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Improving review appointments for people with long-term conditions

Submission date	**Recruitment status**	[_] Prospectively registered
22/07/2022	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[X] Statistical analysis plan
03/08/2022	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
17/02/2025	Other	

Plain English summary of protocol

Background and study aims

General practices regularly review patients with long-term health conditions included in the Quality & Outcomes Framework (QOF) using computerised templates (checklists) for each health condition. Reviewing each disease 'one-at-a-time' leads to fragmented care for people with multiple long-term health conditions (MLTC) and can ignore conditions that are not included in QOF. These are sometimes the problems that bother patients most. Standardisation of care using checklists can improve safety but a priority in the NHS Plan is also to make care more personalised, and tailored to each individual.

Some practices have replaced separate disease-focused reviews with a combined annual review consultation for people with MLTC. A promising way to balance the benefits of templates with the need to personalise care is to use a 'smart' template focused on what matters most to patients, which supports self-management and shared decision-making. It includes links to social prescribing and pharmacist review of complicated medication and involves agreeing a care and support plan. This concept has been shown to improve personalised care in a large research trial. In this project, we will adapt a template already developed for MLTC and make it more personalised. We will make it widely available to general practices, supported with training and other tools e.g. to identify patients with multimorbidity and to use patient questionnaires to gain feedback to improve the process. Working with primary care networks in three areas of England we will support the implementation of this approach (whole-person review, template, training, tools).

To reduce health inequalities, we will start with practices in deprived areas and patients with cardiovascular diseases alongside other conditions. In three practices in deprived areas of Bristol, we will provide more in-depth support and training, as part of developing a broader system change called 'Maxwell'. We will conduct a more detailed evaluation in this small sub-set of practices to understand whether the additional support and training is useful and what it adds to the provision of the template alone.

Who can participate?

Adults, registered with a participating GP practice, who are due to be invited to an annual review of their long-term conditions within the next 12 months. Participation is by invitation only.

What does the study involve?
Implementation will be informed by established theories that help explain how innovations are adopted into normal practice. Implementation will be evaluated using a range of methods including routinely collected activity and clinical data, questionnaires, and interviews with patients and staff. This project will provide evidence to support and inform the widespread implementation of a 'whole-person' review for patients with MLTC in line with the NHS Comprehensive Model for Personalised Care.

What are the possible benefits and risks of participating?
There are no direct benefits from taking part, but participants may find it useful to have the opportunity to talk about their experiences in an interview. Disadvantages of taking part include the time taken for the interview (about 35-45 minutes).

Where is the study run from?
University of Bristol (UK)

When is the study starting and how long is it expected to run for?
From October 2021 to December 2023

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
Dr Andrew Turner, andrew.turner@bristol.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
303831

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 303831, CPMS 51700

Study information

Scientific Title
Personalised Primary care for Patients with Multimorbidity (PP4M) – a primary care service improvement initiative

Acronym
PP4M

Study objectives
This is a study to implement and evaluate a computerised template for clinicians to conduct combined annual reviews with patients with multiple conditions. The study seeks to explore how best to implement the template and explore the impact of implementing it.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/01/2022, Wales REC 6 (Swansea University, Swansea, SA2 8PP; +44 (0)7920 565664, +44 (0)2920 230457; Wales.REC6@wales.nhs.uk), ref 22/WA/0018

Study design
Non-randomized study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
GP practice

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Primary care, multimorbidity

Interventions
This is a study to implement and evaluate a computerised template for clinicians to conduct combined annual reviews with patients with multiple conditions. The study seeks to explore how best to implement the template and explore the impact of implementing it.

There are three stages to the study development of the intervention, implementation and evaluation.

Development of the intervention:
The development of the template has already been completed. This involved the research team refining an existing template to make it more patient-centred. The development process drew on the research team's experience and insights developing a similar template for a previous trial, which was informed by extensive patient and public involvement.

Implementation of the template:
Implementing the template involves using the new template instead of the existing templates that clinicians currently use for conducting annual reviews with patients. The use of templates is already well-integrated into practices' computer systems, meaning this study is not about the technical task of getting the template into practice. Instead, implementation is focused on service improvement, generating buy-in from practice staff for the new template, examining how the template can best fit their needs, and exploring what further refinements may be needed. Implementation will be informed by established theories that help explain how innovations are adopted into normal practice. This will help tailor our implementation strategies to the needs of those using the template.

Evaluation of the template:
We will use complementary quantitative and qualitative methods in parallel to evaluate the template: this is known as a 'concurrent mixed-method' design.

Standard care for annual reviews involves patients being invited and then attending one or more review consultations (which are guided by separate templates for each of their health conditions). This process is streamlined in this study, by doing one ‘whole-person’ review which covers all the patient’s health problems and includes attention to the individual’s priorities and needs. This is all made possible by the new ‘person-centred’ and interactive template.

All eligible patients (those with two or more different long-term health conditions) will have anonymous routine data collected about their characteristics and about the health care they receive before and after the use of the template. Up to 200 patients per practice will be asked to complete a questionnaire before and after their review consultation. A small number of patients (about 55 overall, across 24 practices) will additionally be invited to take part in an interview about their experience of the review consultation and/or be invited to have their review consultation observed and recorded by a researcher.

General practice staff participants will be invited to complete a questionnaire about how well the template has been implemented (about 7 members of staff per practice) and a smaller number of practice staff (about 55 overall) will be invited to take part in an interview about their experience using the template in practice, and/or be invited to have a review consultation observed and recorded by a researcher.

More specific details about the design and methods of each of the evaluation components are given below.

Quantitative methods:
1. Collection of anonymous general practice and hospital data from all eligible patients about their general characteristics (e.g. age, sex, ethnicity, health status), about their annual reviews (e. g. attendance, how much was completed), and about outpatient or inpatient care in hospitals. This will be used to explore the uptake of the multimorbidity template, and the costs of and changes in the process of care.
2. Two questionnaire surveys for up to 200 eligible patients per practice: one sent with their invitation to attend a review, and a second sent 2 months after their review. We view this as part of the intervention rather than as a research tool since patient experience surveys are increasingly promoted as a useful part of normal care. The surveys will use an established questionnaire to collect information about how person-centred their experience of care is, along with basic information. This will be used to explore whether and how the template leads to benefits for patients.

3. One questionnaire survey for approximately 7 practice staff (clinical and non-clinical) per practice. The survey will collect information about how well they perceive the template to be implemented, again using a well-established questionnaire designed for this purpose. This will be used to explore how the template leads to benefits for staff and how well it has been integrated into normal care.

Qualitative methods:
1. Observation of about 39 review consultations across the study (about 4 consultations in about 6 practices, plus an additional 15 interviews in the three Maxwell practices subject to more in-depth support and evaluation). Observations will focus on the dynamics of the review conversation and the impact of the template on the structure of the conversation. This will be used to explore the different ways the template is used, what benefits it has for patients and clinicians, and how it may be improved.
2. Interviews with about 55 patients overall (about 31 patients altogether from about 9 practices, plus an additional 24 in the three Maxwell practices), after the review consultation has been completed. Some of these interviews may be with patients who have had their consultation observed. Patient interviews will focus on whether the template altered their consultation, whether it increased their sense of personalisation, choice, and control in their care, and whether it will lead to any change in how they manage their health. This will be used to explore how the template leads to benefits for patients.
3. Interviews with about 55 members of practice staff overall (about 31 staff altogether from about 9 practices, plus an additional 24 in the three Maxwell practices). Some of these interviews may be with staff who have had their consultation observed. Staff interviews will focus on the usability and usefulness of the template, as well as ways in which it could be improved. This will be used to explore how the template leads to benefits for staff.

There will be a cross-site evaluation of projects funded by the funding stream that supports this (and other) projects. As part of this cross-site evaluation of projects, we will ask practice managers if we can pass on their contact details to the relevant research team. However any recruitment or interviews done for that cross-site evaluation are the responsibility of that external research team and outside the scope of our application for ethics application.

Intervention Type
Other

Primary outcome measure
There is no single primary outcome. The study will use a range of qualitative and quantitative measures to evaluate the implementation of the intervention.

Primary quantitative outcome:
1. The number of people who have received a personalised care and support plan as a result of their annual review consultation measured using anonymous general practice and hospital data collected at a single timpoint

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/10/2021

Completion date

31/12/2023

Eligibility

Key inclusion criteria

Practices:
1. Use the EMIS practice computer system
2. Have a subscription to Ardens templates. This applies to most practices within the regions involved in this study.
3. List size of ≥5000 patients

Staff:
1. Have used the intervention to conduct reviews with patients, or will soon be doing so
2. Have been involved in the implementation of the intervention within the practice

Patients:
1. Registered with a practice that agrees to take part in the evaluation
2. Aged ≥18 years
3. Due to be invited by their practice for an annual review (face-to-face or remote) of their long-term conditions at the practice within the next 12 months
4. Fall under at least two of the following 11 groups of long-term health conditions, including at least one of the conditions asterisked:
4.1. Cardiovascular disease: Coronary heart disease*, hypertension*, heart failure*, peripheral arterial disease, or chronic kidney disease (stage 3 to 5)
4.2. Stroke/TIA* or Atrial fibrillation*
4.3. Diabetes*
4.4. Chronic Obstructive Pulmonary Disease* or Asthma*
4.5. Epilepsy
4.6. Depression or Severe mental health problems (schizophrenia or psychotic illness)*
4.7. Dementia*
4.8. Learning disability
4.9. Rheumatoid arthritis*
4.10. Frailty (severe)
The chronic conditions listed above are included because they are common and they benefit from regular review in general practice. The conditions asterisked already lead to annual review consultations in most general practices, to meet the requirements of the QOF. Some conditions (e.g. the first group listed above) are grouped so that two or more diagnoses within the group just count as one for the purpose of defining multimorbidity. Frailty is included because although it is not a single diagnosis, patients with severe frailty are normally reviewed annually so it makes sense to do this as part of the annual multimorbidity review, rather than calling the patient back again.

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex
Both

Target number of participants
Planned Sample Size: 954; UK Sample Size: 954

Total final enrolment
70

Key exclusion criteria
Practices:
1. Not a subscriber to Ardens clinical templates
2. Does not use EMIS clinical software
3. <5000 registered patients

Staff:
1. Not likely to be involved in the implementation or use of the intervention

Patients:
1. On a palliative care register
2. Would be excluded from an annual review for individual reasons. For example, for some patients who are housebound or in a nursing home it may not be possible to conduct the same type of 'template-based' review away from the surgery. In many cases, community nurses undertake a review without a template, so these reviews would not be relevant to this study of implementation of a template. In some cases, practices offer 'virtual' reviews for these patients, and in such cases the practice will be encouraged to use the multimorbidity template. The usefulness of a virtual review will depend on the patient's combination of conditions and this will be left to the discretion of the practice and clinician.
3. Have declined a review OR have been contacted multiple times unsuccessfully

Date of first enrolment
01/04/2022

Date of final enrolment
06/10/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
NIHR CRN: West of England
Whitefriars
Lewins Mead

Bristol
United Kingdom
BS1 2NT

Study participating centre
NIHR CRN: West Midlands
James House
Newport Road
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Study participating centre
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Sponsor type
University/education

Website
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ROR

https://ror.org/0524sp257

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
NIHR Applied Research Collaboration East Midlands

Results and Publications

Publication and dissemination plan
Planned publication of study protocol. Planned publication of results in a high-impact peer-reviewed journal

Intention to publish date
30/11/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Rachel Johnson (rachel.johnson@bristol.ac.uk). In accordance with the University of Bristol's "Guidance on the retention of research records and data", electronic audio recordings will be held until the study is finished. After this period, electronic audio recordings will be deleted. Anonymised interview transcripts and anonymised analysed data and summaries

of data will be held for 10 years after the study is finished unless consent has been provided to permit sharing this data with bona fide researchers, in which case this data will be held for a minimum of 20 years

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 3.0	25/08/2022	13/04/2023	No	No
HRA research summary			28/06/2023	No	No
Protocol file	version 3.1	14/03/2023	17/08/2023	No	No
Statistical Analysis Plan	version 0.4	21/11/2023	21/11/2023	No	No
Basic results		17/02/2025	17/02/2025	No	No