Personalised Primary care for Patients with Multimorbidity (PP4M)

Statistical Analysis Plan

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Table of Contents

1. Introduction to the SAP 4
1.1 Scope 4
1.2 Document approval 4
1.3 Updates to the document following approval 4
1.4 Skeleton tables and figures 4
2. Amendments to the SAP 4
3. Abbreviations and Definitions 5
4. background, objectives and outcomes 6
4.1 Background 6
4.2 Objectives 7
4.3 Primary outcome 7
4.4 Secondary outcomes 8
4.4.1 Adoption 8
4.4.2 Reach 8
4.4.3 Fidelity 8
4.4.4 Feasibility 9
4.4.5 Acceptability 9
4.4.6 Sustainability 9
4.4.7 Impact on practice workload 9
4.4.8 Having regular reviews for specific diseases 10
4.4.9 Other workload indicators 10
4.4.10 Impact on patient outcomes 10
4.4.11 Costs 10
5. methods 10
5.1 Design and population 10
5.1.1 Practice eligibility 10
5.1.2 Patient eligibility 11
5.1.3 Practice sampling 11
5.2 Consent 12
5.3 Flow of participants 12
5.4 Withdrawals 12
6. Data collection 13
6.1 Patient questionnaires 13
6.2 Routinely collected data 13
6.3 Staff questionnaires 14
7. Data sources 15
8. Derivations 16
9. Statistical analyses 17
9.1 Analysis populations 17

9.2 Descriptive data 17
9.3 Practice and patient characteristics 17
9.4 Descriptive analyses 17
9.5 Comparison groups 18
9.6 Comparative analyses 18
9.7 Sub-group analyses 19
9.8 Sensitivity analyses ....**Error! Bookmark not defined.**
9.9 Statistical software 19
10. References 19
Appendix: Skeleton tables and figures 20

1. INTRODUCTION TO THE SAP

1.1 Scope

This document details information regarding the statistical analysis of Personalised Primary care for Patients with Multimorbidity (PP4M). The analysis will be conducted by the National Institute for Health Research Collaboration for Leadership in Applied Health Research and Care West (NIHR ARC West). The purpose of this evaluation is to investigate the implementation of a new template to support personalised care for patients with multimorbidity. This analysis plan only includes the quantitative analysis; plans for the qualitative analysis are presented elsewhere.

1.2 Document approval

One of the ARC West effectiveness team lead Frank de Vocht will authorise this document. Other members of the project team will also be invited to comment prior to approval.

1.3 Updates to the document following approval

Any changes made to this statistical analysis plan (SAP) after approval must be clearly justified and documented as an amendment below. The SAP should then be re-approved.

1.4 Skeleton tables and figures

Throughout this document references are made to any skeleton tables and figures to be used in the reporting of the project (e.g. Table 1 or Figure 1). Such tables and figures can be found in the Appendix of this document and are intended as a guide for evaluation reporting. Final versions of the tables/figures may differ- tables may be combined, and/or their layout or numbering may change. However, the content should be consistent with the Appendix.

2. AMENDMENTS TO THE SAP

Version	Summary of changes
V1 → V2	
V2 → V3	
V3 → V4	

3. ABBREVIATIONS AND DEFINITIONS

Abbreviations	Definitions
AHSN	Academic Health Science Networks
ARC	Applied Research Collaboration
BNSSG	Bristol, North Somerset and South Gloucestershire
CI	Confidence Interval
CCG	Clinical Commissioning Groups
COPD	Chronic Obstructive Pulmonary Disease
GP	General Practitioner
EMIS	Egton Medical Information Systems
HCA	Health Care Assistant
IQR	Interquartile range
IRR	Incident Rate Ratio
LTC	Long term condition
MD	Mean Difference
NHS R&D	National Health Service Research & Development
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health Research
NoMAD	Implementation measure based on Normalisation Process Theory
NPT	Normalisation Process Theory
PP4M	Personalised Primary Care for Multimorbidity
PROMs	Patient reported outcome measures
PC3EQ	Person-Centred Coordinated Care Experience Questionnaire
OR	Odds Ratio
RCT	Randomised Control Trial
REDCap	Research Electronic Data Capture
SAP	Statistical Analysis Plan
SD	Standard Deviation
SOP	Standard Operating Procedure
QOF	Quality & Outcomes Framework

4. BACKGROUND, OBJECTIVES AND OUTCOMES

4.1 Background

General practices regularly review patients with long-term health conditions included in the Quality & Outcomes Framework (QOF) using computerised templates (checklists). This approach can lead to fragmented care for people with multiple health problems (multimorbidity) and can ignore conditions that are not included in QOF. These are sometimes the problems that bother patients most. In the NHS Plan it is a priority to make care more personalised, as described in the NHS Comprehensive Model for Personalised Care.

Some practices have replaced separate disease-focused reviews with a combined annual review consultation for people with multimorbidity (eligible cohort). A promising way to improve personalised 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, while also meeting QOF requirements. This approach of providing a personalised review has been shown to improve personalised care in several research trials.

In this project we will adapt a template already developed for multimorbidity and make it more personalised. We will make it widely available to general practices, supported by training and other tools e.g. to identify patients with multimorbidity, and to incorporate use of patient reported outcome measures. With CCGs, AHSNs and primary care networks in three areas, we will support implementation of this approach (whole-person review, template, training, tools). To reduce health inequalities, we will prioritise practices in deprived areas.

The multimorbidity review facilitated by the template consists of two consultations, each using slightly different versions of the template. The first consultation, usually with a health care assistant (HCA), collects information using an 'initial assessment' template. The second, usually conducted by a nurse, uses an 'annual review' template which includes most of the same questions as in the initial assessment template so that the nurse can review the results, and also includes additional questions and culminates in agreeing a care and support plan with the patient with specific actions. Throughout this analysis plan when we refer to the 'template' this refers to both consultations in combination, although some patients may just receive the first or second consultations.

The template was rolled out across all practices in Bristol, Gloucester and Somerset, Stoke-on-Trent/Staffordshire and Hampshire areas involved in the PP4M study in October 2021, with our package to support the template starting in April 2022 (start of intervention). Participating clinical commissioning groups (CCGs) will encourage implementation amongst all practices in their area, but we will collect data in about 16 'beacon' practices. Further, in three of these practices in the Bristol, Gloucester and Somerset area, we will explore the benefit of a wider service change (labelled 'Maxwell', to reflect maximising well-being), by facilitating community engagement in implementation, together with support and in-depth training from Year of Care Partnerships, in addition to provision of the template and associated tools. We will also collect data in a number of 'control' practices where no package support is being provided.

The template and package support will be evaluated using mixed qualitative and quantitative methods. The aim is to evaluate implementation and effectiveness of the intervention using a realist approach (how does it work, for whom, in what circumstances), using Normalisation Process Theory (NPT) as a theoretical evaluation framework.

This statistical analysis plan (SAP) includes the quantitative and health economics analysis; plans for the qualitative analysis is presented elsewhere. However, these will all be integrated in the final report to answer the research questions.

As far as possible, the quantitative analysis will include the items specified within the Finance, Commissioning and Contracting Handbook for Personalised Care (e.g. % eligible people receiving a personalised care plan, % referred to social prescribing).[27]

4.2 Objectives

All nine objectives for this project are listed below. The objectives which will not be addressed quantitatively are included here for consistency with the protocol but shown in grey italics. The objectives to be addressed in this SAP are shown in black.

1. *To optimise an existing multimorbidity template already provided by Ardens and include more patient-centred elements in line with the NHS Comprehensive model of Personalised Care*
2. *To implement this template in general practices in three areas of England, supported by West of England AHSN, Keele Impact Accelerator Unit and local CCGs*.
3. *Through interviews with general practice staff to understand factors that lead to, or impede, implementation of the multimorbidity template in general practices in these three areas. This includes how training influences implementation.*
4. Using the NoMAD questionnaire based on an NPT framework, to understand the extent to which the template becomes normalised within general practices (Staff questionnaires).
5. Through analysis of quantitative data from practice records, to explore the extent of implementation and factors influencing uptake of the multimorbidity template (Routine clinical data).
6. *Through consultation observations and interviews to examine the different ways in which staff use the template*
7. *Through qualitative research based on interviews,* analysis of patient reported outcome measures *and direct observation of consultations*, to examine under what circumstances, for which patients and in what ways the template leads to benefits for patients and/or practice staff (Patient questionnaires).
8. *Through interviews with patients and staff, to explore how the template and its implementation could be improved to ensure wider adoption and reach.*
9. *To explore the feasibility of the Maxwell approach to broader system change to support patients with multimorbidity in a sub-set of practices which receive training from Year of Care Partnerships in addition to the template.*

4.3 Primary outcome

The concept of a primary outcome is less relevant to this implementation study than to some other study designs. However, the designated primary quantitative outcome for analysis is the number/proportion of eligible patients who received a Personalised Care and Support Plan in the intervention practices post-intervention compared to pre-intervention, adjusting for control practices in the two time periods. This primary outcome is defined by having one of the codes for “Personalised Care and Support Plan agreed or

reviewed" and/or a code for "Provision of a copy of care plan"- see code lists in appendix for details.

4.4 Secondary outcomes

4.4.1 Adoption

This represents the extent to which the general practices have implemented the template in the first 15 months (April 2022-June 2023). This will be assessed quantitatively using the routine clinical data to explore the proportion of eligible patients receiving multimorbidity reviews (defined using the following codes).

Table A Code terms for template use

Topic	Snomed code term
Attended initial review and initial template used	Template entry – EHR composition type plus text multimorbidity initial review
Sent preparation documents for multimorbidity annual review	Long term condition summary sent to patient
Attended annual review and annual review template used	Template entry – EHR composition type plus text multimorbidity annual review
Annual review completed	Chronic disease management annual review completed

4.4.2 Reach

This describes the number, proportion, and representativeness of eligible patients for whom the template is actually used. Routine clinical data will be used to describe:

- The proportion of eligible patients for whom the multimorbidity review template is used. Describe the proportion who have the initial, the annual review template, and both
- The proportion of eligible patients who use the template, split by patient characteristics (e.g. age, sex, etc).
- The proportion of eligible patients who did not use the template and did not receive a personalised care and support plan but were (a) offered or invited for a review or (b) declined a review or a personalised care and support plan. See code list appendix for details.

4.4.3 Fidelity

Routine clinical data will be used to assess the extent to which key personalised care elements of the consultation take place. The proportion of eligible patients in whom the following codes were entered at least once in the pre- and/or post-periods will be described (for full list of codes see appendix):

Table B Code terms for fidelity indicators

Indicator	Snomed code term themes
○ Mobility	Fully mobile; Difficulty walking
○ Activities of daily life	Ability to perform activities of everyday life; disability affecting daily living
○ Mood assessed	PHQ-2 or PHQ-9 (any of the items)
○ Memory assessed	Initial memory assessment or memory

	function normal or assessment for dementia or initial memory assessment declined
○ Falls assessed	Does not fall or number of falls
○ Pain or discomfort	No pain/discomfort/pain
○ Frailty assessed	Rockwood clinical frailty scale code or any Rockwood score
○ Medication review	Medication review done; medication review done by (doctor/nurse/pharmacist); medication review declined; structured medication review
○ Medication adherence raised	Drug compliance good or drug compliance poor
○ Social prescribing offered or declined	Social prescribing offered or social prescribing declined or seen by health and well-being coach or seen by care co-ordinator
○ Referred for social prescribing	Referral to social prescribing service
○ At least one patients goal identified	Identifying goals or Review of patient goals or Goal achieved or Goal not achieved
○ Care and support plan given to patient	Provision of copy of care plan
○ Care plan agreed or reviewed	Personalised care and support plan agreed or Review of personalised care and support plan

Further, the use of these measures throughout the year (regardless of whether they are used in the same appointment as a template) will be compared in eligible patients in pre- vs. post- intervention and intervention vs. control practices to assess whether the use of the template increases these things overall.

4.4.4 Feasibility

This will not be addressed using quantitative data.

4.4.5 Acceptability

This will be measured quantitatively through the staff NoMAD questionnaires. Specifically, the average scores on Part C sections C1 to C4 on the questionnaire which represent the NPT concepts ‘coherence’, ‘cognitive participation’, ‘collective action’, reflexive monitoring’.

4.4.6 Sustainability

This will be assessed quantitatively using responses to three specific questions on the staff NoMAD questionnaire:

- Part B Q2 Do you feel the template is currently a normal part of your work? (11 point Likert scale from ‘not at all’ to ‘completely’)
- Part B Q3 Do you feel the template will become a normal part of your work? (11 point Likert scale from ‘not at all’ to ‘completely’)
- Part C QC2.4 I will continue to support the use of the template (5 point scale from ‘strongly agree’ to ‘strongly disagree’)

4.4.7 Impact on practice workload

Routine clinical data will be used to explore:

- The number of consultations (telephone/video; face-to-face; in total) in eligible patients in intervention and control practices.
- Number of consultations which include use of the template (these consultations are a sub-set of all consultations).

4.4.8 Having regular reviews for specific diseases

Proportion of eligible patients with each of the following conditions who have had a review for that condition:

- Dementia
- Diabetes
- Heart disease
- Heart failure
- Stroke
- Atrial fibrillation
- COPD
- Asthma
- Rheumatoid arthritis
- Severe mental health problems
- Learning disability

4.4.9 Other workload indicators

Table C Code terms for other workload indicators

Indicator	Info
Number of different drugs prescribed	Based on number of different drug names (generic names) prescribed irrespective of dose or formulation
Cost of drugs prescribed	Based on costs within Emis system

4.4.10 Impact on patient outcomes

This will be assessed quantitatively using responses to the patient questionnaire:

- PC3EQ total score
- Sub-scale scores for person-centred care and care co-ordination.

4.4.11 Costs

Drug costs will be assessed using the routine clinical data.

5. METHODS

5.1 Design and population

This is a mixed methods study, and the qualitative and quantitative data will be analysed separately but considered together.[23-25] Normalisation Process Theory (NPT) constructs will be used to interrogate the data and inform interpretations about implementation.[11]

5.1.1 Practice eligibility

To be eligible, both intervention and control practices will need to use the EMIS practice computer system and have a practice list size of at least 5000 patients. Further, intervention practices will be required to have a subscription to Ardens templates.

Within the area covered by BNSSG CCG, we will invite three practices to implement the full Maxwell approach, including more in-depth training from Year of Care Partnerships, funded by the CCG. These three practices will all be in areas of above average deprivation.

5.1.2 Patient eligibility

Patients are eligible for inclusion if they:

- Are registered with a practice that agrees to take part in the evaluation
- Are aged 18 or over
- Have at least three of the types of long-term health condition listed below, including at least one of those asterisked (these are conditions which are already subject to annual review in most general practices to meet the requirements of the QOF).

The following long-term conditions are included because they benefit from regular review in general practice. Some conditions (e.g. the first group listed) are grouped so that two or more diagnoses within the group just count as one for the purpose of defining multimorbidity.

- Cardiovascular disease: coronary heart disease*, hypertension*, heart failure*, peripheral arterial disease or chronic kidney disease (stage 3 to 5), Atrial fibrillation
- Stroke/TIA*
- Diabetes*
- Chronic Obstructive Pulmonary Disease* or Asthma*
- Epilepsy
- Depression OR Severe mental health problems (schizophrenia or psychotic illness)*
- Learning disability
- Rheumatoid arthritis*
- Dementia* or Frailty (severe)*: although not a single diagnosis, if a patient is on the frailty register it makes sense to do their annual review as part of this annual multimorbidity review, rather than calling the patient back again.

5.1.3 Practice sampling

We will purposively sample general practices within the 3 study areas, seeking to recruit practices so that across the study as a whole there is wide variation in practice size and urban/rural location and in the characteristics of their patient populations in terms of deprivation and ethnicity. In particular, we will seek to ensure that more than half of the recruited practices are from areas of above average deprivation. Control practices will be recruited in a similar way.

For the quantitative data, we anticipate:

- NPT NoMAD questionnaire[22] from about 80 clinical staff (About 5 per practice in 16 intervention practices)

- Patient questionnaire data from about 1440 patients from intervention practices (assuming about 200 patients per practice are invited for multimorbidity review, and 30% of these complete baseline and follow-up surveys)
- Routine clinical data from about 4800 patients from intervention practices (about 300 eligible patients per practice with multimorbidity based on the 3D study[5], across 16 practices)
- Routine clinical data from about 4800 patients from control practices (about 300 per practice across 16 practices)

The size of the sample is primarily driven by the size of the relevant patient population and the number of reviews that practices might be able to conduct, but is sufficiently large to ensure that all estimates will have narrow confidence limits.

5.2 Consent

Staff will be sent the NoMAD questionnaire with a covering letter that explains the nature of the evaluation and how their data will be used. Return of the questionnaire will indicate consent. The respondents will not be identifiable by the research team. Both the covering letter and the questionnaire may be administered electronically or on paper.
Patients sent a baseline questionnaire will be told that their responses will be shared with the research team. Although return of the questionnaire can be said to imply consent, participants will tick boxes to confirm this and to give consent to being sent a follow-up questionnaire. Patients will receive information with the questionnaires in a covering letter (paper questionnaires) or an initial screen (online questionnaires).
Consent will not be sought for routine clinical data from medical records. This will be anonymised prior to extraction, and we will not hold any data which makes it possible to link the patient questionnaires (which are identifiable) with the anonymous routine clinical data.

5.3 Flow of participants

All eligible patients will be included in the analysis of routine clinical data. A proportion of these will be invited for review, most of these will probably attend the review and the HCP in intervention practices will probably use the template where available, but the extent to which the HCP fully completes the template will be variable, and a smaller number of patients will receive a care and support plan (the primary outcome). All patients who are invited for annual review in intervention practices will also be asked to complete the patient questionnaire. See Figure 1.

5.4 Withdrawals

Withdrawals only applies to the questionnaire data. If patients withdraw consent, we will not contact them to collect any further data, but we will retain in the analysis any data they have already provided.

6. DATA COLLECTION

	Before each patient's review	Two months after each patient's review	1 January 2021 – 31 March 2022* ('before' period)	1 April 2022 – 30 June 2023* ('intervention' period	July 2023	3-6 months after the practice starts using the template
Patient demographics and long-term conditions					x	
Patient questionnaires	x	x				
Staff NoMAD questionnaires						x
Routine detailed data about process and outcome in study cohort			x	x	x	
*** (collected retrospectively)**						

6.1 Patient questionnaires

There is increasingly interest within the NHS in using patient-reported outcome measures in the context of routine care, to inform clinicians about the needs of individual patients and as a quality improvement method, rather than as research tools. We will seek to implement this principle by asking patients to complete a brief patient questionnaire before and two months after their annual review consultation. We view this as part of the intervention rather than as a research tool. We will ask patients to complete the Person-Centred Coordinated Care Experience Questionnaire (P3CEQ).[20] Practice administrative staff will send patients the initial questionnaire when they send their appointment for their multimorbidity. Patients will be asked to return their questionnaire to the research team for analysis. The questionnaire will invite patients to give their consent to the research team sending them a follow-up questionnaire two months after the consultation.

6.2 Routinely collected data

First, summary data will be extracted from the computerised record system within each participating general practice. Full anonymous aggregate data will be provided about the total number of patients in the practice by age-sex group. In combination with the more detailed data (including age and sex) available for the multimorbidity cohort (see below), this makes it possible to describe the proportion of patients in each age-sex group that has multimorbidity.

Secondly, we will collect pseudonymised patient-level data for our eligible cohort. This will include which chronic diseases they have, their age-group, month of birth, sex, ethnicity and deprivation (Index of Multiple Deprivation decile).

Pseudonymised patient-level data will also be extracted about the process and outcomes of care for this cohort of eligible patients, before and after implementation of the template. This will comprise all their consultation data including details of whether patients were invited for a long-term conditions review, whether they attended, the level of completion of different aspects of the review, whether the template was used, number of drugs prescribed, number of primary care consultations.

In order to compare the level of completion of different aspects of the review between intervention and control practices, we will create code lists for each of the key concepts to be explored, which are targeted within the template. This is because control practices might have undertaken the same tasks but not used the specific codes mandated by the template, or intervention practices might have done the tasks but not used the template.

6.3 Routine data extraction

Patient level data will be extracted in pseudonymised form from the computer system and only identified by a pseudonymised ID from which the research staff cannot identify individual patients. This pseudonymised ID is a long alphanumeric code generated automatically by the EMIS software, and not the same as the patient's EMIS number which is the standard identifier used within EMIS practices. We will ensure that no features are included which raise a risk of identification e.g. we will use age-group and month of birth rather than date of birth, deprivation decile rather than post code, and will only include details of common long-term conditions so that patients cannot be identified through having a particular rare condition.

Data will be extracted for the period from 1 January 2021 to 31 June 2023 in both intervention and control practices. This period is to ensure an understanding of consultation patterns before (1 January 2021 to 31 March 2022) and after (1 April 2022 to 31 June 2023) the implementation of the PP4M intervention, in both intervention and control practices. All data will be extracted retrospectively in July 2023. This will therefore include all patients who are eligible, registered and alive on the date of extraction. In addition, we will extract a list of anonymised IDs of the patients who were eligible on 1 January 2021 and another list for 1 April 2022; we will use these lists to exclude any patients who appear in the main extracts, but who were not eligible in January 2021 and/or April 2022. Therefore, our included cohort of patients will be those who were eligible in January 2021 and April 2022, and still eligible, registered and alive in July 2023.

Note. Data will be correct as of extraction date. So, if someone developed diabetes during the evaluation period, they will be assumed to have had diabetes for the whole study period. This hopefully won't be an issue for most patients (as they are likely to have had their conditions for a long time which is why they are included in the cohort) but is a potential limitation of the data extraction.

6.4 Staff questionnaires

All members of staff who are involved in using the template in the 16 intervention practices will be asked to complete a NoMAD questionnaire, which explores the extent of coherence, cognitive participation, collective action and reflexive monitoring (the key constructs from the NPT framework). These questionnaires will be sent after staff have had at least 3 months experience of using the new multimorbidity template. Practice managers will distribute these questionnaires which will be returned to the research team

in pseudonymised form, using staff code numbers not identifiable by the research team. We will offer completion of the questionnaire either online or on paper. The research team will inform the practice manager about the ID numbers of people who have responded, and the practice manager will send up to two reminders to non-participants.

7. DATA SOURCES

Variable(s)	Data sources	Further information
NoMAD questionnaire, attached for details	NoMAD questionnaire – paper and online version for staff delivering the intervention. Data entered into REDCap database and extracted for analysis.	Explores the key constructs of NPT framework. Collected at different stages of the intervention period.
P3CEQ, attached for details	Person-Centred Coordinated Care Experience Questionnaire (P3CEQ) - paper questionnaire completed by participant patients before and after intervention. Data entered into REDCap database and extracted for analysis.	PC3EQ total score and sub-scale scores for person-centred care and care co-ordination.
Routinely collected data	Routinely collected data from Electronic Medical Records in practices using the EMIS system. Extracted as a series of tables in CSV or XLS format. Each indexed by a patient pseudonymised ID known only to the practice (not the EMIS number).	Tables for: • Patient demographics and conditions • Relevant snomed codes for variables in Tables A,B,C apart from drugs • Lists of drugs prescribed with costs • Consultations, including date, type of consultation, type of professional.

8. DERIVATIONS

The below table describes rules for key derivations.

New variables	Derivation rules
Age	Age on 1 Jan 2021 (assume all Jan birthdays are after the 1st of the month).
NoMAD	Each individual question in Part C is scored from 4 for strongly agree to 0 for strongly disagree, with don't know coded as missing. The 4 sections C1 to C4 represent the NPT concepts 'coherence', 'cognitive participation', 'collective action', reflexive monitoring'. For each section, the average score will be calculated from the questions completed, as long as at least half the questions in the section are completed. If less than half the questions are completed, the score for that section is missing. NB. These are rules Chris proposed as there is not standard scoring system. First, Question 7 score is calculated by averaging the individuals score from 7a, 7b, 7c, and 7d. Total score= the sum of questions 1-10. Resultant scores are between 0-30, higher scores represent better experience of care.
PC3EQ	Person-centred subscale=sum of questions 1,2,3,4,5,8,9,10 Care coordination subscale= sum of questions 5,6,7,8,9 See https://uob.sharepoint.com/:b:/t/grp-PP4M/ERa9zhGri91OpYOHkuSTlhwBEKtmskzTLxjOveKUsD6Ovw?e=3cXNXo for details of scoring. (Double check that the question numbers and response numbers are the same on our version first).

9. STATISTICAL ANALYSES

9.1 Analysis populations

We will consider two different analysis populations for analysis.

The first population will include all eligible patients, regardless of whether they used the template. The analyses using this population will be similar to, but not the same as, an intention to treat analysis, in that it is explicitly the case that intervention practices can choose which group of patients they focus on in the first year of using the new template, and control practices may have chosen to use the template.

The second population will include a subset of patients from within the eligible cohort who (a) were from intervention practices and actually used the template post intervention (either in an initial review, a full review, or both) compared to (b) matched controls who were registered at control practices where the template was never used; this is similar to a per protocol analysis. Matching will be done 1:1 without replacement (i.e. a control patient may only be match to one intervention patient). The control patients will be matched using hierarchical matching criteria first on age group (5 year age bands), then deprivation decile (+/- 2 deciles), then number of conditions (3, 4, or 5+), and finally sex. For those who cannot be matched on all four criteria, we will try to match them to the first three, then the first two, and then the first one only.

For all analyses, we will include patients who were eligible in January 2021, still eligible in June 2023, and who were patients at the participating practices for the whole study period (Jan 2021 – Jun 2023). The number of patients who were eligible for part of the study period will be briefly described but they will not be included in any of the analyses.

9.2 Descriptive data

Continuous variables will be summarised using means and standard deviations (SD), or medians and interquartile ranges (IQR) if the distribution is highly skewed. Categorical data will be summarised as numbers and percentages. The summary statistic headings given in the skeleton tables are those expected to be used based on a priori knowledge of the measurements gained from previous studies. However, if distributional assumptions are not satisfied, changes will be made.

9.3 Practice and patient characteristics

Using the routine clinical data, practice characteristics, including list size and number of GPs, nurses, etc, will be presented in Table 1. Age and sex of all patients at included practices, and whether or not they met the definition for multimorbidity will be presented in Table 2. Patient characteristics, including age, sex, deprivation, etc, will be presented in Table 3. The intervention group will be presented by whether or not they are one of the three Maxwell practices, as well as overall. No formal statistical comparisons will be made.

9.4 Descriptive analyses

Routine clinical data will be used to assess the adoption, reach and fidelity of the template (in the year 2022/23). This will include exploring the proportion of eligible patients who attended a review and the extent to which key elements of the template were completed. We will also explore whether this differed by particular patient groups (e.g. by age, sex, etc). The intervention group will be presented by whether or not they are one of the three Maxwell practices, as well as overall. See Tables 4, 5, 6 and 7. Note. formal comparative analysis will also be performed for the fidelity measures; this analysis is described below in section 10.6.

The NoMAD staff questionnaires will be used to assess acceptability and sustainability of the template in intervention practices (Table 8 and 9). The questionnaire will explore coherence, cognitive participation, collective action, and reflexive monitoring, as well as understanding whether staff believe the template will become part of their normal working and whether they support this. This will be explored by different staff groups, such as GPs, nurses, etc, as well as by different experience in use of the template (from never used to used >15 times). Data will be described but no formal comparisons will be made.

9.5 Comparison groups

For the primary outcome, fidelity and practice workload outcomes, the measure of interest will be the additional effect of the intervention in the post-intervention period, over and above any effect of period (April 2022-June 2023 vs. January 2021-March 2022) and/or intervention group (intervention vs. control) alone.

For the patient questionnaire outcomes, the comparison of interest will be the post-review questionnaire vs. the pre-review questionnaire (for the year April 2022-June 2023, i.e. the review where the template has in theory been used).

For the adoption and reach outcomes, the comparison of interest is the effect of the patient characteristics on adoption and reach in the post-period in the intervention group only.

9.6 Comparative analyses

The first set of comparative analyses will look at whether the primary outcome of receipt of a personalised care and support plan differs between pre- and post- intervention periods, adjusting for control practices. Logistic regression will be used to assess whether or not a patient received a plan in each time period, in a difference-in-difference analysis framework. Intervention (a binary variable indicating intervention or control practices), period (Jan 2021-Mar 2022 vs. Apr 2022-Jun 2023), and the interaction between the two will be fitted as fixed effects; the model will also be adjusted for age, sex, IMD and ethnicity as fixed effects. Patient ID nested within practice will be fitted as random effects, if possible, or else patient or practice will be fitted as a random effect alone. An odds ratio for the interaction term (i.e. the additional effect of the intervention in the post-intervention period, over and above any effect of period and/or intervention group alone) and corresponding 95% confidence intervals (CIs) and p-values will be presented. See Table 10. Whether or not a patient has been assessed for any of the fidelity type measures (e.g. memory or mood; Table 7), and whether or not a patient received a review for a specific disease (Table 11), are also binary variables and will also be assessed using logistic regression and difference-in-difference models, as above.

The second set of comparative analyses will look at the impact on practice workload, including frequency and type of consultation, as well as the staff group who performed the consultation (Table 12), and drugs prescriptions and costs (Table 13). These outcomes are counts, so negative binomial regression will be used to assess the number of instances of the outcomes in each of the practices in each of the time periods. The models will be fitted with mean age, mean IMD decile, percentage female and percentage white ethnicity as fixed effects and practice as a random effect, and the offset will be the number of patients in each practice. Again, the effect of interest will be the interaction term. Subgroup analyses (e.g. exploring telephone consultations only) may be analysed by adding additional interactions into the model. Whether it is worthwhile (or even possible) conducting sub-group analyses will depend on the number of patients who have used the template.

The third set of comparative analyses will look at changes in responses on patient questionnaires (given only to the intervention group; Table 14). Responses given approximately two months after their 2022/23 review will be compared to responses given shortly before the review. Outcomes are continuous so mixed effects linear regression will be used to compare the means at the two timepoints. A pre/post indicator will be fitted as a fixed effect and, if computationally possible, patient will be fitted as a random effect (else practice will be fitted as a random effect instead). Models will be adjusted for age and sex (if available). Mean differences and corresponding CIs and p-values will be presented.

The final set of analyses will look at the effects of patient characteristics on whether or not a template (either initial or main) has been used; these analyses will be restricted to the post-intervention period in intervention sites. The main model will fit practice as a random effect, and adjusted for age, sex, ethnicity and IMD as fixed effects. Additional models will add each of the long term conditions of interest in turn, to assess differences in template use by condition. Odds ratios and corresponding 95% CIs and p-values will be presented for each of the patient characteristics of interest.

For all methods outlined, underlying assumptions in statistical models will be checked using standard methods, e.g. residual plots, etc. If assumptions are not valid, alternative methods of analysis will be sought. If outlying observations are found which mean models do not fit the data adequately, such observations will be excluded from the main analyses and comments made in footnotes.

9.7 Sub-group analyses

Three practices in the Bristol area will receive extra support and training from Year of Care partnerships (‘Maxwell practices). We will compare the main findings in these three practices with all intervention practices in the study. Given the small sample size, this comparison will be exploratory and descriptive.

9.8 Statistical software

All data management and analyses will be performed in Stata version 17.0.

10. REFERENCES

Provide references for any citations in the main body of the SAP.

APPENDIX: SKELETON TABLES AND FIGURES

Tables	
Table 1	Description of participating practices
Table 2	Description of all patients at included practices and the number and percentage who had multimorbidity
Table 3	Baseline description of patient cohort
Table 4	Adoption & Reach- Initial review template used (April 2022-June 2023)
Table 5	Adoption & Reach- Main template used (April 2022-June 2023)
Table 6	Adoption & Reach- Initial and/or main template used (April 2022-June 2023)
Table 7	Fidelity
Table 8	Acceptability/ Sustainability – by staff group
Table 9	Acceptability/ Sustainability – by experience using the template
Table 10	Primary outcome - Receipt of a Personalised Care and Support Plan
Table 11	Regular reviews for specific diseases
Table 12	Impact on practice workload
Table 13	Drugs and Costs
Table 14	Impact on patient outcomes
Figures	
Figure 1	Flowchart for patients at intervention practices
Figure 2	
Figure 3	

Table 1 Description of participating practices

	Intervention practices							
	Excluding Maxwell (n=xx)		Maxwell practices only (n=xx)		All intervention practices (n=xx)		Control practices (n=xx)	
	n	%	n	%	n	%	n	%
Characteristics								
List size (mean, SD)								
CCG (expand categories)								
Number of HCAs per practice (mean, SD)								
Number of practice nurses or Nurse practitioners per practice (mean, SD)								
Number of fully qualified GPs per practice (mean, SD)								
Percentage of patients who meet eligibility criteria (mean, SD)								

Table 2 Description of all adult patients at included practices and the number and percentage who had multimorbidity

	Intervention practices									Control practices (n=xx)		
	Excluding Maxwell (n=xx)			Maxwell practices only (n=xx)			All intervention practices (n=xx)					
	N	n	%	N	n	%	N	n	%	N	n	%
All patients at included practices												
By age groups												
18-49												
50-59												
etc												
By sex												
Male												
Female												

Note. This table includes all patients meeting the definition and currently registered at the point of data extraction (around July 2023). Numbers will therefore not match up to the eligible patients included in the rest of the analyses.

Table 3 Description of eligible patient cohort

	Intervention practices							
	Excluding Maxwell (n=xx)		Maxwell practices only (n=xx)		All intervention practices (n=xx)		Control practices (n=xx)	
	n	%	n	%	n	%	n	%
Demography								
Number of conditions Long term conditions (expand categories) Age groups (expand categories) Male gender Deprivation decile (expand categories) Ethnicity categories (expand categories)								

Table 4 Adoption & Reach- Initial review template used (April 2022-June 2023)

	Intervention practices							
	Excluding Maxwell (n=xx)		Maxwell practices only (n=xx)		All intervention practices (n=xx)		Control practices (n=xx)	
	n	%	n	%	n	%	n	%
Eligible patients who used initial review template:								
By long term conditions								
Coronary heart disease								
Hypertension								
Etc								
By age groups								
18-49								
50-59								
etc								
By sex								
Male								
Female								
By deprivation decile								
1								
2								
Etc								
By ethnicity categories								
White								
Etc								

Table 5 Adoption & Reach- Main review template used (April 2022-June 2023)

	Intervention practices							
	Excluding Maxwell (n=xx)		Maxwell practices only (n=xx)		All intervention practices (n=xx)		Control practices (n=xx)	
	n	%	n	%	n	%	n	%
Eligible patients who used main review template:								
By long term conditions								
Coronary heart disease								
Hypertension								
Etc								
By age groups								
18-49								
50-59								
etc								
By sex								
Male								
Female								
By deprivation decile								
1								
2								
Etc								
By ethnicity categories								
White								
Etc								

Table 6 Adoption & Reach – Initial and/or main review template used (April 2022-June 2023)

	Intervention practices									
	Excluding Maxwell (n=xx)		Maxwell practices only (n=xx)		All intervention practices (n=xx)		Control practices (n=xx)		Predictors of template use in intervention practices	
	n	%	n	%	n	%	n	%	Odds ratio* (95% CI)	p-value
Eligible patients who used initial or main review template:										
By long term conditions										
Coronary heart disease										
Hypertension										
Etc										
By age groups										
18-49										
50-59										
etc										
By sex										
Male										
Female										
By deprivation decile										
1										
2										
Etc										
By ethnicity categories										
White										
Etc										

Table 7 Fidelity

	Intervention practices						Control practices		Comparison	
	Maxwell practices only Pre-period (n=xx)		Maxwell practices only Post-period (n=xx)		All intervention practices Pre-period (n=xx)		All intervention practices Post-period (n=xx)		Control practices Pre-period (n=xx)		Control practices Post-period (n=xx)		Odds ratio* (95% CI)	p-value
	n	%	n	%	n	%	n	%	n	%	n	%		
All eligible patients (intention to treat analyses):														
Mobility assessed														
Activities of daily life assessed														
Mood assessed														
Memory assessed														
Falls assessed														
Frailty assessed														
Pain assessed														
Medication adherence raised														
Medication reviewed														
Referred for social prescribing														
At least one patient goal identified														
Sent patient preparation document														
Care plan agreed or reviewed														

	Intervention practices				Control practices		Comparison	
	Maxwell practices only Pre-period (n=xx)	Maxwell practices only Post-period (n=xx)	All intervention practices Pre-period (n=xx)	All intervention practices Post-period (n=xx)	Control practices Pre-period (n=xx)	Control practices Post-period (n=xx)	Odds ratio* (95% CI)	p-value
	n %	n %	n %	n %	n %	n %		
Care and support plan given to patient								
Annual review completed								
Per protocol analyses								
Mobility assessed								
Activities of daily life assessed								
Mood assessed								
Memory assessed								
Falls assessed								
Medication adherence raised								
Medication reviewed								
Referred for social prescribing								
At least one patient goal identified								
Sent patient preparation document								
Care plan agreed or reviewed								
Care and support plan given to patient								
Annual review completed								

*The presented odds ratios will be the interaction term between time period and intervention/control group from the difference in difference model. I.e. the additional effect of the intervention in the post-intervention period, having adjusted for the effect of time period and intervention/control group. Maxwell practice data are presented here for descriptive comparison- no formal comparisons will be made.

Table 8 Acceptability/ Sustainability – by staff group

	HCAs		Nurses		GPs		Admin staff		Other*		All	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
NoMAD questionnaire												
When you use the template, how familiar does it feel (0=New, 10=Familiar)?												
Do you feel the template is currently a normal part of your work (0=Not at all, 10=Completely)?												
Do you feel the template will become a normal part of your work (0=Not at all, 10=Completely)?												
Coherence (1=Strongly agree, 5=Strongly disagree)												
I can see how the template differs from usual ways of working												
Staff in this organisation have a shared understanding of the purpose of the template												
I understand how the template affects the nature of my own work												
I can see the potential value of the template for my work												
Cognitive participation (1=Strongly agree, 5=Strongly disagree)												
There are key people who drive the use of the template forward and get others involved												
I believe that participating in the use of the template is a legitimate part of my role												
I'm open to working with colleagues in the new ways to												

	HCAs		Nurses		GPs		Admin staff		Other*		All	
	Mean	**SD**	**Mean**	**SD**	**Mean**	**SD**	**Mean**	**SD**	**Mean**	**SD**	**Mean**	**SD**
use the template												
I will continue to support the use of the template												
Collective action (1=Strongly agree, 5=Strongly disagree)												
I can easily integrate the template into my existing work												
The template disrupts working relationships												
I have confidence in other people's ability to use the template												
Work is assigned to those with skills appropriate to the template												
Sufficient training is provided to enable staff to implement the template												
Sufficient resources are available to support the use of the template												
Management adequately supports the use of the template												
Reflexive monitoring (1=Strongly agree, 5=Strongly disagree)												
I am aware of feedback about the effects of the template												
The staff agree that the template is worthwhile												
I value the effects that the template has had on my work												
Feedback about the template can be used to improve it in the future												
I can modify how I work with the template												

* Describe professions of others

Table 9 Acceptability/ Sustainability – by experience using template

	Not at all		1-4 times		5-9 times		10-15 times		>15 times		all	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
NoMAD questionnaire												
When you use the template, how familiar does it feel (0=New, 10=Familiar)? Do you feel the template is currently a normal part of your work (0=Not at all, 10=Completely)? Do you feel the template will become a normal part of your work (0=Not at all, 10=Completely)?												
Coherence (1=Strongly agree, 5=Strongly disagree)												
I can see how the template differs from usual ways of working Staff in this organisation have a shared understanding of the purpose of the template I understand how the template affects the nature of my own work I can see the potential value of the template for my work												
Cognitive participation (1=Strongly agree, 5=Strongly disagree)												
There are key people who drive the use of the template forward and get others involved I believe that participating in the use of the template is a legitimate part of my role I'm open to working with colleagues in the new ways to use the template I will continue to support the use of the template												

	Not at all		1-4 times		5-9 times		10-15 times		>15 times		all	
	Mean	**SD**	**Mean**	**SD**	**Mean**	**SD**	**Mean**	**SD**	**Mean**	**SD**	**Mean**	**SD**
Collective action (1=Strongly agree, 5=Strongly disagree)												
I can easily integrate the template into my existing work												
The template disrupts working relationships												
I have confidence in other people's ability to use the template												
Work is assigned to those with skills appropriate to the template												
Sufficient training is provided to enable staff to implement the template												
Sufficient resources are available to support the use of the template												
Management adequately supports the use of the template												
Reflexive monitoring (1=Strongly agree, 5=Strongly disagree)												
I am aware of feedback about the effects of the template												
The staff agree that the template is worthwhile												
I value the effects that the template has had on my work												
Feedback about the template can be used to improve it in the future												
I can modify how I work with the template												

* Describe professions of others

Table 10 Primary outcome – Receipt of a Personalised Care and Support Plan

	Intervention practices				Control practices		Comparison	
Receipt of a Personalised Care and Support Plan	Maxwell practices only Pre-period (n=xx)	Maxwell practices only Post-period (n=xx)	All intervention practices Pre-period (n=xx)	All intervention practices Post-period (n=xx)	Control practices Pre-period (n=xx)	Control practices Post-period (n=xx)	Odds ratio* (95% CI)	p-value
	n %	n %	n %	n %	n %	n %		
All eligible patients (intention to treat analyses):								
By long term condition*								
Coronary heart disease								
Hypertension								
Etc								
By age-group								
18-49								
50-59								
etc								
By sex								
Male								
Female								
By deprivation decile								
1								
2								
Etc								
By ethnicity								
White								

	Intervention practices				Control practices		Comparison	
Receipt of a Personalised Care and Support Plan	Maxwell practices only Pre-period (n=xx) n %	Maxwell practices only Post-period (n=xx) n %	All intervention practices Pre-period (n=xx) n %	All intervention practices Post-period (n=xx) n %	Control practices Pre-period (n=xx) n %	Control practices Post-period (n=xx) n %	Odds ratio* (95% CI)	p-value
etc								
Per protocol analyses								
By long term condition**								
Coronary heart disease								
Hypertension								
Etc								
By age-group								
18-49								
50-59								
etc								
By sex								
Male								
Female								
By deprivation decile								
1								
2								
Etc								
By ethnicity								
White								
etc								

* The presented odds ratios will be the interaction term between time period and intervention/control group from the difference in difference model. I.e. the additional effect of the intervention in the post-intervention period, having adjusted for the effect of time period and intervention/control group. Maxwell practice data are presented here for descriptive comparison- no formal comparisons will be made. ** NB Since all eligible patients have 3+ LTCs, these categories are not mutually exclusive. Greyed out cells will be left blank. I.e. odds ratios will not be calculated for subgroups.

Table 11 Reviews for specific diseases

	Intervention practices				Control practices		Comparison	
	Maxwell practices only Pre-period (n=xx)	Maxwell practices only Post-period (n=xx)	All intervention practices Pre-period (n=xx)	All intervention practices Post-period (n=xx)	Control practices Pre-period (n=xx)	Control practices Post-period (n=xx)	Odds ratio* (95% CI)	p-value
	n %	n %	n %	n %	n %	n %		
All eligible patients (intention to treat analyses):								
Dementia								
Diabetes								
Heart disease + CVD								
Heart failure								
Stroke								
Atrial fibrillation								
COPD								
Asthma								
Severe mental health problems								
Rheumatoid arthritis								
Learning disability								

	Intervention practices				Control practices		Comparison	
	Maxwell practices only Pre-period (n=xx)	Maxwell practices only Post-period (n=xx)	All intervention practices Pre-period (n=xx)	All intervention practices Post-period (n=xx)	Control practices Pre-period (n=xx)	Control practices Post-period (n=xx)	Odds ratio* (95% CI)	p-value
	n %	n %	n %	n %	n %	n %		
Per protocol analyses								
Dementia								
Diabetes								
Heart disease								
Heart failure								
Stroke								
Atrial fibrillation								
COPD								
Asthma								
Severe mental health problems								
Rheumatoid arthritis								
Learning disability								

N.B. denominators are patients who have a diagnosis for the specific disease. For some diseases, numbers may be too small to calculate odds ratios. * The presented odds ratios will be the interaction term between time period and intervention/control group from the difference in difference model. I.e. the additional effect of the intervention in the post-intervention period, having adjusted for the effect of time period and intervention/control group. Maxwell practice data are presented here for descriptive comparison- no formal comparisons will be made.

Table 12 Impact on practice workload

	Intervention practices				Control practices		Comparison	
	Maxwell practices only Pre-period (n=xx)	Maxwell practices only Post-period (n=xx)	All intervention practices Pre-period (n=xx)	All intervention practices Post-period (n=xx)	Control practices Pre-period (n=xx)	Control practices Post-period (n=xx)	Incident rate ratio* (95% CI)	p-value
	Median IQR	Median IQR	Median IQR	Median IQR	Median IQR	Median IQR		
All eligible patients (intention to treat analyses):								
Number of consultations								
By consultation type								
Telephone/video/e-consult								
Face-to-face/home								
By practitioner								
GP								
Nurse/paramedic								
HCA								
Pharmacist/pharmacy technician								
Other								
Per protocol analyses								
Number of consultations								
By consultation type								
Telephone/video/e-consult								
Face-to-face/home								

	Intervention practices				Control practices		Comparison	
	Maxwell practices only Pre-period (n=xx)	Maxwell practices only Post-period (n=xx)	All intervention practices Pre-period (n=xx)	All intervention practices Post-period (n=xx)	Control practices Pre-period (n=xx)	Control practices Post-period (n=xx)	Incident rate ratio* (95% CI)	p-value
	Median IQR	Median IQR	Median IQR	Median IQR	Median IQR	Median IQR		
By practitioner GP Nurse/paramedic HCA Pharmacist/pharmacy technician Other								

* The presented incident rate ratios will be the interaction term between time period and intervention/control group from the difference in difference model. I.e. the additional effect of the intervention in the post-intervention period, having adjusted for the effect of time period and intervention/control group. Maxwell practice data are presented here for descriptive comparison- no formal comparisons will be made.

Table 13 Drugs and costs

	Intervention practices								Control practices				Comparison	
	Maxwell practices only Pre-period (n=xx)		Maxwell practices only Post-period (n=xx)		All intervention practices Pre-period (n=xx)		All intervention practices Post-period (n=xx)		Control practices Pre-period (n=xx)		Control practices Post-period (n=xx)		Incident rate ratio* (95% CI)	p-value
	Median	IQR												
All eligible patients (intention to treat analyses):														
Number of drugs prescribed														
Cost of drugs prescribed														
Per protocol analyses														
Number of drugs prescribed														
Cost of drugs prescribed														

* The presented incident rate ratios will be the interaction term between time period and intervention/control group from the difference in difference model. I.e. the additional effect of the intervention in the post-intervention period, having adjusted for the effect of time period and intervention/control group. Maxwell practice data are presented here for descriptive comparison- no formal comparisons will be made.

Table 14 Impact on patient outcomes (intervention practices only)

	Baseline (before 2022/2023 review) (n=xx)		Follow-up (after 2022/2023 review) (n=xx)		Mean difference (95% CI)	p-value
	mean	SD	mean	SD		
Eligible patients:						
PC3EQ total score Person-centred subscale Care coordination subscale						
Sub-group Maxwell practices only:						
PC3EQ total score Person-centred subscale Care coordination subscale						

Figure 1: Flowchart of patients at intervention practices