-participation.

#### **Criteria for progression to a full trial.**

A protocol for a definitive trial will be developed if this study's findings demonstrate that the ACP intervention is acceptable to most (>70%) patients, their carers and health professionals; if the ACP is perceived by GP practice staff to be readily implemented; if >50% of eligible patients are recruited and >65% of recruited patients are retained; if there is a detected difference in the primary and secondary expected outcomes between the intervention and usual care groups; and the features of the economic evaluation are found to be feasible [30].

#### **Data Analysis.**

Quantitative analysis: data will be expressed as a mean, standard deviation (SD) or median and for continuous variables and count (percent) for categorical variables. The analysis of indicators will be based on descriptive statistics reported as estimates with confidence intervals. Outcome analyses will be conducted to compare the intervention and control groups, recognizing that this analysis will be underpowered for a robust statistical analysis. Means and SD will be reported for each combination of baseline and final data. Frequency and percentage will be reported in the same manner for categorical variables. The SD of the difference in primary outcome (EuroQol EQ-5D-5L at 6 months) will be determined and the intra cluster correlation of this difference will be estimated to inform the sample size required for the definitive trial. Recruitment and retention rates at 6 months will also be used to inform the sample size calculation. We will also consider acceptability of the mode and timing of the administration of impact measures. Incremental cost effectiveness and cost utility analyses will be conducted for the purposes of the economic evaluation. All quantitative analysis will be conducted in a manner consistent with guidelines for the analysis of data from cRCTs.

Qualitative analysis: the software package, NVivo 10.0 [31] will be used to help organize and analyze the qualitative data. We will analyze interview data following the template analysis style outlined by Miles and Huberman [32] and will develop an open-ended and modifiable codebook. We will use this tool to generate themes, patterns, and interrelationships in an interpretive fashion, drawing on the expertise of our research team and our Personal and Public Involvement advisors.

## **Ethical considerations**

Ethical approval was obtained in the Republic of Ireland from the Research Ethics Committee, Irish College of General Practitioners (reference: ICGP2018.4.10, date of approval: 28/01/2019; and, in Northern Ireland from the Office for Research Ethics, Northern Ireland (ORECNI)I (reference: 19/NI/0001. IRAS Project ID: 247572), date of approval; 07/02/2019. All participating GP practices completed a letter of support confirming that they had appropriate insurance to cover their staff member's participation in the study. In addition, general practices also completed a data sharing agreement to guide the processing and provision of personal data under the terms of the General Data Protection Regulation (GDPR) and the Data Protection Act (DPA) 2018.

## **Discussion**

This study will inform the feasibility for a definitive trial to evaluate the implementation and outcomes of an ACP intervention in primary care to assist older adults aged  $\geq 70$  years and assessed as being at risk of functional decline. Recent systematic reviews have failed to identify any trials of anticipatory and integrated care on the island of Ireland [33, 34], so this study will be the first to determine the feasibility of evaluating an ACP intervention on the island of Ireland. This study will span two jurisdictions with different health systems but similar health challenges, providing novel findings. Important issues, such as different interpretations of legislation such as General Data Protection Rules, can be explored during the implementation of the study, and will provide vital learning for other cross-border trials on the island of Ireland.

From a methodological perspective, due to the different nature of the healthcare systems in the Republic of Ireland and Northern Ireland and the potential for contamination associated with individual patient randomisation, we opted for a cluster-randomised trial in both jurisdictions. Cross-border cooperation exemplified in this trial will provide an evidence-based assessment on the potential impact of the ACP intervention on patient quality of life, healthcare utilisation, costs, and appropriate prescribing in an all-Ireland context. The cross-border approach will also identify optimal system delivery supports for effective implementation and impact of the ACP intervention. Overall, our findings will inform the feasibility of developing a large, cross-border, trial on ACP for older adults on the island of Ireland.

## **Trial Status**

The study started in April 2019. Protocol version number 2, approved in January and February 2019 (see above). At the time of writing (September 2019), recruitment and baseline data collection are in progress, with the final participants expected to be recruited in October 2019, while we expect the results of the cRCT to be published in 2020.

## **Abbreviations**

ACP: Anticipatory Care Planning; CES-D; Centre for Epidemiological Studies Depression scale; cRCT: Cluster Randomised Controlled Trial; DPA: Data Protection Act; GAD-7: Generalized Anxiety Disorder – 7 questionnaire; GDPR: General Data Protection Regulation; GMS: General Medical Services; GP; General Practitioner; ICGP; Irish College of General Practitioners; MMSE: Mini Mental State Examination; MOS; Medical Outcomes Survey; NHS; National Health Service; NI: Northern Ireland; ORECNI: Office for Research Ethics, Northern Ireland; PACIC: Patient Assessment of Chronic Illness Care scale; QALY; Quality Adjusted Life Years; RoI: Republic of Ireland; SD: Standard Deviation.

## **Declarations**

### **Ethics approval and consent to participate**

The study protocol and associated documentation were approved by the Office of Research Ethics, Northern Ireland (19/NI/0001. IRAS Project ID: 247572) and the Irish College of General Practitioners in the Republic of Ireland (ICGP2018.4.10). Informed consent will be obtained from all study participants prior to their participation in the study.

### **Consent for publication**

Not applicable

### **Availability of data and material**

Not applicable for this protocol but a data sharing plan will be in place when the study's findings are available.

### **Competing interests**

The authors declare that they have no competing interests

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report; and the decision to submit the report for publication, including any ultimate authority over any of these activities.

### **Authors' contributions**

KB is the principal investigator and FD is a senior co-investigator who assisted with conceptual development and study implementation in Rol. CC developed the statistical analysis plan and PG developed the health economic analysis. MC is the study methodologist who advised on the study design and undertook randomisation procedures. GC and DS helped develop educational content for training. PH, PG, ET, TF, KM were involved in the conceptual development, and implementation of the study. DS assisted in writing and editing the manuscript. All authors read and approved the final version of the publication.

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## **References**

1. Global status report on noncommunicable diseases 2010: description of the global burden of NCDs, their risk factors and determinants. Geneva: World Health Organisation, 2011.  
[http://www.who.int/nmh/publications/ncd\\_report2010/en](http://www.who.int/nmh/publications/ncd_report2010/en) (accessed July 2017).
2. Christensen K, Doblhammer G, Rau R, Vaupel J. Aging populations: the challenges ahead. 2009; 374: 1196-1208.

3. Coulter A, Roberts, S., Dixon, A. *Delivering Better Services for People with Long-Term Conditions: Building the House of Care*. London: King's Fund; 2013.
4. Smith S, Soubhi H, Fortin M, Hudon C, O'Dowd T. Managing patients with multi-morbidity: systematic review of interventions in primary care and community settings. *BMJ*. 2012; 345: e5205 doi: 10.1136/bmj.e5205.
5. Wallace E, Guthrie B, Fahey T. Managing patients with multi-morbidity in primary care. 2015; 350: doi:10.1136/bmj.h176
6. Health and Social Care Northern Ireland. *Transforming your care: a review of health and social care in Northern Ireland*. 2011. Available from: <http://www.transformingyourcare.hscni.net/wp-content/uploads/2012/10/Transforming-Your-Care-Review-of-HSC-in-NI.pdf> (accessed July 2017).
7. Department of Health. *Future health; a strategic framework for reform of the health service 2012-2015*. Available from [http://health.gov.ie/wp-content/uploads/2014/03/Future\\_Health.pdf](http://health.gov.ie/wp-content/uploads/2014/03/Future_Health.pdf)
8. Coulter A, Entwistle VA, Eccles A, Ryan S, Shepperd S, Perera R. Personalised care planning for adults with chronic or long-term health conditions. *Cochrane Database of Systematic Reviews*. 3; CD10523. Doi: 10.1002/1461858
9. Health Service Executive. *Primary care eligibility and reimbursement plan: Strategic plan 2019-2021*; 2019. Available from: <https://www.hse.ie/eng/staff/pcrs/about-pcrs/pcrs-strategic-plan-2019-2021.pdf>
10. Clegg A, Rogers L, Young J. Diagnostic test accuracy of simple instruments for identifying frailty in community-dwelling older people: a systematic review. *Age and Ageing*. 2015; 44: 148-152.
11. Lyndon H, Stevens, G. *Toolkit for General Practice in supporting older people with frailty and achieving the requirements of unplanned admissions: Enhanced service 2014*. London: NHS; 2014.
12. British Geriatrics Society. *Fit for Frailty - consensus best practice guidance for the care of older people living in community and outpatient settings - a report from the British Geriatrics Society*. London; 2014.
13. Devlin N, Shah K, Feng Y, Mulhern B, van Hout B. *Valuing health related quality of life: an EQ-5D-L value set for England*. London: Office of Health Economics, 2016. Research Paper 16/01. 2016
14. Billingham S, Whitehead A, Julious S. An audit of sample sizes for pilot and feasibility trials being undertaken in the United Kingdom registered in the United Kingdom Clinical Research Network database. *BMC Medical Research Methodology*. 2013; 13: 104.
15. Wallace E, McDowell R, Bennett K, Fahey T, Smith S. External validation of the probability of repeated admission risk prediction tool in older community-dwelling people attending general practice: a prospective cohort study. *BMJ Open*. 2016; 6:11: e012336. Doi10.1136/bmjopen-2016-012336
16. Philip KE, Alizad V, Oates A, Donkin DB, Pitsillides C, Syddall SP, et al. Development of EASY-Care, for brief standardized assessment of the health and care needs of older people; with latest information about cross-national acceptability. *J Am Med Dir Assoc*. 2014;15:42-6.
17. Northern Ireland Pharmacists working with Older People (NIPOP) Network. *A guide to support medication review in older people*. Belfast: Northern Pharmacies Ltd Trust Fund; 2017.

18. Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health promotion interventions: the RE-AIM Framework. *American Journal of Public Health*. 1999; 89; 1322-1327.
19. Gaglio B, Glasgow RE. The Re-AIM Framework: a systematic review of use over time. *American Journal of Public Health*. 103: 6; e38-e46. Doi: 10.2105/AJPH.2013.301299
20. Gaglio B, Phillips S, Heurtin-Roberts S, Sanchez, M Glasgow R. How pragmatic is it? Lessons learned using PRECIS and RE-AIM for determining pragmatic characteristics of research. *Implementation Science*. 2014; 9: 96. doi: 10.1186/s13012-014-0096-x.
21. Sherbourne CD, Stewart AL, Wells KB. Role functioning measures. In Stewart AL, Ware JE Jr, eds. *Measuring functioning and wellbeing: the Medical Outcomes Study approach*. Durham, North Carolina: Duke University Press; 1992. 173-181.
22. Kane RL, Kane RA. *Assessing older persons: measures, meaning and practical applications*. New York: Oxford University Press; 2000.
23. Man MS, Chaplin K, Mann C, Bower P, Brookes S, Fitzpatrick B, et al. Improving the management of multi-morbidity in general practice: protocol of a cluster randomized controlled trial (The 3D Study). *BMJ Open*. 2016; 6(4); doi: 10.1136/bmjopen-2016-011261.
24. Bleijenberg N, Drubbel I, Schuurmans MJ, tenDam H, Zuithoff N, Numans M, et al. Effectiveness of a proactive primary care program on preserving daily functioning of older people: a cluster randomized controlled trial. *Journal of the American Geriatrics Society*. 2016; 64: 1779-1788.
25. Radloff LS. The Centre for Epidemiological Studies – Depression Scale: A self-report depression scale for research in the general population. *Applied Psychological Measurements*. 1977; 3: 385-401.
26. Glasgow RE, Wagner EH, Schaefer J, Mahoney LD, Reid RJ, Greene SM. Development and validation of the Patient Assessment of Chronic Illness (PACIC). *Medical Care*. 2005; 43(5): 436-444.
27. Katz S, Ford AB, Moskowitz RW, Jackson BA, Jaffee MW. Studies of illness in the aged. The index of ADL: A standardized measure of biological and psychological function. *Journal of the American Medical Association*. 1963; 185(12): 914-919.
28. Spitzer RL, Kroenke K, Williams J, Lowe B. A brief measure for assessing generalized medical disorder: The GAD 7. *Archives of Internal Medicine*. 2006; 166: 1092-1097.
29. Clyne B, Smith S, Hughes C, Boland F, Bradley M, Cooper J et al. Effectiveness of a multi-faceted intervention for potentially inappropriate prescribing in older patients in primary care: a cluster-randomized controlled trial (OPTI-SCRIPT study). *Annals of Family Medicine*. 2015; 13(6): 545-553.
30. Avery K, Williamson P, Gamble C, O'Connell-Francischetto E, Metcalfe C, Davidson P et al. Informing efficient randomized controlled trials: exploration of challenges in developing progression criteria for internal pilot studies. *BMJ OPEN*. 2016; 7; e013537. doi: 10.1136/bmjopen-2016-013537
31. NVIVO 11. 11 ed. Victoria, Australia: QSR International.
32. Miles MB and Huberman HA. *Qualitative Data Analysis*. 2<sup>nd</sup> Thousand Oaks: California: Sage Publications; 1994.

33. Baxter S, Johnson M, Chambers D, Sutton A, Goyder E, Booth A. The effects of integrated care: a systematic review of UK and international evidence. *BMC Health Services Research*. 2018; 18(350). <https://doi.org/10.1186/s12913-018-3161-3>
34. Looman WM, Huijsman R, Fabbricotti IN. The (cost-) effectiveness of preventive, integrated care for community-dwelling frail older people: A systematic review. *Health and Social Care in the Community*. 2019; 27(1): DOI: [10.1111/hsc.12571](https://doi.org/10.1111/hsc.12571)

## Additional Files

Additional file 1 – WHO registry checklist

Additional file 2 – SPIRIT Checklist

## Figures

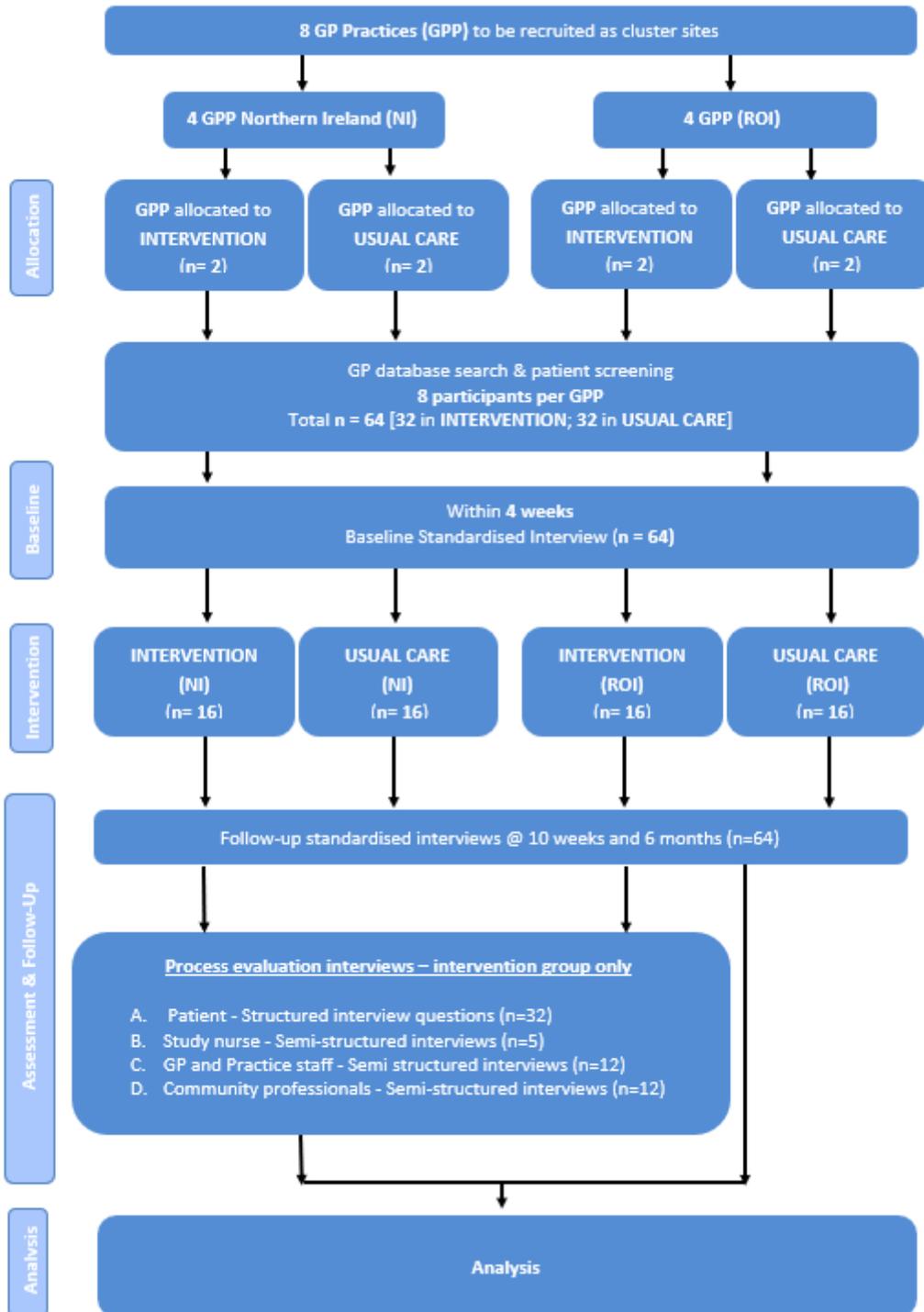


Figure 1

Study procedures.

## Supplementary Files

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