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PROTOCOL

This protocol has regard for the HRA guidance and order of content

Title page

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Quantifying, Understanding and Enhancing Relational Continuity of Care

Short title/acronym:
QUERCC

Research Protocol Reference numbers and date:

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ETHICAL APPROVAL HAS BEEN OBTAINED FOR WP1, WP2 AND WP3. SUB PROTOCOLS ARE IN APPENDIX 4. THE LINK TO CPRD APPROVALS IS SUPPLIED IN TABLE ABOVE

APPROVALS FOR WP5 IS SCHEDCULED TO COMMENNCE IN NOVEMBER 2025 AHEAD OF FIELDWORK DUE TO COMMENCE IN 2026.

Signature page

The undersigned confirm that the following protocol has been agreed and accepted and that the CI agrees to adhere to the signed University of Birmingham's sponsorship CI declaration.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the project will be given; and that any discrepancies from the project as planned in this protocol will be explained.

Full project title:	**Q**uantifying, **U**nderstanding and **E**nhancing **R**elational **C**ontinuity of **C**are
Protocol version number:	1.0
Protocol version date:	3.7.2025

Chief Investigator (CI)	
Name:	Professor Tom Marshall Institute of Applied Health Research College of Medical and Dental Sciences University of Birmingham Edgbaston Birmingham, B15 2TT
Date:	**3.7.2025**
Signature:	

Sponsor statement

Where the University of Birmingham takes on the sponsor role for protocol development oversight, the signing of the IRAS form by the sponsor will serve as confirmation of approval of this protocol.

TABLE OF CONTENTS

Key contacts

Chief Investigator	Professor Tom Marshall Primary Care Clinical Sciences Institute of Applied Health Research College of Medical and Dental Sciences University of Birmingham Edgbaston Birmingham, B15 2TT
Study Co-ordinator	Dr Fiona Scheibl Research Fellow Institute of Applied Health Research College of Medical & Dental Sciences University of Birmingham Edgbaston Birmingham B15 2TT
Sponsor	Research Governance University of Birmingham Edgbaston Birmingham B15 2TT Research Strategy and Services Central researchgovernance@contacts.bham.ac.uk
Joint-sponsor(s)/co-sponsor(s)	n/a
Funder(s)	The Authority's Representative for contract management purpose: Dr Kay Pattison Science Research and Evidence Directorate Department of Health and Social Care Quarry House Quarry Hill Leeds LS2 7UE The Authority's Representative for project management purposes: NETSCC Operations Finance Alpha House Enterprise Road Southampton Science Park Southampton SO16 7NS
Key Protocol Contributors	Professor Tom Marshall

Primary Care Clinical Sciences
Institute of Applied Health Research
College of Medical and Dental Sciences
University of Birmingham Edgbaston B15 2TT
Telephone +44 (0)121 414 7832
Email: t.p.marshall@bham.ac.uk

Professor Shelia Greenfield
Institute of Applied Health Research
College of Medical and Dental Sciences
Murray Learning Centre
University of Birmingham Edgbaston B15 2TT
Telephone: +44 0121 414 6493
Email: s.m.greenfield@bham.ac.uk

Professor Iestyn Williams
Director of Research School of Social Policy
Health Services Management Centre, Park House
University of Birmingham
Edgbaston B15 2RT
Tel:+44 121 414 7063
Email: i.p.williams@bham.ac.uk

Professor Krishnarajah Nirantharakumar
Health Data Science and Public Health
Institute of Applied Health Research
University of Birmingham
Edgbaston B15 2TT
tel:+44 121 414 8344
k.nirantharan@bham.ac.uk

Dr Brian Willis
Senior Clinical Lecturer in General Practice & MRC Fellow
Institute of Applied Health Research
University of Birmingham
Edgbaston B15 2TT
b.h.willis@bham.ac.uk
tel:+44 121 414 7949

Dr Panagiotis Kasteridis
Research Fellow Health Economics
Centre for Health Economics
University of York
Panos.kasteridis@york.ac.uk
(01904) 321429

Mr Kamil Sterniczuk
Lay co-applicant Lay advisor.
Chair patient advisory group,
Institute of Applied Health Research
University of Birmingham
Edgbaston B15 2TT
kamil.sterniczuk@gmail.com

Project summary

Relational continuity of care (RCC) is the extent to which patients see the same clinicians over time. Considered a core feature of general practice, it is linked to patient satisfaction and better health outcomes, especially for older patients, those with long-term conditions and the vulnerable. Although current NHS policy is to maintain continuity for patients with long-term conditions, it has been declining for at least a decade. Contributing factors are thought to include growth in practice size, more part-time working, greater staff and patient turnover. It may also be because practice policies have focused on access, rather than continuity.

Because they often neither measure nor monitor it, general practices may be unaware how their within-practice policies impact RCC. Furthermore, conceptions of RCC differ between clinicians and between patients, and there are different ways of measuring RCC which reflect these different conceptions. A shared understanding of continuity will help practices decide on the purpose of measurement, what they want to measure and which RCC index best meets their aims. We do not know the extent to which practice-level characteristics - practice size, part-time working, staff turnover and patient turnover - affect RCC. We therefore do not know the extent to which within-practice policies to maintain RCC can mitigate the effects of practice-level characteristics. The health of older patients and those with chronic diseases may benefit most from continuity. The optimum balance between access and continuity may therefore vary across different patient groups. For a realistic strategy to improve RCC it would help to know if there are groups in which there is a stronger case for RCC and in which it should therefore be prioritised. There are potentially many ways to optimise continuity. As no two general practices are the same, the most successful approach is likely to depend on the practice context. This project uses a variety of methodologies to address these questions, with the overall aim of helping practices optimise continuity of care.

First, we develop an understanding of RCC to help practices determine how best to measure and monitor their own RCC. This will be achieved by hosting consensus workshops of patients, primary care clinicians and researchers.

Second, in a large number of general practices, we will model the association between RCC and practice-level characteristics including staff turnover, part-time working, practice size and if linkage is possible, practice funding per patient. From this we will understand the drivers of RCC and identify practices showing higher-than-predicted RCC (positive deviants) for investigation as case studies.

Third, we will undertake detailed case studies in a sample of general practices, focusing on positive deviants. We will explore staff and patient experience of continuity (including possible trade-offs between access and continuity) and investigate the interplay between measured RCC and informational or management continuity. We will identify practice policies contributing to RCC, along

with barriers and facilitators to their implementation. Qualitative findings will be triangulated with the practice's measured continuity and subjectively reported continuity in the General Practice Patient Survey (GPPS).

Fourth, we will undertake economic analysis to estimate the projected effects of RCC on resource costs and health outcomes, using linked primary and secondary care data. This will help us understand the likely effects of changing RCC in a general practice and whether these effects vary in different patient groups (by age, sex, deprivation status and chronic disease status).

Fifth, we will develop empirically-informed practical guidance to improve continuity of care, collating findings of our quantitative analysis of predictors of RCC, case studies, economic analysis, and existing work on continuity of care in the UK and internationally.

We have already established links to report our findings to, and develop training materials for, the Royal College of General Practitioners (RCGP). Patient and public involvement (PPI) is embedded in the project. Our PPI co-applicant will chair a lay advisory group whom we will consult quarterly and will be trained in and contribute to analysis of qualitative data.

Funding and support in kind

Funder(s)	Financial and non-financial support given
NIHR Health Services and Delivery Researcher Led (standard) HS & DR Project NIHR152277	**£1,000,102.71**

Role of sponsor and funder

1. In consideration of the rights and obligations recorded in the Contract_for_Project_NIHR152277.pdf dated 13th October 2022

a. The Contractor will undertake a research project entitled Quantifying, Understanding and Enhancing Relational Continuity of Care (QUERCC) in accordance with the work specified in SECTION 3, being project application NIHR152277, dated 10 October 2022, the "Research".
b. In the event of a Public Health Emergency (as defined below), the Authority may direct the Contractor to perform further work in addition to (or in replacement of) the Research in accordance with SECTION 2, Clause 3.5.

2. The Authority will pay the Contractor the Approved Cost as set out in SECTION 4 in respect of undertaking the Research in accordance with this Contract.
3. This Form of Contract (SECTION 1) together with the attached SECTION 2 to SECTION 7 inclusive are the documents which collectively form the "Contract" (as defined in SECTION 2).
4. Where the Contractor is a health service body within the meaning of Section 9 of the National Health Service Act 2006 then this Contract is an NHS Contract within the meaning of that Act.
5. The Contract effected by the signing of this Form of Contract constitutes the entire agreement between the Parties relating to the subject matter of the Contract and supersedes all prior negotiations, representations or understandings.

Roles & responsibilities of management committees/groups & individuals

The QUERCC study management group

Oversight and review of the day-to-day management and coordination of the project will be undertaken at monthly meetings of the Study Management Group. This group draws together expertise from the University of Birmingham and independent expertise from the University of York. The core members are:

Members of QUERCC Study Management group

Tom Marshall	t.p.marshall@bham.ac.uk	IAHR
Sheila Greenfield	s.m.greenfield@bham.ac.uk	IAHR
Fiona Scheibl	f.scheibl@bham.ac.uk	IAHR
Iestyn Williams	I.P.Williams@bham.ac.uk	HSMC
Panos Kasteridis	panos.kasteridis@york.ac.uk	University of York
Zecharias Anteneh	zecharias.anteneh@york.ac.uk	University of York
Brian Willis	B.H.Willis@bham.ac.uk	IAHR
Krishnarajah Nirantharakumar	K.Nirantharan@bham.ac.uk	IAHR

The role and responsibility of this group is to ensure project milestones are met, research problems are resolved and forward planning to achieve agreed study outputs is undertaken.

A further key responsibility of the management group is to prepare and obtain ethical approval for the study from the NHS REC committee and Health Research Authority (HRA) along with relevant research governance approvals.

The management group ascertain that the main ethical questions relate to participant anonymity and the safeguarding of any private data. These are addressed in this application and will be advanced in greater detail for the HRA processes for 9 and 11 in subsequent approvals applications for those work packages.

To ensure ethical compliance in WP1 we will obtain informed consent from all workshop participants on the day of the workshop if they attend in person. Where participants attend a virtual workshop we will obtain consent electronically via a typed signature on an email copy

of the study consent form ahead of the workshop. If a participant is unable to complete the form electronically the study RF will run through verbal consent when participants join the online platform to confirm they have understood and accept the terms of the study prior to commencing the workshop proceedings on the day of the workshop . We will provide all potential participants with information about the study, and time to consider participation. Data will be stored in line with institutional policies. Interview participants will not be named or identifiable and we will use pseudonyms to report any direct quotes. We provide further details of the processes in place to achieve this in section 5.3.2 below.

Project research expertise

TM is Professor of Public Health and Primary Care with expertise in health services research in particularly using electronic primary care records. He will lead the project and directly supervise RF2 (quantitative). He will be supported in this by BW.

BW has extensive experience of analysis of primary care records and is both a practising GP and an Associate Professor. He holds a PhD in Medical Statistics.

SG is Professor of Medical Sociology. She is a qualitative methodologist and with extensive experience in the design and implementation of qualitative methodology as a component of mixed methods research, particularly in primary care. Recent research has included practices' use and attitudes to patient safety tools and the role of receptionists. SG leads 9.

IW is an experienced health services researcher focussing on health organisation, implementation research and complex intervention development. He has methodological expertise in mixed methods including consensus methods and will lead **Error! Reference source not found.**. He has extensive experience of qualitative case studies and, through his role at the Health Services Management Centre, is linked to extensive networks of current and future NHS leaders, for example through the national Nye Bevan and Elizabeth Garrett Anderson Leadership programmes.

SG and IW will supervise RF1 (qualitative). Both are highly experienced qualitative researchers. Their expertise and leadership will provide oversight on qualitative data management processes. Although supervision will be provided by SG and IW for FS neither they or any other member of the research team, the PPI / PAG members or external

advisory group members will have access to primary research data /participant data. If and when data is shared or reported to these study members they will only view and have access to summary data which will be fully anonymised. Only the lead qualitative researcher (FS) will have access to raw data and will organise the transfer of data files to the transcription agency and check the accuracy of their work.

PK is a health economist with an econometrics background. He has an interest in quality in primary care and extensive experience of analysis of using linked electronic health records for research. This includes analysis of the effects of continuity of primary care on admissions for mental health problems.

KS is a patient with a chronic condition who will lead PPI, chairing Patient Advisory Group meetings and liaising with the Project Steering Group.

The External Advisory Group

An External Advisory Group will be convened including Dr Mairead Murphy (University of Bristol) a qualitative researcher with an interest in continuity of care; Dr Otto Maarsingh (Amsterdam University Medical Centre) who leads the TOOL study, and Nicolas Thomas a member of the RCGP. This group will be convened and meet with the Project Steering Group every third month: half of the meetings will be online.

All members of the external advisory steering group are independent from the Sponsor and the Investigators. Each member brings expertise in the field of relational continuity of care.

(QUERCC) External Advisory Group Members

Nicholas Thomas	Nicholas.Thomas@rcgp.org.uk	RCGP
Jenna Collins	Jenna.Collins@health.org.uk	The Health Foundation
Otto R Maarsingh	o.maarsingh@amsterdamumc.nl	Amsterdam University Medical Centers
Theo Bartholomew	theo.bartholomew@nhs.net	NHS England
Mairead Murphy	Mairead.Murphy@bristol.ac.uk	University of Bristol

Oversight External Advisory Group: Meeting Annually

The Oversight External Advisory group is comprised of expert stakeholders, two are co-opted members of the funding body (tbc). The role of the group is advisory, and their responsibility is to review study documents and outputs to ensure the research is addressing wider trends and issues and raise awareness of potential collaborations and new developments. The core members, all of whom are independent of the Sponsor and Investigators. Core members are:

Oversight External Advisory Group

Funding body representative	tbc	NIHR HSDR
Funding body representative	tbc	NIHR HSDR
Nicholas Thomas	Nicholas.Thomas@rcgp.org.uk	RCGP
Jenna Collins	Jenna.Collins@health.org.uk	The Health Foundation
Otto R Maarsingh	o.maarsingh@amsterdamumc.nl	Amsterdam University Medical Centers
Theo Bartholomew	theo.bartholomew@nhs.net	NHS England
Mairead Murphy	Mairead.Murphy@bristol.ac.uk	University of Bristol
Mai Stafford	Mai.Stafford@health.org.uk	The Health Foundation
William Whittaker	william.whittaker@manchester.ac.uk	University of Manchester
Janina Ruszczynska	goth4you@gmail.com	

Patient & public involvement group

The Patient Advisory Group will meet three monthly and provide input into the monthly Project Steering Group meeting to ensure that PPI input is ongoing throughout the project.

The PPI lead (KS) is a co-applicant. KS contributed to study design, planning, study documentation and collaborated with team members to assist with study set-up and recruitment. KS will sit on the Project Steering Committee and will contribute to recruitment of a Patient Advisory Group (PAG) of 6-8 participants which he will chair.

KS will receive training in budget management, research methods (statistics and qualitative research) through formal study of core research methods modules at University of Birmingham. He will contribute to analysis and interpretation of interview and focus group transcripts from the relevant work packages. KS will not have access to primary research data /participant data. If and when data is shared or reported to KS or other members of the

PAG they will only view and have access to summary data which will be fully anonymised. Only the lead qualitative researcher (FS) will have access to raw data and will organise and manage the dissemination of data to the PAG.

He will also contribute to writing for publication and has contributed to the plain English summary and related study documents.

To ensure broad representation, when recruiting to PAG we will liaise with the well-established NIHR ARC West Midlands patient and public involvement infrastructure and with Dudley Integrated Health & Care Trust's. Experience of continuity of care varies by age, gender, education level, ethnicity and chronic disease status, and we will work to achieve diverse representation to the study PAG.

We will provide Potential PAG members with a description of the roles and expectations for involvement ahead of recruitment. Recruitment will aim at lay people with and without previous experience of PPI. After recruitment, the study investigators will provide training and induction on the project. Participation in the induction will be paid in line with INVOLVE rates and will equip PPI members with transferrable skills for future use in other PPI activities.

We will provide updates to the PAG on the progress of the research and on preliminary findings. The group will meet quarterly throughout the project and provide feedback to the Project Steering Group. The lay co-applicant will act as a point of contact for other lay members. It is anticipated that the PAG will contribute to the interpretation of relational continuity of care, advise on recruitment and involvement of patient participants in workshops and case studies, contribute to the design of dissemination materials including the study website. They will also provide a lay view on the acceptability and feasibility of possible solutions to enhance continuity of care. This will help inform the development of guidance for general practices on how to improve continuity of care in the final work package. An opportunity will be provided for PAG members to write about their experience. The PAG will contribute to dissemination by publishing results on the study website, social media and Health Unlocked.

The PAG and lay co-applicant will help implement findings by working with policy makers and patient support groups. The Study Investigators will host a 'thank you' event for the PAG at the study's end.

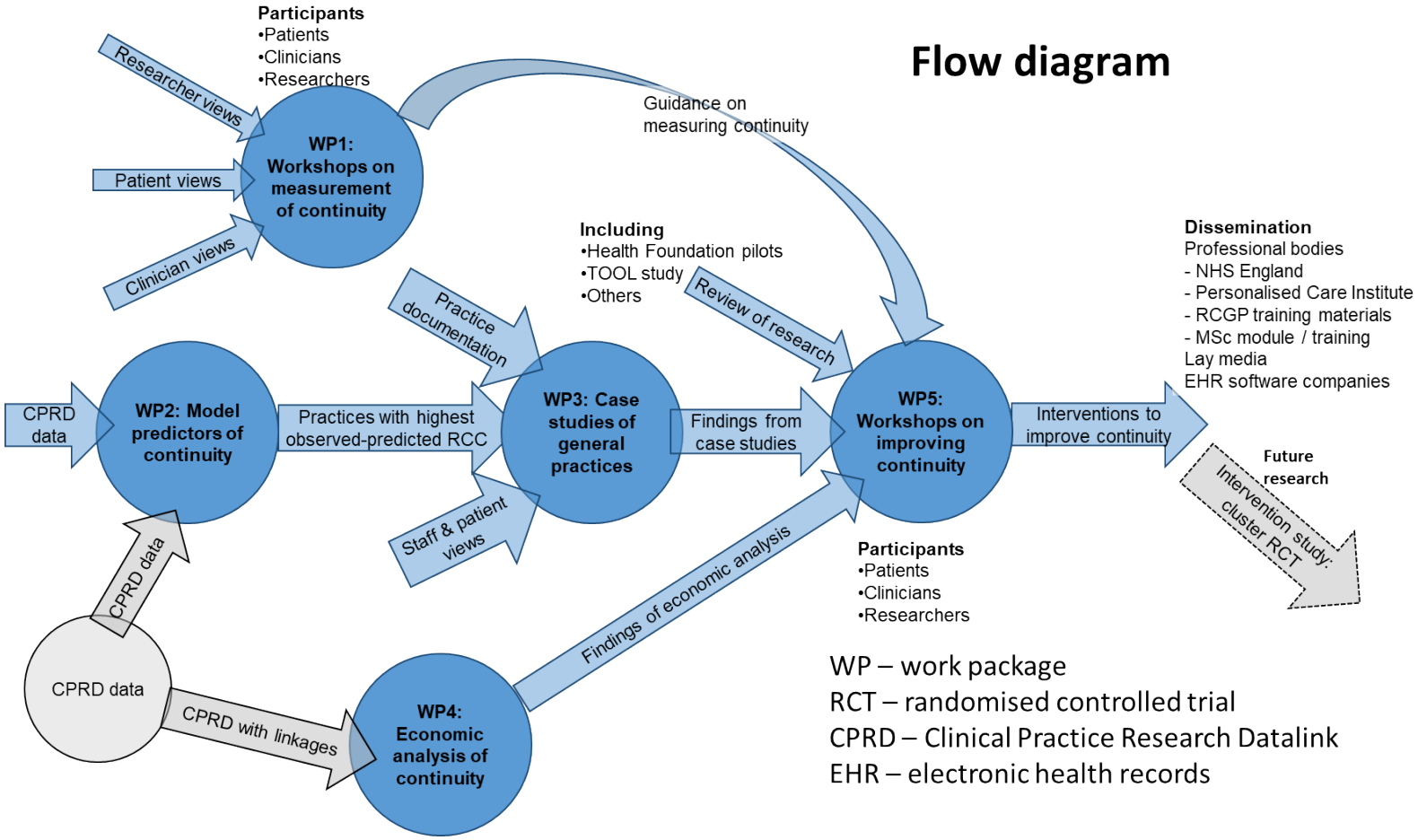
Protocol contributors

Key Protocol Contributors	Professor Tom Marshall Institute of Applied Health Research College of Medical and Dental Sciences University of Birmingham Edgbaston B15 2TT Telephone +44 (0)121 414 7832 Email: t.p.marshall@bham.ac.uk Professor Shelia Greenfield Institute of Applied Health Research College of Medical and Dental Sciences University of Birmingham Edgbaston B15 2TT Telephone: +44 0121 414 6493 Email: s.m.greenfield@bham.ac.uk Professor Iestyn Williams Director of Research School of Social Policy Health Services Management Centre, Park House University of Birmingham Edgbaston B15 2RT tel:+44 121 414 7063 Email: i.p.williams@bham.ac.uk Professor Krishnarajah Nirantharakumar Health Data Science and Public Health Institute of Applied Health Research University of Birmingham Edgbaston B15 2TT k.nirantharan@bham.ac.uk tel:+44 121 414 8344 Dr Brian Willis Senior Clinical Lecturer in General Practice & MRC Fellow Institute of Applied Health Research University of Birmingham Edgbaston B15 2TT b.h.willis@bham.ac.uk tel:+44 121 414 7949 Dr Panagiotis Kasteridis Research Fellow Health Economics Centre for Health Economics University of York Panos.kasteridis@york.ac.uk (01904) 321429 Mr Kamil Sterniczuk Lay co-applicant Lay advisor. Chair patient advisory group, Institute of Applied Health Research University of Birmingham Edgbaston B15 2TT kamil.sterniczuk@gmail.com

Key words

Continuity
Primary care
Optimise
Health outcomes
Health systems
Mixed methods research

Project flow chart



PROTOCOL

Summary of Research (abstract)

Relational continuity of care (RCC) is the extent to which patients see the same clinicians over time. Considered a core feature of general practice, it is linked to patient satisfaction and better health outcomes, especially for older patients, those with long-term conditions and the vulnerable. Although current NHS policy is to maintain continuity for patients with long-term conditions, it has been declining for at least a decade. Contributing factors are thought to include growth in practice size, more part-time working, greater staff and patient turnover. It may also be because practice policies have focused on access, rather than continuity.

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1. Background

Continuity of care can include **informational** continuity, sharing information between clinicians and organisations; **management** continuity, following the same management plan across different clinicians and organisations; and **relational** continuity, patients seeing the same clinician.[i] Informational and management continuity are facilitated by shared medical records and treatment plans. Both are also enabled and supported through relational continuity, an ongoing affiliation between a clinician and a patient across many illness episodes.[ii] This project focuses on relational continuity of care (RCC) in primary care. RCC is important for two main reasons: it is valued by patients and GPs, and it is associated with better health care delivery and with better health. Policy documents express the need to maintain RCC for patients to whom it is important.[iii,iv] Professional bodies actively promote increasing RCC.[v] In the UK concerns about declining RCC have been identified as a potential disadvantage of the advent of primary care networks and large practices.[vi]

Valued by patients

Patients value continuity of care, especially older patients and those with chronic conditions and it is strongly linked to positive patient experience.[vii,viii] They associate RCC with doctors taking responsibility, trust, respect, safety and avoiding having to repeat their story.[vii,ix,x,xi,xii,xiii,xiv] Evidence suggests continuity is important in delivery of primary care to diverse populations. In the UK those not in work, women, South Asians, with chronic conditions or mental health problems more often prefer continuity (i.e. have a preferred GP) but reported continuity is lower in some of these groups (South Asians, blacks and women).[xv,xvi] Among young people, relational continuity with a GP is associated with better health care system navigation and engagement.[xvii] Multimorbid patients also say it helps them navigate health care systems and to feel safe.[xviii,xix]

Systematic review of qualitative research has identified a high degree of congruence between doctors' and patients' views of RCC. Both doctors and patients see it as enabling person-centred care; increasing quality of care; and giving patients greater confidence in medical decision-making. Both groups also identify some drawbacks (access, overfamiliarity, physician burden). Both see absence of RCC leading to harm (misdiagnosis, patients withdrawing from care) and loss of trust in the care team.[xx] In a quantitative analysis of survey data, having a named GP and being proactive in seeking to use them were both strong predictors of satisfaction with primary care.[xxi]

In the conception and development of this proposal we consulted 8 patients in 2 workshops in 2019. Participants felt RCC was important and shared many narratives illustrating RCC or its absence in primary care consultations. They generally stressed the importance of developing a relationship with a GP and avoiding the need to explain their circumstances at every visit. They felt continuity would reduce over prescription and unnecessary medication changes. Some felt RCC was crucial, but others were less concerned about seeing the same GP or even valued a different GP's opinion. All participants acknowledged the importance of continuity for patients with long term conditions, the elderly, and more disadvantaged patients. They perceived RCC as becoming more difficult to maintain with longer waiting times and pressure on health services to provide better access. They

identified part-time working, larger practices and automated booking systems as potential barriers to continuity and identified receptionists as playing a key role in continuity. When asked about measuring continuity patients emphasised that RCC did not have to be with a single GP but a small number of GPs (e.g. 2 to 3) would count as continuity. They also said continuity could be with another healthcare professional (e.g. a nurse). They were supportive of the proposed research, some adding that it was important to elicit the views of healthcare professionals on continuity. We found a striking congruence between the personal observations and intuitions of our patient participants and the findings of published research. This suggests patients have considerable insight into RCC and have an important role in shaping this research.

Valued by GPs

Research shows GPs identify RCC as the most essential feature of general practice but consider it has been eroded by changes in working practices.[xv,xxii,xxiii,xxiv] Like patients, they see it as having an important role in patient safety.[xxv] Doctors see RCC as particularly important for patients with serious, chronic, complex, or psychological problems.[xx] They also say it brings joy and meaning to their work.[xx] The RCGP values RCC, encouraging research and supporting practices to improve continuity.[v] Recent policy emphasises the need to preserve RCC for patients with long-term conditions, but while policy mandates extended opening hours to improve access, it gives no advice on how to improve continuity.[iii]

In preparation for this bid, in May 2019 we surveyed 43 GPs from teaching practices. Respondents overwhelmingly confirmed they viewed RCC as important to GPs and patients, that it influences health and is generally declining. Importantly for this proposed research, two thirds believed it is possible to increase RCC and the vast majority wanted to know how to do so. Views on regular measurement of RCC were more nuanced: 21% felt it would be useful, 21% felt it would not, but most were uncertain of its value. Themes in free-text comments included: tension between rapid access and continuity; the greater importance of RCC for older patients and those with long-term conditions; challenges to continuity posed by part-time working and trends towards larger practices. A few GPs also drew attention to drawbacks of RCC and the value of a second opinion. Others suggested interventions to improve continuity, such as patients having assigned GPs or receptionist training.

Continuity is linked to health outcomes

Longstanding evidence shows RCC is associated with reduced emergency care consultations, unplanned admissions and even mortality.[xxvi,xxvii,xxviii,xxix,xxx,xxxi,xxxii,xxxiii] This is true for patients with diabetes, COPD, asthma, serious mental illness and dementia.[xxxiv,xxxv,xxxvi, xxxvii,xxxviii,xxxix] Natural experiments provide further evidence of causation: disruption of RCC by departure of a physician is followed by increased use of specialty, urgent, and emergency care by older patients.[xl,xli] Systematic reviews of RCC in both primary care and specialist settings, have found an association with reduced mortality.[xlii,xliii]

Continuity is linked to resource use

RCC in primary care is associated with reduced health care resource use in secondary care.[xliv,xlv] Recent analyses confirms RCC is associated with reduced emergency department attendance;[xlvi] reduced hospital readmission in patients with stroke;[xlvii] older patients,[xlviii] patients with dementia,[xlix] and with serious mental illness.[l] A Norwegian cohort study also found continuity measured at a practice level to be associated with significant reductions in emergency admissions.[li] RCC is also associated with reduced resource use in primary care. Analysis of UK primary care data found patients aged 65+ at the 25th rather than the 75th percentile of measured RCC, have 56 per 1000 fewer emergency admissions and 900 per 1000 fewer GP consultations annually.[lii] This is equivalent to 1708 fewer consultations and 106 fewer admissions for an average practice (list 8757 of whom 22% are 65+). While higher RCC may have as significant impact on healthcare utilisation and health outcomes it is likely the impact also across different population groups, no economic analysis has quantified the

costs and benefits of higher RCC or how this may vary by patient age, socioeconomic status and chronic disease status.

Drawbacks of continuity

Potential disadvantages of RCC include the value of a second opinion and increased burden on individual GPs. There is a potential trade-off between access and continuity for both patients and practices. Patients value rapid access for acute problems and may prioritise access over continuity.[liii,liv,lv,lvi,lvii] In an analysis of 287 Catalonian general practices, those optimised for access had poorer continuity.[lviii] Yet, improving access may also improve continuity. An analysis of 190 primary care physicians that improved their access also increased RCC.[xlvi] Moreover, in the long run, higher continuity may improve access by reducing demand, with over 65s in the highest quartile of RCC having 0.9 fewer GP visits per year than those in the lowest.[lii]

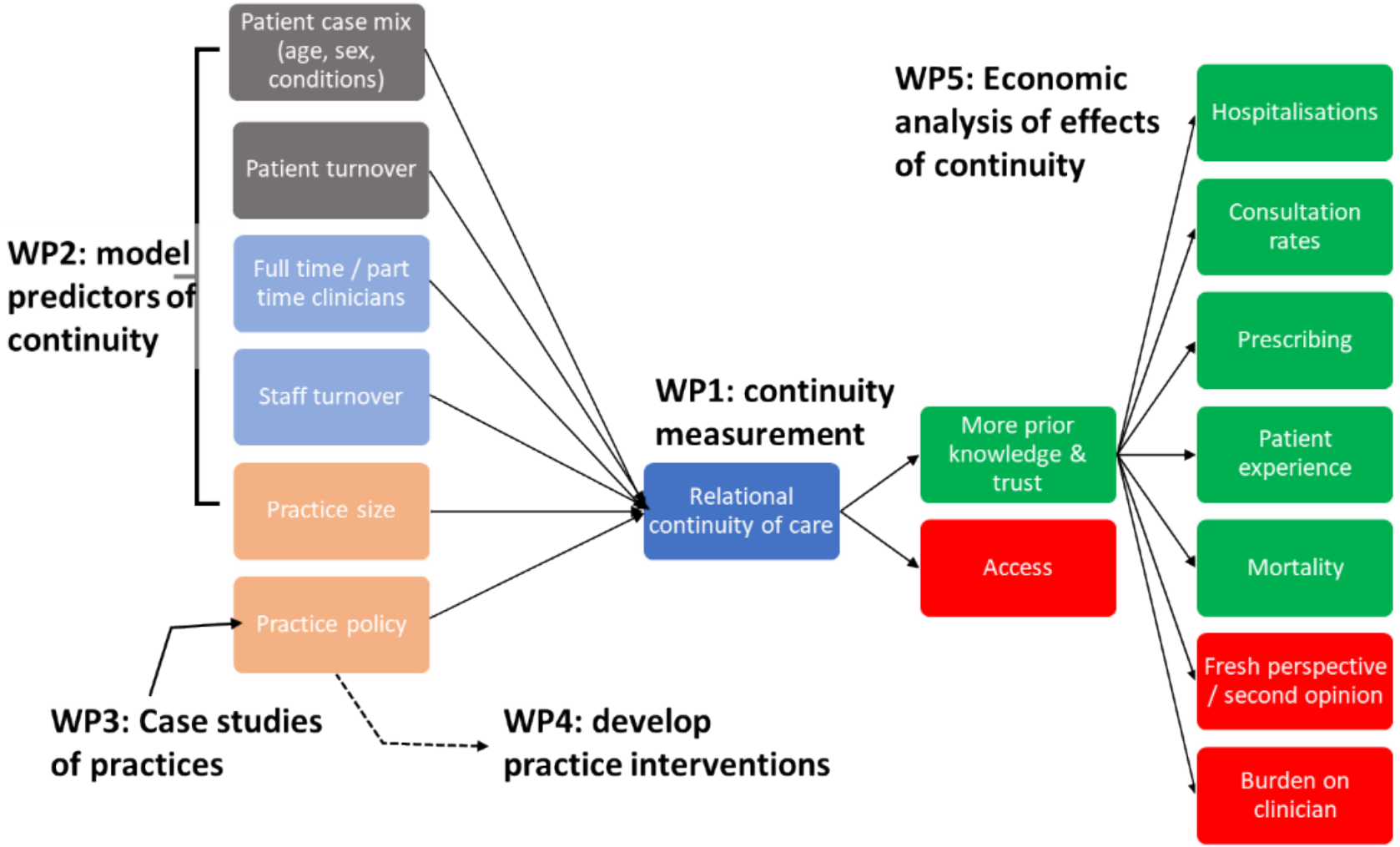
Figure 1 illustrates the possible determinants of RCC (patient characteristics, patient and staff turnover, part-time and full time working, practice size and within-practice policies) and its effects. Both positive effects (on hospitalisations, consultation rates, prescribing, patient experience and mortality) and negative effects (lack of a second opinion, clinician burden) are thought to be mediated through better clinician knowledge and patient trust. RCC also has effects on access.

Mechanisms by which RCC may influence health

There are a number of ways in which RCC could influence health and health service use. Qualitative research suggests longitudinal RCC increases GP communication with, knowledge of, and responsibility for patients.[ii,ix,lix] It reduces the tendency for successive GPs to deal only with immediate problems.[ix,lx] Patients with a deep relationship with their GP discuss more problems and issues.[lxi] However, we don't fully know how RCC influences health in different contexts.

RCC seems to influence GP decision-making. Personal knowledge of patients affects diagnostic test and referral decisions, and GPs interpret patients' symptoms in the light of personal knowledge about how likely they are to consult.[lxii] RCC reduces antibiotic prescribing for self-limiting illness in children.[lxiii] Comparing the 25th to the 75th percentile of RCC, patients aged over 65 are prescribed antibiotics less frequently (aOR=0.58; 95%CI: 0.56-0.66) and if prescribed any, receive fewer (aRR=0.66; 95%CI: 0.58-0.75).[lii] RCC is associated with more appropriate prescribing in patients with dementia.[xxxix] GPs are more likely to deprescribe if they know the patient.[lxiv]

Figure 1: Determinants of and effects of relational continuity of care



RCC may also affect patients' knowledge and behaviour. Studies report associations with better chronic disease management,[lxv,lxvi,lxvii] better medication adherence,[lxviii,lxix,lxx,lxxi,lxxii,lxxiii] patient behaviour change[lxxiv] and a reduced intention to use emergency departments.[lxxv] These associations between RCC and health care delivery processes, patient intentions and patient outcomes are plausible explanations for the relationship between RCC and health outcomes.

Measurement of RCC

There is a long-recognised need for consistent measures of RCC.[xxxi,lx,lxxvi] The RCGP emphasises the need to measure relational continuity as a first step in its management.[v] But choosing an appropriate measure is complex.[lxxvii] Subjective RCC (the patient's experience of continuity), measured through questionnaires, is impractical for monitoring.[lxxviii,lxxix,lxxx,lxxxi] Objective RCC measurement (a quantitative measure of frequency of consultation with the same clinician) is feasible using electronic health records (EHR) and correlates with subjective measures.[lxxxii] But different objective measures capture different conceptions of RCC.[lxxxiii] Continuity may be with the GP or with any clinician; it may be in all patients or in specific patient groups (e.g. ≥65 years); it may be measured quarterly, monthly, or weekly. There are different RCC indices. Some measure density: Usual Provider of Care index (UPC) % of consultations with most frequently seen GP, or the St Leonard's Index of Continuity of Care (SLICC) % of consultations with a named GP.[lxxxiv] Others measure dispersion, taking account of the number of different clinicians consulted, using the Bice-Boxerman (BB) or Herfindahl (HI) indices. There is a measure of Sequential Continuity (SECON). (

Table 1) Research has also explored effects of regularity and minimum frequency of contact on patients with chronic conditions.[lxxxv,lxxxvi] Density measures decline with consultation frequency but dispersion measures are less affected.[lii] In practice, BB, HI, UPC and SECON are often highly correlated.[lxxxvii] SLICC is easy to calculate at the practice level and does not require patients to have a minimum number of consultations, but it may differ from the UPC if the patients' usual GP and named GPs differ.[lxxxviii]

2. Rationale

There are questions about measuring RCC and the answers vary with the aim of measurement. Should RCC be measured only in older or chronic disease patients? Should it include consultations with all clinicians or only with GPs? Should RCC reflect the patient's, the doctor's, or the healthcare system's perspectives of RCC? Over what time period should RCC be assessed? Which RCC index should be used?[lxxvi] A measure of RCC should be practical, understandable and reflect what patients and clinicians mean by continuity. For example, our patient workshop participants (see above) emphasised RCC could be provided by non-GP clinicians, or by 2 or 3 rather than 1 clinician. This view is consistent with a RCC index including consultations with all clinicians and measuring dispersion. But density indices are more widely used and to date no measure includes consultations with non-GPs. Our survey of 43 GPs (see above) revealed some support for monthly (or 2-3 monthly) RCC

monitoring. While measurement of RCC is both feasible and useful, the aims of measurement vary and neither what to measure nor the optimum choice of index are clear.

Table 1: Main indices of relational continuity of care (RCC)

Name	What is measured	Formula
Bice-Boxerman (BB)	Dispersion	$\frac{\left(\sum_{i=1}^{p} n_i^2\right) - n}{n(n-1)}$
Herfindahl Index (HI)	Density	$\sum_{i=1}^{p}\left(\frac{n_i}{n}\right)^2$
Usual Provider of Care ($UPC^{Patient}$)	Density	$\max\left(\frac{n_i}{n}\right)$
St Leonards Continuity of Care (SLICC or $UPC^{GP\ level}$)	Density	$\text{named clinician}\left(\frac{n_i}{n}\right)$
Sequential (SECON)	Handoffs	$\frac{\left(\sum_{j=1}^{n-1} c_j\right)}{(n-1)}$

p = total number of providers (clinicians); n = total number of visits during episode; n_i = number of visits to provider i; c_j = indicator of sequential visits to same providers, equal to 1 if visits j and j+1 are to the same provider, 0 otherwise

Trends in RCC in the UK

RCC is declining.[xxxii,lxxxix,xc,xci,xcii] In the GPPS, subjectively reported continuity (seeing preferred GP a lot, almost always or always) fell from 73% in 2011 to 45% in 2021.[xciii] From 2011 to 2017, it fell more rapidly in older patients, but downward trends were similar by sex, ethnicity and deprivation status.[xvi] The decline was observed across rural or urban practices, with high or low baseline continuity, and high or low deprivation.[xciv] The decline was faster (-6.6%) in practices that grew larger between 2013 and 2017 than those that did not.[xcv] The downward trend continued from 2018 to 2021: falling from 59% to 49% in those aged 65+, and from 47% to 44% in those aged <65. The underlying trend in continuity continued in the Covid-19 pandemic, declining in all age groups from 2019 to 2020. But in 2021 it then rose slightly in those aged <55, stabilised in ages 55-64, and fell further in those aged 65+.[xciii] Within general practices, subjective continuity shows some consistency over time: 40% of practices in the top quintile and 52% in the bottom quintile of continuity in 2011 were in the same quintiles in 2021. [TM analysis of GPPS]

Objectively measured RCC shows similar trends. In an analysis of 100 general practices' electronic health records, RCC declined from 2007 to 2016, with greater declines among patients aged ≥75 years or with ≥3 comorbidities. This analysis also found that the rate of decline varied greatly between general practices.[lii]

Determinants of relational continuity of care (RCC)

In Canada, RCC was observed to vary both by practice and patient characteristics.[xcvi] It was lower in city practices, practices with more doctors and in some types of practice organisation. It also varied by patient age, sex, ethnicity, length of time in the practice and the presence of psychological or longstanding problems. In the UK 20 years ago, RCC was shown to be markedly lower in practices with over 6300 registered patients, but higher in practices with personal list systems, higher in older patients and those with long-term conditions.[xcii] As the average UK practice now has ≈9000 patients, growing practice size is one external practice-level factor which may explain declining RCC. Others include, scaling-up of practices into networks,[xcvii] increased part-time working by GPs, greater patient turnover and greater turnover of GPs.[xcviii,xcix,c] Indeed GP turnover is directly associated with unplanned hospital admissions. However, declining RCC may not be inevitable. The association between RCC and practice organisation (e.g. personal list systems) and extent of between-practice variation suggests general practices can still influence RCC through their within-practice policies. Indeed, some large practices (list sizes >10,000) report intentionally maintaining or increasing RCC.[ci,cii] We need to identify what these general practices do that enables them to maintain high RCC, and establish if their policies might be desirable and practical in other general practices.

Interventions to improve RCC

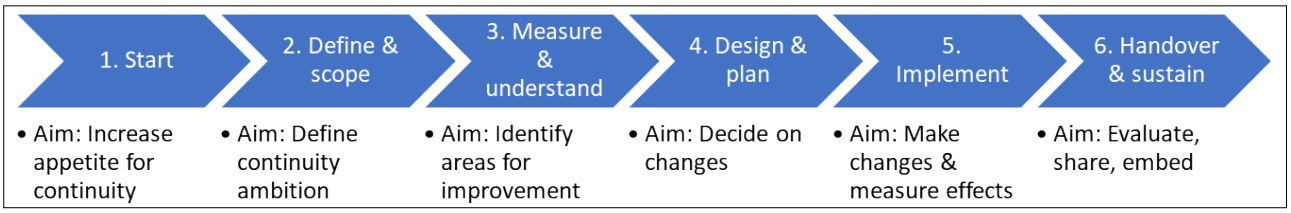
Interventions to improve RCC can operate at multiple levels, from national to practice, although evidence suggests mixed results.

High-level policies: In England, a national requirement to have a named GP for older patients had no effect on RCC.[ciii] Systematic review suggests, fee for service payment may increase RCC.[civ] An Australian cluster RCT is investigating financial incentives for improved RCC.[cv] Higher primary care funding is associated with better GPPS scores on continuity, access, professionalism and overall satisfaction.[cvi] However increased resources or financial incentives are unlikely to be realistic given economic constraints and post-pandemic demands on health care. Implementing changes at this level is therefore outside of the scope of this research, but using the Consolidated Implementation Framework for Research (CFIR) these effects can be considered as part of the Outer Setting.[cvii]

Within-practice policies: Practice policies can influence RCC. Some UK practices use personal lists, where patients usually consult a single GP.[ci,cviii,cix] Others operate as micro-teams, allocating patients to a small group of clinicians (such as two GPs and a nurse), which may be more resilient where some practice staff are part-time.[cx] Other approaches include: reserving appointments for patients who benefit most from continuity; encouraging patients to seek continuity by making them aware of its importance; using receptionists supported by flexible booking systems and written practice policies, to direct patients to the right clinician.[xv]

Some within-practice initiatives have been shown to increase continuity. A policy requiring patients to consult their own GP substantially increased continuity in a large Israeli primary care provider.[cxi] In Germany, a programme to strengthen general practice increased continuity of care.[cxii] In the UK an RCT promoting patient-centred micro-teams for older, complex patients, significantly improved their continuity of care.[cxiii] In 2019, The Health Foundation funded five projects to improve RCC through within-practice changes in organisation.[cxiv]

Figure 2: Health Foundation and RCGP six-step continuity toolkit

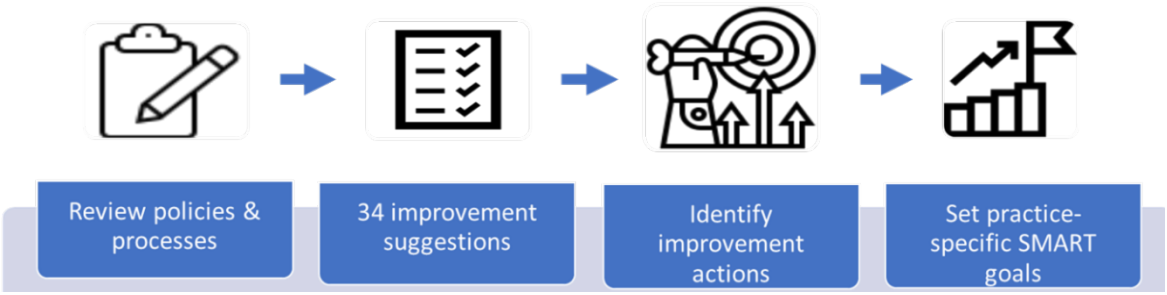


Health Foundation projects: In five Exeter general practices, staff support for continuity was built by running seminars on the advantages of continuity and challenging myths. The project measured RCC monthly using SLICC (UPC$^{GP\ level}$) and implemented a personal list approach. Four practices significantly increased continuity. South Cumbria Primary Care Collaborative developed a dashboard to measure and compare continuity. They also implemented a usual GP approach, which increased continuity in most of the 10 participating practices, despite the impact of the Covid-19 pandemic. One Care developed a software tool for 23 practices to measure their own RCC. Of these, 22 increased their RCC, either through adoption of personal lists or micro-teams models. Both patient experience and staff job satisfaction improved. In Pier Health (North Somerset), 9 practices were experiencing excessive workload, an unsatisfactory working environment and difficulties recruiting staff. After implementing personal lists they demonstrated substantial improvements in continuity and improved staff experience.[cxv] The Valentine Health Partnership in Woolwich focused on improving continuity for those patients who were consulting more frequently due to new symptoms. They successfully increased their RCC. Staff were overwhelmingly supportive, but did identify some drawbacks, including delays in accessing GPs, patients becoming dependent on one GP and a lack of a second opinion (fresh pair of eyes).[cxvi]

Across all five projects, key facilitators were persuading clinicians of the potential benefits and staff engagement. Barriers included external factors (e.g. recruitment, reorganisation), the Covid-19 pandemic, a focus on access over continuity and the increased burden challenging patients can put on GPs. Additional benefits included improved patient and GP experience. In collaboration with the RCGP these projects resulted in development of a 6-step continuity toolkit [cxvii] (Figure 2).

TOOL study: The TOOL study in the Netherlands is a stepped wedge RCT evaluating an intervention intended to improve continuity of care among complex older patients.[cxviii] The intervention asks practices to review their current practice in relation to continuity and offers a menu of 34 evidence-based suggestions to help practices improve continuity. Practices then develop their own improvement plans with specific, measurable, achievable, relevant & time-bound goals. (Figure 3) The TOOL intervention emphasises flexible, practice-led, sustainable approaches to improving continuity. There is less focus on quantitative measurement of RCC. The outcome of the intervention is assessed using the Nijmegen Continuity Questionnaire, supplemented by staff and patient interviews.[lxxx] The study finishes in early 2022.

Figure 3: The TOOL study intervention to improve continuity



Within-practice policies can optimise RCC. But as within-practice policies and general practices differ. It is not known which solutions work best in which practices. The Health Foundation's pilot projects share some similarities: all were supported by funding, generally made sophisticated use of IT and were implemented across groups of general practices. The TOOL study, in the Netherlands' broadly similar primary care system, adopted a more flexible approach with less use of IT or measurement. Applying the CFIR analytical framework, suggests that the Health Foundation interventions emphasise Process, whereas the TOOL study emphasises adaptation to the Internal Setting. Other UK practices have developed varying home-grown innovations, often without external support and within a single practice.[ci,cii,cix,cx] Mapping within-practice strategies for improvement to an appropriate implementation framework such as CFIR will provide a fuller understanding of the range of within-practice policies to improve RCC.

Summary

RCC is important to patients and GPs. It is associated with improved health outcomes and resource use. Despite its advantages, it is declining, more rapidly among older patients, who may most need continuity. The contribution of different factors to its decline is not fully understood. Some practices achieve high continuity and within-practice interventions have shown RCC can be increased. General practices seeking to improve continuity will need to measure and monitor their own continuity, but need guidance about how best to do so, to meet their own needs. To inform expectations about managing continuity, we need a better understanding of the contribution of a practice population's demographics, practice size, staff and patient turnover and part-time working to changes in RCC. There are invaluable lessons to be learned from general practices which have maintained higher than predicted RCC (positive deviants). There is a need to combine learning from home-grown approaches to improving continuity, including recent UK pilot studies funded by the Health Foundation, and other innovations such as the recent intervention study in the Netherlands. From the experience of general practices, UK pilot studies and interventions in other settings (e.g. Netherlands) it would be useful to develop interventions to improve RCC in primary care, while maintaining other features of care such as access. Because it is associated with better health outcomes and lower health care costs, higher RCC may be cost-effective but this has not been demonstrated and the economic case for improving RCC has not been articulated. Furthermore, costs and effects are likely to vary by patient group (e.g. age band, chronic disease status) and this may help clarify where to prioritise efforts to improve continuity.

Evidence explaining why this research is needed now

There are calls for research into the meaning of different measures of RCC; the role of continuity with clinicians other than doctors; which patients benefit from continuity; and how general practices may optimise RCC.[cxix] Recent plans for improving access in general

practice specifically state that NHS England will work with the NIHR to understand the role of continuity of care.[cxx] In 2022, some key stakeholders in health policy have emphasised the need for continuity of care. For example a recent report by The Policy Exchange (endorsed by the present health secretary) notes that primary care is scaling up into larger practices and federations, with some practices run by hospitals. It envisages acceleration of this trend and emphasises the importance of maintaining continuity of care.[iv] The report endorses a model based on Modality (in the West Midlands), where within a large general practice organisation, care teams are organised around groups of 3500-5000 patients, in order to maintain continuity of care.[iv] The Rebuilding General Practice campaign of March 2022 (led by the BMA and a former health secretary) emphasises the importance of continuity of care, warning against the 'Uberisation' of GP services.[cxxi] Continuity is a salient, pressing issue, but practices need clarity about whether to develop their own solutions to improve continuity, or to adopt, for example, a micro-team model, those described in the Health Foundation's projects or the TOOL study.

The Covid-19 pandemic dramatically affected primary care. In spring 2020, consultation rates were a third lower than pre-pandemic and face-to-face appointments fell from 80% to under 50%. By late 2021 consultations had risen to above pre-pandemic levels, with 64% face-to-face.[cxxii] But there was little change in long-term trends in RCC during the pandemic. This supported by the views of at-risk patients in Switzerland, who felt that continuity did not suffer during the pandemic and reported their GPs made efforts to maintain continuity.[xciii,cxxiii] Overall the pandemic's effects on RCC may have been less dramatic than its effects on consultation frequency. However, in the longer term, the disruption is argued to be a decisive change point in primary care, both an opportunity to improve RCC and a danger that if overlooked, it may decline further.[cxxiv] In the emergence of long-Covid, the pandemic has also generated a new need for RCC, with recent NICE guidelines recognising the importance of relational continuity in its management.[cxxv]

3. Theoretical framework

Synthesis and interpretation of data collected across the five work-packages will be guided by the recently updated Consolidated Framework for Implementation Research (CFIR). CFIR is one of the most widely used frameworks to organise and interpret data on factors that shape implementation of change within health care settings [cxxvi], [cxxvii]. It provides a framework of 39 implementation constructs which facilitates the organisation and interpretation of data across five core domains: outer setting (e.g., the economic, political, and social context), inner setting (e.g., the structural, political and cultural context where the implementation takes place, such as an organization), characteristics of individuals (e.g., attitudes, values and believes of the individuals involved) and process (e.g., components that impact the implementation process). Working in this way the analysis will aim to unpack the key components of a workable intervention.

4. Research question/aims

Aim: to understand how to enhance relational continuity of care (RCC) in primary care.

Objectives:

- Develop guidance for general practices on quantitative measurement of RCC
- Quantify the practice-level determinants of RCC: including staff and patient turnover, part-time working, practice size and practice funding.
- Identify practices showing unusual variation (positive deviants) in RCC
- Conduct in-depth case-studies to understand how practices achieve high RCC

- Undertake economic analysis of the likely causal effects of changing RCC on resource costs and health outcomes across different segments of the registered practice population
- Develop empirically informed practical guidance to help general practices optimise RCC

5. Study Design and Methods

The research uses a variety of methods. **Error! Reference source not found.** develops a shared understanding of RCC to guide the choice of measurement indices. 8 undertakes quantitative analysis to investigate determinants of RCC and to identify outlier practices. 9 is an investigation of outlier practices (positive deviants) as case studies. 10 is an economic analysis of the effects of RCC. 11 develops empirically informed practical guidance to help general practices optimise RCC.

6. Outputs

- WP1: Output: A menu of approaches to measuring RCC for monitoring in primary care.
- WP2: Output: A model of the contribution of patient and general practice-level characteristics to trends and variations in RCC. An observed to predicted ratio of RCC in CPRD practices. A list of general practices in the top decile for RCC in the most recent data quartile for inclusion as potential case studies.
- WP3: Output: The primary output of 9 is an understanding of the practice characteristics which contribute to RCC and understanding of barriers and facilitators to RCC and the mechanisms by which RCC influences health.
- WP4: Output: A model assessing the impact of changes in RCC on healthcare resources and health outcomes. The model will describe the effects of changing RCC on different population groups.
- WP5: Output Develop guidance deriving from existing research and the findings of 8, 9 and 10 to make recommendations on how practices can improve RCC whilst continuing to meet other requirements and objectives. The aim is to produce in-depth empirical data on the strategies for increasing and/or maintaining RCC in primary care settings. We will document the full range of these strategies and interventions and provide a summary of evidence on their efficacy and implementation in different settings.

These outputs will feed into our dissemination and knowledge exchange activities and to inform practice in the immediate term. We will also identify areas where there might be a need for intervention *adaptation* or de novo intervention *development and* put forward evidence-based recommendations for how this should be pursued.

7. **Work package 1** Deliberative workshops with key stakeholders

RCC indices in use to date have mainly been selected by researchers and measurement has only included consultations with doctors. We will host two facilitated workshops on RCC with a mix of clinicians, patients and researchers to work towards a shared understanding on the meaning and measurement of RCC.

Method

In WP1 we will hold two workshops. The first will draw relevant stakeholders together to establish common understandings, the second will work with the same stakeholders to build consensus. The workshops will be held two months apart. The key stakeholders we will ask to join the workshops as research participants will be: clinicians, patients and researchers. The workshops will be coordinated by a professional facilitator who will be supported by members of the research team.

We will recruit clinicians using the professional contacts that the study PI team have established with the Royal College of General Practitioners (RCGP) and by releasing invitations on social media (www.doctors.net.uk).

We will recruit researchers by emailing an invitation to (1) professional contacts (established by the PI team and members of the advisory group) and (2) researchers who have recently published in the field (using the email address available in public domain provided on their recent publications).

We will recruit patient representatives to the workshops by:

(1) displaying posters in medical practices in the Birmingham region; negotiations have achieved formal agreement to show posters from one practice (Thornley Street Practice, Dr Anna Stone with support from Wolverhampton City Primary Care Trust Dr Mona Sidhu);

(2) consultation and collaboration with local patient facing groups along with direct approach to Community Connections and Healthwatch to gain access to members of the public who will be interested to join the workshops

We will supply printed copies of the Participant Information Sheet (PIS) to the practices so that potential participants can take time to read about the study. An electronic PIS will be made available to the ARC West Midlands PPI representative so that this can be disseminated to potential participants and allow them time to consider their involvement in the study and the implications it might have for them.

We have funding to support accessibility for lay participants (accessible transport, childcare costs, interpretation).

Sampling

Our main sampling objective is to achieve a balance between patient and professional (clinicians and researchers) participants that is broadly equal (total n ≈ 15). We will over-sample to each of the categories of participant and hold a reserve of +3 of each category (clinical, patient and researcher) to account for circumstances where there is attrition from the sample (n=15) when participants are recalled to join the second work-shop two months later (as outlined below). We will obtain consent from the over-sampled (n=9) participants to contact them again using a permission to contact form. We will aim to ensure a diversity of patients, clinicians and researchers by age, gender, ethnicity, education level and chronic disease status. We will use an equality and diversity form to collect details of participants' age, gender, educational background, ethnicity and chronic disease status in order to monitor the sample representation. This will be a paper form completed on the day. It will be anonymised and no participant ID number will be attributed or recorded onto it.

Written consent will be obtained from participants on the day of the workshops as detailed above and the consent process will obtain permission to audio record under assurances of anonymity and confidentiality. To ensure both workshops run efficiently we will use a professional facilitator. The workshops will take place at the central Birmingham venue named 'The Exchange' in rooms with privacy and professional recording equipment.

Data Collection Workshop 1

In workshop 1 we will use the nominal group technique (NGT), a face-to-face, structured interaction, for identifying areas of consensus and divergence in priorities between different groups.[cxxviii] NGT is efficient as a means of gathering such data, and is especially useful where a range of perspectives exist and some groups may be more vocal than others.[cxxix] Although typically used to gather professional views, NGT has been successfully employed with patients.[cxxx] It is less resource intensive than alternatives (such as Delphi) and more likely to both reach a clear outcome, and provide a sense of achievement for participants.[cxxxi] In this instance, NGT will be important in enabling us to bridge any discursive gap between lay and medical understandings of RCC.[cxxxii]

The professional facilitator and theme lead will begin by explaining the workshop purpose and methodology in a short presentation with questions, clarify ground rules regarding respect, voice and confidentiality. The theme lead will explain the problem of RCC measurement. This will be followed by information giving regarding the problem of RCC measurement, based on existing evidence.**Error! Bookmark not defined.** This stage is crucial in translating the topic into simple language and reducing the requirement for technical knowledge, in order that all participants are able to contribute to subsequent discussion.

Participants will then be asked to individually reflect on the key components of RCC (e.g. "Is continuity primarily with one GP, more than one GP or all clinicians?" "What aspects of care are most important in providing continuity?" "How frequently should it be measured?") and to record their views in note form. We will devote between 10 and 20 minutes to this task and researchers will be on hand for any participants requiring assistance. These notes will then be shared with the full group, without discussion, and recorded by facilitators on flipcharts. This will be followed by facilitated group discussion in which verbal explanation and elaboration are provided between group members in relation to each of the identified components. This clarification phase may involve grouping of items and further inclusion/exclusion where this is universally agreed.

The final phase involves participants in developing a series of questions to help identify characteristics or dimensions of a measure of RCC: first identifying the purpose of a measure, then identifying the characteristics we might seek in an ideal measure. This is likely to involve list reduction and/or voting, and will be facilitated so as to respect diversity of opinion, enabling full and equal participation across each of the groups. We anticipate asking participants to identify the potential purposes of measuring RCC. They will then select the characteristics of a measure of RCC (e.g. which population, density v dispersion, GPs or all clinicians, understandability etc) that correspond to the potential purposes. We will give participants clear instructions and dedicate ample time for them to carry out the selection process. A researcher will quality check the process, for example by reviewing submitted suggestions as these are handed in.

In total, the workshop will be attended by 3 members of the research team. IW or TM will lead the discussions, a second researcher will be responsible for visual materials (e.g. whiteboards) used in the discussion, and a third will take notes and ensure workshops are audio-recorded. If Covid-19 restrictions make face-to-face workshops impractical, or if a different mode of delivery supports more diverse participation, we will conduct hybrid or virtual workshops. Workshop conduct will be informed by research on best practice and guided by recommendations in the literature.[cxxxiii,cxxxiv]

We will enter summary data of the characteristics of a RCC index into a Microsoft Excel Database. It is our intention that practices will prioritise these characteristics themselves, in order to identify their own preferred measure. However if a consensus emerges, we may also provide a recommendation on the most important characteristics in a measure, based on the views of workshop participants. We will report the outputs to participants towards the end of the workshop. Qualitative data derived from the audio-recordings will be analysed to enable us to provide context to the summary results, and to understand the rationale behind them. After the workshops, transcriptions will be entered into NVivo 11 and we will develop a coding framework inductively during a process of qualitative content analysis carried out independently by two members of the research team.**Error! Bookmark not defined.**

Output: a framework to work towards a synthesis of patient and professional conceptions of the meaning of RCC

Data Collection Workshop 2

At a separate 2-hour workshop, held approximately 2 months later, the research team will present the same participants (or substitutes if some cannot attend the second workshop) with a summary of currently existing indices (e.g. BB, HI, $UPC^{Patient}$ or $UPC^{GP\ level}$), or modified indices reflecting views on how RCC should be measured from the first workshop.[cxxxv,cxxxvi] To aid discussion, illustrations of the types of measures will be provided using analysis of anonymised primary care electronic health records data. A slide presentation showing the pros and cons of different measures will be shared and discussed with workshop participants.

Table 2: Illustration of pros & cons of different measures of relational continuity of care

Clinician group	Patient group	Criterion	Continuity index				
			SLICC	UPC	BB	HI	Secon
Consultations with GPs only	All ages	Understandable	Good	Good	Fair	Fair	Fair
		Unaffected by consultation rate	Poor	Poor	Good	Good	Fair
		Patient conception	Fair	Fair	Good	Good	Poor
		Clinician conception	Fair	Fair	Fair	Fair	Fair
	Aged 65+ only	Understandable					
		Unaffected by consultation rate					
		Patient conception					
		Clinician conception					
Consultation with all clinical staff	All ages	Understandable					
		Unaffected by consultation rate					
		Patient conception					
		Clinician conception					
	Aged 65+ only	Understandable					
		Unaffected by consultation rate					
		Patient conception					
		Clinician conception					

Facilitated group discussion will be used to map current tools against the characteristics identified in the first workshop. This process will enable the group to identify the extent to which each RCC index addresses the desirable characteristics. It will also identify what is unknown. The outcome of this phase will be a menu of RCC indices from which practices might choose depending on which characteristics they prioritise in a measure. If a

consensus emerges from the workshop participants about a single best RCC index, it will be reported. We will again audio-record these discussions and analyse the qualitative data in order to provide context and rationale to the final outcome. Acknowledging the challenges of integrating qualitative and quantitative data, all participants (patients, clinicians and researchers) will be involved in final decisions.[cxxxvii]

Output: A menu of approaches to measuring RCC for monitoring in primary care.

We do not anticipate agreeing on a single way to measure RCC, but expect to produce a menu of approaches, along with guidance to help practices choose the approach most appropriate to their particular needs.

illustrates assessing the pros and cons of different approaches.

8. Work package 2 Investigation of determinants of relational continuity of care & identification of outliers

RCC is influenced by the practice population's characteristics (age, sex and chronic disease status) and practice characteristics (practice size, patient turnover, clinician turnover, part-time working) and may be influenced by practice funding levels. We will investigate the determinants of RCC through analysis of a large primary care database, linked to data on practice funding and subjectively reported continuity. The overall aim is to investigate patient and practice-level determinants of measured RCC in general practices and to identify practices showing unusually high continuity given their characteristics.

Method

Clinical Practice Research Datalink (CPRD) collects fully coded and de-identified patient electronic health records from a network of GP practices using the Vision® (CPRD GOLD) or EMIS® (CPRD Aurum) software systems. We have full access to both datasets. CPRD includes records of clinical events (medical diagnoses), referrals to specialists and secondary care settings, prescriptions issued in primary care, records of immunisations/vaccinations, diagnostic testing, and all other types of care administered as part of routine general practice. Clinical information is captured as hierarchical Read codes, which are recorded by practice staff as part of routine data entry. CPRD data are broadly representative of the English general population.[cxxxviii] We will use data from the CPRD GOLD database for the period 1st January 2005 until the most recent data upload, with two additional linkages. One is to GPPS data (2007 onwards), to allow comparison between subjectively reported continuity to objectively and measured RCC. The other is to the General and Personal Medical Services database (NHS Digital), to obtain data on average funding per registered patient.

Measuring RCC

We will measure monthly RCC outcome at the level of general practice using the continuity index most strongly associated with health outcomes and resource use. The chosen index may differ to indices prioritised in **Error! Reference source not found.**, which are selected to reflect staff and patient preferences and are for internal practice use. To assess its construct validity, we will correlate practice-level measured RCC with annual subjectively reported RCC from the GPPS. Candidate predictors of RCC include patient characteristics

and practice-level characteristics, all measured monthly. Patient characteristics are mean age (a), percentage female ($f_{\%}$), prevalence of chronic disease ($CD_{\%}$) and prevalence of multimorbidity ($M_{\%}$). Chronic disease prevalence is the proportion of patients with one or more of the chronic diseases in the Quality and Outcomes Framework (QOF) and multimorbidity is the proportion of patients with ≥4 chronic diseases. We already have code lists for over 80 chronic conditions including those in QOF. Practice list size (L) is based on monthly counts and patient turnover (P_T) from monthly registration and deregistration data. We will determine total number of GPs (GP_n) in the practice month from the numbers with attributable consultations in that month. We will infer a GP has left when they have no consultations for >13-weeks and use this to calculate a monthly turnover rate of GPs (GP_t). We will do the same for non-GP clinicians if our RCC index requires it. We will infer part-time working from the usual pattern of weekday consultation over each month (consultations morning and afternoon on 5 days = full time) and calculate an appropriate summary measure of part-time working: percentage full time equivalent ($FTE_{\%}$). If available we will include linked data on practice funding per registered patient ($F_{£}$).

Regression Model

We expect to have roughly 15 years-worth of data, from 1800 general practices. Using monthly summaries will provide 180 (15×12 observations) for each practice. We will model the association between monthly RCC outcome and candidate predictors (listed above and including both patient and practice characteristics, all measured at the practice-level: a, $f_{\%}$, $CD_{\%}$, $M_{\%}$, L, P_T, GP_n, GP_t, $FTE_{\%}$, $F_{£}$) using regression analysis. To examine the independent contributions of these characteristics to RCC, the regression analysis will include all ten candidate predictors of interest in the model regardless of statistical significance - no stepwise variable selection will be used - as is recommended.[cxxxix] Using monthly practice summary statistics for each candidate predictor will ensure there will be no missing data in either candidate predictors or RCC outcome. Monthly practice RCC outcomes are expected to be correlated - with outcomes measured close in calendar time expected to be more highly correlated than those measured further apart in calendar time. To allow for this serial correlation all regression analysis will allow for auto-correlations. The exact form of these correlations will be dependent on the data, but we will explore various forms, such as auto-regressive structures as well as allowing for seasonality, using recommended approaches to identify best fitting structures.[cxl] The contribution of the ten candidate predictors will be modelled to allow for non-linear effects, and without categorising any continuous predictors.[cxli] Again, appropriate forms to model non-linear effects will be explored and are likely to include splines or fractional polynomials. To internally validate the model all coefficients and standard errors (including associated confidence intervals) will use bootstrap-based confidence intervals with shrinkage. The ability of the model to correctly identify high performing RCC practices will be summarised using calibration and discrimination statistics (again using appropriate shrinkage to avoid over fitting).

It has long been recognised that unusual variation in a process is more likely to have an assignable cause.[cxlii] Evidence from analysis and simulation shows that selecting case studies from outliers (deviant cases) is an efficient way to find out about causal pathways and causes of heterogeneity.[cxliii] We will identify potential case studies from the top decile of general practices over a period of one year. In the most recent year's data, we will use the derived prediction model to identify practices which, given their patient and practice characteristics, appear to be consistent high performers in RCC. Using the derived model, we will calculate a predicted monthly RCC for each participating general practice for each month. We can then calculate an observed to predicted ratio of RCC. These monthly practice level observed / predicted ratios averaged over the most recent year, ranked and practices in the top decile of these ratios identified.

Output

A model of the contribution of patient and general practice-level characteristics to trends and variations in RCC. An observed to predicted ratio of RCC in CPRD practices. A list of general practices in the top decile for RCC in the most recent data quartile for inclusion as potential case studies.

9. **Work package 3** Case studies to determine barriers and facilitators of RCC

Method

RCC is a complex and multi-faceted topic and therefore an exploratory multiple case study design is best suited to achieve our aim as this enables exploration and description of the complex underpinning links and processes in practices which display unusual RCC variation.[cxliv] Evidence from analysis and simulation indicates that selecting case studies from outliers (deviant cases) is an efficient way to find out about causal pathways and causes of heterogeneity.[cxliii] A similar method has been used to investigate wards providing safe hospital care.[cxlv]

Sampling

From 8 we will identify approximately 180 practices in each decile of observed to predicted ratio of RCC. In order to achieve the required depth and breadth of perspectives, we aim to recruit 8 practices as in-depth case studies.[cxlvi] Through CPRD we will purposively select 6 positive deviants (top decile) practices and 2 average practices (median decile). We will aim to include practices of diverse sizes, inner-city urban and rural locations, however CPRD's anonymity rules mean we are unable to identify individual practices in advance of recruitment and are thus limited to those which agree to take part.

Data collection

We will collate any practice documentation, guidelines or policies regarding RCC e.g. some practice websites emphasise RCC as an objective.[cxlvii] In each selected practice we will undertake 2 focus groups, each including between 6 and 12 participants: one with a range of clinical and non-clinical staff; and one with practice patient participation groups.[cxlviii,cxlix] These will be supplemented with semi-structured interviews with up to 3 key informants per practice (identified during the focus groups). This will provide transcripts from 16 focus groups and between 8 and 24 interviews in total. Amalgamating documentation and transcripts will enable us to undertake an in-depth analysis for each case and cross-case comparison. We will use a Framework approach to analysis as it is focussed, systematic and efficient.[cl] Based on our previous experience this is manageable, particularly if data are analysed as soon as it is collected.[cli] Data collection is illustrated in Table 3. Focus groups will inform subsequent interview topic guides. The focus groups and interview topic guides will explore positive and negative experience and effects of RCC from the perspective of patients, clinical and non-clinical staff and possible mechanisms by which RCC affects clinical care. This will specifically include the potential negative effects of higher RCC: the trade-off between access and continuity, potential burden on GPs, patient dependency on one GP and a lack of a second opinion. They will also explore examples of good practice in addressing barriers and facilitating RCC (e.g. patient engagement, organisational culture, appointments systems, leadership, philosophy, formal/informal policies on RCC).

In the focus groups the facilitator will enable discussion of RCC between practice staff allowing participants themselves to introduce and debate views and practice processes

around RCC and the areas in the topic guide.[cliii] We will take into account documented guidance for maximising success of focus groups in healthcare settings e.g. sample heterogeneity, difference in status of participants, timing of groups.[cliii] In contrast in the interviews the researcher and stakeholder will be involved in dialogue designed to explore that participant's responses to the areas within the topic guide. Within each practice we will also collect any documentation on formal or informal policies which refer to RCC.[cxlvi,cliv,clv] If required because of Covid-19 restrictions, focus groups and interviews will be conducted online using video conferencing software. We will follow best practice in this approach.[clvi]

Table 3: Data collection and analysis for case studies

Source	Data obtained	Analysis	Between practices
Focus groups (staff) - Clinical (GPs, nurses, allied health professionals) - Non-clinical (receptionists, practice managers) Interviews with key informants identified from focus groups	Staff experience Implementation of practice policies	Framework analysis	Cross-case comparison
Documentation of policies	Practice policies		
Focus groups (patients) - With and without long-term conditions - Older and younger - Diverse educational level - Diverse ethnicity Interviews with key informants identified from focus groups	Patient experience Experience of policies		

Data analysis

Focus group and interview data will be recorded, transcribed and entered into NVivo11 for data management. Thematic analysis of transcripts will be carried out using the Framework Method and themes compared within and across practices, focus group, interview and documentary data.[clvii] A summary of overall themes from their discussion will be sent to participants for comment. PPI representatives and members of the multi-disciplinary research team will read a selection of transcripts and documents, then discuss and agree on emerging themes to develop the data coding framework. Overall data will then be combined to seek common features associated with positive deviant RCC. To ensure robustness and quality our research is also guided by the COREQ checklist for reporting qualitative research.[clviii] We will follow good practice and consider or 'triangulate' our findings from the qualitative data with the findings from the other pieces of work in the study. Comparing individual findings to see where they might be similar or different is likely to provide additional insights and enhance understanding of overall findings. Overall findings will then be brought together and considered by the whole research team.[clix,clx] The overall aim is to understand in depth the internal features of general practices which are barriers and facilitators to RCC and how external features are experienced within practices.

Output

The primary output of 9 is an understanding of the practice characteristics which contribute to RCC and understanding of barriers and facilitators to RCC and the mechanisms by which RCC influences health.

A secondary output will be identifying individuals as potential advocates for general practices which have maintaining high levels of continuity. These may be research participants or individuals identified as champions within individual general practices.

10. **Work Package 4** Economic analysis of the effects of RCC

We anticipate that higher RCC may result in better information flow between patients and their GPs, potentially affecting: consultation rates and prescribing in primary care; unplanned inpatient admissions; A&E attendances; and outpatient appointments in secondary care. We also anticipate higher RCC may influence management of patients with specific chronic diseases (e.g. diabetes, COPD, asthma, mental health, dementia, heart failure) thus affecting health outcomes. We will analyse the potential effects on resource use and health outcomes of changes in practice-level RCC using patient-level data. We will analyse the effects across different population groups within the registered practice population.

Data

We will use primary care data from the CPRD database from 1st January 2005 until the most recent upload, with standard linkages to: i) Hospital Episode Statistics data (including inpatient admissions, outpatient appointments and A&E attendances), ii) Office for National Statistics (ONS) mortality data, and iii) area level deprivation. We will also use one non-standard linkage to funding per patient. CPRD Gold includes about 9 million patients eligible for linkage, in around 400 general practices and CPRD Aurum 38 million eligible patients in around 1400 general practices.[clxi]

We will analyse the effects of RCC on i) two types of primary care use: consultations and prescribing; ii) three types of hospital use, unplanned admissions, A&E presentations, outpatient appointments; iii) costs, and iv) mortality. We will identify primary care activity from the CPRD records of consultations, clinical events, and prescription records and secondary care activity from HES inpatient, outpatient and A&E records. We will cost primary and secondary care activities using a methodology that we have previously used.[clxii]

Method

We will undertake a patient-level analysis with the explanatory variable of interest (RCC) measured at practice level. We will undertake preliminary analyses to explore the relationship between RCC and unplanned admissions (the main driver of costs) over time. If the relationship was altered during the pandemic years we will consider whether to model pre-pandemic and post-pandemic years separately. We will also undertake preliminary analyses to explore whether the relationship between RCC and unplanned admissions varies by chronic disease status (using chronic diseases included in the Quality and Outcomes Framework) to determine whether analysis should be stratified by chronic disease status.

The study population will consist of patients who were registered with a GP practice any time during the period from 1 January 2006 to 31 March 2021 (or the most recent CPRD upload available). We will observe these patients until outcome or censoring, where censoring is due to the patient changing GP practice, death, or the end of the study period (date of last upload). The observation period for each patient will be divided into periods of 3 months and outcomes will be binary variables indicating whether or not the particular event occurred in each 3-month period (except from costs which are a continuous variable). For instance, a

patient who was first observed on 1st January 2017 and experienced an inpatient hospitalisation in March 2018 will contribute to the data in five quarters: four quarters in 2017 where the outcome takes values of zero and one quarter in 2018 where the outcome takes a value of one. The resulting dataset will be an unbalanced panel as individuals contribute to the sample in a different number of quarters. RCC will be measured at practice level over the 12 months prior to the outcome period using the indices from **Error! Reference source not found.** and 8 (e.g. in the above example the RCC associated with patient's first observation will be measured over the period 1st January 2016 – 31st December 2016). We will include a mix of patient level confounders such as age, sex, deprivation status, ethnicity, chronic disease status, prior healthcare utilisation and practice level confounders such as practice size, practice funding, staff turnover and part-time working.

We will employ discrete time survival analysis to evaluate the association between risk of each outcome in a particular 3-month period and RCC in the prior 12 months. Specifically, we will estimate complementary log-log (cloglog) models (the discrete-time analogue of the continuous-time proportional hazards models) which are appropriate when an outcome occurs rarely.

Output: A model assessing the impact of changes in RCC on healthcare resources and health outcomes. The model will describe the effects of changing RCC on different population groups.

11. **Work package 5** Develop empirically informed practical guidance to help to improve RCC in primary care

We anticipate varied within-practice policies will contribute to maintaining RCC in different general practices and varying factors which may adversely affect continuity. Some strategies or principles will be context specific and others more generalisable. The final phase of this research is to collate and integrate findings from different settings and work-packages, generate and disseminate learning, and create impact. 11 uses co-design principles and methodologies to develop guidance on how to improve and enhance RCC.

Our aim is to develop empirically-informed practical guidance to help general practices optimise RCC, using a behaviour change framework and disseminate findings to stakeholders.

Method

We will undertake a rapid review of evidence on within-practice interventions (e.g. the Health Foundation pilot projects, the TOOL study, any other published or grey literature studies), making use of ongoing reviews on this topic.[clxiii] We will follow good practice and consider or 'triangulate' findings from the evidence review and from our own study's work packages: 8 (determinants of RCC), 9 (detailed case-studies) and preliminary results from 10 (economic analysis). Each separate WP will have individual and stand-alone findings analysed separately using techniques appropriate to their methods, but we will additionally look at all of the different sets of findings together, to identify what each contributes to the overall picture. Overall findings will then be brought together and considered by the whole research team. We will convene two 3-hour deliberative facilitated workshops (either face-to-face, hybrid or online) to integrate these findings and develop practical guidance on how best to improve RCC. This process will be informed by existing research on how to ensure the needs of diverse groups are taken into consideration.[clxiv] 11 follows the MRC framework.[clxv] It synthesises an understanding of determinants of RCC within a wider context (8), evidence on the within-practice impacts of policies to increase RCC (9), estimates of the value of RCC

relative to the resources required to deliver it and how it contributes to system change (WP4), to build an overall understanding of how to develop optimal policies to improve RCC.

Sampling

As with **Error! Reference source not found.**, participants will include a purposive sample of clinical and non-clinical professionals and patient representatives. Workshop participants from **Error! Reference source not found.** will be given the opportunity to participate again. If needed we will recruit additional participants, drawing on networks and groups identified through **Error! Reference source not found.**, 8 and 9 while continuing to ensure diversity. To help workshops run efficiently we will again use a professional facilitator. The aims of the facilitated workshops are to co-design guidance on optimising RCC, to identify practical strategies to overcome barriers to RCC optimisation and to develop an action plan for implementation.[clxvi] It also will ensure the recommendations are acceptable to both patients and clinicians, and that they are realistically deliverable.[clxvii]

Data collection

The first workshop will therefore be carried out with the patients only (n ≈ 15), in order to determine their views. In this workshop we will investigate what role patients and the public might have in facilitating RCC in different settings. We will explain the background to the project and share preliminary findings from our case-studies (9) on the characteristics of general practices with high RCC and the perspectives of staff and patients in these practices. We will also share relevant findings on measurement of RCC (**Error! Reference source not found.**), on external practice-level characteristics linked to RCC (8) and from our economic analysis (10). Before the workshop we will provide the findings in written form, for participants to read and will briefly present the findings at the start of the workshop. We will ask participants to reflect on the evidence in relation to their own experience, to identify which practice characteristics might form the basis of practice policies which are acceptable to patients and feasible for general practices. We will also ask them to consider any potential negative effects of greater RCC, including effects on access, and to identify possible knowledge gaps. To encourage discussion, participants will be broken up into smaller groups (6 or less). At the end of the workshop, its headline conclusions will be summarised, to ensure these have been captured accurately. Workshop notes and minutes will be collated and summarised by the research team, then circulated to workshop participants for their final approval.

In the second workshop both patients and practice staff (n ≈ 30) will meet together for joint discussion. We will again provide the findings from 9 in written form for participants to read before the workshop and briefly present findings at the start of the workshop. For the second workshop this will include a brief overview of the findings of the first (patient) workshop. We will ask participants to identify practice characteristics which might form the basis of acceptable and feasible practice policies on RCC. We will ask them to consider how each policy might work (IF □ THEN logic model) and how a practice might find evidence they are working. We will ask participants to achieve satisfactory agreement on the information content and medium of delivery of a final report on optimising RCC. We will also ask participants to identify any knowledge gaps. To encourage discussion participants will be broken up into smaller groups (6 or less). Overall conduct of the workshop will be overseen by the professional facilitator. Two members of the study team will facilitate the small groups, the workshop will be audio-recorded with recordings deleted following verification of anonymised transcript. Transcripts will be analysed using the principles of Framework analysis with the specific purpose of informing the development of good practice principles to support RCC.[clxviii] Following the workshop deliberations, the key conclusions of the workshop

will be summarised at the end of the workshop. This will include possible actions to improve continuity, the logic model explaining how the actions achieve their effect and practical ways a practice could seek evidence they are working (e.g. structural changes, process measures or by assessing interpersonal process). We will map these to appropriate frameworks depending on whether they are intended to influence individuals (e.g. change patients', receptionists' or clinicians' behaviour) or to alter processes (e.g. appointment systems, named GPs, micro-teams). The research team will then draft a written document with recommendations and circulate this to participants for final comment.

We have experience of developing guidance for general practices in this way. In a previous study on communication of diagnostic test results we identified six areas of weakness in communication of diagnostic test results in general practices and proposed solutions. Practices and patients were then asked to consider which were most pertinent, acceptable and logically feasible in their own practice and we worked with them to decide which measures would be adopted, the operational requirements and timescale.[clxix]

Output: From these workshops we will develop guidance deriving from existing research, 8, 9 and 10 on how practices can improve RCC whilst continuing to meet other requirements and objectives. 11 will produce in-depth empirical data on the strategies for increasing and/or maintaining RCC in primary care settings. We will document the full range of these strategies and interventions and provide a summary of evidence on their efficacy and implementation in different settings. These outputs will be a key part of our dissemination and knowledge exchange activities and will therefore inform practice in the immediate term. We will also identify areas where there might be a need for intervention *adaptation* or de novo intervention development and put forward evidence-based recommendations for how this should be pursued.

Data storage

Personal data will be collected and subject to analysis and we will observe the following regularity processes:

Personal data will be collected from participants after they have provided written consent. Data relating to participants will be assigned a unique identifier. Audio files from the workshops will be transferred from the encrypted audio recorder into an encrypted folder on to the secure university server as soon as possible after the workshops. The recordings on the digital audio recorder will be deleted as soon as successful transfers to University of Birmingham secure servers have been confirmed. The audio files will be securely shared with an approved transcription service authorised by the University of Birmingham. Only anonymised quotes from the transcript will be used in any publications or reports arising from the data. Personal data will be encrypted and password protected and only accessed by agreed members of the team. Anonymised data will be stored on a secure server within the University of Birmingham for a period of 10 years. If a participant decides to withdraw after the workshop has taken place, the data they provided up to that point will still be used in subsequent analysis. All essential documentation and study records will be stored by the study team in accordance with the applicable regulatory requirements and access to stored information will be restricted to authorised personnel including sponsor representatives and regulatory authorities. The main study portfolio will be kept in the Institute of Applied Health Research, University of Birmingham.

Appropriate controls will be in place to ensure be in place to ensure that access to confidential research information is restricted to those who need access. Researchers at the University of Birmingham will only have access to anonymised transcripts for the purposes of

future research. Completed consent forms will be stored in a study folder in a secure locked cabinet in the trials unit/ IAHR. All audio material will be stored on secure servers at the University of Birmingham accessible to authorised research personnel only. All data will be anonymised ahead of analysis. All workplace issue laptops are secured by VPN login and code authentication. All data on the University of Birmingham secure drive is protected.

Safety reporting

The study Investigators and research team will observe appropriate safeguarding regulations for data handling as set out in The University of Birmingham's Data Management Policy and Procedures accessible here: Research Data Management Policy (birmingham.ac.uk) and the Data Security Policy is here: https://www.birmingham.ac.uk/Documents/university/legal/data- prot-policy.pdf. Research data will be kept on University of Birmingham computer servers. These guidance documents will be observed to ensure the protection of the rights, safety and wellbeing of research participants.

The data collected during the study will be archived as per the University of Birmingham Data Management Policy and all access will be removed unless access is requested directly from the chief investigator. The University of Birmingham's Data Security Policy is here: The University of Birmingham Data Protection Policy

Research data will be kept on University of Birmingham computer servers. Once the study has been completed and results published, data accesses will be limited to the chief investigator, the research team and IT staff at the University of Birmingham.

12. Ethical and regulatory considerations

The main ethical questions relate to participant anonymity and the safeguarding of any private data. These will be addressed in the WP1 application and in greater detail for the HRA processes for WP3 and WP5 where we will submit data collection instruments such as topic guides for review.

We will ensure informed consent for all workshops and will provide potential participants with information about the study, and time to consider participation. Data will be stored in line with institutional policies as set out above. Workshop participants will not be named or identifiable and we will use pseudonyms to report any direct quotes.

Assessment and management of risk

Success in WP1 would be developing guidance for general practices on how they can measure their own RCC. There are few risks to achieving this as there is no requirement that we reach agreement on measurement, just an understanding of what criteria need to be considered.

Clinicians will receive payment for taking part in workshops which is considered appropriate and fair at locum rates and does not constitute a coercive inducement.

Patient participants will receive INVOLVE rates of £25.00 per hour and be reimbursed for their travel costs. These are considered appropriate rates and determined by NIHR and INVOLVE recommendations.

Research ethics committee (REC) and other regulatory review & reports

Before the start of the study, a favourable opinion will be sought from the REC and also approval from the HRA.

- Substantial amendments that require review by NHS REC will not be implemented until that review is in place and other mechanisms are in place to implement at site.
- All correspondence with the REC will be retained.
- It is the Chief Investigator's responsibility to produce the annual reports as required.
- The Chief Investigator will notify the REC and sponsor of the end of the study.
- An annual progress report (APR) will be submitted to the REC and sponsor within 30 days of the anniversary date on which the favourable opinion was given, and annually until the study is declared ended.
- If the study is ended prematurely, the Chief Investigator will notify the REC and sponsor, including the reasons for the premature termination.
- Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC and sponsor.

Before any site can enrol participants into the study, the Chief Investigator/Principal Investigator or designee will ensure that appropriate approvals from participating organisations are in place.

Regulatory review & compliance

The study Investigators will observe the principles of the UK Policy Framework for Health and Social Care Research which sets out principles of good practice in the management and conduct of health and social care research in the UK including responsibilities for the four elements of research transparency:

1. registering research studies
2. reporting results
3. informing participants
4. sharing study data and tissue

All research staff have completed good clinical practice training and will observe regulations and ethical procedures advised by the Sponsor following ethical review and the Authority as set out in the contract dated 13 October 2022 which protect the rights, safety and wellbeing of research participants. In the QUERCC study the principal safeguards apply to the handling and storage of data as follows:

Appropriate controls will be in place to ensure that access to confidential research information is restricted to those who need access. Researchers at the University of Birmingham will only have access to anonymised transcripts. Completed consent forms will

be stored on secure servers at the University of Birmingham accessible to authorised research personnel only. All data is anonymised ahead of analysis. All workplace issue laptops are secured by VPN login and code authentication. All data on the University of Birmingham secure drive is protected. Personal data will be collected from participants after they have provided written consent. Data relating to participants will be assigned a unique identifier. Audio files from the interviews will be transferred from the audio recorder into an encrypted folder on to the secure university server as soon as possible after the workshops. The recordings on the digital audio recorder will be deleted as soon as successful transfers to University of Birmingham secure servers have been confirmed. The audio files will be securely shared with an approved transcription service authorised by the University of Birmingham. Only anonymised quotes from the transcript will be used in any publications or reports arising from the data. Personal data will be encrypted and password protected, and only accessed by agreed members of the team. Anonymised data will be stored on a secure server within the University of Birmingham for a period of 10 years. All essential documentation and study records will be stored by the study team in accordance with the applicable regulatory requirements and access to stored information will be restricted to authorised personnel including sponsor representatives and regulatory authorities. The main study portfolio will be kept in the Institute of Applied Health Research. University of Birmingham

Amendments

If the sponsor recommends or study team request to make changes to any aspect of the study a request for an amendment will be submitted to the appropriate regulatory bodies (as appropriate).

Both minor and substantial amendments will be submitted to the sponsor for review and approval prior to submission on IRAS and subsequent approval by relevant regulatory bodies and participating sites.

Peer review

The research study was peer reviewed by NIHR during the funding submission.

Patient & public involvement

During the development of this proposal, we consulted eight patients in two focus groups in 2019. Participants provided views on the importance of the research, their perception of changes in continuity of care, measuring continuity of care and possible problems with high continuity of care. Participants felt researching continuity was important. They all shared experiences of lack of continuity of care and stressed the importance of a personal relationship with a general practitioner (GP). Advantages included not needing to explain their circumstances at every visit and avoiding unnecessary medication changes. All acknowledged the importance of continuity, especially for older patients and those with long term conditions. There was a shared perception that continuity of care is becoming more difficult with pressure to provide better access.

They identified part-time working by GPs and larger surgeries with many GPs as important factors. Some also indicated that automated booking systems had a key role impeding continuity, others said receptionists had a big influence on which doctor was seen. Because

of the need to be both savvy and assertive to maintain continuity, and that patients with language barriers, disability, or mental health conditions were disadvantaged. Continuity in primary care was thought to be better than in secondary care. When discussing measurement of continuity, participants were clear that continuity does not necessarily have to be with a single GP, or even with a single healthcare professional. Continuity could be seeing 2 or 3 GPs for most of their care or even a multi-disciplinary team. Participants also thought it important to take account of views of healthcare professionals' views on continuity. Considering drawbacks of continuity, some participants mentioned the value of a second opinion. Others acknowledged that a practice focus on access would compromise continuity, implying that continuity and access could be conflicting objectives.

We found considerable agreement between the personal observations and intuitions of our patient participants and the findings of published research on continuity. This suggests patients have considerable insight into continuity and can play an important role in shaping this research. Changes following lay consultation In published research, objectively measured continuity has only considered consultations with doctors. One of the most common measures (usual provider of care index) only takes account of consultations with a one doctor. Our consultation with patients suggests this does not reflect lay conceptions of continuity. A measure of dispersion (number of different clinicians), including consultations with non-doctors would more closely reflect their views. We therefore included a work package where the views of patients, clinicians and researchers are discussed to try to improve our understanding of what continuity means to different stakeholders and how it should be measured. Prompted by observations about possible drawbacks of continuity we also propose to explicitly explore the trade-off with access and other possible disadvantages in our case studies. We recruited a workshop participant as a lay co-applicant. He will chair a Patient Advisory Group, contribute to interpretation and analysis of interviews focus groups. We followed the advice of our lay co-applicant to create a project website and commission a short animation version of our final report.

A Patient Advisory Group of 6-8 members of the public drawn from a range of backgrounds will meet three monthly and provide into the monthly Project Steering Group meeting. PPI input will be ongoing throughout the management of the project. Our lay co-applicant (KS) will chair the Project Steering Committee and will contribute to recruitment of a Patient Advisory Group (PAG) of 6-8 participants. Patient advisory group (PAG) members will receive a description of the roles and expectations of the lay advisory Group in advance of recruitment. PAG membership will be offered both to lay people with and without previous experience of PPI.

Protocol compliance

Should any unforeseen issues to arise during the course of the study that may affect the safety or integrity of the study data or participants the Investigators team will manage these as protocol deviations as set out by the UoB Quality Management System https://www.birmingham.ac.uk/research/activity/mds/mds-rkto/governance/qms.aspx. The PI team will take corrective and preventative measures to avert further breaches. Any incident observed by study researchers will be reported to the PI and used to advance improvement.

Data protection and confidentiality

Data from the workshops will be stored on a secure server at the University of Birmingham and will be electronically archived (10 years) according to the University of Birmingham's Research Governance Framework. Participants will not be named or identifiable and we will use pseudonyms to report any direct quotes. Data will be treated as confidential at all times including during collection, handling and use. Personal Data will be stored securely on University servers to prevent unauthorised access or disclosure.

The workshop recordings will be transcribed by a professional transcription company that holds a contract with the University. All data once deposited back at the university will be anonymised (all names and other identifiable information will be removed) by a professional company that is approved by the University of Birmingham and will sign a confidentiality agreement. The recordings will be transferred to them through a secure file transferring website. The transcription company will delete the recording once the study team have approved the accuracy of the transcript. The recording will be deleted from the handheld secure audio recorder once the transfer is complete. A copy of the recording will be stored and saved to a secure computer at the University of Birmingham and once it is deleted from the recorder. Audio recordings will be stored until the end of the project. Transcription and analysis will be complex on this project because we are using a workshop methodology involving a range of different speakers and checks will need to be made to determine which speaker has contributed an idea or viewpoint.. This will require careful tracking of voice across recordings – to be completed by the study RF. Transcripts will be kept for 10 years once the study ends. Transcript information will be kept and analysed on the University of Birmingham computer servers. Only designated members of the research team who hold a DBS / research passport and current Good Clinical Practice certificate will have access to these personal details.

University of Birmingham. The sponsor is the legal data controller for data collected and its data management policies are fully compliant with Data Protection Legislation, HRA guidance contained in the UK Policy Framework for Health and Social Care Research, and The Concordat to support Research Integrity. The Principle Investigators are employees of the study sponsor and use methods that are scientifically sound, safe, ethical, legal and feasible and remain so for the duration of the research, taking account of developments while the research is ongoing.

Indemnity

The University has in force a Public Liability Policy and/or Clinical Trials policy which provides cover for claims for "negligent harm" and the activities here are included within that coverage. .

End of study and archiving

Data from the workshops will be stored on a secure server at the University of Birmingham and will be electronically archived (10 years) according to the University of Birmingham's Research Governance Framework.

Access to the final dataset

The research team will observe the University of Birmingham's Policy on Research Data Management (RDM). The policy lays out requirements and responsibilities for the University and for researchers as currently understood. It will be updated annually as the external landscape develops and amendments will be approved by the University's Research Committee. The Concordat on Open Research Data [PDF - 178kb], as produced by HEFCE, JISC, RCUK, UUK and Wellcome, sets a framework for best practice within UK HEIs with respect to the management of all research data, and has guided the formulation of key aspects of this Policy.

13. Dissemination policy

Dissemination will make use of a number of methods tailored to each audience. We will seek to maximise impact through a range of pathways, and these will be a standing agenda item on project team and steering group meetings.

Debates about continuity of care to date have been led by clinicians and researchers. A key benefit of our work is involvement of the public and a key output will be in making publicly accessible the findings of our research on the causes of declining RCC, its effects and solutions to the problem. For a lay audience, we will create a project website and commission a short animation version of our final report to communicate findings in an accessible way. A project website will make available regular publicly accessible bulletins of interest to the general public. We will ensure these bulletins are press released so that the media are aware of each developing stage of the research. We will write short articles for relevant forums online and international newspapers. We will initiate a social media campaign to garner interest in our findings and share information about the project, and will share research progress and encourage feedback via blogs and personal stories of continuity of care. Through our digital profile we will engage with patient representative groups and 3rd sector organisations as intermediaries and knowledge brokers to help us develop an effective implementation and dissemination strategy and to ensure we engage heterogeneous groups of stakeholders.

For an academic audience we anticipate a report for NIHR and five peer-reviewed publications: a shared understanding of measures of RCC (BJGP, BMC Fam Pract); an analysis of the determinants of RCC in UK primary care (BJGP, BMC Fam Pract); learning from our case study practices (BMJ, Ann Fam Med); practical guidance to improve RCC (BJGP, BMC Fam Pract); an economic analysis the effects of RCC (BJGP, BMC Fam Pract). We will present our findings at SAPC and RCGP conferences. After **Error! Reference source not found.** we will engage with software manufacturers (Samir Dhalla of Cegedim and Chris Bates of TPP) to share findings on measurement of RCC in primary care to stimulate work on development of tools to measure RCC. We will provide an interim report on measurement of RCC and a final report on completion of 11 to regional GP networks (Dudley Integrated Care Service, Our Health Partnership), to national bodies (the RCGP and

NHS England). To directly reach primary-care clinicians we will develop a podcast or short video with the Personalised Care Institute to disseminate to clinicians and have fully costed development of two webinars and a package of marketing and communications with the RCGP. University of Birmingham's Centre for Primary Care Improvement will create a postgraduate module for primary care professionals on managing continuity of care. We will write a brief lay summary for use as a discussion document at practice Patient Participation Groups.

Authorship eligibility guidelines and any intended use of professional writers

The PIs will follow the guidelines on authorship as set out in The International Committee of Medical Journal Editors has defined authorship criteria for manuscripts submitted for publication, known as the Vancouver Protocol on the final report.

14. Appendices

If the sponsor recommends or study team request to make changes to any aspect of the study a request for an amendment will be submitted to the appropriate regulatory bodies (as appropriate).
Both minor and substantial amendments will be submitted to the sponsor for review and approval prior to submission on IRAS and subsequent approval by relevant regulatory bodies and participating sites.

The PI and study team are responsible for the decision to amend the protocol in consultation with Research Governance team at University of Birmingham and the REC determine if the amendment is substantial or non-substantial. Substantive changes will be communicated to relevant stakeholders [REC, R&D, regulatory agencies RRDN]. Amendment history will be tracked to identify the most recent protocol version.

Appendix 1 – Study Documentation

WP1: final document set assessed and approved by HRA and HCRW Approval is listed below.

- QUERCC volunteers needed for research finalised 1.0 18 July 2023
- Insurance letter RG_22 174_signed_28 July 2023
- QUERCC workshop topic guide_1.0 02 June 2023
- IRAS Application Form [IRAS_Form_31072023] 31 July 2023
- Letter from funder 24 July 2023
- Sponsor letter RG_22-174_signed_28 July 2023
- Email invitation to clinicians and researchers vs 1.0_finalised 02 June 2023
- ED monitoring form vs 1.0_finalised 02 June 2023
- Consent to contact form vs 1.0_finalised 18 July 2023
- SCHEIBL CV signed and dated 26 6 2023
- REMINDER email clinicians and researchers vs 1.0_finalised18 July 2023
- Study consent form protocol vs 1.0_finalised 02 June 2023

- Participant information sheet 1.0_finalised 10 July 2023
- NIHR152277-Stage two application (long duration) 07 April 2022
- WP1 protocol vs 1.0 _2 6 2023 _finalised 02 June 2023
- SoECAT [Schedule-events-excel IRAS ID 329566 _RG 22174_24 July 2023
- Summary CV for Chief Investigator (CI) [CV (2023) 2 page _TM_1.0 03 May 2023
- Summary of any applicable exclusions to sponsor insurance (non NHS sponsors only) Products_28 7 2023

WP3 final document set assessed and approved by HRA and HCRW Approval is listed below.

- OID RG_23-141
- SOECAT
- IRAS form signed by sponsor on 6.12.2023
- Protocol vs 113/09/2023
- Protocol vs 2 1/8/2024
- Protocol vs 3 21/1//25
- Protocol vs 4 27/3/2025
- Staff invite vs 1.3 14/03/2024
- Lay persons invite 1.3 14/03/2024
- CPRD Template letter vs 1 23/08/2023
- Poster vs 1 09/11/2023
- ED Form vs 1.207/03/2024
- CTC focus group vs 1.1 01/03/2024
- CTC Interview vs 1.1 01/03/2024
- Staff focus group topic guide vs 1 21/03/2024
- Patient focus group topic guide vs 1.3 14/03/2024
- Staff Interview topic guide vs 0.1 21/03/2024
- Patient Interview topic guide vs 1.3 14/03/2024
- Focus group consent form vs 1.3 14/03/2024
- Interview consent form vs 1.3 14/03/2024
- PIS Focus group staff vs 1 23/08/2023
- PIS interview staff vs 1 23/08/2023
- PIS focus group patients vs 2.10/04/2024
- PIS interview patient vs 2. 10/04/2024

Appendix 2 – Schedule of Procedures

not applicable

Appendix 3 Amendment history

The following amendments and/or administrative changes have been made to this protocol since the implementation of the first approved version

Amendment number	Date of amendment	Protocol version number	Type of amendment	Summary of amendment
AM01	1.8.2024	WP3 sub protocol 2.0	AM	Add snowball sampling as method to WP3. Required change to protocol. Supplementing sampling for WP3 with a snowball approach is required due to any potential delays in approvals for WP2 data linkage of CPRD data.. It is imperative therefore to pre-empt and avert the risk of low recruitment to WP3. The snowball sampling approach will ensure that WP3 can commence data collection and the delays caused by delay in approvals for WP2 can be mitigated. To follow the snowball sampling approach through we will draw on contacts across professional networks and desk research. We have made contacts with sites fitting the criterion of high and average RCC during our engagement with clinical stakeholders during WP1. Some WP1 stakeholders volunteered sites known to them as high performing or interested in improving their RCC. Additionally, some primary care sites identify themselves as high performing on RCC on their study website. To follow this snowball method through we will identify a contact at the site and approach them directly and send them a copy of the invite letter (Letter template CPRD vs 1.0 23 8 2023) asking them to participate. If the partners at the site agree to take part, we will contact the relevant CRN / RD office to obtain LoA approvals. When these are in place we will proceed with recruitment. Analysis by the PI (Professor Tom Marshall) using data obtained from GPPS (General Practice Patient Survey) gives details of when patients report on how often they can see the doctor of their choice / preference. These data give some indication of RCC and can be used as a proxy to identify primary care sites that are performing high on relational continuity of care. Using these combined strategies we will invite sites to join the study.
NSA01	22.8.2024	WP3 sub protocol 2.0	NSA	Add CRN/ RDN as research partners no change required to protocol. To further advance the progress of data collection the PI team requested a minor amendment listing all CRN sites as potential partners. North East and North Cumbria North West Coast Yorkshire and Humber Greater Manchester East Midlands West Midlands West of England Thames Valley and South Midlands East of England Kent, Surrey and Sussex Wessex South West Peninsula North Thames South London
NSA02	2.12.2024	WP3 Subprotocol 2.0	NSA	Change made to a study document [CPRD invite letter on the request of CPRD research lead] which required no change to the protocol. The change to the letter was to insert the email addresses of all CRN/RDN partners into

				the letter so that primary care contacts can follow up with their service support partners as required to request support with joining or taking part in QUERCC in WP3.
NSA03	9.1.2025	WP3 Subprotcol 3.0	NSA	Add GPPS to sampling method in WP3. This required change to protocol as a methodological change. There have been delays with the release of data and contracts from CPRD in WP2 and letters of invitation to high performing primary care sites have not been sent out. Due to these delays WP3 of the project is running 6 months behind schedule. We already sought and obtained approval to use snowball sampling to recruit high performing practices to compensate for this delay. We now want to add the use of data from the General Practice Patient Survey. We seek permission for this because GPPS data will permit data triangulation. We can check that the sites we identify using snowball methods are high performing on relational continuity using an alternative question included in the GPPS [do you see your preferred GP always, a lot of the time]. We can also identify high performing sites and write to them directly to ask them to join the study. This amendment does not seek to replace the use of CPRD data to identify high performing sites. It is intended to supplement sample selection and overcome delays.
NSA04	2.4. 2025	WP3 Subprotocol 4.0	NSA	Add another researcher to contribute to data collection and analysis in WP3. Study documents were changed to reflect their role in data collection and the protocol. An additional researcher [Serge Engamba, currently in contract at the University of Exeter and a clinician] is added to the research team to undertake data collection on WP3. SE has an honorary contract at UoB and will collect qualitative data in interviews recruited to case study in WP3. The purpose of adding Serge Engamba to the research team is to increase data collection. No additional scientific critique has been obtained. SE will use a secure laptop to collect and analyse data for online focus groups and interviews and will collect data face to face using a handheld recorder [as per protocol below]. Consent will be obtained by email from participants and witnessed in the online interview or focus group. No data will be collected or stored on Exeter servers or research instruments. A range of guidelines have been discussed to enable Serge to collect data as follows: - SE will be issued with a UoB recorder to conduct and record face to face interviews / focus groups - SE will be issued with a UoB laptop for data collection online using teams and or zoom - All data will be stored (recordings) on a UoB laptop - SE will use the transcription service already in use by UoB team - SE will get a UoB email address with the honorary contract. This email address will be added to the invite letter and information sheet so contacts can be made with practices. - If a general practice agrees to take part in the study, SE will apply to relevant RDN to obtain a Letter of Access from the appropriate regional Research Delivery Network (used to be called the Clinical Research Network) SE will follow the approved procedures for consent as stated in WP3 protocol

				- The retained copy of the consent forms, this is a paper copy will be signed and returned to UoB - SE will share the study RISP [Research Information Sheet for Practices] which sets out the payments available to sites and what taking part involves for them. - SE will use the Local Information Pack, OiD and SoECAT in line with protocol and share will share with the sites and RDN once a site expresses interest. Study documents will be made accessible through secure University of Birmingham area on Share Point and the study RF [Fiona Scheibl] will provide guidance to the use of said documents and the process as part of an induction to the team.

APPENDIX 4 SUB PROTOCOLS

SUB - PROTOCOL WORK PACKAGE 1

Title page

Full/long title of the project **Q**uantifying, **U**nderstanding and **E**nhancing **R**elational **C**ontinuity of **C**are

Short title/acronym QUERCC

Protocol version number and date

PROTOCOL VERSION NUMBER AND DATE	V_1.0 dated 2/6/2023
IRAS NUMBER	IRAS Project ID: 329566
SPONSORS NUMBER	UoB RG_22-174
REC REFERENCE NUMBER	23/SW/0101
PUBLIC REGISTRY NUMBER	
FUNDERS NUMBER	HS&DR Project: NIHR152277

Signature page

The undersigned confirm that the following protocol has been agreed and accepted and that the CI agrees to adhere to the signed University of Birmingham's sponsorship CI declaration.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the project will be given; and that any discrepancies from the project as planned in this protocol will be explained.

Full project title:	**Q**uantifying, **U**nderstanding and **E**nhancing **R**elational **C**ontinuity of **C**are
Protocol version number:	1
Protocol version date:	02.06.2023

Chief Investigator (CI)	
Name:	Professor Tom Marshall Institute of Applied Health Research College of Medical and Dental Sciences University of Birmingham Edgbaston Birmingham, B15 2TT
Date:	**2 6 2023**
Signature:	

Sponsor statement

Where the University of Birmingham takes on the sponsor role for protocol development oversight, the signing of the IRAS form by the sponsor will serve as confirmation of approval of this protocol.

Key contacts

Chief Investigator	Professor Tom Marshall Primary Care Clinical Sciences Institute of Applied Health Research College of Medical and Dental Sciences University of Birmingham Edgbaston Birmingham, B15 2TT
Study Co-ordinator	Dr Fiona Scheibl Research Fellow Institute of Applied Health Research College of Medical & Dental Sciences University of Birmingham Edgbaston Birmingham B15 2TT
Sponsor	Research Governance University of Birmingham Edgbaston Birmingham B15 2TT Research Strategy and Services Central researchgovernance@contacts.bham.ac.uk
Joint-sponsor(s)/co-sponsor(s)	n/a
Funder(s)	The Authority's Representative for contract management purpose: Dr Kay Pattison Science Research and Evidence Directorate Department of Health and Social Care Quarry House Quarry Hill Leeds LS2 7UE The Authority's Representative for project management purposes: NETSCC Operations Finance Alpha House Enterprise Road Southampton Science Park Southampton SO16 7NS
Key Protocol Contributors	Professor Tom Marshall Primary Care Clinical Sciences Institute of Applied Health Research College of Medical and Dental Sciences University of Birmingham Edgbaston B15 2TT Telephone +44 (0)121 414 7832 Email: t.p.marshall@bham.ac.uk

	Professor Shelia Greenfield Institute of Applied Health Research College of Medical and Dental Sciences Murray Learning Centre University of Birmingham Edgbaston B15 2TT Telephone: +44 0121 414 6493 Email: s.m.greenfield@bham.ac.uk Professor Iestyn Williams Director of Research School of Social Policy Health Services Management Centre, Park House University of Birmingham Edgbaston B15 2RT Tel:+44 121 414 7063 Email: i.p.williams@bham.ac.uk Professor Krishnarajah Nirantharakumar Health Data Science and Public Health Institute of Applied Health Research University of Birmingham Edgbaston B15 2TT tel:+44 121 414 8344 k.nirantharan@bham.ac.uk Dr Brian Willis Senior Clinical Lecturer in General Practice & MRC Fellow Institute of Applied Health Research University of Birmingham Edgbaston B15 2TT b.h.willis@bham.ac.uk tel:+44 121 414 7949 Dr Panagiotis Kasteridis Research Fellow Health Economics Centre for Health Economics University of York Panos.kasteridis@york.ac.uk (01904) 321429 Mr Kamil Sterniczuk Lay co-applicant Lay advisor. Chair patient advisory group, Institute of Applied Health Research University of Birmingham Edgbaston B15 2TT kamil.sterniczuk@gmail.com

Project summary

Relational continuity of care (RCC) is the extent to which patients see the same clinicians over time. Considered a core feature of general practice, it is linked to patient satisfaction and better health outcomes, especially for older patients, those with long-term conditions and the vulnerable. Although current NHS policy is to maintain continuity for patients with long-term conditions, it has been declining for at least a decade. Contributing factors are thought to include growth in practice size, more part-time working, greater staff and patient turnover. It may also be because practice policies have focused on access, rather than continuity.

Because they often neither measure nor monitor it, general practices may be unaware how their within-practice policies impact RCC. Furthermore, conceptions of RCC differ between clinicians and between patients, and there are different ways of measuring RCC which reflect these different conceptions. A shared understanding of continuity will help practices decide on the purpose of measurement, what they want to measure and which RCC index best meets their aims. We do not know the extent to which practice-level characteristics - practice size, part-time working, staff turnover and patient turnover - affect RCC. We therefore do not know the extent to which within-practice policies to maintain RCC can mitigate the effects of practice-level characteristics. The health of older patients and those with chronic diseases may benefit most from continuity. The optimum balance between access and continuity may therefore vary across different patient groups. For a realistic strategy to improve RCC it would help to know if there are groups in which there is a stronger case for RCC and in which it should therefore be prioritised. There are potentially many ways to optimise continuity. As no two general practices are the same, the most successful approach is likely to depend on the practice context. This project uses a variety of methodologies to address these questions, with the overall aim of helping practices optimise continuity of care.

First, we develop an understanding of RCC to help practices determine how best to measure and monitor their own RCC. This will be achieved by hosting consensus workshops of patients, primary care clinicians and researchers.

Second, in a large number of general practices, we will model the association between RCC and practice-level characteristics including staff turnover, part-time working, practice size and if linkage is possible, practice funding per patient. From this we will understand the drivers of RCC and identify practices showing higher-than-predicted RCC (positive deviants) for investigation as case studies.

Third, we will undertake detailed case studies in a sample of general practices, focusing on positive deviants. We will explore staff and patient experience of continuity (including possible trade-offs between access and continuity) and investigate the interplay between measured RCC and

informational or management continuity. We will identify practice policies contributing to RCC, along with barriers and facilitators to their implementation. Qualitative findings will be triangulated with the practice's measured continuity and subjectively reported continuity in the General Practice Patient Survey (GPPS).

Fourth, we will undertake economic analysis to estimate the projected effects of RCC on resource costs and health outcomes, using linked primary and secondary care data. This will help us understand the likely effects of changing RCC in a general practice and whether these effects vary in different patient groups (by age, sex, deprivation status and chronic disease status).

Fifth, we will develop empirically-informed practical guidance to improve continuity of care, collating findings of our quantitative analysis of predictors of RCC, case studies, economic analysis, and existing work on continuity of care in the UK and internationally.

We have already established links to report our findings to, and develop training materials for, the Royal College of General Practitioners (RCGP). Patient and public involvement (PPI) is embedded in the project. Our PPI co-applicant will chair a lay advisory group whom we will consult quarterly and will be trained in and contribute to analysis of qualitative data.

Funding and support in kind

Funder(s)	Financial and non-financial support given
NIHR Health Services and Delivery Researcher Led (standard) HS & DR Project NIHR152277	**£1,000,102.71**

Role of sponsor and funder

6. In consideration of the rights and obligations recorded in the Contract_for_Project_NIHR152277.pdf dated 13th October 2022

c. The Contractor will undertake a research project entitled Quantifying, Understanding and Enhancing Relational Continuity of Care (QUERCC) in accordance with the work specified in SECTION 3, being project application NIHR152277, dated 10 October 2022, the "Research".
d. In the event of a Public Health Emergency (as defined below), the Authority may direct the Contractor to perform further work in addition to (or in replacement of) the Research in accordance with SECTION 2, Clause 3.5.

7. The Authority will pay the Contractor the Approved Cost as set out in SECTION 4 in respect of undertaking the Research in accordance with this Contract.
8. This Form of Contract (SECTION 1) together with the attached SECTION 2 to SECTION 7 inclusive are the documents which collectively form the "Contract" (as defined in SECTION 2).
9. Where the Contractor is a health service body within the meaning of Section 9 of the National Health Service Act 2006 then this Contract is an NHS Contract within the meaning of that Act.
10. The Contract effected by the signing of this Form of Contract constitutes the entire agreement between the Parties relating to the subject matter of the Contract and supersedes all prior negotiations, representations or understandings.

Roles & responsibilities of management committees/groups & individuals

The QUERCC study management group

Oversight and review of the day-to-day management and coordination of the project will be undertaken at monthly meetings of the Study Management Group. This group draws together expertise from the University of Birmingham and independent expertise from the University of York. The core members are:

Members of QUERCC Study Management group

Tom Marshall	t.p.marshall@bham.ac.uk	IAHR
Sheila Greenfield	s.m.greenfield@bham.ac.uk	IAHR
Fiona Scheibl	f.scheibl@bham.ac.uk	IAHR
Iestyn Williams	I.P.Williams@bham.ac.uk	HSMC
Panos Kasteridis	panos.kasteridis@york.ac.uk	University of York
Zecharias Anteneh	zecharias.anteneh@york.ac.uk	University of York
Brian Willis	B.H.Willis@bham.ac.uk	IAHR
Krishnarajah Nirantharakumar	K.Nirantharan@bham.ac.uk	IAHR

The role and responsibility of this group is to ensure project milestones are met, research problems are resolved and forward planning to achieve agreed study outputs is undertaken.

A further key responsibility of the management group is to prepare and obtain ethical approval for the study from the NHS REC committee and Health Research Authority (HRA) along with relevant research governance approvals.

The management group ascertain that the main ethical questions relate to participant anonymity and the safeguarding of any private data. These are addressed in this application and will be advanced in greater detail for the HRA processes for 9 and 11 in subsequent approvals applications for those work packages.

To ensure ethical compliance in WP1 we will obtain informed consent from all workshop participants on the day of the workshop if they attend in person. Where participants attend a virtual workshop we will obtain consent electronically via a typed signature on an email copy

of the study consent form ahead of the workshop. If a participant is unable to complete the form electronically the study RF will run through verbal consent when participants join the online platform to confirm they have understood and accept the terms of the study prior to commencing the workshop proceedings on the day of the workshop . We will provide all potential participants with information about the study, and time to consider participation. Data will be stored in line with institutional policies. Interview participants will not be named or identifiable and we will use pseudonyms to report any direct quotes. We provide further details of the processes in place to achieve this in section 5.3.2 below.

Project research expertise

TM is Professor of Public Health and Primary Care with expertise in health services research in particularly using electronic primary care records. He will lead the project and directly supervise RF2 (quantitative). He will be supported in this by BW.

BW has extensive experience of analysis of primary care records and is both a practising GP and an Associate Professor. He holds a PhD in Medical Statistics.

SG is Professor of Medical Sociology. She is a qualitative methodologist and with extensive experience in the design and implementation of qualitative methodology as a component of mixed methods research, particularly in primary care. Recent research has included practices' use and attitudes to patient safety tools and the role of receptionists. SG leads 9.

IW is an experienced health services researcher focussing on health organisation, implementation research and complex intervention development. He has methodological expertise in mixed methods including consensus methods and will lead **Error! Reference source not found.**. He has extensive experience of qualitative case studies and, through his role at the Health Services Management Centre, is linked to extensive networks of current and future NHS leaders, for example through the national Nye Bevan and Elizabeth Garrett Anderson Leadership programmes.

SG and IW will supervise RF1 (qualitative). Both are highly experienced qualitative researchers. Their expertise and leadership will provide oversight on qualitative data management processes. Although supervision will be provided by SG and IW for FS neither they or any other member of the research team, the PPI / PAG members or external

advisory group members will have access to primary research data /participant data. If and when data is shared or reported to these study members they will only view and have access to summary data which will be fully anonymised. Only the lead qualitative researcher (FS) will have access to raw data and will organise the transfer of data files to the transcription agency and check the accuracy of their work.

PK is a health economist with an econometrics background. He has an interest in quality in primary care and extensive experience of analysis of using linked electronic health records for research. This includes analysis of the effects of continuity of primary care on admissions for mental health problems.

KS is a patient with a chronic condition who will lead PPI, chairing Patient Advisory Group meetings and liaising with the Project Steering Group.

The External Advisory Group

An External Advisory Group will be convened including Dr Mairead Murphy (University of Bristol) a qualitative researcher with an interest in continuity of care; Dr Otto Maarsingh (Amsterdam University Medical Centre) who leads the TOOL study, and Nicolas Thomas a member of the RCGP. This group will be convened and meet with the Project Steering Group every third month: half of the meetings will be online.

All members of the external advisory steering group are independent from the Sponsor and the Investigators. Each member brings expertise in the field of relational continuity of care.

(QUERCC) External Advisory Group Members

Nicholas Thomas	Nicholas.Thomas@rcgp.org.uk	RCGP
Jenna Collins	Jenna.Collins@health.org.uk	The Health Foundation
Otto R Maarsingh	o.maarsingh@amsterdamumc.nl	Amsterdam University Medical Centers
Theo Bartholomew	theo.bartholomew@nhs.net	NHS England
Mairead Murphy	Mairead.Murphy@bristol.ac.uk	University of Bristol

Oversight External Advisory Group: Meeting Annually

The Oversight External Advisory group is comprised of expert stakeholders, two are co-opted members of the funding body (tbc). The role of the group is advisory, and their responsibility is to review study documents and outputs to ensure the research is addressing wider trends and issues and raise awareness of potential collaborations and new developments. The core members, all of whom are independent of the Sponsor and Investigators. Core members are:

Oversight External Advisory Group

Funding body representative	tbc	NIHR HSDR
Funding body representative	tbc	NIHR HSDR
Nicholas Thomas	Nicholas.Thomas@rcgp.org.uk	RCGP
Jenna Collins	Jenna.Collins@health.org.uk	The Health Foundation
Otto R Maarsingh	o.maarsingh@amsterdamumc.nl	Amsterdam University Medical Centers
Theo Bartholomew	theo.bartholomew@nhs.net	NHS England
Mairead Murphy	Mairead.Murphy@bristol.ac.uk	University of Bristol
Mai Stafford	Mai.Stafford@health.org.uk	The Health Foundation
William Whittaker	william.whittaker@manchester.ac.uk	University of Manchester
Janina Ruszczynska	goth4you@gmail.com	

Patient & public involvement group

The Patient Advisory Group will meet three monthly and provide input into the monthly Project Steering Group meeting to ensure that PPI input is ongoing throughout the project.

The PPI lead (KS) is a co-applicant. KS contributed to study design, planning, study documentation and collaborated with team members to assist with study set-up and recruitment. KS will sit on the Project Steering Committee and will contribute to recruitment of a Patient Advisory Group (PAG) of 6-8 participants which he will chair.

KS will receive training in budget management, research methods (statistics and qualitative research) through formal study of core research methods modules at University of Birmingham. He will contribute to analysis and interpretation of interview and focus group transcripts from the relevant work packages. KS will not have access to primary research data /participant data. If and when data is shared or reported to KS or other members of the

PAG they will only view and have access to summary data which will be fully anonymised. Only the lead qualitative researcher (FS) will have access to raw data and will organise and manage the dissemination of data to the PAG.

He will also contribute to writing for publication and has contributed to the plain English summary and related study documents.

To ensure broad representation, when recruiting to PAG we will liaise with the well-established NIHR ARC West Midlands patient and public involvement infrastructure and with Dudley Integrated Health & Care Trust's. Experience of continuity of care varies by age, gender, education level, ethnicity and chronic disease status, and we will work to achieve diverse representation to the study PAG.

We will provide Potential PAG members with a description of the roles and expectations for involvement ahead of recruitment. Recruitment will aim at lay people with and without previous experience of PPI. After recruitment, the study investigators will provide training and induction on the project. Participation in the induction will be paid in line with INVOLVE rates and will equip PPI members with transferrable skills for future use in other PPI activities.

We will provide updates to the PAG on the progress of the research and on preliminary findings. The group will meet quarterly throughout the project and provide feedback to the Project Steering Group. The lay co-applicant will act as a point of contact for other lay members. It is anticipated that the PAG will contribute to the interpretation of relational continuity of care, advise on recruitment and involvement of patient participants in workshops and case studies, contribute to the design of dissemination materials including the study website. They will also provide a lay view on the acceptability and feasibility of possible solutions to enhance continuity of care. This will help inform the development of guidance for general practices on how to improve continuity of care in the final work package. An opportunity will be provided for PAG members to write about their experience. The PAG will contribute to dissemination by publishing results on the study website, social media and Health Unlocked.

The PAG and lay co-applicant will help implement findings by working with policy makers and patient support groups. The Study Investigators will host a 'thank you' event for the PAG at the study's end.

Protocol contributors

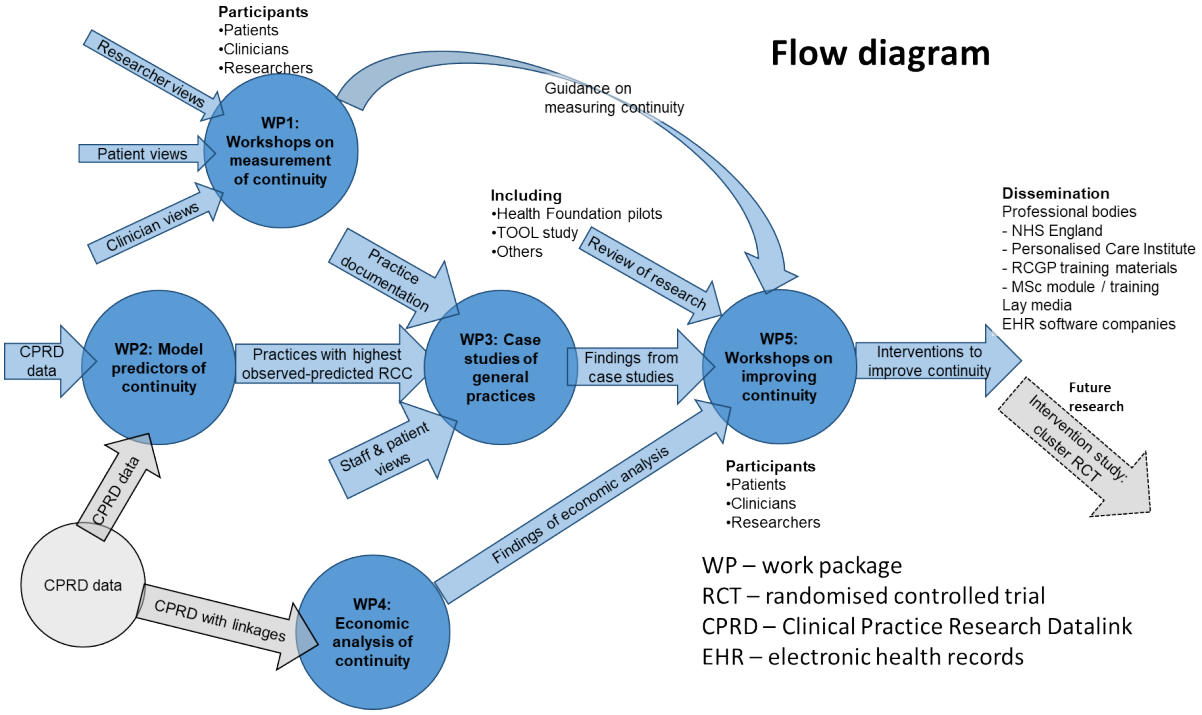
Key Protocol Contributors	Professor Tom Marshall Institute of Applied Health Research College of Medical and Dental Sciences University of Birmingham Edgbaston B15 2TT Telephone +44 (0)121 414 7832 Email: t.p.marshall@bham.ac.uk Professor Shelia Greenfield Institute of Applied Health Research College of Medical and Dental Sciences University of Birmingham Edgbaston B15 2TT Telephone: +44 0121 414 6493 Email: s.m.greenfield@bham.ac.uk Professor Iestyn Williams Director of Research School of Social Policy Health Services Management Centre, Park House University of Birmingham Edgbaston B15 2RT tel:+44 121 414 7063 Email: i.p.williams@bham.ac.uk Professor Krishnarajah Nirantharakumar Health Data Science and Public Health Institute of Applied Health Research University of Birmingham Edgbaston B15 2TT k.nirantharan@bham.ac.uk tel:+44 121 414 8344 Dr Brian Willis Senior Clinical Lecturer in General Practice & MRC Fellow Institute of Applied Health Research University of Birmingham Edgbaston B15 2TT b.h.willis@bham.ac.uk tel:+44 121 414 7949 Dr Panagiotis Kasteridis Research Fellow Health Economics Centre for Health Economics University of York Panos.kasteridis@york.ac.uk (01904) 321429 Mr Kamil Sterniczuk Lay co-applicant Lay advisor. Chair patient advisory group, Institute of Applied Health Research University of Birmingham

	Edgbaston B15 2TT kamil.sterniczuk@gmail.com

Key words

Continuity
Primary care
Optimise
Health outcomes
Health systems
Mixed methods research

Project flow chart



Protocol

Relational continuity of care (RCC) is a core feature of primary care, it is valued by patients and is linked to better health outcomes. RCC is also declining. The overall aim of this project is to understand better how to improve continuity of care. We will develop our understanding of how to measure RCC. We will analyse the practice factors contributing to RCC and undertake case studies of practices with high RCC. We will quantify the health and resource effects of RCC. We will do this across five work packages:

Error! Reference source not found.*1*, develops a shared understanding of RCC to guide the choice of measurement indices.
8, undertakes quantitative analysis to investigate determinants of RCC and to identify outlier practices.
93, will investigate primary care practices with high levels of relational continuity of care (positive deviants) as case studies.
Work package 10, will undertake an economic analysis of the effects of RCC.
Work package 11, develops empirically informed practical guidance to help general practices optimise RCC.

We seek approval in this application to commence the work of WP1 during which we will host facilitated workshops on RCC measurement, to develop a shared understanding and guidance for practices choosing a RCC index to meet their own needs. To this end the current protocol provides details of the methods used in WP1 for ethical review. We will make submissions and seek approval for the other work packages as a separate application.

1. Background

RCC indices in use to date have mainly been selected by researchers and measurement has only included consultations with doctors. Depending on the practice's preferences, RCC indices could include consultations with all patients or with some patients (e.g. age 65+); consultations with all clinicians, or only with GPs; may measure density or dispersion (see **Table 1** p.22 below).

In the conception and development of this proposal we consulted 8 patients in 2 workshops in 2019. Participants felt relational continuity of care (RCC) was important and shared many

narratives illustrating RCC or its absence in primary care consultations. They generally stressed the importance of developing a relationship with a GP and avoiding the need to explain their circumstances at every visit. They felt continuity would reduce over prescription and unnecessary medication changes. Some felt RCC was crucial, but others were less concerned about seeing the same GP or even valued a different GP's opinion. All participants acknowledged the importance of continuity for patients with long term conditions, the elderly, and more disadvantaged patients. They perceived RCC as becoming more difficult to maintain with longer waiting times and pressure on health services to provide better access. They identified part-time working, larger practices and automated booking systems as potential barriers to continuity and identified receptionists as playing a key role in continuity. When asked about measuring continuity patients emphasised that RCC did not have to be with a single GP but a small number of GPs (e.g. 2 to 3) would count as continuity. They also said continuity could be with another healthcare professional (e.g. a nurse). They were supportive of the proposed research, some adding that it was important to elicit the views of healthcare professionals on continuity. We found a striking congruence between the personal observations and intuitions of our patient participants and the findings of published research. This suggests patients have considerable insight into RCC and have an important role in shaping this research.

There is a long-recognised need for consistent measures of RCC [1-3]. The RCGP emphasises the need to measure relational continuity as a first step in its management [4]. But choosing an appropriate measure is complex [5]. Subjective RCC (the patient's experience of continuity), measured through questionnaires, is impractical for monitoring [6-9]. Objective RCC measurement (a quantitative measure of frequency of consultation with the same clinician) is feasible using electronic health records (EHR) and correlates with subjective measures [10]. But different objective measures capture different conceptions of RCC [3]. Continuity may be with the GP or with any clinician; it may be in all patients or in specific patient groups (e.g. ≥65 years); it may be measured quarterly, monthly, or weekly. There are different RCC indices. Some measure density: Usual Provider of Care index (UPC) % of consultations with most frequently seen GP, or the St Leonard's Index of Continuity of Care (SLICC) % of consultations with a named GP [11]. Others measure dispersion, taking account of the number of different clinicians consulted, using the Bice-Boxerman (BB) or Herfindahl (HI) indices. There is a measure of Sequential Continuity (SECON) (summarised in

Table 1 below)

Table 4: Main indices of relational continuity of care (RCC)

Name	What is measured	Formula
Bice-Boxerman (BB)	Dispersion	$\frac{\left(\sum_{i=1}^{p} n_i^2\right) - n}{n(n-1)}$
Herfindahl Index (HI)	Density	$\sum_{i=1}^{p}\left(\frac{n_i}{n}\right)^2$
Usual Provider of Care ($UPC^{Patient}$)	Density	$\max\left(\frac{n_i}{n}\right)$
St Leonards Continuity of Care (SLICC or $UPC^{GP\ level}$)	Density	$\text{named clinician}\left(\frac{n_i}{n}\right)$
Sequential (SECON)	Handoffs	$\frac{\left(\sum_{j=1}^{n-1} c_j\right)}{(n-1)}$

p = total number of providers (clinicians); n = total number of visits during episode; n_i = number of visits to provider i; c_j = indicator of sequential visits to same providers, equal to 1 if visits j and j+1 are to the same provider, 0 otherwise

Research has also explored effects of regularity and minimum frequency of contact on patients with chronic conditions. [12, 13] Density measures decline with consultation frequency but dispersion measures are less affected [14]. In practice, BB, HI, UPC and SECON are often highly correlated [15]. SLICC is easy to calculate at the practice level and does not require patients to have a minimum number of consultations, but it may differ from the UPC if the patients' usual GP and named GPs differ [16].

There are questions about measuring RCC and the answers vary with the aim of measurement. Should RCC be measured only in older or chronic disease patients? Should it include consultations with all clinicians or only with GPs? Should RCC reflect the patient's, the doctor's, or the healthcare system's perspectives of RCC? Over what time period should RCC be assessed? Which RCC index should be used? A measure of RCC should be practical, understandable and reflect what patients and clinicians mean by continuity. For example, our patient workshop participants (see above) emphasised RCC could be provided by non-GP clinicians, or by 2 or 3 rather than 1 clinician. This view is consistent with a RCC index including consultations with all clinicians and measuring dispersion. But density indices

are more widely used and to date no measure includes consultations with non-GPs. Our survey of 43 GPs (see above) revealed some support for monthly (or 2-3 monthly) RCC monitoring. While measurement of RCC is both feasible and useful, the aims of measurement vary and neither what to measure nor the optimum choice of index are clear.

2. Theoretical framework

In WP1 we use the Nominal Group Technique [17] to work with qualitative data in the workshop setting. We draw on the Consolidated Framework for Implementation Research [18] and Normalisation Process Theory [19] in our interpretation and synthesis of data across the five work packages.

Method – WP1

In WP1 we will hold two workshops. The first will draw relevant stakeholders together to establish common understandings, the second will work with the same stakeholders to build consensus. The workshops will be held two months apart. The key stakeholders we will ask to join the workshops as research participants will be: clinicians, patients and researchers. The workshops will be coordinated by a professional facilitator who will be supported by members of the research team.

We will recruit clinicians using the professional contacts that the study PI team have established with the Royal College of General Pracitioners (RCGP) and by releasing invitations on social media (www.doctors.net.uk).

We will recruit researchers by emailing an invitation to (1) professional contacts (established by the PI team and members of the advisory group) and (2) researchers who have recently published in the field (using the email address available in public domain provided on their recent publications).

We will recruit patient representatives to the workshops by:

(1) displaying posters in medical practices; negotiations have achieved formal agreement to show posters from one practice (Thornley Street Practice, Dr Anna Stone with support from Wolverhampton City Primary Care Trust Dr Mona Sidhu);
(2) consultation and collaboration with West Midlands PPI network lead contact (Dr Magdalena Skrybant PPIE Lead, ARC West Midlands) to gain access to members of the public who will be interested to join the workshops

We will supply printed copies of the Participant Information Sheet (PIS) to the practices so that potential participants can take time to read about the study. An electronic PIS will be made available to the ARC West Midlands PPI representative so that this can be disseminated to potential participants and allow them time to consider their involvement in the study and the implications it might have for them.

We have requested funds to support accessibility for lay participants (accessible transport, childcare costs, interpretation).

Our main sampling objective is to achieve a balance between patient and professional (clinicians and researchers) participants that is broadly equal (total n ≈ 15). We will over-sample to each of the categories of participant and hold a reserve of +3 of each category (clinical, patient and researcher) to account for circumstances where there is attrition from the sample (n=15) when participants are recalled to join the second work-shop two months later (as outlined below). We will obtain consent from the over-sampled (n=9) participants to contact them again using a permission to contact form. We will aim to ensure a diversity of patients, clinicians and researchers by age, gender, ethnicity, education level and chronic disease status. We will use an equality and diversity form to collect details of participants' age, gender, educational background, ethnicity and chronic disease status in order to monitor the sample representation. This will be a paper form completed on the day. It will be anonymised and no participant ID number will be attributed or recorded onto it.

Written consent will be obtained from participants on the day of the workshops as detailed above and the consent process will obtain permission to audio record under assurances of anonymity and confidentiality. To ensure both workshops run efficiently we will use a professional facilitator. The workshops will take place at the central Birmingham venue named 'The Exchange' in rooms with privacy and professional recording equipment.

Stage 1: the key characteristics (dimensions) of RCC

In stage 1 we will use the nominal group technique (NGT), a face-to-face, structured interaction, for identifying areas of consensus and divergence in priorities between different groups [17]. NGT is efficient as a means of gathering such data, and is especially useful where a range of perspectives exist and some groups may be more vocal than others [20]. Although typically used to gather professional views, NGT has been successfully employed with patients [21]. It is less resource intensive than alternatives (such as Delphi) and more likely to both reach a clear outcome, and provide a sense of achievement for participants [22]. In this instance, NGT will be important in enabling us to bridge any discursive gap between lay and medical understandings of RCC [23].

The professional facilitator and theme lead will begin by explaining the workshop purpose and methodology in a short presentation with questions, clarify ground rules regarding respect, voice and confidentiality. The theme lead will explain the problem of RCC measurement and illustrate the range of measures:

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Table 5: Illustration of pros & cons of different measures of relational continuity of care

Clinician group	Patient group	Criterion	Continuity index				
			SLICC	UPC	BB	HI	Secon
Consultations with GPs only	All ages	Understandable	Good	Good	Fair	Fair	Fair
		Unaffected by consultation rate	Poor	Poor	Good	Good	Fair
		Patient conception	Fair	Fair	Good	Good	Poor
		Clinician conception	Fair	Fair	Fair	Fair	Fair
	Aged 65+ only	Understandable					
		Unaffected by consultation rate					
		Patient conception					
		Clinician conception					
Consultation with all clinical staff	All ages	Understandable					
		Unaffected by consultation rate					
		Patient conception					
		Clinician conception					
	Aged 65+ only	Understandable					
		Unaffected by consultation rate					
		Patient conception					
		Clinician conception					

This will be followed by information giving regarding the problem of RCC measurement, based on existing evidence [16]. This stage is crucial in translating the topic into simple

language and reducing the requirement for technical knowledge, in order that all participants are able to contribute to subsequent discussion.

Participants will then be asked to individually reflect on the key components of RCC (e.g. “Is continuity primarily with one GP, more than one GP or all clinicians?” “What aspects of care are most important in providing continuity?” “How frequently should it be measured?”and to record their views in note form. We will devote between 10 and 20 minutes to this task and researchers will be on hand for any participants requiring assistance. These notes will then be shared with the full group, without discussion, and recorded by facilitators on flipcharts. This will be followed by facilitated group discussion in which verbal explanation and elaboration are provided between group members in relation to each of the identified components. This clarification phase may involve grouping of items and further inclusion/exclusion where this is universally agreed.

The final phase involves participants in developing a series of questions to help identify characteristics or dimensions of a measure of RCC: first identifying the purpose of a measure, then identifying the characteristics we might seek in an ideal measure. This is likely to involve list reduction and/or voting, and will be facilitated so as to respect diversity of opinion, enabling full and equal participation across each of the groups. We anticipate asking participants to identify the potential purposes of measuring RCC. They will then select the characteristics of a measure of RCC (e.g. which population, density v dispersion, GPs or all clinicians, understandability etc) that correspond to the potential purposes. We will give participants clear instructions and dedicate ample time for them to carry out the selection process. A researcher will quality check the process, for example by reviewing submitted suggestions as these are handed in.

In total, the workshop will be attended by 3 members of the research team. IW or TM will lead the discussions, a second researcher will be responsible for visual materials (e.g. whiteboards) used in the discussion, and a third will take notes and ensure workshops are audio-recorded. If Covid-19 restrictions make face-to-face workshops impractical, or if a different mode of delivery supports more diverse participation, we will conduct hybrid or virtual workshops using the UoB Zoom or Teams accounts. Workshop conduct will be informed by research on best practice and guided by recommendations in the literature [24, 25].

We will enter summary data of the characteristics of a RCC index into a Microsoft Excel Database. It is our intention that practices will prioritise these characteristics themselves, in order to identify their own preferred measure. However, if a consensus emerges, we may also provide a recommendation on the most important characteristics in a measure, based on the views of workshop participants. We will report the outputs to participants towards the end of the workshop. Qualitative data derived from the audio-recordings will be analysed to enable us to provide context to the summary results, and to understand the rationale behind them. After the workshops, transcriptions will be entered into NVivo 11 and we will develop a coding framework inductively during a process of qualitative content analysis carried out independently by two members of the research team [21].

Stage 2: identifying and appraising current measures

The second 2-hour workshop will be held approximately 2 months later at the same venue with the same participants (n=15). If any of the 15 participants who took part in the first workshop are unavailable we will make the numbers up from the reserve of +3 patients +3 clinicians +3 researchers (n=9) we over-sampled during recruitment and gave consent to be contacted and held in reserve for the second workshop using the contact form as detailed above..

Participants will be introduced to a summary of current existing indices (e.g. BB, HI, $UPC^{Patient}$ or $UPC^{GP\ level}$), and indices on how RCC should be measured [26, 27]. To aid discussion, illustrations of the types of measures will be provided using synthetic data manufactured by the research team. Facilitated group discussion will be used to map current tools against the characteristics identified in the first workshop. This process will enable the group to identify the extent to which each RCC index addresses the desirable characteristics. It will also identify what is unknown. It is anticipated that this review will generate a menu of RCC indices from which practices might choose depending on which characteristics they prioritise in a measure. If a consensus emerges from the workshop participants about a single best RCC index, it will be reported. We will again audio-record the discussions and analyse the qualitative data in order to provide context and rationale to the final outcome. Acknowledging the challenges of integrating qualitative and quantitative data, all participants (patients, clinicians and researchers) will be involved in final decisions [28].

3. Research question/aims

- Gather patient, practitioner and researcher views on the characteristics of RCC relevant to its measurement, including inclusion of non-GPs and in which populations to measure RCC
- Develop guidance for general practices choosing to measure their own RCC

3.1. Outcome

Output: A menu of approaches to measuring RCC for monitoring in primary care.

We do not anticipate agreeing on a single way to measure RCC, but expect to produce a menu of approaches, along with guidance to help practices choose the approach most appropriate to their particular needs.
above illustrates assessing the pros and cons of different approaches.

4. Project setting

Primary care drawing on the views and experience of service users, service providers and their representatives and key stakeholders involved in decision making and policy development.

5. Participant recruitment

5.1. Inclusion criteria for clinicians

- Persons with capacity
- Lower age limit: 20 Years - Upper age limit: 95 Years
- Current or former registration as general practitioner in UK primary care setting

5.2. Inclusion criteria for nurses and allied health professionals

- Persons with capacity
- Lower age limit: 20 Years - Upper age limit: 95 Years
- Current or former registration as nurse / allied professional in UK primary care setting

5.3. Inclusion criteria for staff support staff / receptionist

- Persons with capacity

- Lower age limit: 20 Years - Upper age limit: 95 Years
- Current or former employment as a member of reception staff in UK primary care setting

5.4. Inclusion criteria for researchers

- Persons with capacity
- Lower age limit: 20 Years - Upper age limit: 95 Years
- Current or former employment at a University, or policy or research institute
- Has published peer reviewed research in the field of continuity of care

5.4.1. Exclusion criteria for staff clinicians

- Persons who lack capacity
- No current or former status as registered as GP

5.4.2. Exclusion criteria for staff nurses

- Persons who lack capacity
- No current or former status as registered as Nurse

5.4.3. Exclusion criteria for receptionist/ allied health professional

- Persons who lack capacity
- No current or former status as allied health professional in UK primary care system
- Has no experience of primary care systems similar to that developed in UK

5.4.4. Exclusion criteria for researchers

- Persons who lack capacity
- Has no experience of primary care systems similar to that developed in UK
- Has no evidence of contributing published peer reviewed research in field of primary care

5.1.2 Inclusion criteria for patients

- Persons with capacity
- Lower age limit: 20 Years
- Upper age limit: 95 Years
- Patients currently or formerly registered with general practitioner in UK primary care system.

5.1.3 Exclusion criteria for patients

- Patients who lack capacity.
- Not currently or formerly registered with a UK primary care system

5.5. Sampling

The study uses a purposive approach to sampling. We will monitor the diversity of the sample representation by age, gender, ethnicity, education level and chronic disease status. To do this we will use an equality and diversity form to collect details of participants' age, gender, educational background, ethnicity and chronic disease status in order to ensure representation. An interpreter will be made available to any potential participant whose first language is not English and wants to take part, we will translate the PIS/ E&D/ ICF documents on their behalf to enable them to fully consult the terms of the study and consider the implications of participation.

5.5.1. Size of sample

Sample size for WP1 is N= 15 comprising, 5 clinicians, 5 researchers and 5 patients.

5.5.2. Sampling technique

The formal sample size of 15 participants is broadly in line with recommendations for workshops using Nominal Group Techniques. Groups with more participants can become difficult to work in as there are too many people to include in the discussion.

5.6. Recruitment

Clinicians will be recruited through established links with the Royal College of General Practitioners (RCGP). We will also release a general invitation / call to take part on social media (www.doctors.net.uk).

The approach to contacts at RCGP and social media will be made by the study PI Prof Tom Marshall by email. Each potential participant / contact will be emailed a brief introduction and summary slides. Expressions of interest from potential participants who contact the study team after receiving this introductory email from the PI will be followed by the study RF Dr Scheibl who will send them the PIS.

Researchers will be recruited to the study through a direct approach by email. The study PI Tom Marshall will email an invitation to: (1) professional contacts known to team members and the advisory group and (2) researchers who have recently published in the field (using the email address available in public domain provided on their recent publications).

Expressions of interest from potential participants who contact the study team after receiving this introductory email from the PI will be followed by the study RF Dr Scheibl who will send them the PIS.

The study RF will follow up the initial email sent by the PI at 2 week and 4 week intervals. Allowing 2 weeks will give potential participants time to consider their participation. Follow up at 4 weeks will act as a reminder. If no response is received the contact will be closed and not followed up any further.

We will recruit patient representatives, receptionists and allied health professionals to the workshops using two methods of approach:

1) Posters will be displayed in two West Midlands medical practices. Negotiations have been held and formal agreement obtained from two practices (Thornley Street Practice and Wolverhampton City Primary Care Trust). We will supply each practice with electronic and printed copies of the Participant Information Sheet (PIS) so that potential participants can read it and consider their participation. The poster has contact details for the study RF (DR Scheibl). If potential participants email the RF asking for more details the RF will email the PIS to them.
2) The poster and an electronic PIS will also be released to ARC West Midlands PPI network lead contact (Dr Magdalena Skrybant) and Healthwatch West Midlands contacts. The electronic PIS can be disseminated by the PPI lead to potential participants and allow them time to consider their involvement in the study. The poster has contact details for the study RF (DR Scheibl). If potential participants email asking for more details the RF will email the PIS to them.

The study RF will follow up the initial email at 2 week and 4 week intervals. Allowing 2 weeks will give potential participants time to consider their participation. Follow up at 4 weeks will act as a reminder. If no response is received the contact will be closed and not followed up any further.

As outlined above we will use an equality and diversity form to collect details of participants' age, gender, educational background, ethnicity and chronic disease status in order to ensure representation. Invites and information sheets will be sent by email.

5.6.1. Sample identification

As explained above, we will identify and recruit participants for workshop involvement by following up contacts across a range of professional networks including:

For clinicians:

- RCGP and the social media network www.doctors.net.uk . These organisations will not promote the study or display information about it. Membership of these organisations is an indicator that persons belonging to them meet the study inclusion criteria (as listed above). Hence we will email individual members of these organisations and invite them to personally take part.

For patients, allied health professionals and receptionists:

- Community health care representative organisations in the Birmingham area for example: NHS Clinical Commissioners, NHS Providers and Integrated Care Organisations will be contacted by the study PI's and asked to flag the study across their networks and to share the study RF contact details with potential participants. The Study RF will email the study PIS to contacts once these are established. A poster will also be supplied as described above. A briefing meeting held with contacts established to date has secured agreement from two individual practices in the Birmingham area to work with the study. As described above these two participating general practices will display posters and copies of the PIS for patients, allied health professionals and receptionists as potential participants to consult and consider taking part. A poster had been developed and provides contact the details for the study RF and participants are asked to contact the RF for further information.

5.6.2. Consent

Written consent will be obtained from participants by the study RF Dr Scheibl who holds a full Research Passport and DBS. Dr Scheibl has over 20 years' experience of social science research and taking informed consent on clinical trials. Consent will be obtained on the day of the workshops using a standardised consent form which sets out the terms for permission to audio record under assurances of anonymity and confidentiality and storage and use of data. This form will be completed electronically if participants are attending the workshop virtually as detailed above. If any participant has difficulty completing the consent form by signing an email, consent will be obtained on the day virtually over zoom by the study RF (Dr Fiona Scheibl) who will lead the participant through the consent process step by step using the study consent form. The process will be witnessed by another member of the research

study team (TM/ IW/SG) and the consent form will be completed and signed on the participants behalf with their permission.

6. Data storage

Personal data will be collected and subject to analysis and we will observe the following regularity processes:

Personal data will be collected from participants after they have provided written consent. Data relating to participants will be assigned a unique identifier. Audio files from the workshops will be transferred from the encrypted audio recorder into an encrypted folder on to the secure university server as soon as possible after the workshops. The recordings on the digital audio recorder will be deleted as soon as successful transfers to University of Birmingham secure servers have been confirmed. The audio files will be securely shared with an approved transcription service authorised by the University of Birmingham. Only anonymised quotes from the transcript will be used in any publications or reports arising from the data. Personal data will be encrypted and password protected, and only accessed by agreed members of the team. Anonymised data will be stored on a secure server within the University of Birmingham for a period of 10 years. If a participant decides to withdraw after the workshop has taken place, the data they provided up to that point will still be used in subsequent analysis . All essential documentation and study records will be stored by the study team in accordance with the applicable regulatory requirements and access to stored information will be restricted to authorised personnel including sponsor representatives and regulatory authorities. The main study portfolio will be kept in the Institute of Applied Health Research, University of Birmingham.

Appropriate controls will be in place to ensure be in place to ensure that access to confidential research information is restricted to those who need access. Researchers at the University of Birmingham will only have access to anonymised transcripts for the purposes of future research. Completed consent forms will be stored in a study folder in a secure locked cabinet in the trials unit/ IAHR. All audio material will be stored on secure servers at the University of Birmingham accessible to authorised research personnel only. All data will be anonymised ahead of analysis. All workplace issue laptops are secured by VPN login and code authentication. All data on the University of Birmingham secure drive is protected.

7. Safety reporting

The study Investigators and research team will observe appropriate safeguarding regulations for data handling as set out in The University of Birmingham's Data Management Policy and Procedures accessible here: Research Data Management Policy (birmingham.ac.uk) and the Data Security Policy is here: https://www.birmingham.ac.uk/Documents/university/legal/data- prot-policy.pdf. Research data will be kept on University of Birmingham computer servers. These guidance documents will be observed to ensure the protection of the rights, safety and wellbeing of research participants.

The data collected during the study will be archived as per the University of Birmingham Data Management Policy and all access will be removed unless access is requested directly from the chief investigator. The University of Birmingham's Data Security Policy is here: university-of-birmingham-data-protection-policy.pdf

Research data will be kept on University of Birmingham computer servers. Once the study has been completed and results published, data accesses will be limited to the chief investigator, the research team and IT staff at the University of Birmingham.

8. Ethical and regulatory considerations

The main ethical questions relate to participant anonymity and the safeguarding of any private data. These will be addressed in the **Error! Reference source not found.** application and in greater detail for the HRA processes for 9 and 11 where we will submit data collection instruments such as topic guides for review.

We will ensure informed consent for all workshops and will provide potential participants with information about the study, and time to consider participation. Data will be stored in line with institutional policies as set out above. Workshop participants will not be named or identifiable and we will use pseudonyms to report any direct quotes.

8.1. Assessment and management of risk

Success in **Error! Reference source not found.** would be developing guidance for general practices on how they can measure their own RCC. There are few risks to achieving this as there is no requirement that we reach agreement on measurement, just an understanding of what criteria need to be considered.

Clinicians will receive payment for taking part in workshops which is considered appropriate and fair at locum rates and does not constitute a coercive inducement.

Patient participants will receive INVOLVE rates of £25.00 per hour and be reimbursed for their travel costs. These are considered appropriate rates and determined by NIHR and INVOLVE recommendations.

8.2. Research ethics committee (REC) and other regulatory review & reports

Before the start of the study, a favourable opinion will be sought from the REC and also approval from the HRA.

- Substantial amendments that require review by NHS REC will not be implemented until that review is in place and other mechanisms are in place to implement at site.
- All correspondence with the REC will be retained.
- It is the Chief Investigator's responsibility to produce the annual reports as required.
- The Chief Investigator will notify the REC and sponsor of the end of the study.
- An annual progress report (APR) will be submitted to the REC and sponsor within 30 days of the anniversary date on which the favourable opinion was given, and annually until the study is declared ended.
- If the study is ended prematurely, the Chief Investigator will notify the REC and sponsor, including the reasons for the premature termination.
- Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC and sponsor.

Before any site can enrol participants into the study, the Chief Investigator/Principal Investigator or designee will ensure that appropriate approvals from participating organisations are in place.

8.2.1. Regulatory review & compliance

The study Investigators will observe the principles of the UK Policy Framework for Health and Social Care Research which sets out principles of good practice in the management and

conduct of health and social care research in the UK including responsibilities for the four elements of research transparency:

1. registering research studies
2. reporting results
3. informing participants
4. sharing study data and tissue

All research staff have completed good clinical practice training and will observe regulations and ethical procedures advised by the Sponsor following ethical review and the Authority as set out in the contract dated 13 October 2022 which protect the rights, safety and wellbeing of research participants. In the QUERCC study the principal safeguards apply to the handling and storage of data as follows:

Appropriate controls will be in place to ensure that access to confidential research information is restricted to those who need access. Researchers at the University of Birmingham will only have access to anonymised transcripts. Completed consent forms will be stored on secure servers at the University of Birmingham accessible to authorised research personnel only. All data is anonymised ahead of analysis. All workplace issue laptops are secured by VPN login and code authentication. All data on the University of Birmingham secure drive is protected. Personal data will be collected from participants after they have provided written consent. Data relating to participants will be assigned a unique identifier. Audio files from the interviews will be transferred from the audio recorder into an encrypted folder on to the secure university server as soon as possible after the workshops. The recordings on the digital audio recorder will be deleted as soon as successful transfers to University of Birmingham secure servers have been confirmed. The audio files will be securely shared with an approved transcription service authorised by the University of Birmingham. Only anonymised quotes from the transcript will be used in any publications or reports arising from the data. Personal data will be encrypted and password protected, and only accessed by agreed members of the team. Anonymised data will be stored on a secure server within the University of Birmingham for a period of 10 years. All essential documentation and study records will be stored by the study team in accordance with the applicable regulatory requirements and access to stored information will be restricted to authorised personnel including sponsor representatives and regulatory authorities. The main study portfolio will be kept in the Institute of Applied Health Research. University of Birmingham

8.2.2. Amendments

If the sponsor recommends or study team request to make changes to any aspect of the study a request for an amendment will be submitted to the appropriate regulatory bodies (as appropriate).
Both minor and substantial amendments will be submitted to the sponsor for review and approval prior to submission on IRAS and subsequent approval by relevant regulatory bodies and participating sites.

8.3. Peer review

The research study was peer reviewed by NIHR during the funding submission.

8.4. Patient & public involvement

During the development of this proposal, we consulted eight patients in two focus groups in 2019. Participants provided views on the importance of the research, their perception of changes in continuity of care, measuring continuity of care and possible problems with high continuity of care. Participants felt researching continuity was important. They all shared experiences of lack of continuity of care and stressed the importance of a personal relationship with a general practitioner (GP). Advantages included not needing to explain their circumstances at every visit and avoiding unnecessary medication changes. All acknowledged the importance of continuity, especially for older patients and those with long term conditions. There was a shared perception that continuity of care is becoming more difficult with pressure to provide better access.

They identified part-time working by GPs and larger surgeries with many GPs as important factors. Some also indicated that automated booking systems had a key role impeding continuity, others said receptionists had a big influence on which doctor was seen. Because of the need to be both savvy and assertive to maintain continuity, and that patients with language barriers, disability, or mental health conditions were disadvantaged. Continuity in primary care was thought to be better than in secondary care. When discussing measurement of continuity, participants were clear that continuity does not necessarily have to be with a single GP, or even with a single healthcare professional. Continuity could be seeing 2 or 3 GPs for most of their care or even a multi-disciplinary team. Participants also thought it important to take account of views of healthcare professionals' views on continuity. Considering drawbacks of continuity, some participants mentioned the value of a second

opinion. Others acknowledged that a practice focus on access would compromise continuity, implying that continuity and access could be conflicting objectives.

We found considerable agreement between the personal observations and intuitions of our patient participants and the findings of published research on continuity. This suggests patients have considerable insight into continuity and can play an important role in shaping this research. Changes following lay consultation In published research, objectively measured continuity has only considered consultations with doctors. One of the most common measures (usual provider of care index) only takes account of consultations with a one doctor. Our consultation with patients suggests this does not reflect lay conceptions of continuity. A measure of dispersion (number of different clinicians), including consultations with non-doctors would more closely reflect their views. We therefore included a work package where the views of patients, clinicians and researchers are discussed to try to improve our understanding of what continuity means to different stakeholders and how it should be measured. Prompted by observations about possible drawbacks of continuity we also propose to explicitly explore the trade-off with access and other possible disadvantages in our case studies. We recruited a workshop participant as a lay co-applicant. He will chair a Patient Advisory Group, contribute to interpretation and analysis of interviews focus groups. We followed the advice of our lay co-applicant to create a project website and commission a short animation version of our final report.

Patient and public involvement (PPI) is embedded in the QUERCC project as follows:

Design: Eight members of the public were involved in workshop consultations on the topic for this study in the early stages of our research in 2019. They brought their lived experience and perspectives to the study and suggested themes for further exploration in the work going forward.

Our PPI lead (KS) who lives with a long-term condition is a co-applicant and has collaborated with team members throughout the study development phases and worked with the team to plan study set-up and recruitment. KS has also had input into the acceptability of participant facing information, for example, in the plain English summary, the reference to the Netherlands study was felt to be confusing and could be explained further. We therefore included costs for accessibility and interpretation in WP1 and WP5 and have added an accessibility fund to cover interpretation and translation in these work packages. Our PPI lead is a qualified Polish-English interpreter. KS also led on the recommendation that we

create a translated glossary of terms relating to lay participation in research in the more commonly used non-English languages.

Management: A Patient Advisory Group of 6-8 members of the public drawn from a range of backgrounds will meet three monthly and provide into the monthly Project Steering Group meeting. PPI input will be ongoing throughout the management of the project. Our lay co-applicant (KS) will chair the Project Steering Committee and will contribute to recruitment of a Patient Advisory Group (PAG) of 6-8 participants. Patient advisory group (PAG) members will receive a description of the roles and expectations of the lay advisory Group in advance of recruitment. PAG membership will be offered both to lay people with and without previous experience of PPI.

Site involvement: The recruiting sites will advertise a poster on site alongside copies of the PIS. The sites are not screening any participants for eligibility and no research activities such as taking consent or participating in the workshops will take place at these sites.
Therefore the sites do not currently fall into a research site or PIC site category. Any site agreements/management will follow HRA advice.

Training: After recruitment and sampling is complete the study investigators will provide training and induction on the project for PPI members. Participation in the induction will be paid in line with INVOLVE rates. The involvement in the study will allow them to develop transferrable skills, which they will later be able to use in other PPI activities.

Analysis: Our PPI co-applicant will be trained in and contribute to analysis of qualitative data, he will receive individual training on preparing a study budget, research methods and statistics. This will improve his knowledge and skills as a public contributor to medical research and give him more confidence in his contribution to the study. He will also receive training in qualitative research methods including the opportunity to take part in our Qualitative Research Methods module at University of Birmingham. He will contribute to analysis and interpretation of summary anonymised data. At the end of the study, he will help write a manuscript and texts for a wider audience about the study and the meaning of the findings and a text detailing his experience as a lay co-applicant. Alongside the role of the PPI co-applicant all PPI representatives and members of the multi-disciplinary research team will be engaged in qualitative data analysis by reading a selection of transcripts and

documents, then coming together to discuss and agree on emerging themes to develop the data coding framework.

Dissemination: KS had input into the development of the study documentation, helping to ensure that the consent form and patient information leaflet had clear content and were acceptable to the lay reader.

8.5. Protocol compliance

Should any unforeseen issues to arise during the course of the study that may affect the safety or integrity of the study data or participants the Investigators team will manage these as protocol deviations as set out by the UoB Quality Management System https://www.birmingham.ac.uk/research/activity/mds/mds-rkto/governance/qms.aspx. The PI team will take corrective and preventative measures to avert further breaches. Any incident observed by study researchers will be reported to the PI and used to advance improvement.

8.6. Data protection and confidentiality

Data from the workshops will be stored on a secure server at the University of Birmingham and will be electronically archived (10 years) according to the University of Birmingham's Research Governance Framework. Participants will not be named or identifiable and we will use pseudonyms to report any direct quotes. Data will be treated as confidential at all times including during collection, handling and use. Personal Data will be stored securely on University servers to prevent unauthorised access or disclosure.

The workshop recordings will be transcribed by a professional transcription company that holds a contract with the University. All data once deposited back at the university will be anonymised (all names and other identifiable information will be removed) by a professional company that is approved by the University of Birmingham and will sign a confidentiality agreement. The recordings will be transferred to them through a secure file transferring website. The transcription company will delete the recording once the study team have approved the accuracy of the transcript. The recording will be deleted from the handheld secure audio recorder once the transfer is complete. A copy of the recording will be stored and saved to a secure computer at the University of Birmingham and once it is deleted from the recorder. Audio recordings will be stored until the end of the project. Transcription and analysis will be complex on this project because we are using a workshop methodology

involving a range of different speakers and checks will need to be made to determine which speaker has contributed an idea or viewpoint.. This will require careful tracking of voice across recordings – to be completed by the study RF. Transcripts will be kept for 10 years once the study ends. Transcript information will be kept and analysed on the University of Birmingham computer servers. Only designated members of the research team who hold a DBS / research passport and current Good Clinical Practice certificate will have access to these personal details.

University of Birmingham. The sponsor is the legal data controller for data collected and its data management policies are fully compliant with Data Protection Legislation, HRA guidance contained in the UK Policy Framework for Health and Social Care Research, and The Concordat to support Research Integrity. The Principle Investigators are employees of the study sponsor and use methods that are scientifically sound, safe, ethical, legal and feasible and remain so for the duration of the research, taking account of developments while the research is ongoing.

8.7. Indemnity

The University has in force a Public Liability Policy and/or Clinical Trials policy which provides cover for claims for "negligent harm" and the activities here are included within that coverage. .

8.8. End of study and archiving

Data from the workshops will be stored on a secure server at the University of Birmingham and will be electronically archived (10 years) according to the University of Birmingham's Research Governance Framework.

8.9. Access to the final dataset

The research team will observe the University of Birmingham's Policy on Research Data Management (RDM). The policy lays out requirements and responsibilities for the University and for researchers as currently understood. It will be updated annually as the external landscape develops and amendments will be approved by the University's Research Committee. The Concordat on Open Research Data [PDF - 178kb], as produced by HEFCE, JISC, RCUK, UUK and Wellcome, sets a framework for best practice within UK HEIs with

respect to the management of all research data, and has guided the formulation of key aspects of this Policy.

9. Dissemination policy

Dissemination will make use of a number of methods tailored to each audience. We will seek to maximise impact through a range of pathways, and these will be a standing agenda item on project team and steering group meetings.
Debates about continuity of care to date have been led by clinicians and researchers. A key benefit of our work is involvement of the public and a key output will be in making publicly accessible the findings of our research on the causes of declining RCC, its effects and solutions to the problem. For a **lay audience**, we will create a project website and commission a short animation version of our final report to communicate findings in an accessible way. A project website will make available regular publicly accessible bulletins of interest to the general public. We will ensure these bulletins are press released so that the media are aware of each developing stage of the research. We will write short articles for relevant forums online and international newspapers. We will initiate a social media campaign to garner interest in and share information about the project, and will share research progress and encourage feedback via blogs and personal stories of continuity of care. Through our digital profile we will engage with patient groups and 3rd sector organisations as intermediaries and knowledge brokers to help us develop an effective implementation and dissemination strategy and to ensure we engage heterogeneous groups of stakeholders.

For an **academic audience** we anticipate a report for NIHR and five peer-reviewed publications: a shared understanding of measures of RCC (BJGP, BMC Fam Pract); an analysis of the determinants of RCC in UK primary care (BJGP, BMC Fam Pract); learning from our case study practices (BMJ, Ann Fam Med); practical guidance to improve RCC (BJGP, BMC Fam Pract); an economic analysis the effects of RCC (BJGP, BMC Fam Pract). We will present our findings at SAPC and RCGP conferences. After **Error! Reference source not found.** we will engage with **software manufacturers** (Samir Dhalla of Cegedim and Chris Bates of TPP) to share findings on measurement of RCC in primary care to stimulate work on development of tools to measure RCC. We will provide an interim report on measurement of RCC and a final report on completion of 11 to **regional GP networks** (Dudley Integrated Care Service, Our Health Partnership), to **national bodies** (the RCGP

and NHS England). To directly reach **primary-care clinicians** we will develop a podcast or short video with the Personalised Care Institute to disseminate to clinicians and have fully costed development of **two webinars** and a package of marketing and communications with the RCGP. University of Birmingham's Centre for Primary Care Improvement will create a **postgraduate module** for primary care professionals on managing continuity of care. We will write a brief lay summary for use as a discussion document at practice Patient Participation Groups.

9.1. Authorship eligibility guidelines and any intended use of professional writers

The PIs will follow the guidelines on authorship as set out in The International Committee of Medical Journal Editors has defined authorship criteria for manuscripts submitted for publication, known as the Vancouver Protocol on the final report.

10. Appendices

10.1. Appendix 1 – required documentation

10.2. Appendix 2 – schedule of procedures

10.3. Appendix 3 – amendment history

The following amendments and/or administrative changes have been made to this protocol since the implementation of the first approved version

Amendment number	Date of amendment	Protocol version number	Type of amendment	Summary of amendment

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SUB - PROTOCOL WORK PACKAGE 3

PROTOCOL WP 3

Title page

Full/long title of the project **Q**uantifying, **U**nderstanding and **E**nhancing **R**elational **C**ontinuity of **C**are

Short title/acronym **QUERCC WP3**

Protocol version number and date

PROTOCOL VERSION NUMBER AND DATE	**4.0 27 3 2025**
IRAS NUMBER	333821
SPONSORS NUMBER	RG_23-141
REC REFERENCE NUMBER	24/EM/0031
PUBLIC REGISTRY NUMBER	
FUNDERS NUMBER	HS&DR Project: NIHR152277

Signature page

The undersigned confirm that the following protocol has been agreed and accepted and that the CI agrees to adhere to the signed University of Birmingham's sponsorship CI declaration.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the project will be given; and that any discrepancies from the project as planned in this protocol will be explained.

Full project title:	**Q**uantifying, **U**nderstanding and **E**nhancing **R**elational **C**ontinuity of **C**are
Protocol version number:	1.0
Protocol version date:	27 3 2025

Chief Investigator (CI)	
Name:	Professor Tom Marshall Institute of Applied Health Research College of Medical and Dental Sciences University of Birmingham Edgbaston Birmingham, B15 2TT
Date:	**27 3 2025**
Signature:	

Sponsor statement

Where the University of Birmingham takes on the sponsor role for protocol development oversight, the signing of the IRAS form by the sponsor will serve as confirmation of approval of this protocol.

Key contacts

Chief Investigator	Professor Tom Marshall Primary Care Clinical Sciences Institute of Applied Health Research College of Medical and Dental Sciences University of Birmingham Edgbaston Birmingham, B15 2TT
Study Co-ordinator	Dr Fiona Scheibl Research Fellow Institute of Applied Health Research College of Medical & Dental Sciences University of Birmingham Edgbaston Birmingham B15 2TT
Sponsor	Research Governance University of Birmingham Edgbaston Birmingham B15 2TT Research Strategy and Services Central researchgovernance@contacts.bham.ac.uk
Joint-sponsor(s)/co-sponsor(s)	n/a
Funder(s)	The Authority's Representative for contract management purpose: Dr Kay Pattison Science Research and Evidence Directorate Department of Health and Social Care Quarry House Quarry Hill Leeds LS2 7UE The Authority's Representative for project management purposes: NETSCC Operations Finance Alpha House Enterprise Road Southampton Science Park Southampton SO16 7NS
Key Protocol Contributors	Professor Tom Marshall Primary Care Clinical Sciences Institute of Applied Health Research College of Medical and Dental Sciences University of Birmingham Edgbaston B15 2TT Telephone +44 (0)121 414 7832 Email: t.p.marshall@bham.ac.uk

	Professor Shelia Greenfield Institute of Applied Health Research College of Medical and Dental Sciences Murray Learning Centre University of Birmingham Edgbaston B15 2TT Telephone: +44 0121 414 6493 Email: s.m.greenfield@bham.ac.uk Professor Iestyn Williams Director of Research School of Social Policy Health Services Management Centre, Park House University of Birmingham Edgbaston B15 2RT Tel:+44 121 414 7063 Email: i.p.williams@bham.ac.uk Professor Krishnarajah Nirantharakumar Health Data Science and Public Health Institute of Applied Health Research University of Birmingham Edgbaston B15 2TT tel:+44 121 414 8344 k.nirantharan@bham.ac.uk Dr Brian Willis Senior Clinical Lecturer in General Practice & MRC Fellow Institute of Applied Health Research University of Birmingham Edgbaston B15 2TT b.h.willis@bham.ac.uk tel:+44 121 414 7949 Dr Panagiotis Kasteridis Research Fellow Health Economics Centre for Health Economics University of York Panos.kasteridis@york.ac.uk (01904) 321429 Mr Kamil Sterniczuk Lay co-applicant Lay advisor. Chair patient advisory group, Institute of Applied Health Research University of Birmingham Edgbaston B15 2TT kamil.sterniczuk@gmail.com

Project summary

Relational continuity of care (RCC) is the extent to which patients see the same clinicians over time. Considered a core feature of general practice, it is linked to patient satisfaction and better health outcomes, especially for older patients, those with long-term conditions and the vulnerable. Although current NHS policy is to maintain continuity for patients with long-term conditions, it has been declining for at least a decade. Contributing factors are thought to include growth in practice size, more part-time working, greater staff and patient turnover. It may also be because practice policies have focused on access, rather than continuity.

Because they often neither measure nor monitor it, general practices may be unaware how their within-practice policies impact RCC. Furthermore, conceptions of RCC differ between clinicians and between patients, and there are different ways of measuring RCC which reflect these different conceptions. A shared understanding of continuity will help practices decide on the purpose of measurement, what they want to measure and which RCC index best meets their aims. We do not know the extent to which practice-level characteristics - practice size, part-time working, staff turnover and patient turnover - affect RCC. We therefore do not know the extent to which within-practice policies to maintain RCC can mitigate the effects of practice-level characteristics. The health of older patients and those with chronic diseases may benefit most from continuity. The optimum balance between access and continuity may therefore vary across different patient groups. For a realistic strategy to improve RCC it would help to know if there are groups in which there is a stronger case for RCC and in which it should therefore be prioritised. There are potentially many ways to optimise continuity. As no two general practices are the same, the most successful approach is likely to depend on the practice context. This project uses a variety of methodologies to address these questions, with the overall aim of helping practices optimise continuity of care. This work is done across five work packages:

Work package 1: First, we develop an understanding of RCC to help practices determine how best to measure and monitor their own RCC. This will be achieved by hosting consensus case study s of patients, primary care clinicians and researchers.

Work package 2: Second, in a large number of general practices, we will model the association between RCC and practice-level characteristics including staff turnover, part-

time working, practice size and if linkage is possible, practice funding per patient. From this we will understand the drivers of RCC and identify practices showing higher-than-predicted RCC (positive deviants) for investigation as case studies.

Work package 3: Third, we will undertake detailed case studies in a sample of general practices, focusing on positive deviants. We will explore staff and patient experience of continuity (including possible trade-offs between access and continuity) and investigate the interplay between measured RCC and informational or management continuity. We will identify practice policies contributing to RCC, along with barriers and facilitators to their implementation. Qualitative findings will be triangulated with the practice's measured continuity and subjectively reported continuity in the General Practice Patient Survey (GPPS).

Work package 4: Fourth, we will undertake economic analysis to estimate the projected effects of RCC on resource costs and health outcomes, using linked primary and secondary care data. This will help us understand the likely effects of changing RCC in a general practice and whether these effects vary in different patient groups (by age, sex, deprivation status and chronic disease status).

Work package 5: Fifth, we will develop empirically-informed practical guidance to improve continuity of care, collating findings of our quantitative analysis of predictors of RCC, case studies, economic analysis, and existing work on continuity of care in the UK and internationally.

We seek approval in this application to commence the work of WP3 during which we will conduct case study research using focus group methods across eight purposively sampled practices to better understand the determinants of RCC.

To this end the current protocol provides details of the methods used in WP3 for ethical review. We will make submissions and seek approval for the other work packages as a separate application.

Funding and support in kind

Funder(s)	Financial and non-financial support given
NIHR Health Services and Delivery Researcher Led (standard) HS & DR Project NIHR152277	**£1,000,102.71**

Role of sponsor and funder

11. In consideration of the rights and obligations recorded in the Contract_for_Project_NIHR152277.pdf dated 13th October 2022

e. The Contractor will undertake a research project entitled Quantifying, Understanding and Enhancing Relational Continuity of Care (QUERCC) in accordance with the work specified in SECTION 3, being project application NIHR152277, dated 10 October 2022, the "Research".

f. In the event of a Public Health Emergency (as defined below), the Authority may direct the Contractor to perform further work in addition to (or in replacement of) the Research in accordance with SECTION 2, Clause 3.5.

12. The Authority will pay the Contractor the Approved Cost as set out in SECTION 4 in respect of undertaking the Research in accordance with this Contract.

13. This Form of Contract (SECTION 1) together with the attached SECTION 2 to SECTION 7 inclusive are the documents which collectively form the "Contract" (as defined in SECTION 2).

14. Where the Contractor is a health service body within the meaning of Section 9 of the National Health Service Act 2006 then this Contract is an NHS Contract within the meaning of that Act.

15. The Contract effected by the signing of this Form of Contract constitutes the entire agreement between the Parties relating to the subject matter of the Contract and supersedes all prior negotiations, representations or understandings.

Roles & responsibilities of management committees/groups & individuals

The QUERCC study management group

Oversight and review of the day-to-day management and coordination of the project will be undertaken at monthly meetings of the Study Management Group. This group draws together expertise from the University of Birmingham and independent expertise from the University of York. The core members are:

Members of QUERCC Study Management group

Tom Marshall	t.p.marshall@bham.ac.uk	IAHR
Sheila Greenfield	s.m.greenfield@bham.ac.uk	IAHR
Fiona Scheibl	f.scheibl@bham.ac.uk	IAHR
Iestyn Williams	I.P.Williams@bham.ac.uk	HSMC
Panos Kasteridis	panos.kasteridis@york.ac.uk	University of York
Zecharias Anteneh	zecharias.anteneh@york.ac.uk	University of York
Brian Willis	B.H.Willis@bham.ac.uk	IAHR
Krishnarajah Nirantharakumar	K.Nirantharan@bham.ac.uk	IAHR

The role and responsibility of this group is to ensure project milestones are met, research problems are resolved and forward planning to achieve agreed study outputs is undertaken.

An additional expert [Serge Engamba] a researcher in contract at the University of Exeter and a clinician is added to the research team to undertake data collection on WP3. SE has an honorary contract at UoB and will collect qualitative data in interviews and focus groups at sites recruited to case study. The purpose of adding Serge Egamba to the research team is to increase expertise in data collection. No additional scientific critique has been obtained.

SE will use a secure laptop to collect and analyse data for online focus groups and interviews and will collect data face to face using a hand held recorder [as per protocol below]. Consent will be obtained by email from participants and witnessed in the online interview or focus group. No data will be collected or stored on Exeter servers or research

instruments. A range of guidelines have been discussed to enable Serge to collect data as follows:

- SE will be issued with a UoB recorder to conduct and record face to face interviews / focus groups
- SE will be issued with a UoB laptop for data collection online using teams and or zoom
- All data will be stored (recordings) on a UoB laptop
- SE will use the transcription service already in use by UoB team
- SE will get a UoB email address with the honorary contract. This email address will be added to the invite letter and information sheet so contacts can be made with practices.
- If a general practice agrees to take part in the study, SE will apply to relevant RDN to obtain a Letter of Access from the appropriate regional Research Delivery Network (used to be called the Clinical Research Network)
  SE will follow the approved procedures for consent as stated in WP3 protocol
- The retained copy of the consent forms, this is a paper copy will be signed and returned to UoB
- SE will share the study RISP [Research Information Sheet for Practices] which sets out the payments available to sites and what taking part involves for them.
- SE will use the Local Information Pack, OiD and SoECAT in line with protocol and share will share with the sites and RDN once a site expresses interest. Study documents will be made accessible through sharepoint and the study RF Fiona Scheibl will provide guidance to the use of said documents and the process as part of an induction to the team.

A further key responsibility of the management group is to prepare and obtain ethical approval for the study from the NHS REC committee and Health Research Authority (HRA) along with relevant research governance approvals.

The management group ascertain that the main ethical questions relate to participant anonymity and the safeguarding of any private data. To ensure ethical compliance in WP3 we will obtain informed consent from all participants who agree to take part in focus groups at each of the case study sites. Where possible consent will be obtained in person on the day of the focus group. Where participants attend a focus groups in an online platform as part of the case study, we will obtain consent electronically via a typed signature on an email copy of the study consent form ahead of the case study. If a participant is unable to

complete the form electronically the study RF will run through verbal consent when participants join the online platform to confirm they have understood and accept the terms of the study prior to commencing the case study proceedings on the day of the case study. We will provide all potential participants with information about the study, and time to consider participation. Data will be stored in line with institutional policies. Interview participants will not be named or identifiable in any report or publication and we will use pseudonyms to report any direct quotes. We provide further details of the processes in place to achieve this in section 5.3.2 below.

Project research expertise

TM is Professor of Public Health and Primary Care with expertise in health services research in particularly using electronic primary care records. He will lead the project and directly supervise RF2 (quantitative). He will be supported in this by BW.

BW has extensive experience of analysis of primary care records and is both a practising GP and an Associate Professor. He holds a PhD in Medical Statistics.

SG is Professor of Medical Sociology. She is a qualitative methodologist and with extensive experience in the design and implementation of qualitative methodology as a component of mixed methods research, particularly in primary care. Recent research has included practices' use and attitudes to patient safety tools and the role of receptionists. SG leads 9.

IW is an experienced health services researcher focussing on health organisation, implementation research and complex intervention development. He has methodological expertise in mixed methods including consensus methods and will lead **Error! Reference source not found.**. He has extensive experience of qualitative case studies and, through his role at the Health Services Management Centre, is linked to extensive networks of current and future NHS leaders, for example through the national Nye Bevan and Elizabeth Garrett Anderson Leadership programmes.

SG and IW will supervise RF1 (qualitative). Both are highly experienced qualitative researchers. Their expertise and leadership will provide oversight on qualitative data management processes. Although supervision will be provided by SG and IW for FS neither they or any other member of the research team, the PPI / PAG members or external

advisory group members will have access to primary research data /participant data. If and when data is shared or reported to these study members they will only view and have access to summary data which will be fully anonymised. Only the lead qualitative researcher (FS) will have access to raw data and will organise the transfer of data files to the transcription agency and check the accuracy of their work.

PK is a health economist with an econometrics background. He has an interest in quality in primary care and extensive experience of analysis of using linked electronic health records for research. This includes analysis of the effects of continuity of primary care on admissions for mental health problems. PK who is based at the University of York will not have access to any participant identifiable data or contact details which are collected during WP3 by FS at University of Birmingham. PK works only with CPRD data during WP2 which are anonymised.

KS is a patient with a chronic condition who will lead PPI, chairing Patient Advisory Group meetings and liaising with the Project Steering Group.

The External Advisory Group

An External Advisory Group will be convened including Dr Mairead Murphy (University of Bristol) a qualitative researcher with an interest in continuity of care; Dr Otto Maarsingh (Amsterdam University Medical Centre) who leads the TOOL study, and Nicolas Thomas a member of the RCGP. This group will be convened and meet with the Project Steering Group every third month: half of the meetings will be online.

All members of the external advisory steering group are independent from the Sponsor and the Investigators. Each member brings expertise in the field of relational continuity of care.

(QUERCC) External Advisory Group Members

Nicholas Thomas	Nicholas.Thomas@rcgp.org.uk	RCGP
Jenna Collins	Jenna.Collins@health.org.uk	The Health Foundation
Otto R Maarsingh	o.maarsingh@amsterdamumc.nl	Amsterdam University Medical Centers
Theo Bartholomew	theo.bartholomew@nhs.net	NHS England
Mairead Murphy	Mairead.Murphy@bristol.ac.uk	University of Bristol

Oversight External Advisory Group: Meeting Annually

The Oversight External Advisory group is comprised of expert stakeholders, two are co-opted members of the funding body (tbc). The role of the group is advisory, and their responsibility is to review study documents and outputs to ensure the research is addressing wider trends and issues and raise awareness of potential collaborations and new developments. The core members, all of whom are independent of the Sponsor and Investigators. Core members are:

Oversight External Advisory Group

Funding body representative	tbc	NIHR HSDR
Funding body representative	tbc	NIHR HSDR
Nicholas Thomas	Nicholas.Thomas@rcgp.org.uk	RCGP
Jenna Collins	Jenna.Collins@health.org.uk	The Health Foundation
Otto R Maarsingh	o.maarsingh@amsterdamumc.nl	Amsterdam University Medical Centers
Theo Bartholomew	theo.bartholomew@nhs.net	NHS England
Mairead Murphy	Mairead.Murphy@bristol.ac.uk	University of Bristol
Mai Stafford	Mai.Stafford@health.org.uk	The Health Foundation
William Whittaker	william.whittaker@manchester.ac.uk	University of Manchester
Janina Ruszczynska	goth4you@gmail.com	

Patient & public involvement group

Our lay co-applicant Mr Kamil Sterniczuk (KS) is PPI lead and sits on the Project Steering Committee. KS led recruitment of a Patient Advisory Group (PAG) of 6-8 participants which he will chair. The PAG meets every third month and provide input into the monthly Project Steering Group meeting to ensure their involvement throughout the project.

KS contributed to all aspects of study design and planning and advised on study set-up and participant recruitment. KS will undergo training in a range of core skills (budget management, statistics and qualitative research) by taking part in undergraduate modules at University of Birmingham. He will contribute to data analysis across work packages and contribute to writing for publication as appropriate.

KS will not have access to primary research data /participant data. When data is shared with KS or other members of the PAG they will only have access to fully anonymised summary. Only the lead qualitative researcher (FS) will have access to raw data and will organise and manage the dissemination of data to the PAG.

To ensure broad representation, when recruiting to PAG we will liaise with the well-established NIHR ARC West Midlands patient and public involvement infrastructure and with Dudley Integrated Health & Care Trust's. Experience of continuity of care varies by age, gender, education level, ethnicity and chronic disease status, and we will work to achieve diverse representation to the study PAG.

We will provide potential PAG members with a description of the roles and expectations for involvement ahead of recruitment. Recruitment will aim at lay people with and without previous experience of PPI. After recruitment, the study investigators will provide training and induction on the project. Participation in the induction will be paid in line with INVOLVE rates and will equip PPI members with transferrable skills for future use in other PPI activities.

We will provide updates to the PAG on research progress and preliminary findings. The group will meet quarterly throughout the project and provide feedback to the Project Steering Group. The lay co-applicant will act as a point of contact for other lay members. It is anticipated that the PAG will contribute to the interpretation of relational continuity of care, advise on recruitment and involvement of patient representative / study participants in the workshops and case studies, contribute to the design of dissemination materials including the study website. They will also provide a lay view on the acceptability and feasibility of possible solutions to enhance continuity of care. This will help inform the development of guidance for general practices on how to improve continuity of care in the final work package. An opportunity will be provided for PAG members to write about their experience. The PAG will contribute to dissemination by publishing results on the study website, social media and Health Unlocked.

The PAG and lay co-applicant will help implement findings by working with policy makers and patient representative support groups. The Study Investigators will host a 'thank you' event for the PAG at the study's end.

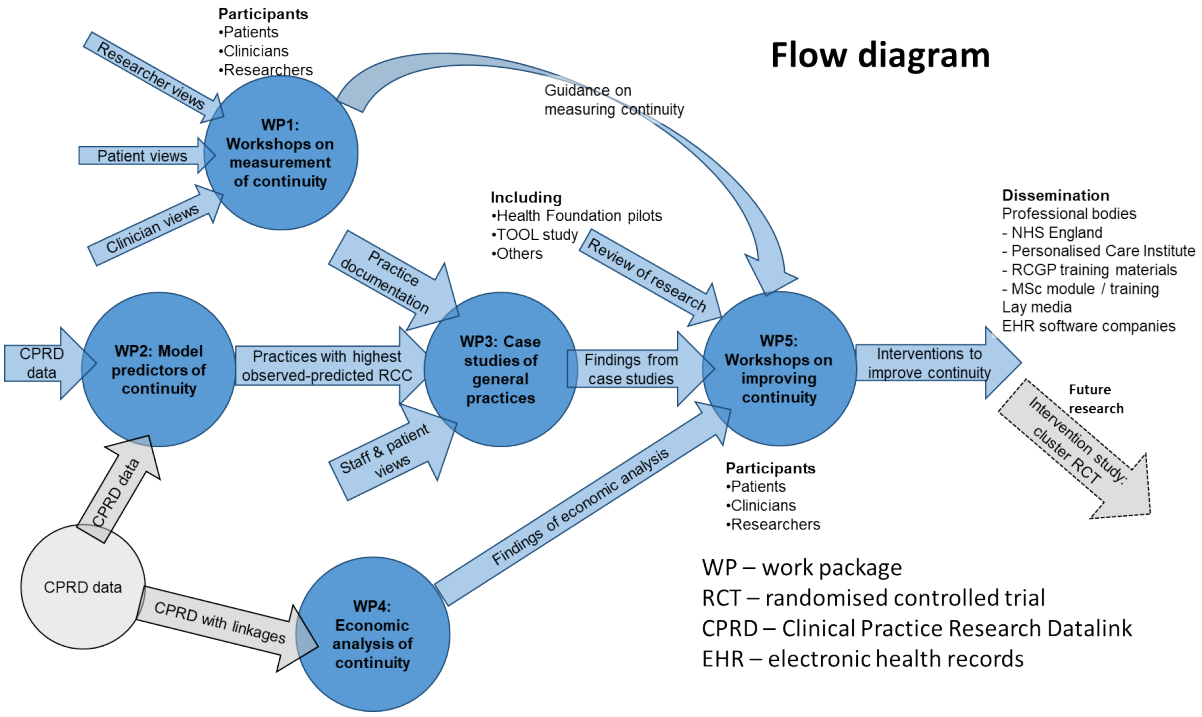
Protocol contributors

Key Protocol Contributors	Professor Tom Marshall Institute of Applied Health Research College of Medical and Dental Sciences University of Birmingham Edgbaston B15 2TT Telephone +44 (0)121 414 7832 Email: t.p.marshall@bham.ac.uk Professor Shelia Greenfield Institute of Applied Health Research College of Medical and Dental Sciences University of Birmingham Edgbaston B15 2TT Telephone: +44 0121 414 6493 Email: s.m.greenfield@bham.ac.uk Professor Iestyn Williams Director of Research School of Social Policy Health Services Management Centre, Park House University of Birmingham Edgbaston B15 2RT tel:+44 121 414 7063 Email: i.p.williams@bham.ac.uk Professor Krishnarajah Nirantharakumar Health Data Science and Public Health Institute of Applied Health Research University of Birmingham Edgbaston B15 2TT k.nirantharan@bham.ac.uk tel:+44 121 414 8344 Dr Brian Willis Senior Clinical Lecturer in General Practice & MRC Fellow Institute of Applied Health Research University of Birmingham Edgbaston B15 2TT b.h.willis@bham.ac.uk tel:+44 121 414 7949 Dr Panagiotis Kasteridis Research Fellow Health Economics Centre for Health Economics University of York Panos.kasteridis@york.ac.uk (01904) 321429 Mr Kamil Sterniczuk Lay co-applicant Lay advisor. Chair patient advisory group, Institute of Applied Health Research University of Birmingham Edgbaston B15 2TT kamil.sterniczuk@gmail.com

Key words

Continuity
General practice
Case studies
Patients
Health systems
Mixed methods research

Project flow chart



Protocol

Relational continuity of care (RCC) is a core feature of primary care, it is valued by patients and is linked to better health outcomes. RCC is also declining. The overall aim of this project is to understand better how to improve continuity of care. We will develop our understanding of how to measure RCC. We will analyse the practice factors contributing to RCC and undertake case studies of practices with high RCC. We will quantify the health and resource effects of RCC. We will do this across five work packages:

Error! Reference source not found.*1*, develops a shared understanding of RCC to guide the choice of measurement indices.
8, undertakes quantitative analysis to investigate determinants of RCC and to identify outlier practices.
93, will investigate primary care practices with high levels of relational continuity of care (positive deviants) as case studies.
Work package 10, will undertake an economic analysis of the effects of RCC.
Work package 11, develops empirically informed practical guidance to help general practices optimise RCC.

11. Background

RCC indices in use to date have mainly been selected by researchers and measurement has only included consultations with doctors. Depending on the practice's preferences, RCC indices could include consultations with all patients or with some patients (e.g. age 65+); consultations with all clinicians, or only with GPs; may measure density or dispersion (see **Table 1** p.22 below).

In the conception and development of this proposal we consulted 8 patients in 2 case studies in 2019. Participants felt relational continuity of care (RCC) was important and shared many narratives illustrating RCC or its absence in primary care consultations. They generally stressed the importance of developing a relationship with a GP and avoiding the need to explain their circumstances at every visit. They felt continuity would reduce over prescription and unnecessary medication changes. Some felt RCC was crucial, but others were less concerned about seeing the same GP or even valued a different GP's opinion. All participants acknowledged the importance of continuity for patients with long term

conditions, the elderly, and more disadvantaged patients. They perceived RCC as becoming more difficult to maintain with longer waiting times and pressure on health services to provide better access. They identified part-time working, larger practices and automated booking systems as potential barriers to continuity and identified receptionists as playing a key role in continuity. When asked about measuring continuity patients emphasised that RCC did not have to be with a single GP but a small number of GPs (e.g. 2 to 3) would count as continuity. They also said continuity could be with another healthcare professional (e.g. a nurse). They were supportive of the proposed research, some adding that it was important to elicit the views of healthcare professionals on continuity. We found a striking congruence between the personal observations and intuitions of our lay participants and the findings of published research. This suggests patients have considerable insight into RCC and have an important role in shaping this research.

There is a long-recognised need for consistent measures of RCC (Saultz and Lochner 2005, Salisbury, Sampson et al. 2009, Freeman G 2010). The RCGP emphasises the need to measure relational continuity as a first step in its management (RCGP 2022). But choosing an appropriate measure is complex (Jackson and Ball 2018). Subjective RCC (the patient's experience of continuity), measured through questionnaires, is impractical for monitoring (Dolovich, Nair et al. 2004, Uijen, Schers et al. 2012, Hill, Twiddy et al. 2014, Ball, Barnes et al. 2018). Objective RCC measurement (a quantitative measure of frequency of consultation with the same clinician) is feasible using electronic health records (EHR) and correlates with subjective measures (Tousignant, Diop et al. 2014). But different objective measures capture different conceptions of RCC (Salisbury, Sampson et al. 2009). Continuity may be with the GP or with any clinician; it may be in all patients or in specific patient groups (e.g. ≥65 years); it may be measured quarterly, monthly, or weekly. There are different RCC indices. Some measure density: Usual Provider of Care index (UPC) % of consultations with most frequently seen GP, or the St Leonard's Index of Continuity of Care (SLICC) % of consultations with a named GP (Sidaway-Lee, Gray et al. 2019). Others measure dispersion, taking account of the number of different clinicians consulted, using the Bice-Boxerman (BB) or Herfindahl (HI) indices. There is a measure of Sequential Continuity (SECON) (summarised in

Table 1 below)

Table 6: Main indices of relational continuity of care (RCC)

Name	What is measured	Formula
Bice-Boxerman (BB)	Dispersion	$\frac{\left(\sum_{i=1}^{p} n_i^2\right) - n}{n(n-1)}$
Herfindahl Index (HI)	Density	$\sum_{i=1}^{p}\left(\frac{n_i}{n}\right)^2$
Usual Provider of Care ($UPC^{Patient}$)	Density	$\max\left(\frac{n_i}{n}\right)$
St Leonards Continuity of Care (SLICC or $UPC^{GP\ level}$)	Density	$\text{named clinician}\left(\frac{n_i}{n}\right)$
Sequential (SECON)	Handoffs	$\frac{\left(\sum_{j=1}^{n-1} c_j\right)}{(n-1)}$

p = total number of providers (clinicians); n = total number of visits during episode; n_i = number of visits to provider i; c_j = indicator of sequential visits to same providers, equal to 1 if visits j and j+1 are to the same provider, 0 otherwise

Research has also explored effects of regularity and minimum frequency of contact on patients with chronic conditions. (Einarsdóttir, Preen et al. 2011, Ha, Harris et al. 2020) Density measures decline with consultation frequency but dispersion measures are less affected (El Turabi 2019). In practice, BB, HI, UPC and SECON are often highly correlated (Pollack, Hussey et al. 2016). SLICC is easy to calculate at the practice level and does not require patients to have a minimum number of consultations, but it may differ from the UPC if the patients' usual GP and named GPs differ (Swanepoel 2020).

There are questions about measuring RCC and the answers vary with the aim of measurement. Should RCC be measured only in older or chronic disease patients? Should it include consultations with all clinicians or only with GPs? Should RCC reflect the patient's, the doctor's, or the healthcare system's perspectives of RCC? Over what time period should RCC be assessed? Which RCC index should be used? A measure of RCC should be practical, understandable and reflect what patients and clinicians mean by continuity. For example, our lay participants (see above) who joined the pre-application workshops emphasised RCC could be provided by non-GP clinicians, or by 2 or 3 rather than 1 clinician. This view is consistent with a RCC index including consultations with all clinicians and measuring dispersion. But density indices are more widely used and to date no measure includes consultations with non-GPs. Our survey of 43 GPs (see above) revealed some

support for monthly (or 2-3 monthly) RCC monitoring. While measurement of RCC is both feasible and useful, the aims of measurement vary and neither what to measure nor the optimum choice of index are clear.

12. WP3 Research question/aims

To understand in depth the internal features of general practices which are barriers and facilitators to RCC and how external features are experienced within practices.

13. Method

RCC is a complex and multi-faceted topic and therefore an exploratory multiple case study design is best suited to achieve our aim as this enables exploration and description of the complex underpinning links and processes in practices which display unusual RCC variation (Yin 1994). Data will be collected across a purposively selected sample of eight general practices in England using focus groups, interviews and documentary analysis. This sample size and mix of data collection methods is considered appropriate to provide a range of data sufficient to cover the required depth and breadth of perspectives (Crowe, Cresswell et al. 2011)

Project timeline: Months 7-32. (Months 7-10 ethical approval; months 10-19 recruit practices for case-studies; months 11-26 practice interviews and focus groups; 12-32 qualitative analysis. Led by SG.

14. Analytical framework

Thematic inductive analysis using the Framework Method with themes compared within and across practices, focus group, interview and documentary data (Braun and Clarke 2006).

14.1. Outcome

The primary output of 9 is an understanding of the practice characteristics which contribute to RCC and understanding of barriers and facilitators to RCC and the mechanisms by which RCC influences health.

To support dissemination of findings, a secondary output will be identifying individuals as potential advocates for general practices which have maintained high levels of continuity.

These may be research participants or individuals identified as champions within individual general practices.

15. Project setting

English general practice.

16. Sampling

A purposive sampling method is used.

Size of sample

- Eight general practices selected from the Clinical Practice Research Datalink (CPRD). This dataset holds anonymised electronic health records of around 1800 general practices and is broadly representative of the English general population.

Sampling technique

In WP2 analysis of CPRD will identify an upper quartile (180) with the highest continuity of care (CoC) and a lower quartile (180) with average CoC. Within these quartiles we will also consider the size of practices with high and low CoC and whether the populations they serve is more, or less, deprived. The analysis of CPRD in WP2 requires approval by an Independent Scientific Advisory Committee and this is currently in progress through colleagues at York University (PK) under direction from PI Tom Marshall. WP2 is analysis of the Clinical Practice Research Datalink (CPRD) database. CPRD has ethical approval for analysis of data (see link below). Requests by researchers to access and analyse CPRD are reviewed by the CPRD Research Data Governance process to ensure that the proposed research is of benefit to patients and public health. We have submitted an application to the CPRD Research Data Governance process and are awaiting a response from CPRD. https://www.hra.nhs.uk/planning-and-improving-research/application-summaries/research-summaries/clinical-practice-research-datalink-cprd-research-database/

In WP3 we will recruit 8 ‘deviant’ cases from CPRD: six general practices from the quartile with the highest continuity of care (from the top 10%) and two general practices from those with average continuity of care (the lowest 10%).

RCC is a complex and multi-faceted topic and therefore an exploratory multiple case study design using deviant cases is best suited to achieve our aim as this enables exploration and description of the complex underpinning links and processes in practices which display unusual RCC variation (Yin 1994). Evidence from analysis and simulation indicates that selecting case studies from outliers (deviant cases) is an efficient way to find out about causal pathways and causes of heterogeneity (Seawright 2016, Baxter, Taylor et al. 2019). A similar method has been used to investigate wards providing safe hospital care (Baxter, Taylor et al. 2019).

Case study recruitment

All data in CPRD are anonymised so it is not possible to identify the case studies prior to obtaining their agreeing to take part. We have been advised by the HRA that we can submit a minor amendment once data work of WP2 is complete and the case study sites can be formally contacted. We will enlist the CPRD agency to send invites to practices that meet the inclusion criteria on behalf of the QUERCC study.

We will supply CPRD with a template letter (included in the documents submitted with this application) to send out to sites that meet the criteria. We will aim to include practices of diverse sizes, inner-city urban and rural locations, however CPRD's anonymity rules mean we are limited to those which agree to take part. Recruitment will be ongoing until 8 sites have been enlisted once they have returned an expression of interest by email to the study co-ordinator (FS).

Strategy to pre-empt and avert the risk of low recruitment to WP3.

Supplementing sampling for WP3 with a snowball approach is required due to any potential delays in approvals for WP2 data linkage of CPRD data.. It is imperative therefore to pre-empt and avert the risk of low recruitment to WP3. The snowball sampling approach will ensure that WP3 can commence data collection and the delays caused by lack of approvals for WP2 can be mitigated.

To follow the snowball sampling approach through we will draw on contacts across professional networks and desk research. We have made contacts with sites fitting the criterion of high and average RCC during our engagement with clinical stakeholders during WP1. Some WP1 stakeholders volunteered sites known to them as high performing or

interested in improving their RCC. Additionally, some primary care sites identify themselves as high performing on RCC on their study website.

To follow this snowball method through we will identify a contact at the site and approach them directly and send them a copy of the invite letter (Letter template CPRD vs 1.0 23 8 2023) asking them to participate. If the partners at the site agree to take part, we will contact the relevant CRN / RD office to obtain LoA approvals. When these are in place we will proceed with recruitment.

Analysis by the PI (Professor Tom Marshall) using data obtained from GPPS (General Practice Patient Survey) gives details of when patients report on how often they can see the doctor of their choice / preference. These data give some indication of RCC and can be used as a proxy to identify primary care sites that are performing high on relational continuity of care. Using these combined strategies we will invite sites to join the study.

We will use the GPPS to formally identify sites in the circumstance where the CPRD data is not forthcoming in time for the project to work with 8 case study sites. We have already used snowball methods and used GPPS to check they are high performing on relational continuity using an alternative question included in the GPPS [do you see your preferred GP always, a lot of the time]. We can also identify high performing sites and write to them directly to ask them to join the study. This is intended to supplement sample selection and overcome delays.

a. Inclusion criteria for the 8 case study sites

- 6 sites with high levels of continuity of care (sampled from 180 practices from the top 10%)
- 2 sites with lower or average levels continuity of care (sampled from 180 practices from the lowest 10%)

b. Exclusion criteria for case study sites

- Levels of continuity of care that fall outside the stated inclusion criteria.

Once an expression of interest is received a study researcher will organise a zoom / Teams call with the site contact to roll out and plan the recruitment strategy. It is anticipated that the site with nominate a research lead (such as the operations director / practice manager / clinical research lead. This contact will be enlisted to send a participant invitation letter, PIS and a consent to contact form to all employees and lay representatives. A lay representative is a patient who takes part in the local Patient Advisory meeting and takes on a role of communicating with the wider patient body about developments and research ongoing at the practice. It is anticipated that lay patient representatives will be willing to work with the study team as a recruitment champion for the study.

We aim to recruit patients registered at the practice and lay representatives who are registered as patients at the practices to the focus groups and interviews.

When a 'consent to contact form' is received by the RF they will contact the potential participant to conduct a check to ensure they meet the study eligibility criteria. If they do not meet the criteria the consent to contact form will not be retained and any data collected deleted.

If the potential participant meets the eligibility criteria the RF will check that they have had a copy of the PIS and have read it. If this is confirmed the RF will check that they still want to join the study. If they confirm their interest the RF will enlist them to the study.

To improve recruitment rates, we will facilitate participation by offering flexible times and either hybrid or in person options for interviews and focus groups. If focus groups or interviews are held remotely these will be conducted in offices supplied for this purpose at the Murray learning Centre UoB and the UoB zoom account will be used or Microsoft teams depending on the preference of the interviewee.

Participant recruitment at case study sites

Using the strategy outlined above we will recruit up to 27 participants at each of the eight case study sites. We will undertake 2 focus groups, each including between 6 and 12 participants: one with a range of clinical and non-clinical staff; and one with a diverse group of patients.

Focus groups will be supplemented with semi-structured interviews with up to 3 key informants per practice. It is anticipated that the informants called to interview will be referred

to the study team during the focus group session or be recommended to the study by contacts snowballed within the practice. Participants invited to interview will be selected according to areas of interest that emerge during the research. This form of snowball sampling is a recognised approach in the social sciences (Kirchherr and Charles 2018). In practice it involves asking current consented participants to mention the study to people whom they think might be interested in participating and could contribute important information to the research. The RF will ask the referring person to hand a PIS to the person they think might be interested together with a contact email and phone number. This means the referrals can contact the researcher directly only if and when they are ready and interested to do so. Under no circumstance will the RF or study team obtain names directly from participants because this will violate the referrals' privacy. This will be averted by having current participants mention the study directly to referrals, who can then contact the researcher if interested. Once they have expressed interest in joining the study and given their permission for the RF to contact them they will be formally recruited and then complete a consent form before undergoing an interview.

This size and number of focus group is optimal for data collection in a case study context (Fusch and Ness 2015, Wilkie 2016). We will monitor the diversity of the sample recruited by age, gender, ethnicity, education level and chronic disease status. To do this we will use an equality and diversity form to collect details of participants' age, gender, educational background, ethnicity and chronic disease status in order to ensure representation. An interpreter will be made available to any potential participant whose first language is not English and wants to take part, we will translate the PIS/ E&D/ ICF documents on their behalf to enable them to fully consult the terms of the study and consider the implications of participation.

The total number of people recruited and consented to take part will be in the region of n=72-216 (2 focus groups (6-12 people) + 3 interviews x 8 sites). This will provide data transcripts for analysis from 16 focus groups and between 8 and 24 interviews in total.

c. <u>Inclusion criteria for focus group and interview participants</u>

i. Inclusion criteria for clinicians

- Persons with capacity
- Lower age limit: 20 Years - Upper age limit: 95 Years
- Currently registered and employed at the case study site

ii. Inclusion criteria for nurses and allied health professionals

- Persons with capacity

- Lower age limit: 20 Years - Upper age limit: 95 Years
- Current registration and employment as nurse / allied professional in the case study site

iii. Inclusion criteria for staff support staff / receptionist staff

- Persons with capacity
- Lower age limit: 20 Years - Upper age limit: 95 Years
- Current employment as a member of reception at the case study site

iv. Inclusion criteria for patients

- Persons with capacity
- Lower age limit: 20 Years
- Upper age limit: 95 Years

Patients currently registered as a patient at the case study site

d. Exclusion criteria for focus group and interview participants

i. Exclusion criteria for clinicians

- Persons who lack capacity
- Not employed at the case study site

ii. Exclusion criteria for nurses

- Persons who lack capacity
- Not employed at the case study site

iii. Exclusion criteria for receptionist/ allied health professional

- Persons who lack capacity
- Not currently employed at the case study site

iv. Exclusion criteria for patients

- Patients who lack capacity.
- Not currently registered at the case study site.

16. Consent

Written consent will be obtained from participants by the study RF (Dr Scheibl) who holds a full Research Passport and DBS. Dr Scheibl has over 20 years' experience of social science research and taking informed consent on clinical trials. Consent will be obtained on the day of the case study focus groups / interviews using a standardised consent form which sets out the terms for permission to audio record under assurances of anonymity and confidentiality and storage and use of data. This form will be completed electronically if participants are attending the case study focus group / interviews virtually as detailed above. If any participant has difficulty completing the consent form by signing an email, consent will be obtained on the day virtually over zoom by one of the study RF [Dr Fiona Scheibl or Serge Engamba] who will lead the participant through the consent process step by step using the study consent form. The process will be witnessed by another member of the research study team (TM/ IW/SG) and the consent form will be completed and signed on the participants behalf with their permission.

17. Data collection

Data collection at case study sites will extend to the sourcing and collation of any practice documentation, receptionist guidelines or policies regarding RCC that are publicly available on practice websites. Where these documents cannot be downloaded from practice websites they will be requested in person by the study Research Fellow on site visit / over the phone when contact is made to organise the case study focus groups.

The range of data collection is illustrated in **Table 1**. Focus groups will inform subsequent interview topic guides. The focus groups and interview topic guides will explore positive and negative experience and effects of RCC from the perspective of patients, clinical and non-clinical staff and possible mechanisms by which RCC affects clinical care. This will specifically include the potential negative effects of higher RCC: the trade-off between access and continuity, potential burden on GPs, patient dependency on one GP and a lack of a second opinion. They will also explore examples of good practice in addressing barriers and facilitating RCC (e.g. patient engagement, organisational culture, appointments systems, leadership, philosophy, formal/informal policies on RCC).

Table 1: Data collection and analysis for case studies

Source	Data obtained	Analysis	Between practices
Focus groups (staff) - Clinical (GPs, nurses, allied health professionals) - Non-clinical (receptionists, practice managers) Interviews with key informants identified from focus groups	Staff experience Implementation of practice policies	Framework analysis	Cross-case comparison
Documentation of policies	Practice policies		
Focus groups (patients) - With and without long-term conditions - Older and younger - Diverse educational level - Diverse ethnicity Interviews with key informants identified from focus groups	Patient experience Experience of policies		

In the focus groups the facilitator will enable discussion of RCC between practice staff *allowing participants themselves to introduce and debate views and practice processes around RCC and the areas in the topic guide* (Nyumba, Wilson et al. 2018). We will take into account documented guidance for maximising success of focus groups in healthcare

settings e.g. sample heterogeneity, difference in status of participants, timing of groups (Tausch and Menold 2016).

In the interviews the approach will be different; the researcher and stakeholder will be involved in a dialogue designed *to explore that participant's responses to the areas within the topic guide*.

Where focus groups and interviews take place in person face to face these will be convened at premises identified as suitable in the locality close to the GP practice. This might be a community centre or library close to the general practice. Or if the GP practice has a suitable meeting room the RF will work with the practice manager to arrange for them to take place on site. Whichever venue is used it will be checked to ensure it provides secure and private rooms suited to providing a noise free space for recording. The venue will be central and with easy access for public transport.

Within each practice we will collect any documentation on formal or informal policies which refer to RCC (Marshall 1996, Guest, Bunce et al. 2006).

If required because of Covid-19 restrictions, focus groups and interviews will be conducted online using UoB zoom video conferencing software or Microsoft Teams. In this circumstance data collection will be carried out in a secure room booked at UoB premises. There are rooms set aside for this purpose in the Murray Learning Centre where the Institute of Applied Health Research has its office. Focus groups will run for approximately 60 to 90 minutes. Interviews will run for approximately 30-60 minutes. We will follow best practice in this approach (Santhosh, Rojas et al. 2021).

18. Data analysis

Focus group and interview data will be recorded, transcribed and entered into NVivo11 for data management. Thematic analysis of transcripts will be carried out using the Framework Method and themes compared within and across practices, focus group, interview and documentary data (Braun and Clarke 2006). Framework approach is best suited to these data as it is focussed, systematic and efficient (Gale, Heath et al. 2013). Based on our

previous experience this is manageable, particularly if data are analysed as soon as it is collected (Heath, Cameron et al. 2012). Amalgamating documentation obtained about practice policies and procedures along with the transcripts (16 from focus groups and between 8 and 24 interviews) will enable us to undertake an in-depth analysis for each case and cross-case comparison.

A summary of overall themes derived from the analysis will be sent to participants for comment. PPI representatives and members of the multi-disciplinary research team will read a selection of transcripts and documents, then discuss and agree on emerging themes to develop the data coding framework. All data shared and documented will be anonymised. Overall data will then be combined to seek common features associated with positive deviant RCC. To ensure robustness and quality our research is also guided by the COREQ checklist for reporting qualitative research (Tong, Sainsbury et al. 2007).

We will follow good practice and consider or 'triangulate' our findings from the qualitative data with the findings from the other pieces of work in the study. Comparing individual findings to see where they might be similar or different is likely to provide additional insights and enhance understanding of overall findings. Overall findings will then be brought together and considered by the whole research team (O'Cathain, Murphy et al. 2010, Tariq and Woodman 2013).

19. Data storage

Personal data will be collected and subject to analysis and we will observe the following regularity processes:

Personal data will be collected from participants after they have provided written consent. Data relating to participants will be assigned a unique identifier.

Audio files from case study interviews and focus groups conducted in face to face settings will be transferred from the encrypted audio recorder into an encrypted folder on to the secure university server as soon as possible after data collection. The recordings on the digital audio recorder will be deleted as soon as successful transfers to University of Birmingham secure servers have been confirmed with the University approved transcription agency.

Sound recordings of focus groups or interviews completed on Zoom or Microsoft Teams software will be stored on secure servers / university laptops. They will be transferred to the transcription agency using their secure email upload system. Audio files on laptops will then be deleted once upload is successful to the transcription agency and a copy of the original sound audio file is installed on the secure server.

Relevant UoB guidance will be followed regarding the use of Zoom/Teams.

All audio files will be securely shared with an approved transcription service authorised by the University of Birmingham.

Only anonymised quotes from the transcript will be used in any publications or reports arising from the data. Personal data will be encrypted and password protected, and only accessed by the study RF (Fiona Scheibl). Access to original data files will only be permitted with agreement of the PI team.

Anonymised data will be stored on a secure server within the University of Birmingham for a period of 10 years. If a participant decides to withdraw after the case study has taken place, the data they provided up to that point will still be used in subsequent analysis. All essential documentation and study records will be stored by the study team in accordance with the applicable regulatory requirements and access to stored information will be restricted to authorised personnel including sponsor representatives and regulatory authorities. The main study portfolio will be kept in the Institute of Applied Health Research, University of Birmingham.

Appropriate controls will be in place to ensure that access to confidential research information is restricted to those who need access. Researchers at the University of Birmingham will only have access to anonymised transcripts for the purposes of future research. Completed consent forms will be stored in a study folder in a secure locked cabinet in the trials unit/ IAHR. All audio material will be stored on secure servers at the University of Birmingham accessible to authorised research personnel only. All data will be anonymised ahead of analysis. All workplace issue laptops are secured by VPN login and code authentication. All data on the University of Birmingham secure drive is protected.

20. Safety reporting

The study Investigators and research team will observe appropriate safeguarding regulations for data handling as set out in The University of Birmingham's Data Management Policy and Procedures accessible here: Research Data Management Policy (birmingham.ac.uk) and the Data Security Policy is here: https://www.birmingham.ac.uk/Documents/university/legal/data- prot-policy.pdf. Research data will be kept on University of Birmingham computer servers. These guidance documents will be observed to ensure the protection of the rights, safety and wellbeing of research participants.

The data collected during the study will be archived as per the University of Birmingham Data Management Policy and all access will be removed unless access is requested directly from the chief investigator. The University of Birmingham's Data Security Policy is here: university-of-birmingham-data-protection-policy.pdf

Research data will be kept on University of Birmingham computer servers. Once the study has been completed and results published, data accesses will be limited to the chief investigator, the research team and IT staff at the University of Birmingham.

21. Ethical and regulatory considerations

The main ethical questions relate to participant anonymity and the safeguarding of any private data. These will be addressed in the **Error! Reference source not found.** application and in greater detail for the HRA processes for 9 and 11 where we will submit data collection instruments such as topic guides for review.

We will ensure informed consent for all case studies and will provide potential participants with information about the study, and time to consider participation. Data will be stored in line with institutional policies as set out above. Case study participants will not be named or identifiable and we will use pseudonyms to report any direct quotes.

a. Assessment and management of risk

Success in **Error! Reference source not found.** would be developing guidance for general practices on how they can measure their own RCC. There are few risks to achieving this as there is no requirement that we reach agreement on measurement, just an understanding of what criteria need to be considered.

If any participant gets tired or upset by the research topic the research process will stop and the person will be given time to leave and told there is no obligation for them to resume the study.

Clinicians will receive payment for taking part in case studies which is considered appropriate and fair at locum rates and does not constitute a coercive inducement.

Patients and allied health professionals / support and managerial staff will receive INVOLVE rates of £25.00 per hour and be reimbursed for their travel costs. These are considered appropriate rates and determined by NIHR and INVOLVE recommendations.

b. Research ethics committee (REC) and other regulatory review & reports

Before the start of the study, a favourable opinion will be sought from the REC and also approval from the HRA.

- Substantial amendments that require review by NHS REC will not be implemented until that review is in place and other mechanisms are in place to implement at site.
- All correspondence with the REC will be retained.
- It is the Chief Investigator's responsibility to produce the annual reports as required.
- The Chief Investigator will notify the REC and sponsor of the end of the study.
- An annual progress report (APR) will be submitted to the REC and sponsor within 30 days of the anniversary date on which the favourable opinion was given, and annually until the study is declared ended.
- If the study is ended prematurely, the Chief Investigator will notify the REC and sponsor, including the reasons for the premature termination.
- Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC and sponsor.

Before any site can enrol participants into the study, the Chief Investigator/Principal Investigator or designee will ensure that appropriate approvals from participating organisations are in place.

i. Regulatory review & compliance

The study Investigators will observe the principles of the UK Policy Framework for Health and Social Care Research which sets out principles of good practice in the management and conduct of health and social care research in the UK including responsibilities for the four elements of research transparency:

5. registering research studies
6. reporting results
7. informing participants
8. sharing study data and tissue

All research staff have completed good clinical practice training and will observe regulations and ethical procedures advised by the Sponsor following ethical review and the Authority as set out in the contract dated 13 October 2022 which protect the rights, safety and wellbeing of research participants. In the QUERCC study the principal safeguards apply to the handling and storage of data as follows:

Appropriate controls will be in place to ensure that access to confidential research information is restricted to those who need access. Researchers at the University of Birmingham will only have access to anonymised transcripts. Completed consent forms will be stored on secure servers at the University of Birmingham accessible to authorised research personnel only. All data is anonymised ahead of analysis. All workplace issue laptops are secured by VPN login and code authentication. All data on the University of Birmingham secure drive is protected. Personal data will be collected from participants after they have provided written consent. Data relating to participants will be assigned a unique identifier. Audio files from the interviews will be transferred from the audio recorder into an encrypted folder on to the secure university server as soon as possible after the case studies.

The recordings on the digital audio recorder and/or Zoom/Teams will be deleted as soon as successful transfers to University of Birmingham secure servers have been confirmed. The audio files will be securely shared with an approved transcription service authorised by the University of Birmingham. Only anonymised quotes from the transcript will be used in any publications or reports arising from the data. Audio files will be deleted in 2025 when the study ends. Personal data will be encrypted and password protected, and only accessed by agreed members of the team. Anonymised data will be stored on a secure server within the

University of Birmingham for a period of 10 years. All essential documentation and study records will be stored by the study team in accordance with the applicable regulatory requirements and access to stored information will be restricted to authorised personnel including sponsor representatives and regulatory authorities. The main study portfolio will be kept in the Institute of Applied Health Research, University of Birmingham

ii. **Amendments**

If the sponsor recommends or study team request to make changes to any aspect of the study a request for an amendment will be submitted to the appropriate regulatory bodies (as appropriate).
Both minor and substantial amendments will be submitted to the sponsor for review and approval prior to submission on IRAS and subsequent approval by relevant regulatory bodies and participating sites.

c. Peer review

The research study was peer reviewed by NIHR during the funding submission.

d. Patient & public involvement

During the development of this proposal, we consulted eight patients in two focus groups in 2019. Participants provided views on the importance of the research, their perception of changes in continuity of care, measuring continuity of care and possible problems with high continuity of care. Participants felt researching continuity was important. They all shared experiences of lack of continuity of care and stressed the importance of a personal relationship with a general practitioner (GP). Advantages included not needing to explain their circumstances at every visit and avoiding unnecessary medication changes. All acknowledged the importance of continuity, especially for older patients and those with long term conditions. There was a shared perception that continuity of care is becoming more difficult with pressure to provide better access.

They identified part-time working by GPs and larger surgeries with many GPs as important factors. Some also indicated that automated booking systems had a key role impeding continuity, others said receptionists had a big influence on which doctor was seen. Because of the need to be both savvy and assertive to maintain continuity, and that patients with language barriers, disability, or mental health conditions were disadvantaged. Continuity in

primary care was thought to be better than in secondary care. When discussing measurement of continuity, participants were clear that continuity does not necessarily have to be with a single GP, or even with a single healthcare professional. Continuity could be seeing 2 or 3 GPs for most of their care or even a multi-disciplinary team. Participants also thought it important to take account of views of healthcare professionals' views on continuity. Considering drawbacks of continuity, some participants mentioned the value of a second opinion. Others acknowledged that a practice focus on access would compromise continuity, implying that continuity and access could be conflicting objectives.

We found considerable agreement between the personal observations and intuitions of our patient participants and the findings of published research on continuity. This suggests patients have considerable insight into continuity and can play an important role in shaping this research. Changes following lay consultation in published research, objectively measured continuity has only considered consultations with doctors. One of the most common measures (usual provider of care index) only takes account of consultations with one doctor. Our consultation with patients suggests this does not reflect lay conceptions of continuity. A measure of dispersion (number of different clinicians), including consultations with non-doctors would more closely reflect their views. We therefore included a work package where the views of patients, clinicians and researchers are discussed to try to improve our understanding of what continuity means to different stakeholders and how it should be measured. Prompted by observations about possible drawbacks of continuity we also propose to explicitly explore the trade-off with access and other possible disadvantages in our case studies. We recruited a case study participant as a lay co-applicant. He will chair a Patient Advisory Group, contribute to interpretation and analysis of interviews focus groups. We followed the advice of our lay co-applicant to create a project website and commission a short animation version of our final report.

Patient and public involvement (PPI) is embedded in the QUERCC project as follows:

Conception and Design: Eight members of the public were involved in case study consultations on the topic for this study in the early stages of our research in 2019. They brought their lived experience and perspectives to the study and suggested themes for further exploration in the work going forward.

Our PPI lead (KS) who lives with a long-term condition is a co-applicant and has collaborated with team members throughout the study development phases and worked with

the team to plan study set-up and recruitment. KS has also had input into the acceptability of participant facing information, for example, in the plain English summary, the reference to the Netherlands study was felt to be confusing and could be explained further. We therefore included costs for accessibility and interpretation in WP3 and WP5 and have added an accessibility fund to cover interpretation and translation in these work packages. Our PPI lead is a qualified Polish-English interpreter. KS also led on the recommendation that we create a translated glossary of terms relating to lay participation in research in the more commonly used non-English languages.

Management: A Patient Advisory Group of 6-8 members of the public drawn from a range of backgrounds will meet three monthly and provide input into the monthly Project Steering Group meeting. PPI input will be ongoing throughout the management of the project. Our lay co-applicant (KS) will chair the Project Steering Committee and will contribute to recruitment of a Patient Advisory Group (PAG) of 6-8 participants. Patient advisory group (PAG) members will receive a description of the roles and expectations of the lay advisory Group in advance of recruitment. PAG membership will be offered both to lay people with and without previous experience of PPI.

Training: After recruitment and sampling is complete the study investigators will provide training and induction on the project for PPI members. Participation in the induction will be paid in line with INVOLVE rates. The involvement in the study will allow them to develop transferrable skills, which they will later be able to use in other PPI activities.

Analysis: Our PPI co-applicant will be trained in and contribute to analysis of qualitative data, he will receive individual training on preparing a study budget, research methods and statistics. This will improve his knowledge and skills as a public contributor to medical research and give him more confidence in his contribution to the study. He will also receive training in qualitative research methods including the opportunity to take part in our Qualitative Research Methods module at University of Birmingham. He will contribute to analysis and interpretation of summary anonymised data. At the end of the study, he will help write a manuscript and texts for a wider audience about the study and the meaning of the findings and a text detailing his experience as a lay co-applicant. Alongside the role of the PPI co-applicant all PPI representatives and members of the multi-disciplinary research team will be engaged in qualitative data analysis by reading a selection of transcripts and documents, then coming together to discuss and agree on emerging themes to develop the data coding framework.

Dissemination: KS had input into the development of the study documentation, helping to ensure that the consent form and study information leaflet had clear content and were acceptable to the lay reader.

e. Protocol compliance

Should any unforeseen issues to arise during the course of the study that may affect the safety or integrity of the study data or participants the Investigators team will manage these as protocol deviations as set out by the UoB Quality Management System https://www.birmingham.ac.uk/research/activity/mds/mds-rkto/governance/qms.aspx. The PI team will take corrective and preventative measures to avert further breaches. Any incident observed by study researchers will be reported to the PI and used to advance improvement.

f. Data protection and confidentiality

Data from the case study s will be stored on a secure server at the University of Birmingham and will be electronically archived (10 years) according to the University of Birmingham's Research Governance Framework. Participants will not be named or identifiable and we will use pseudonyms to report any direct quotes. Data will be treated as confidential at all times including during collection, handling and use. Personal Data will be stored securely on University servers to prevent unauthorised access or disclosure.

All data recordings will be transcribed by a professional transcription company that holds a contract with the University. All data once deposited back at the university will be anonymised (all names and other identifiable information will be removed) by a professional company that is approved by the University of Birmingham and will sign a confidentiality agreement. The recordings will be transferred to them through a secure file transferring website. The transcription company will delete the recording once the study team have approved the accuracy of the transcript. The recording will be deleted from the handheld secure audio recorder once the transfer is complete. A copy of the recording will be stored and saved to a secure computer at the University of Birmingham and once it is deleted from the recorder. Audio recordings will be stored until the end of the project and deleted by the study end date. Transcription and analysis will be complex on this project because we are using a case study methodology involving a range of different speakers and checks will need to be made to determine which speaker has contributed an idea or viewpoint.. This will

require careful tracking of voice across recordings – to be completed by the study RF. Transcripts will be kept for 10 years once the study ends. Transcript information will be kept and analysed on the University of Birmingham computer servers. Only designated members of the research team who hold a DBS / research passport and current Good Clinical Practice certificate will have access to these personal details.

University of Birmingham. The sponsor is the legal data controller for data collected and its data management policies are fully compliant with Data Protection Legislation, HRA guidance contained in the UK Policy Framework for Health and Social Care Research, and The Concordat to support Research Integrity. The Principle Investigators are employees of the study sponsor and use methods that are scientifically sound, safe, ethical, legal and feasible and remain so for the duration of the research, taking account of developments while the research is ongoing.

g. Indemnity

The University has in force a Public Liability Policy and/or Clinical Trials policy which provides cover for claims for "negligent harm" and the activities here are included within that coverage. .

h. End of study and archiving

End of study is when the data collection and analysis is complete in the spring/ summer of 2026. Data from the case studies will be stored on a secure server at the University of Birmingham and will be electronically archived (10 years) according to the University of Birmingham's Research Governance Framework.

i. Access to the final dataset

The research team will observe the University of Birmingham's Policy on Research Data Management (RDM). The policy lays out requirements and responsibilities for the University and for researchers as currently understood. It will be updated annually as the external landscape develops and amendments will be approved by the University's Research Committee. The Concordat on Open Research Data [PDF - 178kb], as produced by HEFCE, JISC, RCUK, UUK and Wellcome, sets a framework for best practice within UK HEIs with respect to the management of all research data, and has guided the formulation of key aspects of this Policy.

22. Dissemination policy

Dissemination will make use of a number of methods tailored to each audience. We will seek to maximise impact through a range of pathways, and these will be a standing agenda item on project team and steering group meetings.
Debates about continuity of care to date have been led by clinicians and researchers. A key benefit of our work is involvement of the public and a key output will be in making publicly accessible the findings of our research on the causes of declining RCC, its effects and solutions to the problem. For a **lay audience**, we will create a project website and commission a short animation version of our final report to communicate findings in an accessible way. A project website will make available regular publicly accessible bulletins of interest to the general public. We will ensure these bulletins are press released so that the media are aware of each developing stage of the research. We will write short articles for relevant forums online and international newspapers. We will initiate a social media campaign to garner interest in our findings and share information about the project, and will share research progress and encourage feedback via blogs and personal stories of continuity of care. Through our digital profile we will engage with patient representative groups and 3rd sector organisations as intermediaries and knowledge brokers to help us develop an effective implementation and dissemination strategy and to ensure we engage heterogeneous groups of stakeholders.

For an **academic audience** we anticipate a report for NIHR and five peer-reviewed publications: a shared understanding of measures of RCC (BJGP, BMC Fam Pract); an analysis of the determinants of RCC in UK primary care (BJGP, BMC Fam Pract); learning from our case study practices (BMJ, Ann Fam Med); practical guidance to improve RCC (BJGP, BMC Fam Pract); an economic analysis the effects of RCC (BJGP, BMC Fam Pract). We will present our findings at SAPC and RCGP conferences. After **Error! Reference source not found.** we will engage with **software manufacturers** (Samir Dhalla of Cegedim and Chris Bates of TPP) to share findings on measurement of RCC in primary care to stimulate work on development of tools to measure RCC. We will provide an interim report on measurement of RCC and a final report on completion of 11 to **regional GP networks** (Dudley Integrated Care Service, Our Health Partnership), to **national bodies** (the RCGP and NHS England). To directly reach **primary-care clinicians** we will develop a podcast or short video with the Personalised Care Institute to disseminate to clinicians and have fully

costed development of **two webinars** and a package of marketing and communications with the RCGP. University of Birmingham's Centre for Primary Care Improvement will create a **postgraduate module** for primary care professionals on managing continuity of care. We will write a brief lay summary for use as a discussion document at practice Patient Participation Groups.

a. Authorship eligibility guidelines and any intended use of professional writers

The PIs will follow the guidelines on authorship as set out in The International Committee of Medical Journal Editors has defined authorship criteria for manuscripts submitted for publication, known as the Vancouver Protocol on the final report.

23. Appendices

a. Appendix 1 – required documentation

b. Appendix 2 – schedule of procedures

c. Appendix 3 – amendment history

The following amendments and/or administrative changes have been made to this protocol since the implementation of the first approved version

Amendment number	Date of amendment	Protocol version number	Type of amendment	Summary of amendment
AM01	1.8.2024	2.0		
NSA01				
NSA02				
NSA03				
NSA04				

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